UNIVERSITY OF STRATHCLYDE

DEPARTMENT OF MARKETING

TRADING OFF: A GROUNDED THEORY OF PHARMACEUTICAL DECISION-MAKING

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Abstract

This thesis contains the findings of a study undertaken in the field of medical decision-making. The Glaserian approach to grounded theory (Glaser and Strauss, 1967; Glaser, 1978) was used in order to build a theoretical representation of this area. Four phases of data collection were used, the first to develop initial theoretical sampling points and obtaining permission to approach medical practitioners. Following this, 12 personal in-depth interviews were performed to collect the primary data. A period of secondary data collection was then performed and finally an appraisal of the draft theory.

Trading Off[1] emerged from the constant comparative method as the core category explaining how pharmaceutical decision-making (as a form of medical decision-making) is performed. Sub core categories that were integrated within the ***Trading Off*** process included ***Focusing*** as the initial period of analysis, ***Self-Referencing*** and ***Surrogating*** reflecting sources and use of information and the ***Shifting*** that occurs as physicians develop expertise.

In order to develop and frame the contribution of this theory within relevant literature, an number of areas of decision-making and medical decision-making research were reviewed. Expertise and its development were also examined.

The main conclusions and recommendations of this research are that physicians ***Trade Off*** levels of confidence held in behaviours and aspects of the behaviour in order to decide on a course of action. ***Trading Off*** can used to direct the efforts of pharmaceutical companies and healthcare providers in order to modify pharmaceutical decision-making and reduce the large volume of prescribing errors. These efforts should be based on an accurate analysis of the individual decision

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[1] The labels used for categories discovered during this research are highlighted with **Bold** and *Italic*. I.e. ***Trading Off***

environment and involve a wide view of possible influencing factors. It is recommended that actual patient case studies supplied from clinical trials are used in these efforts and that an opinion leader should perform the delivery where possible.

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Introduction

This thesis investigates the behaviour of physicians when making decision concerning the pharmaceutical to prescribe for their patients. This behaviour represents a sub-class of all types of decision made within medicine. The importance of this area is demonstrated by the 5.6 billion pounds spent on medicines by the NHS in 1997(ABPI, 1998) and the volume of errors that have been identified in prescribing behaviour[2].

The UK national expenditure on medicines has grown from .43 to .71 of GNP since 1980 (ABPI, 1998)and this is expected to continue to grow due to an ageing population and further pharmaceutical development. The Government has reacted to this environment by implementing administrative changes to the NHS designed to make it more cost effective but retaining the level of quality care to patients.

It is important for both the pharmaceutical industry and health care providers to understand the decision-making behaviour of physicians and therefore pharmaceutical decision-making within this environment. This understanding will allow them to design intervention strategies to modify physician's behaviour to satisfy their objectives.

The pharmaceutical companies require these strategies in order to continue to market their products effectively and to launch new products successfully into this environment. The health care providers need to modify physicians behaviour in order to reduce the volume of prescribing errors and in particular to increase the cost effectiveness of prescribing in order to satisfy their cost containment role.

In order to investigate this area grounded theory was used to build a theory of pharmaceutical decision-making as it emerged from research into the wider area of medical decision-making. The integrated theory is presented in Chapter 3 after a detailed discussion on the methodology and method used in this thesis.

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[2] These errors are detailed in chapter 5 section 5.6.

After the completion of the theory building phase, relevant literature was reviewed in order to frame ***Trading Off*** within the current body of knowledge. Further to this, areas were analysed so to develop this model. A final objective of this stage was to view ***Trading Off's*** ability to synthesise and organise these literatures.

It was decided that it was necessary to investigate the following areas of literature in order to achieve these objectives:

Decision-making (Chapter 4): This chapter was required in order to place ***Trading Off***, pharmaceutical and medical decision-making in a wider decision-making context. It was also needed to provide a background understanding into many of the decision-making concepts used in ***Trading Off*** and in subsequent chapters.

Principles of Medical decision-making: (Chapter 5) It was felt to be necessary to continue the review of literature within a more specific medical context. This was achieved by looking at the principles of medical decision-making and the observed outcomes. Particular attention is paid to the errors and variations discovered.

Medical decision-making Research: (Chapter 6) This literature was looked at in order to analyse the methods used into research in the general and specific areas of medical decision-making. The contribution and development of ***Trading Off*** and its use of grounded theory could then be analysed.

Factors influencing Treatment choice: (Chapter 7) The filtering down on areas of importance within decision-making continued with research into the factors discovered in published research that influence medical decision-making. These were used to develop and expand on those discovered in ***Trading Off***.

Modifying Treatment choice: (Chapter 8) Having looked at the process of pharmaceutical decision-making and its specific influences it was felt that work

should be examined that was able to structure the use of these influences into modification strategies.

Modifying Physician's behaviour, the efforts of Pharmaceutical companies: (Chapter 9) The use of modification strategies and tactics by the pharmaceutical industry required a specific focus. This chapter was also required in order to provide literature upon which to base recommendations for the use of ***Trading Off*** and its concepts by pharmaceutical companies.

Expertise and Expertise development: (Chapter 10) The discovery of ***Shifting*** and the use of information sources necessitated the review of literature in expertise and its development.

This literature review is more comprehensive than is common with grounded theory studies. This is due to the large volume of literature that exists for this area (this is a further reflection of the importance of this field) and the diversity of the findings of the study.

The findings of the literature review and ***Trading Off*** are drawn together in the conclusions and recommendations section. The chapter concentrates on the contribution of this thesis to pharmaceutical marketing, consumer behaviour and expertise.

Having completed the introduction into this thesis and the areas that will be presented, the focus now turns to methodological considerations.

1 Chapter One Methodology

The purpose of this chapter is to justify and outline the research design used in this thesis. In doing so, it is intended that the overall configuration of the research and it's presentation will be looked at not purely the method. The chapter will provide a brief overview of the methodological options considered for this research; however the main emphasis will remain on the one chosen.

This chapter will initially outline the characteristics of the research problem followed by a brief discussion of possible methodologies. The use of grounded theory to provide a solution for the research objectives and problem will then be provided. Following this, a discussion will held on the two approaches to grounded theory that have developed and reasons given why the orthodox approach was chosen. The Glaser view of grounded theory will be detailed as a description of the method used (Glaser and Strauss, 1967a) (Glaser, 1978).

1.1 Characteristics of the Research Problem

This study developed from an original proposal to study physician's decision-making using quantitative predictive models such as the Theory of Reasoned Action (Fishbein and Ajzen, 1975). The pre-reading in this area showed that a number of authors such as (Bagozzi et al. 1992; MacKenzie and Spreng, 1992) had made attempts to develop predictive modelling. Attempts to do this included the addition of other factors such as motivation (MacKenzie and Spreng, 1992) or action orientation (Bagozzi et al. 1992).

These refinements were successful to a degree in improving the predictive performance of the models: however two issues arose from this which suggested a different approach was justified. First, an amount of behaviour remained unpredictable and secondly the

addition of further factors leads to the theory becoming unwieldy and difficult to use. These factors were combined to indicate that in order to predict the decision-making of physicians more accurately a theory building exercise based on this specific area should be attempted.

Using this specific area based theory building approach instead of the adaptation and development of existing models, was also supported by the correspondence rules used with Theory of Reasoned Action (Fishbein and Ajzen, 1975). These authors were able to demonstrate that where these rules were applied (deliberately or not) then attitudes were found to be a reliable predictor of behaviour.

These rules (as detailed in chapter four) provide strict instructions as to how to design components of the Theory of Reasoned Action so that they correspond closely to the specific behaviour being studied. In doing so they simply ensure that the behaviour being measured by the questionnaire is the one under scrutiny.

These rules imply that for these models to work they should used in a context specific fashion. By designing a predictive model from the area which it is to be applied can therefore be seen as taking this a stage further. These factors lead to a context specific, theory building research design being required for this thesis.

1.1.1 Research Approach

The need for a theory building approach indicated the use of an inductive approach to this research. Inductive approaches can involve the development of theory from the specific observations of events, the detection of patterns and the development of these from working hypothesis to theory. This was felt to be the most appropriate approach in light of the characteristics of the problem.

The deductive approach to theoretical testing was considered appropriate for possible post-doctoral work on this thesis that would involve the testing and measurement of the accuracy of this theory developed.

1.1.2 Methodological Approaches

The inductive school of inquiry provides a number of methodologies that can be used to discover "theory" as opposed to comprehension or characterisation of phenomena. Ethnography, phenomenology, and grounded theory are three such approaches that were considered for use in this study.

1.1.2.1 Ethnography

Ethnography is designed for the study of human society and culture (Trochim, 1999). It is concerned with the observation of life as it is apparent in the "real world" and is used to uncover the social order in a particular situation. It's use, though romantically associated with exotic cultures has been demonstrated in situations similar to the decision-making of physicians as seen in work on cocktail waitressing and alcoholics by (Spradley and Mann, 1975).

Ethnography goes beyond the use of simple use of ethnographic techniques such as participant observation, depth interviews that are commonly used in other methodologies (Churchill, 1991). Crucially it also involves the interpretation of the data within a socio-cultural framework (Minnis, 1985).

Whilst ethnography and it's variations would have been able to fulfil the needs for a context specific approach, its reliance on a socio-cultural framework imposes an initial categorisation on the phenomena. It was felt that for this research the generation of theory should not be constrained to a particular environment. Hence ethnography in its wider interpretative form was not chosen for this research.

1.1.2.2 Phenomenology

Phenomenology refers to both a philosophy and a set of techniques that systematically study social behaviour (Goulding, 1998). It involves the description and clarification of the structure of the world as it is perceived by those who live within it.

The application of phenomenology based on the Husserlian philosophical perspective asks for the assumptions of the researcher of the world under scrutiny to be set aside in what Schultz calls "bracketing" (Schultz, 1967). This is in order for the researcher to properly access the subjective knowledge of the group being studied

In order to understand this social structure, phenomenologists attempt to understand the research from the perspectives of the subjects (Trochim, 1999). This leads to a central criticism of this approach where it is asked whether it possible for a researcher to show true empathy in an area that is far outside their realm of experience.

At its centre, is the use of language to transmit meaning indeed the "the words of the informant as seen as the only valid source of data" (Goulding, 1998). This assumption is questioned by the notion that respondents may be unable to describe the world they live in accurately. Further to this, unless the outcome of this type of research is to be pure description then some interpretation from the researcher is needed (Schwandt, 1994).

The phenomenological perspective of the socially structured world with which experience relates meaningfully is felt to be a legitimate view and was used to underpin this research. However, a strict phenomenological process was not chosen for 2 main reasons. First of these is it's view on data and secondly, similar to the reason for rejecting ethnography, because of the use of predetermined framework in analysis. Restricting the valid sources of data to only the words of the informants was thought to

be too constrictive and the use of a predetermined framework may restrict the emergence of the theory called for in the research problem.

Summary.

Ethnography and Phenomenology were looked at as possible methodologies for this research but were rejected primarily because of the frameworks they impose on the emergent data. The specific reasons why grounded theory was chosen will now be examined.

1.1.2.3 Grounded theory

Grounded theory is described as "the systematic generation of theory from data" (Glaser, 1978) and as such promised a method that would be of use for this particular research. It has been used to generate theory in a wide range of contexts including health care (where it was first used) (Glaser and Strauss, 1967b) (Mullen, 1975) and management research (Lowe, 1995) (Haslam, 1997).

Whilst claiming this role grounded theory also provides strict guidelines as how to achieve this without resorting to the production of one own pet theory presented under the guise of inductive research.

This was an important issue due to the prior experience that this author has with pharmaceutical marketing. Therefore the stringent methodology, its acceptance of prior knowledge and steps to try and ensure that these do not interfere, were important characteristics in the choice of grounded theory. These issues will be examined further in the later section dealing with an overview of the method.

Further to these issues, it is proposed as a methodology that can be used to generate theory in areas where a new approach is needed (Glaser, 1978). Medical decision-making is an area that has been researched extensively (as is demonstrated during the review of literature) and even has it's own specific society, journal and website. In addition to the academic communities efforts to investigate this type of behaviour there is a considerable body of work that is unavailable because it is performed by the pharmaceutical industry.

The work of the Society for Medical Decision-making is designed to " promote rational and systematic approaches to decision-making" (Society of Medical Decision Making, 1998). This goal is approached from a predominantly deductive and quantitative stance and leads to the production of, for example, clinical decision aids designed to help practitioners in specific clinical areas, patient outcome assessments and quality of care measures. The society is also the focus of research on methodological issues in order to increase the accuracy and use of decision-making tools.

Margaret Holmesrovner in her presidential address in 1992 calls for the society "to broaden our perspectives", with this plea being made in conjunction with the caveat of maintaining and developing methodological rigour. Beyond this, she talks about the need to increase the accessibility of the societies work to practitioners (Holmesrovner, 1992).

The volume of work that exists for this area coupled with this call for a different approach to medical decision-making specifically supports the use of a rigorous, structured inductive approach such as grounded theory. The requirement for grounded theory that it should be relevant to those who live within the area suggests further that it's successful use would answer Holmesrovner's final objective.

The large volume of work using grounded theory within a broad range of health care settings provided further support for the use of this method. Beyond the initial grounded

theory studies performed by Glaser and Strauss, grounded theory has been used to study the development of alcoholism, recovery from heart attacks and the study of control in mental hospitals (Mullen, 1975; Wilson, 1974; Bigus, 1974).

Indeed Glaser encourages the use of grounded theory in this area when he talked about its use in "impactful domains"(Glaser, 1978) and named heath care as one of these. Health care certainly qualifies as an impactful domain from the perspective of personal and societal wellbeing and from an economic standpoint.

The topic of this research meant from the outset that it was going to have implications for both these areas and from both an industrial and governmental perspective. As such it was felt that the history of grounded theories in this area was a strong indicator for its use in this research.

A final aspect that supported the use of a grounded theory approach was the existence of a research group within the marketing department of Strathclyde University. This group is based around Dr Andy Lowe who has published extensively using grounded theory for example (Lowe, 1995; Lowe, 1996). He also teaches it use on the faculty research methodology courses and has close professional contact with Barney Glaser.

The research group is able to provide mentoring and support for students wishing to use this method. This is an important factor because of the difficulties of using the approach in what Glaser calls a "minus mentoring" way (Glaser, 1995). Glaser is concerned that students who teach themselves or are taught by the self-taught, may be more susceptible to allowing forced preconceived ideas into their work.

This need for experienced mentoring for grounded theory is enhanced unfortunately by the complexity and lack of user friendliness of Discovery of grounded theory and Theoretical Sensitivity. These books represent the core teachings of the Glaser grounded theory method, however the reader needs to be aware that Discovery has

"glossed over or completely neglected" (Glaser, 1978) many of the issues developed in Theoretical Sensitivity. They must be read carefully therefore for the reader to discover the full nature of the method, however this is hampered by a lack of index or meaningful table of contents.

A departmental grounded theory network therefore represented a useful training resource for the research apprenticeship stage and useful support group as the grounded theory process continued. It's function in theory development and writing up will be discussed in chapter 2. These issues contributed to the choice of grounded theory because it was felt that they reduced the risk of poor methodological scholarship and hence poor theory generation.

1.1.2.4 Summary

The preceding discussion has outlined the characteristics of this research and demonstrated the need for a context driven, systematic method of theory generation as the key requirement for any research method to be used. grounded theory has been shown to match these key requirements and also brings with it a rich history of use in health care research. A final issue in the choice of this method was the ready availability of expertise and support in its use.

Having decided on this method it became important to decide on which variation to use. A discussion of the two versions of grounded theory and a justification of why the Glaser version was used will now by turned to.

1.1.3 Version of Grounded theory

This study was based on the Glaser view of grounded theory methodology as outlined in (Glaser and Strauss, 1967a) and developed in Theoretical Sensitivity (Glaser, 1978). The version used cannot be seen as the original or orthodox because it refers to a version understood and developed by Glaser with the other original author being associated latterly with an apparently fundamentally different form.

This section will outline the differences between the versions proposed by the authors. This will then be used to justify the form of grounded theory used and to frame the detailed description of the Glaserian methodology that follows. Hence many of the concepts and procedures discussed in the next section will be outlined in more detail later.

1.1.3.1 **Glaser vs. Strauss: Emergence vs. Forcing**

Grounded theory went through a bitter divorce during the early 1990's as publications by the co-authors of the original book on the methodology (Glaser and Strauss, 1967a) were taken to indicate fundamentally different understandings of the methodology.

Anselm Strauss and Juliet Corbin authored a text on grounded theory (Strauss and Corbin, 1990) which on close scrutiny by Glaser and others, is seen to represent at least a different version of grounded theory and at most as a whole new theory (Glaser, 1992; Melia, 1996). Indeed Glaser refers to the method in this book not as grounded theory but as "Full Conceptual Description" (Glaser, 1992).

At the heart of the differences in the Glaser approach detailed in (Glaser and Strauss, 1967a; Glaser, 1978) and the Strauss and Corbin approach, is the move from theoretical emergence to forcing and verification. This movement is seen in the different

approaches taken to problem development, coding and indeed the complete absence of certain fundamental aspects of the Glaser approach. For example Strauss's later work does not contain references to Basic Social Processes and Saturation (these terms are explained in later sections). This omitance can be seen as support for Glaser's view that a new theory is developed here not just a variation.

These issues will now be discussed in more detail in order to demonstrate the major reasons why the Glaser's understanding to the methodology is the one used. Glaser's feelings on the Strauss and Corbin method will be looked at along with this. However it is felt that in some instances while this method is different, i.e. the open coding stage, these differences do not contribute to its forcing nature individually. They do however contribute to this when performed in conjunction with other changes i.e the preconception of the research question.

1.1.3.1.1 Verification and Forcing

Glasers view of the grounded theory methodology is based on the emergence of theory from the data encouraged by avoiding preconceptions of the area, theoretical sensitivity and a constant comparative method designed for this end.

The Strauss and Corbin version details processes and stages that can force the researchers agenda and ideas onto the area under study and can be used to verify these personal theories. Two main areas of divergence lead to this conclusion. Initially the how the problem is set and secondly the coding procedure detailed in (Strauss and Corbin, 1997).

1.1.3.1.2 Problem Definition

Strauss and Corbin are explicit in detailing a number of possible research questions that the researcher can use when moving into an area of study. It is also suggested that these questions can be derived from relevant literature.

By approaching the data with predetermined questions the researcher is imposing a particular view of the area onto the data, this may result in the method being used to verify this view.

This view of defining the research question is in direct contrast to Glaser's position, where beyond deciding the area of study and original point of sampling the research process is driven by the theory that emerges. A example of this is found in this study which started into the reasons for success or failure of new pharmaceutical products whereas the emergent theory contained considerable focus on information usage and expertise development.

1.1.3.1.3 Coding

The coding strategies suggested by the two authors provide the second fundamental area of divergence. The differences are based around the how to perform the various coding tasks, what they involve and the added complexity involved in the Strauss and Corbin method.

The open coding stage of Strauss and Corbin involves the fracturing and coding of the data on a line by line or incident by incident basis. According to Strauss and Corbin this is "in order not miss anything that might be salient" (Strauss and Corbin, 1990).

Glaser however expounds the line by line analysis of the data but coding only those incidents that through constant comparison to other incident and concepts show patterns within the data. Glaser believes that the labelling approach taken by Strauss leads to an unwieldy over-conceptualisation of the data with too many irrelevant concepts. (Glaser, 1992)

This author has sympathy however with the Strauss and Corbin objective of not missing any important aspects of the data and the line by line approach used. This approach is thought to be especially useful in the early stages of a research apprenticeship with grounded theory where the theoretical sensitivity of the analyst is unlikely to be fully developed. Indeed in this particular research the initial coding was taken to incorporate all the data collected. This is however the only similarity to the Strauss and Corbin coding maxims.

The issue of selective coding is also a source of variation between the authors and is an area where the problems of preconception and forcing reappear. Selective coding is described in Strauss and Corbin as "the process of selecting the core variable" (Strauss and Corbin, 1990). This statement is at odds with the Glaser who states that selective coding occurs after the core variable has emerged from the data (Glaser, 1978).

The Strauss and Corbin method also suggest greater complexity in the instructions given for the coding process. For example they suggest five steps to be used for the integration of categories to each other. Glaser responds to this approach by claiming that these steps are subsumed within the constant comparative method and the outcomes that emerge from it.

A final serious difference in the coding procedures is the area of axial coding. This is seen as the method of reforming the data after open coding, by developing the relationships between categories. This is achieved by the use of a coding paradigm of condition, context, action/interactional strategies and consequences.

This procedure is an equivalent to the Theoretical coding stage of Glaser but as he points out neither he develops these ideas nor clarifies their use. This section leads Glaser to conclude that what is written by Strauss and Corbin is in fact a different method than grounded theory not a version of it.

1.1.3.1.4 In summary

The coding stages of Strauss and Corbin demonstrate different concepts of what they are and how to perform them when compared to the ideas of Glaser. The crucial issue is, I believe, not these changes in procedure but the language in which they are couched. This does not make it clear that the patterns, relationships and categories and core variable should emerge through the process and not be forced out.

Fundamentally the danger in the Strauss and Corbin approach is not the apparent over-complexity of some of its procedures or it's rewriting of the theoretical coding stage, it is in its lack of guard against preconception and forcing. This apparent lack of awareness and the potential therefore for the production of a theory which verifies the analysts ideas on the area is the reason why the Glaserian method is preferred.

The Glaser method will now be looked at in more detail in order to describe the methodology used in this research.

1.2 Grounded Theory

Introduction.

Grounded theory is a theory generation method that "is based on the systematic generation of theory from data, that itself is systematically obtained from social research" (Glaser, 1978). Fundamental to this is the process of allowing the theory emerge and avoiding forcing it, which forms the basis of the public dispute between the originators as discussed earlier.

It is a method that is not limited to the use of either quantitative or qualitative data, though the majority of its applications are in the last category. It is a data analysis method which requires the researcher to view "all as data" (Glaser, 1978) in order to generate well fitting and workable theories. The specific criteria for evaluating a grounded theory will be discussed in more detail later.

Grounded theory is based on the philosophical assumption that there is integration in the social organisation of the world (Glaser and Strauss, 1967a). This leads to the role of the grounded theorist as being to:

1) Discover the patterns of behaviour that exist
2) Discover how the processes of social organisation are maintained.

In a more specific sense, the job of the researcher is to generate theory that accounts for patterns of behaviour and that are important in the lives of those people being investigated. This theory is based around the discovery of a core category that explains the majority of the variation in this behaviour.

Broadly, this is achieved by discovering the conceptual issues that exist within the substantive arena being researched. The characteristics of a core category will be outlined in detail later. Beyond this, the completion of the theory should allow people to understand the data irrespective of whether they have experience in the field or not.

In order to perform these jobs effectively the inherent creativity of the researcher needs to be used. (Glaser, 1978) links a number of the procedural steps of grounded theory with the mobilising and use of an analyst's creativity so necessary in its production. For example, memoing, sorting, and rewriting drafts are seen as techniques for this.

A further necessary ability (or at least a situation to be aware of and managed) is dealing with the "regression" that accompanies this use of creativity. This manifests itself in a feeling of being lost and even stupidity that occurs when faced with the volume of data and ideas produced by techniques used to mobilise creativity. (Lowe, 1996) discusses this further and recommends that the researcher is prepared to surrender control and embrace the chaos that they feel. This is in order to use this characteristic of the process to help the theory emerge.

1.2.1 Further characteristics of Grounded theory.

Grounded theory is based on the use of analytic induction in order "to discover the logic of peoples lives" (Lowe, 1996). The use of analytic induction and the importance of avoiding forced theories require that the literature review step is performed after the inductive process of theory generation and development is finished. This is in order to avoid having your ideas concerning the data preconceived or attempts to generate theory stifled by what is already thought or "known".

In an area such as medical decision-making where there is a considerable body of literature Glaser suggests that the findings of a grounded theory study can be used to organise and synthesise this body (Glaser, 1992). The literature review in this study will

take this approach with conclusions drawn throughout the analysis and brought together in a conclusions and recommendations chapter.

The substantive literature is then used to develop and compare against and with the theory discovered. Indeed, as the emergent theory will often take the researcher into substantive and theoretical areas that could not be predicted at the start of the study, it can be impossible to know which literatures to review.

It is accepted however that researchers will bring with them an amount of knowledge and theoretical baggage to an area. Indeed, many of the applications of grounded theory have been to areas where the researcher is intimately involved in what Glaser calls "the life style interests of the authors" (Glaser, 1996). Indeed, this is the case within this research.

It is important for a successful emergent theory to develop that as far as possible this knowledge is suspended. In order to achieve this (Gummesson, 1990) suggests that the author admits these to themselves by writing their knowledge down in the form of a formal pre-understanding.

A further characteristic is that it is a "delayed action phenomenon" that requires the development of a number of skills including developing theoretical sensitivity and being able to communicate conceptual ideas in plain English. This characteristic manifests itself in what (Lowe, 1996) describes as the "drugless trip" where periods of confusion with the data are terminated by periods of enlightenment. This trip is characterised by rapid discovery or concepts and relationships that help in the discovery and development of the core category, and other constituent parts of the theory.

A crucial characteristic of grounded theory is the simultaneous collection and analysis of data. The researcher analyses and generates hypothesis concerning the area and uses these emergent ideas to direct further data collection. This direction is designed to shed

light on the areas that the previous data has suggested is important and where a further widening or deepening of knowledge is required. Theoretical sampling (the sampling procedure used in grounded theory) is then used to direct the researcher toward those individuals or situation where this data could be found.

In this instance the researcher can be said to be following the data though to where, is unclear to them. This is another area where regression and dealing with uncertainty are apparent and need to be coped with rather than attempting to control the process. This control may lead to preconception and forcing of the data.

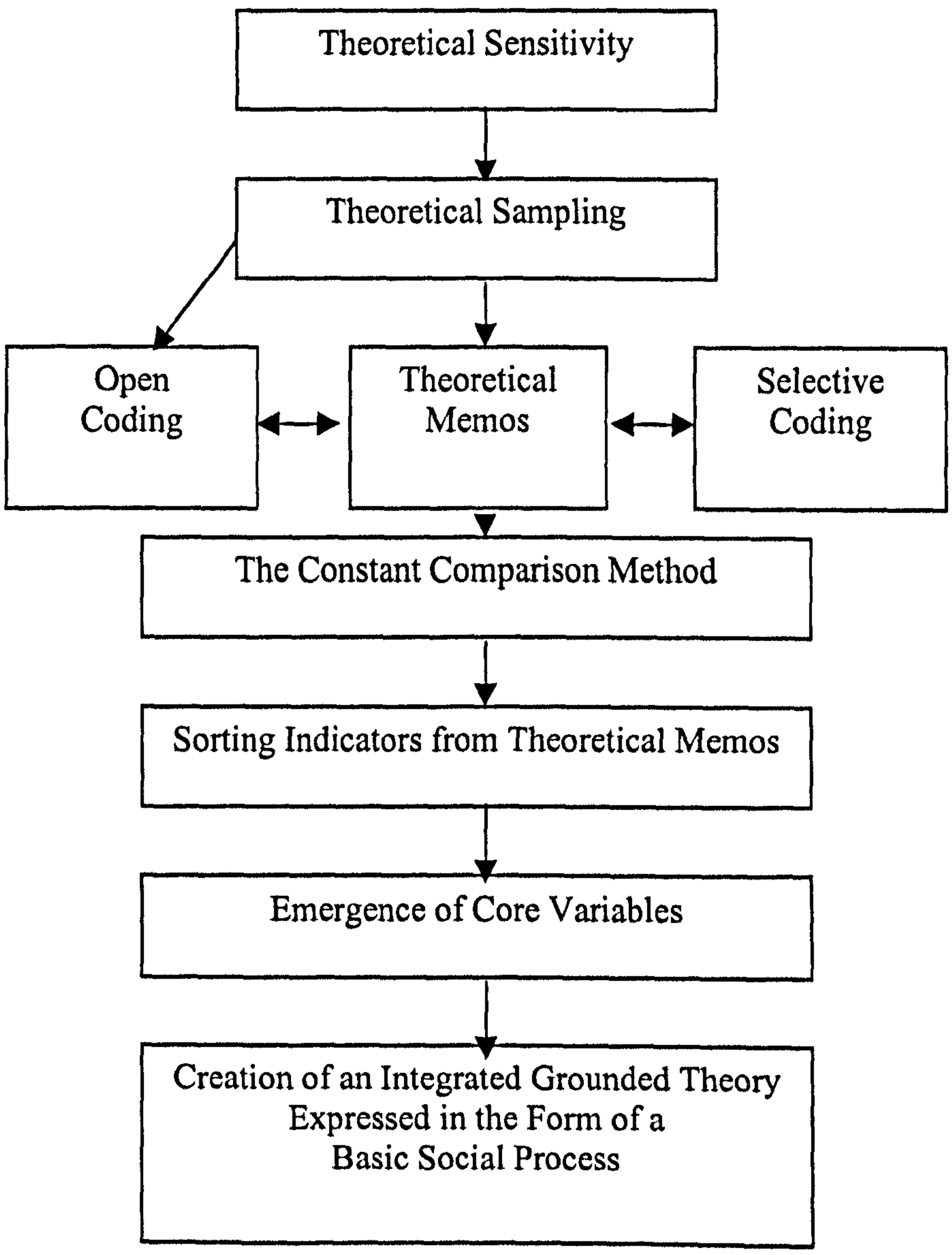
1.2.2 Summary

Grounded theory is based on the use of analytic induction in order to discover core categories that account for patterns of behaviour that are important in peoples lives. It involves the systematic generation of theory from data that allows theory to emerge. It is further characterised by the use of the creativity of the researcher's, simultaneous collection and analysis of data and integration with existing literature. The grounded theory research process will now be detailed.

1.3 Grounded Theory Research Process

Figure One represents the grounded theory process and highlights the steps that are performed in order generate theory from the data collected. The joint collection, coding and analysis of data (which will be detailed in this section) means that this diagram can be seen as representing the overall process and for dealing with data collection points (interviews, observations etc).

Figure 1: Grounded Theory Research Process



1.4 Theoretical sensitivity

Theoretical sensitivity refers to the crucial ability by which the researcher "can render theoretically their discovered substantive, grounded categories" (Glaser, 1978)P1. In other words theoretical sensitivity is the key ability used to achieve the theoretical, conceptual goal of grounded theory.

This sensitivity to the data, which allows the analyst to see the logic in behaviour of the subjects, is developed during a period of research apprenticeship. This development is based on the use of literature throughout the research process.

Glaser is strong in his dictat that literature from the substantive area should be avoided until the theory has emerged. This is order that the researcher does not enter the field with preconceived ideas of what will be found there. He is also strong however in the recommendation for reading to develop sensitivity.

It is recommended that well written theoretical books, articles, monographs etc should be read at the start of the process that are in apparently unrelated and variable fields. Glaser also recommends that grounded theorists should fully understand the 18 coding families set out in (Glaser, 1996). These pieces should be read while considering the theoretical structure and how these structures could be used in different substantive areas with the objective "to get the theory imagery in him or her" (Glaser, 1978)

The use of literature in the development of this imagery and sensitivity to the data is a necessary starting point of the grounded theory process. Without it, the analyst may use the following steps to produce only a descriptive account of the substantive area.

1.5 Theoretical Sampling

Theoretical sampling is the process whereby the emergent theory directs future data collection. The simultaneous collection, coding and analysis of data produces questions that need to be answered and areas that need to be covered. In doing so, it suggests where this information may be found. In this way the theory is directing the analyst and hence as previously mentioned it is impossible to predetermine the areas where the theory will be relevant. This was demonstrated in this study's discovery of "***Shifting***" which is relevant to expertise development.

Theoretical sampling is a deductive process that is contrasted to the inductive nature of the method overall. The codes that are generated by induction are then used deductively to suggest groups sub-groups and individuals for future data collection and hence theory development.

Glaser described grounded theory as being based on "multiple slices of data" (Glaser, 1996) and the quality of the data. He points out that if the same data is discovered from two people as ten people then it was unnecessary to talk to the extra 8 people. This leads to studies that are based on a unknown number of data collection points (interviews, observations) though Glaser gives a rule of thumb of fifteen being sufficient usually, though two may enough!

The theoretical sampling process finishes when subsequent data collection fails to provide any further data that can develop properties of categories. In this instance, the theory is said to be saturated and theoretical sampling is concluded.

1.6 Coding

Coding provides the building blocks for the process of moving the data from a description of the area to a theoretical understanding. A code "conceptualises underlying patterns of a set of empirical indicators within the data" (Glaser, 1978). Codes therefore represent the relationship between the data and the theory. There are three forms of coding used in grounded theory production.

1.6.1 Open Coding

The initial stage of coding in grounded theory is "open coding" where the data is broken up and all possible incidents and relationships are noted. The analysts starts this process with no preconceived ideas of what will be found in the data and in this way is said to be "open" to all the concepts that may exist in the data.

The process of open coding involves the systematic cataloguing of all interesting phenomena as they strike the researcher. In order for this stage to be used correctly and to help the researcher remain theoretically sensitive (Glaser, 1978) advises that the following questions be asked to oneself throughout the process:

- What is this data a study off
- What category does this incident indicate
- What is actually happening in the data

The first of these questions highlights one of the main differences between the original Glaser and Strauss approach and that proposed by (Strauss and Corbin, 1990). This question demonstrates the researcher remaining open to what the data tell them is the main concern of the people in this area and so remains un-preconceived. Strauss and Corbin however advocate the setting of a research question and attempting to answer it.

It is also recommended that the researcher codes the data line by line in order that the open coding stage fully covers all possible theoretical areas and that these ideas are grounded in the data. The analyst should also perform this task themselves.

The open code stage also sees the development of theoretical memos, (which will be explained in greater detail in a later section). A further rule of open coding is that it should be stopped at any time, in order to write up any ideas that strike the analyst (memos). This rule ensures that any concepts and relationships are not lost which can occur if the idea is "stored" and written up later.

Coding moves from the open to the selective when the use of memo's and the constant comparative method (to be outlined in a later section) shows that a core category has emerged from the data.

1.6.2 Selective Coding

As the analysis of the data continues with open coding, memoing and the constant comparative method a possible core category emerges and coding occurs for ideas that are related to this. This is selective coding, that involves conceptual examination and write up of the data.

It is possible that more than one core category is discovered in the data. The choice of which of the emergent categories to follow as the core category becomes an issue of the intellect of the analyst. It is pointed out however that the other data and the categories that these represent remain intact and can be looked at as core variables in later studies. This is demonstrated by Glaser and Strauss's original study which was written up as "Awareness of Dying" (Glaser and Strauss, 1967b) and "Time for dying" (Glaser and Strauss, 1967c) because of the emergence of two categories that could be considered as core.

The selective coding process not only involves the development and saturation of the core variable itself but also explores its relationship to the other categories that have emerged. These conceptual relationships and the discovery and development of them is referred to as "Theoretical coding."

1.6.3 Theoretical Coding

The use of theoretical codes is crucial in the movement of the understanding of the area from the descriptive substantive arena to the conceptual theoretical level.

(Glaser, 1978) provides a comprehensive list of Theoretical codes and suggests that the analyst becomes familiar with them in order to understand the subtleties and complexities of the relationships. For example he quotes the coding families (Causes, Contexts, Contingencies, Consequences, Covariances and Conditions) as the "bread and butter" code used in sociology.

It has been mentioned previously that the development of coding and the emergence of core categories is done, in part, by the use of theoretical memos. This is where we now turn our attention

1.7 Theoretical Memos

Theoretical memos are "the theorising write up of ideas about codes and their relationships as they strike the analyst which coding" (Glaser, 1978). This definition emphasises the rule mentioned earlier that the analyst should stop to memo as the idea comes to them. It also emphasises their importance throughout coding and their role in developing the conceptual ideas of the analyst.

Memos are a useful source for ideas where and what to theoretical sample. They also provide the analyst with the volume of writing to sort and constantly compare to develop core and other categories. Memoing is a process that goes on throughout the grounded theory process which is described as the "bedrock of theory generation" (Glaser, 1978).

Memos which may be one sentence long or many pages long (Glaser and Strauss, 1967a) and should consist of four parts. The first is the Title, which is the category or property that the memo refers to. The second and third parts represent the main body of the memo with the second part describing the categories that it relates to. Memos represent a form of written free ideation, designed to explore the boundaries of the categories and properties to which they refer. The relevance, and fit of these ideas will be determined during sorting and the constant comparative method and therefore the analyst should feel free to develop the ideas fully. The third part describes the properties of each of the categories.

The final part of a memo and one which is described in (Lowe, 1996) as crucial to the development of the core category, is the indicator. Indicators provide the link between the data and the memo and show where the categories and properties are indicated.

Memos, representing the conceptual development of categories and their properties, provide the analyst with the fund of concepts to develop the relationships between categories. The process that is used to achieve this is called theoretical sorting. Before moving on to this section it is important to describe the Constant Comparative Method because of its importance in the production of memos and categories.

1.8 Constant Comparative Method

This method refers to the systematic coding and analysis of data throughout grounded theory process that is performed by constantly comparison of data and concepts in order to suggest feasible categories, properties and hypotheses. It therefore goes on throughout open coding, memoing and selective coding.

The Constant Comparative Method used in open coding is based partly of the data being constantly questioned as to "what category or property of a category does this incident indicate"

The comparison is performed on a number of levels and using a number of forms of data. Initially it involves the comparison of indicator with indicator to develop properties of categories. As the study develops properties are compared to properties that develop the categories. In turn categories and categories are compared as are memos whilst memoing the ideas that emerge during it. This is performed until saturation is reached. Saturation refers to the state when the constant comparative method does not yield any further properties of categories.

As is mentioned above the development of the relationships between codes is provided by theoretical sorting.

1.9 Theoretical Sorting

Sorting is the process of preparing the saturated memos in a theoretical outline that is ready to be written up. It is described as the "key to formulating the theory" (Glaser, 1978) and is a step which prepares the emergent grounded theory for writing up.

Sorting of the memos involves starting anywhere in the memo fund and sorting them out looking for relationships, similarities, and conceptual order. It has to be repeated in order for the resultant core category and theory to have earned its place through saturation.

The sorting process is based on the core category that has emerged ordering of all other categories takes place around this. Further memoing may occur as ideas and relationships strike the analyst. These too are sorted until the analyst is able to integrate all the ideas held in the memos and a robust pattern emerges.

Having discussed the core activities in grounded theory it is now important to detail the fundamental component of the outcome of this process.

1.10 Core Variables/Categories and Basic Social Processes

A core category "accounts for most of the variation in a pattern of behaviour" (Glaser, 1978) and its discovery is the principle concern of grounded theory. A core category integrates the emergent theory and limits the research area. Glaser (Glaser, 1978) provides eleven criteria for evaluating whether a category is core (see Appendix One for full list) among these are that it must be central, occur frequently and it is easily related to other categories.

As mentioned previously there may be more than one category discovered during a study that could be core, if this is the case one should be promoted for the sake of a paper. The other category can then be used as core in a separate write up of the data.

The explanation and differences between core variable and core categories in the grounded theory literature however leads to confusion as to the principle concern of grounded theory. These two statements are used interchangeably without apparent explanation that leads to confusion because of the semantic differences between a

category and a variable. For example, in (Glaser, 1978) Glaser says "the generation of theory occurs around a core *category*". However in (Glaser and Lowe, 1996) this becomes "the generation of theory occurs around a core *variable*".

When asked during a seminar to explain the difference between these two cores, Glaser's answer was confused and non-committal, being based on "it depends" on what has been discovered. For the purposes of this study, the phrase "core category" is used.

A further point made by Glaser is that Core categories can be any kind of theoretical code. This brings us on to the Basic Social Processes (BSP) which are processional core categories. This type of core category reflects the core social patterns of people lives that exist throughout society. The basic social nature of these categories means that they are easily demonstrated outside the substantive area of the study and as such add to the theoretical grab and use of the theory.

BSP's come in two forms, the first of these is the basic social psychological process (BSPP) which is concerned with the personal psychological processes, in this study the BSPP of ***Shifting*** was discovered. The second type refers the social system within which the first operates and is called a basic social structural process (BSSP).

Glaser suggests that grounded theory is an ideal method to use in the discovery of Basic Social Processes and the discovery of them (again confusingly) is described as the principle concern of grounded theory! (Glaser and Lowe, 1996).

This initial confusion can be cleared if the authors would describe the issue in the following way. "The concern of grounded theory is discovering a core category and of all the theoretical codes that this can be in the form of, a preferred option is the Basic Social Process".

1.11 Evaluation of Grounded Theory

(Glaser and Strauss, 1967a) provide a number of criteria to be examined for the evaluation of research using grounded theory. They suggest six questions that should be asked of the theory:

1. What is the ultimate power for the emerged theory to explain across a range of different contexts.
2. What are the categories and what properties does each category contain
3. What are the basic social processes that have been revealed?
4. How has the process of Constant Comparison Method evolved.
5. Has the saturation process of the data been demonstrated
6. How has the theoretical sampling process emerged.

These questions are designed to determine whether grounded theory (as proposed by Glaser and Strauss) has been used or whether the theory proposed involves aspects of the grounded theory process but not in it's entirety.

In addition four criteria are also proposed which are designed to test the use of the theory to the people in the area that was studied, these are:

- Fit. This refers to the validity of the concepts in the theory in explaining the data it say it does.
- Workability. Do the concepts explain how the main concern of the people under study is solved. Does the theory work?
- Relevance. The theory that emerges should been seen as having relevance to the people who were studied. This study demonstrated it's relevance when it was presented to the original actors and who was able to see straight away how it represented what was done in this field.

- Modifiability. Can the theory incorporate new ideas and concepts as these emerge after the completion of the study. The use of literature after the development of the study determines that the theory should be able to be changed to take into account further data or integrate it.

1.12 Conclusions

The preceding section has explained the Glaserian form of grounded theory that was used in this study. Grounded theory is a theory building method that generates theory from data. Its construction is based around the discovery of a core category, this is category which is able to explain the majority of variation in behaviour in an area that is important to the people in that area. The core category is the central point around which other categories are developed and linked, and without it the resultant theory would be unsustainable.

Core categories emerge and are densified initially using the coding of data, the constant comparative method, and the production of theoretical memos. These processes develop a conceptual and theoretical view of the data that is developed further during sorting where the theoretical relationships between the categories in the theory are developed. The outcome of this is theory that has emerged through a primarily inductive process which is able to explain important behaviour in the original field but more importantly has conceptual grab over a wide range of situations.

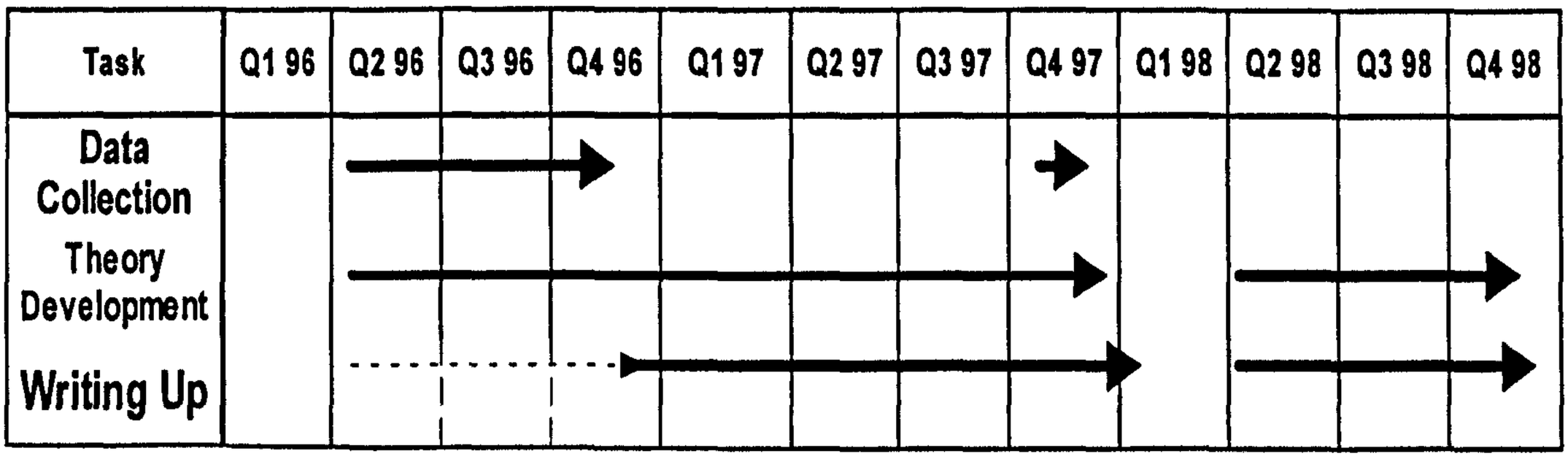
1 Chapter Two Method

The chapter will detail the method used in the development of ***Trading Off*** as an integrated grounded theory. It will be discussed in two parts the first will be a description of the process used in data collection, theory development and writing up. The second will demonstrate the critical path of development of the core category and a sub-core variable that emerged. To illustrate further the grounded theory process an example will be shown of a category that failed to "pattern out."

1.1 Time Line of the Research

The research process and theory development stages can be represented by the following time line. It demonstrates the simultaneous nature of many of the tasks within grounded theory in developing the saturated theory. The theory developments then leave a large body of writing that requires only further integration and development with the literature rather than wholesale construction.

Figure 1: Time line of Research.



The Theory development process consisted of:

- Acknowledging Pre-understanding
- Theoretical Sensitivity

- Theoretical Sensitivity
- Data Collection
- Theoretical Sampling
- Open Coding
- Selective Coding
- Memoing,
- Constant Comparative method
- Sorting,
- Saturation,
- Literature review
- Writing up

These activities take took place individually and conjunction with each other as the concepts emerged and densified into a core category and integrated theory. This section will now describe how these activities were performed.

2.2 Acknowledgement of Pre-Understanding

An acknowledgement of the level of experience and knowledge that this author has in the field of pharmaceutical marketing and how this may impact on the emergence of theory was required. Therefore, these thoughts were crystallised on paper as suggested by Glaser (Glaser, 1978). This pre-understanding can be seen in Appendix Two.

2.3 Theoretical Sensitivity

To develop a level of theoretical sensitivity a limited session of wider reading was undertaken. Incorporated into this was the reading that was performed as part of the development of the research proposal and choice of method.

The material read included literature on:

Cognitive Psychology

Social Psychology

Grounded theory (Glaser and Corbin and Strauss)

Consumer Behaviour

Research design

Management research

Sherlock Holmes novels

Quality Press.

These literatures where chosen due to their conceptual nature, in accordance with Glasers method literature concerned with pharmaceutical marketing and the adoption of new products was avoided.

A further characteristic of the literature chosen was its connection with areas of theory that were required to be reviewed in order to progress with the design and completion of the research proposal. It is agreed that a wider range of literature completely divorced from research and marketing could have been incorporated however practical reasons were behind the choice of these literatures.

At the end of this process it was felt that the author had been successful in becoming receptive to recognising and critiquing rigorously written material. This retraining was particularly necessary because of the shallow marketing literature and poor quality

research data that were encountered daily during time at MSD![1] Once this cognitive preparation had been performed (though the reading of sensitising literature continues to this date) the collection of data could begin.

2.4 Data Collection

Data collection for this project was divided into four phases.

2.4.1 First Phase

The first phase of data collection was designed to elicit support for the project and provide initial ideas for sampling. Toward this end contact was made with the local medical council and telephone discussion performed with a General Practitioner.

The permission of the chair of the Local Medical Council to conduct this research was sought primarily as a courtesy to this professional body and also as and aid to gaining access to local physicians. The letter of request (See Appendix Three) demonstrates the research topic at the time and is an interesting demonstration of how the emergent nature of grounded theory moved these ideas into different areas.

The reply, while appreciative of approach made, was unable to express support for the project because of the volume of work faced by physicians and similar requests. It did however assert that no exception was made to it. (Appendix Four)

2.4.2 Interview with GP

The second aspect of this phase consisted of a twenty minute telephone conversation with a GP from North Uist who had offered his services as source of information and contacts. This conversation provided details on the nature of the shared care and

[1] Merck Sharpe Dohme. The UK affiliate of Merck and Co.

education between primary and secondary care and the growing role of local prescribing advisors and local health boards.

As an example of the role of the health boards issue, a newsletter that was sent by the Highlands and Islands health authority is provided[2]. This demonstrated the style of information that is provided to physicians concerning new products and topics concerning existing ones (Appendix Five).

2.4.2.1 Directions taken

The existence and nature of the relationship between primary and secondary care in treatment matters and the health board involvement were used to form the basis for the next stage of data collection. It was decided that in the first instance interviews should be arranged with a primary and secondary health care provider. Access at later date to a prescribing advisor was also envisaged.

The development of the theoretical sampling that started with the discussion with the GP from North Uist will be shown in a later section. The second phase of data collection process and the specific methods and data sought will now be outlined.

2.4.3 Second Phase

The second phase represents the bulk of the information collected during this research process. From May until early December 1996 data was collected from both primary and secondary sources. The primary data collection was via a series of in-depth interviews, from the following sources:

- Primary care physicians

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[2] Produced by the Scottish Medicines Resource Centre.

- Secondary care physicians
- Greater Glasgow Health board Prescribing Advisor
- Chair of local new therapeutic sub committee
- Director of Undergraduate Medical Education Edinburgh University Medical School

The secondary sources analysed consisted of a review of prescribing data and marketing support data provided by commercial sources. These will be reviewed at the end of the section concerning the primary data collection.

2.4.3.1 Methods of Data Collection

The reliance on in-depth discussions as the primary method of data collection may be questioned on the basis of its narrow focus and that quality of information given by the respondents. In turn question may be asked of why a form of observation, (participant or independent) or group depth interviews were not used. These other forms of data collection will be addressed after justification for the use of in-depth interviews is provided.

2.4.3.1.1 Personal In Depth Interviews

This technique involving a detailed one to one discussion around a predetermined topic provides the backbone for much of the qualitative inquiry undertaken (Churchill, 1991). It has the advantages that it allows the researcher to probe areas of interest that are brought up during the discussion and provides a less threatening environment for the respondent.

This form of interviewing is subject to biases, introduced by poor interviewer technique for example leading questions, failure to probe important areas and lack of rapour building (Webb, 1992). Respondents who are either not motivated or able to divulge truthful answers to the issues being raised can compound these problems. This may be

driven by ability, or political or self esteem pressures that contrive to make the respondent answer in ways that are untruthful. It may also manifest itself in the respondent providing the interviewer with answers they think they want to here.

2.4.3.1.2 Application

These issues were guarded against during this research initially by an awareness of them and the researcher experience in using these techniques. The questions of quality of answers were addressed partly by the academic nature of the research and a period of rapour building used at the start of each discussion.

The academic nature of the research was felt to be particular benefit in this area. It helped put the physicians at ease and allowed them to be more open because the beneficiaries of their efforts were seen as worthy. This is in contrast to the pharmaceutical industry that throughout the research was found to be perceived in a negative light. It also was helpful in gaining access to the respondents in the first place. In anticipation of this the nature of the research and it's funding was made clear in all formal requests for access (See Appendix Six).

The use of contacts to set up discussions was also thought to benefit the quality of the answers and the building of rapour. For example one Dundee based general practitioner was instrumental in setting up a meeting that was needed with a Consultant in the care of the elderly. This method lent the research greater levels of trustworthiness and hence provided the physicians with the environment to feel free to discuss sensitive issues.

To further allow for the uninhibited discussion of sensitive issues, in a number of cases the tactic of switching off the tape recorder when the discussion had apparently finished was used. This period was then used to explore potentially sensitive areas or allowed the respondents to bring up further issues that they felt were important.

In summary, it was felt that despite the potential drawbacks of the in-depth interviews the experience of the interviewer and tactics used were able to gain accurate information and insight into the areas under scrutiny.

2.4.3.2 Other possible Data Collection Methods

2.4.3.2.1 Group Depth Interviews

Group depth interviews are a variation of the in-depth interview that involves discussions being held with small numbers of individuals within a groups setting. These groups are usually between six and ten people in size and provide benefits of group interaction during the discussions (Webb, 1992). It was not felt however, that this method would be suitable for this research.

It was felt that group pressures would restrict the honesty of the physicians when describing their prescribing motivations. It was thought that the presence of colleagues and peers may lead to sanitised and "correct" lists of influences being quoted that reflect the theory of medical decision-making not their practice.

It was also felt the this method may encourage an unwanted debate on best practice (i.e. whether drug x is better than drug y in certain circumstances) when examples were called for to illustrate points made in the discussion.

2.4.3.2.2 Observation

The use of observational techniques (Webb, 1992) to scrutinise directly the physicians and their interactions with patients and colleagues was rejected for a number of reasons. Primary amongst these was the issue of researching an essentially unobservable phenomena and question marks of the quality of data that would be produced.

Inquiries were made into achieving access to GP consultation rooms and Hospital ward. However in conjunction with the difficulty in finding physicians willing to be observed, it was felt that the need to secure patients consent would be extremely difficult. Whilst these problems were not insurmountable, the permissions required were also likely to increase the biases that observation can cause to data and hence undermine the quality of the data.

A drawback of observation is that the respondents may change their behaviour because they are being observed. The use of unobtrusive methods to overcome this was not available because of the need for physicians and patient permission to observe. Therefore, the data produced may have been further reduced. For these reasons observation was not chosen as a data collection method. For further details on the use of observation and depth interviews see (Easterby-Smith et al. 1991) or (Chisnall, 1986).

2.4.3.3 Primary Data

The in-depth interviews were conducted on a face to face basis and were tape recorded in order to provide a comprehensive record of the meeting. For further details on the in-depth interview as a method of data collection and supplemental techniques see (Chisnall, 1986; Easterby-Smith et al. 1991).

The interviews were arranged via a combination of informal approaches by telephone and subsequent formal requests in the form of a letter. These letters outlined the structure of the discussion and indicated a general topic. It was felt that this information was needed to in order for the respondents to decide whether they would like to participate. An example of one of these formal letters is in Appendix Six.

These discussions lasted between one half and two hours with a number of the subjects suggesting that they could be contacted again if necessary. This was done in two cases, the first of these was conducted by telephone in order to clarify the importance of various influences. The other formed the basis of the third phase of data collection.

2.4.3.4 Nature of the Data Collection

The discussions were guided primarily by the requirements of selective coding from previous discussions. These acted as broad overviews, subsequent to this initial questioning, the areas that emerged and seemed important to the respondent were followed and probed.

An example of a discussion guide used can be found in Appendix Seven. This guide refers to the discussion conducted with the Director of Undergraduate Medical Education at a University in Scotland. This meeting was designed to develop information on the nature of Conservatism and it's foundations. This concept had appeared at the beginning of the research and at this point was seen as an important cause of the "Balancing" process that was considered core at this point.

It should be noted that the topic was not introduced directly, instead it was introduced via a discussion on types of doctor. Possible causes of it were then explored by discussing standards known to affect physicians behaviour.

The guiding nature of the interviews is further illustrated in the following transcript of a discussion held with a trainee GP. This shows the development of issues concerning the influence of other physicians and cost that had been highlighted previously. It also shows an important probing tactic that was used throughout data collection that involved the asking for examples to illustrate seemingly important areas. This passage was found to be crucial in the development of ***Surrogating***.

IB " Why is that, your influences being the other GP's?"

CB: "' Cos they are more experienced than I am in general practice and they have probably tried and tested a lot of them and have their favourites themselves and I tend to gain from their experience really as to what they use"

IB: " You mentioned cost looking for the cheapest. Why is that is that a drive that the health centre...? "

CB: " No not just the health centre it is kind of something that has been drummed into you form a medical student upwards. I don't know whether I was one of the first ones when they started going on about cost benefit and all this lot. Not so much in hospitals, they don't really think about the cost so much there but when you've got when your in a general practice and your accountable for the prescriptions you write and what they cost then you are, tend to be more careful."

IB: " Can you think of any examples?"

CB: " Well for example we are trying to change everyone from Ranitidine onto Cimetidine at the moment, because Ranitidine is more expensive and they both do the same thing. So that is a big drive at the moment"

IB: " So an ideal situation would be for Ranitidine to no longer be prescribed in practice? "

CB " Well as little as possible, you try, put the patients on it but if they don't like it they come back and say I want to go back on Zantac, then you are obliged to pout them back, but you at least try and get them to have a go on Tagamet first."

2.4.3.4.1 Post Formal Discussion Data Collection

As has been mentioned previously, the turning off of the tape recorder was used as a tactic to change the atmosphere of the discussion from formal to informal. This is a tactic that was suggested by Dr Lowe as a useful method for use in grounded theory studies as it allows respondents to feel less inhibited when discussing topics that may be sensitive.

This was used in all the interviews conducted. It was particularly successful when in discussion with the chair of a local new therapy sub committee who provided a strong party line throughout the taped discussion but changed to his views when the discussion was no longer being taped. This change provided data itself.

2.4.3.4.2 Secondary Data Sources.

In order to augment the data that was emerging on medical decision-making, the influences on it and pharmaceutical usage, an analysis of commercially available information on pharmaceutical marketing effort and prescribing was attempted. This was conducted in July 1996 and ran parallel with the primary data collection.

2.4.3.4.3 Information on Pharmaceutical Marketing efforts.

Information on the marketing efforts of the pharmaceutical industry was obtained from a multinational research agency located in London. The report provided contained information on the number and type of representative activity provided for each product. In addition information was provided on whether the panel were aware of the drug, had been "detailed" it, or had ever prescribed it.

This data is produced by a using a diary based panel method that reports monthly (see (Chisnall, 1986) for further details on this method). Selections of pages from this report are available in Appendix Eight.

It was intended that analysis of this report would reveal relationships between the type and volume of marketing effort provided for them and the levels of awareness and use. Specifically it was used to analyse a number of products that were launched in 1995 and 1996.

2.4.3.4.4 Prescribing Information

In conjunction with the collection of data on marketing effort described above, retail and hospital sales figures were collected and analysed (see Appendix Nine). It was felt that this information would provide an objective summary of the success or failure of the marketing efforts. This in turn would provide tentative conclusions on which approach and which individual influences effected physician's behaviour.

2.4.3.4.5 Lack of Success

Despite considerable effort in applying the constant comparative method and memoing these data sources the analysis was abandoned after approximately 3 weeks. This was

due to it becoming apparent that it was providing no relevant information to the core category as had now emerged from the primary data collection.

The data collection was therefore concentrated back on the discussion process from which a core category had been discovered and was felt to be providing rich and dense sources of concepts and relationships.

2.4.4 Third Phase of Data Collection

Once the point of saturation was reached from the discussions and the core category and theory had emerged from the sorting of the theoretical memos a further discussion was held with one of the original respondents. This represented the third phase of data collection and was centred on the diagram of traded confidence. This diagram and notes from the discussion can be seen in Appendix Ten.

This consultation directed a re-examination of memos and original data and lead to a number of developments within ***Trading Off***, most noticeably changing the label of the core category from Confidence Trading to ***Trading Off***. This reflected the increased grab of ***Trading Off*** to represent what was felt to be the main concern of physicians acting to make decisions.

Indeed the physicians said directly that "***Trading Off*** is the world GP's live in". The discussion also provided further data on ***Self-Referencing***, ***Focusing***, ***Shifting*** and ***Surrogating***. These developments will be examined further in the later section dealing with Theory Development.

2.4.5 Fourth Phase

A final period of primary data collection was felt to be necessary after the completion of the draft literature review. There was a need for a brief, further inquiry into the efforts of pharmaceutical companies to modify physician's behaviour for their own objectives.

This was primarily based on the need for further information that was unavailable from published literature. In particular, pharmaceutical companies spend enormous amounts of money on market and marketing research they are secretive in their application of these findings within a strategic and tactical framework. Views on future health care developments and their impact on marketing efforts were also required

Beyond some information only being available from primary research, it was also felt that these strategic and tactical issues would provide a framework with which published data could be integrated. As much of this literature discovered was found to be of poor quality in it's production and reporting, the views of practitioner would provide a useful point of comparison.

The decision was made to conduct qualitative interviews using the outline of the draft literature chapter as a discussion guide. Two individual depth interviews were conducted over the phone and these were able to provide the information required.

In keeping with the reluctance to publish marketing information, both interviewees requested not to be tape recorded and that all reference to company products and therapy areas be removed from the data. The interviews were conducted using the telephone, though one company supported this with examples of their marketing literature sent after the discussion had taken place.

The completion of these interviews heralded the end of the data collection phase. The Theoretical Sampling process used will now outlined.

2.5 Theoretical Sampling

An explanation of the Theoretical Sampling procedure and its importance to the development of a grounded theory is provided in chapter one. The following section will highlight, in chronological order, the individuals used to develop the emergent categories, the information requirements and the reasons why these individuals were approached. Primarily the path of the development of the core category will be followed however, other important discoveries will also be indicated.

This process will also show how the research question was re-defined and developed as the categories and concepts emerged. This moved the original area from the prescription of new drug compound by UK physicians to a wider view of decision-making used for choice between medications.

The applicability of ***Trading Off*** to represent Medical Decision-making in all it's forms[3] beyond choice of pharmaceuticals, requires further theoretical sampling and theory development. The examples used during data collection refer primarily to this area however other examples of medical decisions were given. The theory was delimited to explain one area though where necessary for this process to be completed other decisions are included.

2.5.1 Individuals Sampled

2.5.1.1 Dr J. MacLeod. Experienced GP, North Uist, trained in Glasgow. Telephone interview, 10/5/96.

Dr MacLeod was used to provide an initial briefing on the area under scrutiny and to suggest important avenues that should be explored. He was chosen for this role because

[3] For example Diagnosis, Treatment, Referral, Surgery, Physiotherapy, Psychiatry, etc

of his experience as a physician and his contacts with the medical community in Glasgow built up during his training.

This discussion highlighted three major parties that he believed were important in the use of new compounds. These were Primary care physicians, Secondary care physicians (particularly consultants) and local Health boards. Discussions were therefore set up in these settings with the intention of discovering further details on the role of these parties.

2.5.1.2 Dr S. Hillis. Consultant, Department of Cardiology, Western Infirmary Glasgow. Face to face interview 17/5/96.

The high ranking position and the large volumes of experience held by this physician within an important department made him a target to start the investigation into the role of secondary care.

The open coding of this discussion suggested that the important aspects in the prescribing of new compounds included Conservatism, Comparing and Balancing as an overall approach to medicine. Of interest at this stage was also the trivialising of the role of pharmaceutical marketing in influencing behaviour.

It was felt that these categories should be explored further in a physician with a junior position to Dr Hillis. This was because of a number of references made to the privileged position that consultants have within the current hierarchy of the NHS.

It was also perceived during this discussion that a wider view of pharmaceutical decision-making was developing. Whilst a number of examples were set around newly launched products the area that appeared more relevant to the physicians was pharmaceutical decision-making.

2.5.1.3 Dr Ronald Gordon. Senior Partner in a General Practice based in the Gorbals Glasgow. Face to face discussion 7/6/96.

The experience and senior position of this physician within general practice were the important characteristics used to gain an initial understanding of the role of the GP and it's interactions with the other parties.

This discussion provided data on the approach taken to medicine and the constraints that are and are perceived to be in place over this. The importance of Independence was found as was Weighing Up. These areas formed the basis for the next discussion.

As with the previous discussions it was felt that a broader view of the original topic was more important in the data being produced. Therefore this more general area was taken as the focus of the research. This focus did not change during the remaining data collection, however the emergence of ***Shifting*** during Sorting provided a distinct BSPP which could be the focus of further sampling.

2.5.1.4 Dr D. Brewster. Partner in a rural General Practice based in Perthshire. Face to Face discussion, 26/6/96.

In order to develop further Independence, Weighing Up and Balancing a general practitioner with similar characteristics but a difference practice setting was sampled.

The findings from this data collection showed further the Independence of physicians and the struggle that the currently face to maintain this. A feeling from the data concerning the Individual nature of medicine was conceptualised and was looked to be developed further at the next opportunity. The Conservatism shown in the previous discussions also manifested itself here though in the form of Ethnocentrism.

During this discussion the codes concerning the building of trust appeared which were found to be of great importance during the sorting and densifying of the theory that occurred after data collection had finished.

The next discussion had been arranged originally to elaborate on the role of Conservatism, and Balancing in Secondary care. However, issues of Weighing Up, Independence and the Individual nature of medicine from primary care appeared similar and were also developed.

2.5.1.5 Dr E. Swan, Clinical Assistant, Cardiology Department, Western Infirmary Glasgow, Face to Face discussion 28/06/96

The characteristics of this physician which were important centred on the lower levels of experience and position held as indicated as important in the discussion with Dr Hillis.

This discussion saw the emergence of Adopting and Role Playing as developments of Balancing and the Individual nature of Medicine. Further information was also gained on the volume of influences found in medicine and the need for Confidence in these.

The coding and analysis of this discussion saw an important shift from open coding to selective coding around the centre of Weighing up/Balancing and the individual nature of medicine as means of resolving medical decision-making. This therefore changed the focus of the study from the prescribing of new pharmaceutical compounds to decision-making behaviour of physicians.

It was felt that further access to physicians in similar circumstances would refine the overall discovery of an Individualised Balancing /Weighing up process.

2.5.1.6 Dr D. Birnie. Registrar Cardiology department, Western Infirmary, Glasgow. Face to Face discussion. 19/7/96.

As mentioned previously, this discussion was set up based on the very similar characteristics and experiences of this physician to the one previously sampled. The concepts of the Individual nature of medicine and Weighing up Balancing/Adopting/Role Playing were refined further into Bottomlining.

Also developed during this discussion was the feeling of Control that surrounds the practice of lower ranked physicians. This Controlling concept was thought to be related to knowledge and Knowledge Controlling

From Knowledge Controlling the category of Experience Substituting developed. This category proved to be the forerunner for ***Surrogating***. Further development of the trivialising of marketing's influence was also made.

This movement toward selective coding and the emergent core category (Bottomlining) was helped by the realisation of the close similarities between primary and secondary care in their decision-making behaviour. Further discussion were planned in both environments to see if this similarity patterned out.

2.5.1.7 Dr M. Duffy. Partner in City Centre practice in Dundee. Face to Face discussion 26/07/96

This physician had recently moved from Secondary care to Primary care where he had held a lower-middle rank. As it was suspected for the previous discussions that there were more similarities than differences in fundamental approach to prescription decision-making, it was felt that this physician would provide an ideal source for data on the Bottomlining.

The combination within Bottomlining of Balancing and the Individual nature of medicine was rejected after the analysis of this discussion and a review of related memos. It was felt that a cause-consequence relationship had emerged between these two categories with Balancing being the preferred label for the core category.

This discussion also developed the Controlling category and the theme of Independence reappeared. Whilst Independence was found to relate easily to Balancing, Controlling was shown to be of decreased importance.

As a result of the fracturing of the core category and a need to further develop the individualising category, it was felt that information should be gathered from an area of medicine that is characterised by it's complexity. The care of the elderly was suggested as such an area.

Before this interview could take place a previously arranged discussion with a Prescribing Advisor would take place. This interview had been set up in light of discussions with GP's and the perceived importance of the Controlling category.

2.5.1.8 Dr E. Forrester, Medical Prescribing Advisor Royal Infirmary Glasgow. Face to Face discussion. 14/08/96.

The role of this physician in advising on and attempting to change the prescribing of local general practitioners made him a crucial informant on the practice of the health boards. This group constitutes the third important party in medical decision-making described initially by Dr MacLeod and developed by others.

The committee aspects and practice of decision-making were developed here under the core category, Balancing and also Individualising. This discussion lead to the emergence of a feeling of Matching that bridged the gap between Individualising and the

knowledge held by the physicians or committee. The further exploration of Matching was then used as a key objective of the next interview.

Information was discovered for Controlling which continued it's decline in importance. This was partly due to the importance of physician's Independence though it was noted that a property of independence is that it is being eroded.

The selective coding process made the integration of these developments into the next discussion that took place later the same day possible. It is acknowledged that data collection from separate points in this way does not allow the benefits of full coding and conceptualisation to be integrated. However practical reasons regarding the difficulty in gaining access to the Prescribing advisor and the Consultant in the care of the elderly made this necessary.

2.5.1.9 Dr J. Hanslip. Consultant in the care of the Elderly, Royal Victoria Hospital, Dundee, Face to Face discussion 14/08/96.

As mentioned previously, data collection was needed from a speciality that was complicated by the particularly individual nature of it's problems in order to develop individualising. The importance of this category to Balancing and Matching resulted in these categories also being elaborated. A consultant level respondent, it was felt would be able to provide a more conceptual and deeper understanding of this process.

This interview was successful in developing the integration between these three categories and particular in widening the scope of individualising to a number of factors beyond the core problems suffered by the patient.

It was felt that a junior level respondent may be able to show the integration of these categories with Controlling and further develop them from a situation of considerably less knowledge and experience.

First however a previously arranged meeting to discover the origins of Conservatism and Ethnocentrism would be held. Again the meeting took place without full coding of the previous interview. However, because of the specific information requirements and a well developed selective coding process, it was perceived that this would not reduce the benefit of the discussion.

2.5.1.10 Dr S. Fleming, Director of Undergraduate Medical Education. Edinburgh University Medical School. Edinburgh, Face to Face discussion 15/08/96

As the director of education at a major medical school Dr Fleming was thought to be ideally suited to providing an insight into the causes of Conservatism that may come from a physicians training.

This discussion revolved around the causes of the Conservatism that had been found throughout previous meetings. This short interview was able to provide institutional causes of Conservatism and indicators of a move from the basis of medical practice on internal to external sources. The conceptualisation of this movement represented an important step in the development of the use of information sources.

It was felt that this discussion had satisfied the need to develop Conservatism and that the information provided concerning information usage should be developed in inexperienced practising physicians who may show this movement between sources.

2.5.1.11 Dr K. Briggs, GP trainee, Maryhill Health Centre, Glasgow. Face to Face discussion 6/11/96

The position of GP trainee is held by those physicians wishing to enter general practice and is performed after they have completed their medical training and their hospital rotations. They therefore possess a high level of knowledge but lack patient experience and were thought to be an ideal category of respondent for the information needs outlined above.

This discussion added a number of further aspects to Matching and Balancing. Information usage was also developed and Individualising moved on to Centreing. A greater number of repeated concepts and properties also emerged from this interview.

In order to develop further the committee practice of Matching and Balancing, a discussion was needed with a member of a committee that consider the use of pharmaceuticals on a health board wide basis.

2.5.1.12 Dr C. Semple, Chair of the New Drug Sub-committee Glasgow Health Board. Face to Face discussion 13/11/96.

The role of this physician in the selection of drugs for the wider health board was supported by his position as a practising consultant in general medicine with a particular interest in Diabetes. The categories of Matching and Balancing as developed over the previous discussions were found to contain many properties coded during this discussion though the process performed in committee was formalised.

A further discussion with these categories was planned to explore these categories again in situation of greater freedom therefore a GP was targeted. It was felt that the categories were nearing saturation however.

2.5.1.13 Dr J. Wilford, GP Bridgeton Health centre, Glasgow, Face to Face discussion 4/12/96

This experienced GP who had many years of experience of training and practising in the 3rd world was able to provide a different perspective on the Matching, Balancing, Centreing, and ***Surrogating***. However conceptually she provided no new properties of these categories only different indictors for them.

At this stage it was felt that saturation had been reached because of the findings of this discussion and those previous to it. This point had been reached early within the normal bounds of the number of data collection points used with grounded theory.

Summary.

This section has demonstrated the use of the Theoretical Sampling procedure use in this research. It has shown the categories that were developed at each interview and the link between these categories and the individuals used as a source of information. A brief description of the remaining grounded theory procedures will now be examined before examples of theory development are given.

2.6 Open Coding

The open coding procedures used during this research were based around a literal interpretation of Glaser's second rule of open coding. This rule states that "to analyse the data line by line, constantly coding each sentence"(Glaser, 1978) p57. Codes/labels and memos were produced so that all incidents of the data collected were labelled and memoed. This may have been a paragraph or a single word but it resulted in an over production of initial concepts and memos.

For example:

(Dr. S. Hillis)

Transcript	Codes/labels	Memo
SH OK I think basically most of us are conservative as far as our choice of therapies are concerned.	A1 Therapeutic conservatism	Feels that they are not con in other places
In cardiology obviously we have a lot of therapies which means we've got reasonable choices.	A2 Reasonable therapeutic choice	but therapies are different
If something is working for us then it will take something fairly major to change it,	A3 Normally major evidence needed to change	if it isn't broken don't fix it
in terms of tweaking a product then most of us will have to have very good evidence about .	A4 Evidence based	Better than in other areas but no perfect

The true meaning of this rule as it refers to the analysis on a line to line behaviour with the comparison of incidents looking for patterns and concepts became apparent at a later stage.

2.6.1 Correction of misunderstanding

This over-fracturing of the data was corrected using the constant comparative method to search for the patterns and concepts. In (Glaser, 1992), Glaser's attack on (Strauss and Corbin, 1990), he comments that the labelling process suggested by Strauss will not allow feelings of relevance to appear. The approach suggested by Straus is essentially the same as the approach used initially in this study. Key to this criticism is the lack of comparison in Strauss's method. Therefore in applying the constant comparative method to the initial level of labelling the potential problems with the Strauss method are avoided.

Essentially the open coding used in this study can be seen as consisting of 2 stages, first the initial labelling incorporating the coding questions suggested by Glaser, and is detailed below. Second followed by the application of the constant comparative methods and the memoing of the subsequent ideas, concepts and potential categories.

The corrective action taken lead to the following output, (Further examples can be seen in Appendix Eleven)

For example:

Codes	Open code	Memos
A18 PR and paper role of rep A19 Will be seen once but reminders difficultA20 Supportive accessA21 Educational papers access A22 Book access A23 No papers no tends no access	Supportive educational access	The access issue is dependent on supportive books and educational of the reps
A58 Super marketing message A60 Phrase struck cord A68 Concept picture	Super Marketing message	The picture and phrases are sticking with the physicians. They manage to encapsulate the problems of the disease area

The initial process was however carried out adhering to Glaser's rules of coding:

1) That the data was constantly questioned in what is it a study of, what does this indicate and what is actually happening here. (forming the basic questions for the Constant Comparative Method of coding)

2) The coding was performed by the author
3) Coding was interrupter to memo at any stage where a memo emerged.
4) No value for demographic variables was assumed.

(Glaser, 1978) p57

A further level of data was applied to the open codes as specified by Dr. Lowe. The following notation was used to track where the particular piece of information had come from. This added information was used as an added level of data to help determine which concepts were important to the respondent.

A Yellow = interview guide
B Green = supplemental
C Pink = Not asked

2.6.2 Continued Indexing and Labeling of Data

It was decided to continue with this level of indexing and labelling during the selective coding stage. This deviation from the teachings of Glaser was based on a number of reasons. In continuing to index the data in this way, a comprehensive understanding of the substantive information was maintained. This therefore provided the grounding for the conceptualisation and theory development performed throughout the rest of the grounded theory process.

A second reason was that this level of indexing had proven useful in allowing easy access to the data in its original form via the labels used. This in turn allowed for in-vivo codes and the demonstration of the theories grounded nature. To continue in this style and using a corrective period also provided the coding with consistency. It was felt therefore that this activity would be of benefit throughout the process.

2.6.3 Summary

The open coding phase was performed in according to rules set out in (Glaser, 1978) and an additional aspect suggested by Dr. Lowe. A misinterpretation however of one of these rules lead to an over-fracturing of during the initial attempts at coding.

Due to the corrective action that was taken using grounded theory procedure it is felt that the only negative consequence of this misinterpretation was a longer and more painstaking coding phase. It contributed positively however to the in depth understanding of the data.

2.7 Selective Coding

The selective coding phase started after the selection of Weighing up/Balancing as means of resolving decision-making for medical treatments. These different labels referring to the same category, had emerged (as detailed in Theoretical development) at an early stage. During the coding of the discussion with Dr Swan it was felt that this had shown itself as the central issue within the data and therefore formed the basis for future data collection and theory development.

At this stage the coding and memoing as driven by the constant comparative method became centred on only those variables that were related to the core. The selective codes became increasingly complex and conceptual in nature reflecting the development of the categories. Examples of selective coding showing this movement are to be found in Appendix Eleven. These codes also demonstrate the use of the indexing process during the open coding phase.

2.8 Memoing

Examples of memos produced throughout the data collection and theory development stages can be seen in Appendix Eleven. The memos used throughout this section show the development in the output of this process. This moves from simplistic questioning of the data and suggestion of possible concepts and relationships to the integrated write up of a category and it's properties that when sorted provided the information for the final categories of the grounded theory.

Memoing was performed whenever necessary in order for the ideas and concepts to be captured. The critical property of a memo is the theoretical concepts and ideas that they contain, Glaser stressed strongly that they are not an exercise in correct English, (Glaser, 1978) therefore the memos presented in the appendix are left unedited.

The outcome of memoing was to produce a fund of writing and a depth of understanding of the concepts within the data that when subsequently sorted formed the basis for substantive grounded theory discovered.

2.9 Constant Comparative method

The constant comparative method was used throughout the substantive and theoretical coding stages of this research. The output of this method is seen in the integrated theory produced by the research, its use is effectively demonstrated in the examples of the diagrams shown in Appendix Twelve.

These diagrams were produced as physical representation of the outcome of comparisons made within the data during both coding and sorting. A further example produced during selective coding is seen in Appendix Thirteen, this demonstrates how the comparison of codes has been used to produce memos on the potential relationships and concepts within the data. The diagrams produced during coding represented

relationships between codes that were examined further as data collection continued. Similarly, diagrams were also produced during the repeated sorting of the memo fund that produced the integrated theory and its theoretical codes.

2.10 Sorting

The repeated sorting of the memo fund performed to develop the integrated theory was performed over a 3 month period at the start of 1997. Mechanically it involved the use of the departmental "board room" because of the large amount of continuous desk space available as a "canvas" on which to sort the memos.

Also invaluable was the availability of large white boards that were used to hold in view the outcome of previous sorts and so to allow easy tracking of developments and changes. The easily modifiable nature of a white board also allowed for small sections of the theory to be advanced and to be able to retain the larger picture.

Two examples of the outcome of sorting are shown in Appendix Fourteen. These demonstrate the movement from related categories to a fully integrated theory that is developed fully in chapter 3. These diagrams show attempts at the integration of a larger number of categories and illustrates the basic process that ***Trading Off*** involves. They also demonstrate the amalgamation of smaller categories into the core category and the sub-core categories.

The sorting process was revisited after the literature of review was undertaken and it was found that a superior fit of the data occurred when ***Confidence Building*** was integrated within ***Surrogating, Self-Referencing*** and ***Trading Off.***

2.11 Review of Literature

The completion of Sorting and writing up in early 1998 moved the focus of the research on to a review of relevant literature. The developed theory indicated the following areas should be looked:

1. Decision-making
2. Medical Decision-making
3. Factors influencing Treatment decisions
4. Modifying Treatment choice
5. Modifying Physician's behaviour- The efforts of pharmaceutical companies.
6. Expertise Development.

These literatures that are presented in chapters 4 to 10 were performed according to three objectives:

- Frame the specific findings of ***Trading Off*** within the current body of knowledge.
- Discover further concepts and properties that may develop ***Trading Off***.
- Use ***Trading Off*** to synthesise and organise these literatures.

Accordingly, the literature review process can be seen as part theof theory development process within grounded theory.

2.12 Writing up

The writing up process within grounded theory is a continuous process that is primarily based around the development of memos. This moves from the original attempts used during labelling and open coding through the memos produced while sorting and finally involving issues that emerge during the review of literature.

The writing up process is therefore demonstrated through the stages shown in the Theory development section and in chapter 4 representing the finished ***Trading Off*** theory.

This phase was aided by the grounded theory writing group run by Dr Lowe. The regular meetings of this group provided a forum for its member to present research problems and issues for discussion. This group proved extremely useful as an editorial forum where current writings could be critiqued and improvements suggested. This included the labels used to encapsulate categories and the clear expression of their sub-categories, properties, indicators and axial codes.

During the writing up of the final versions of ***Trading Off*** it was decided to use summaries as a method of aiding the reader and structuring the output. This is contradiction to Glasers view in Theoretical Sensitivity who see them as "an affront to those readers who have actually read the paper and a cop out for those who have not read it" (Glaser, 1978) p132. He asks why they should be provided when the chapters are themselves summaries of concepts.

However, summaries of the main concepts were included in this research because of the inevitable difficulty in following a chapter that contains over ninety pages of densely written theory. Glasers refusal to use summaries in his writings along with indexes and table of contents, have I believe contributed to the growth of the Strauss and Corbin approach to the method. These aspects make the writing accessible rather than insult or compensate for lazy readers.

Glaser does however recommend the use of conclusion and recommendation chapters particularly when writing on practical subjects. This is provided in chapter 11.

2.13 Summary

The preceding sections have been provided in order to demonstrate the application of the grounded theory process in this research. The reader must be cautioned that the linear nature of this description does not accurately reflect the process undertaken because of the simultaneous and repeated nature of many of the tasks (for example writing up and the constant comparative method).

In order to provide a link between this chapter and chapter 4 detailing the integrated theory of ***Trading Off*** two sections will now be provided illustrating the development of the core category and ***Focusing***.

The rise and subsequent fall of Controlling as a category that was originally thought to be of central importance will also be demonstrated. Finally the theoretical coding of the relationships between categories will be demonstrated.

2.14 Development of Categories

2.14.1 Development of the Core Category

Figure 1: Development of the Core Category

2.14.2 Explanation:

This evolution is illustrated further by examples of quotes, codes and memos in Appendix Eleven. These emerged and were elaborated on during the open and selective coding phases and subsequently sorting and writing up.

The "Central Theme" tracks the development of the category that emerged early in the coding process and subsequently was picked as the core category. The label for the category changed as the theme became more refined and was influenced by other categories.

The column referring to "rejected developments" tracks where the suspected core category was taken in a direction that was subsequently shown by the data to have moved away from the central theme. In these instances the conceptual developments that took the category in these rejected directions were integrated into the core or into sub-core variables.

"Developmental Categories" refers to concepts that appeared in the data and were subsequently integrated into the developing core variable. In some instances, for example ***Confidence Building*** these became fundamental aspects of the core variable.

The fundamental characteristic of the variations of the core category, was the process used to deal with the large number of factors and variables present in medical decision-making. The number and complexity of the variables and factors became apparent very early in the study and around this developed the physician's response to resolving this primary concern.

The issues of conservatism and profiting had important consequences for how this ***Trading Off*** takes place. These factors underpinned the need that the physicians have for confidence in their behaviours. Without the concern for a wider audience, the

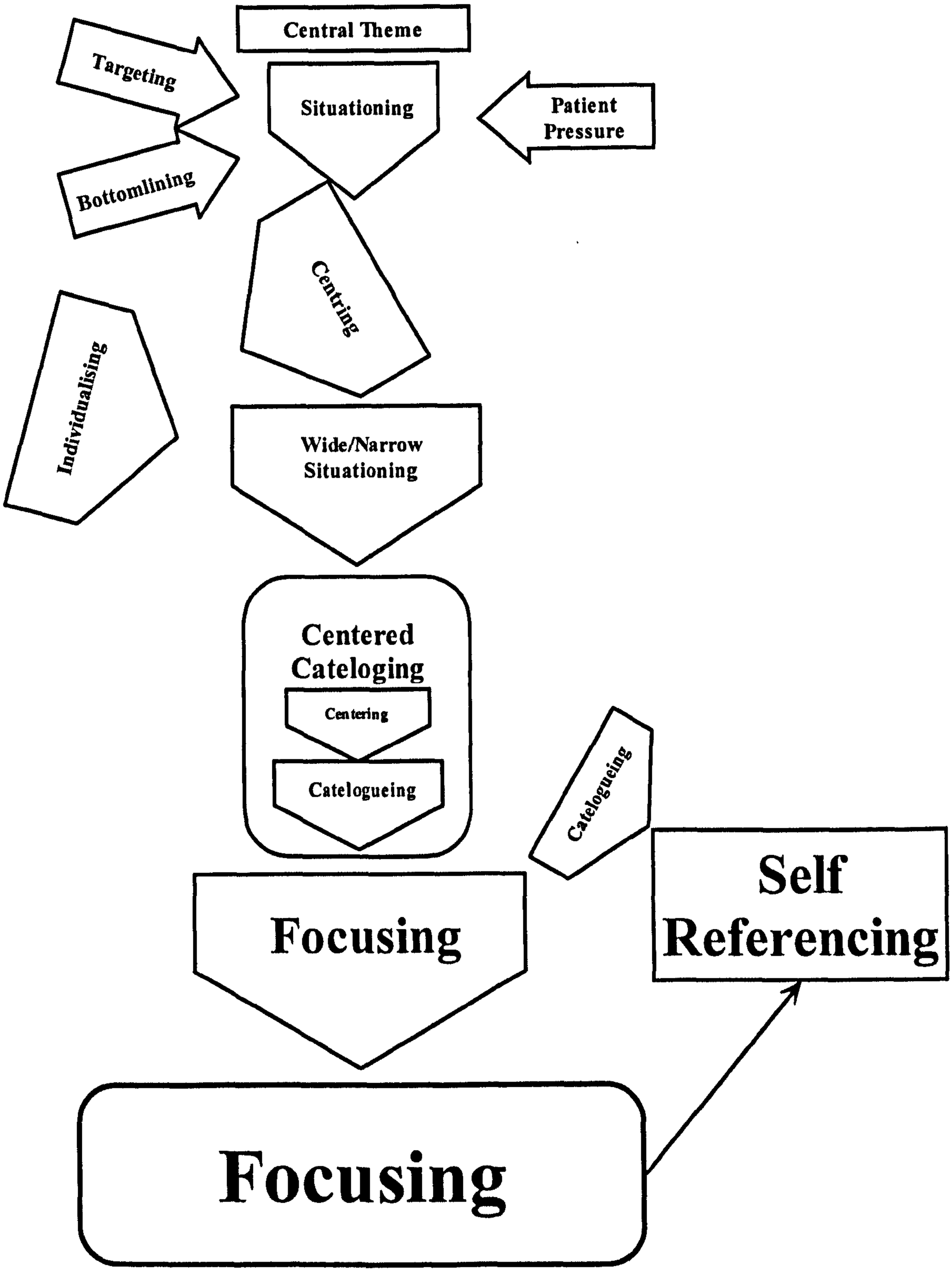
reticence to change and hence the need for confidence, ***Trading Off*** would be performed in a less stringent, detailed manner.

It would be the topic for further research to see if medical communities who do not posses these factors demonstrated a different kind of ***Trading Off***.

The final issue that emerged from the data was the superior fit of the core category incorporating ***Confidence Building*** rather than as a separate sub category. It was found that many of the concepts of ***Confidence Building*** were replicated in ***Surrogating***, ***Shifting*** and ***Self-Referencing***. The factor that is ***Traded Off***, confidence, was then found to fit easily into the core category of ***Trading Off***.

2.14.3 Development of Focusing

Figure 1: Development of Focusing.



The emergence of ***Focusing*** as an initial period of discovery and definition of the problem faced by the physicians is based primarily on the complexity of situation and the need to act in a beneficial way. These tenets interact to produce a category that attempts to discover the important aspects of a potentially dangerous situation in order for subsequent behaviour to be based on an accurate assessment of reality.

The importance of the very specific nature of medicine became apparent at an early stage within this research, this is reflected in the stable nature of the labels used. The width and depth of the factors involved in this process developed throughout the initial coding stages and with it, a growing feeling of the key of the individual nature of medicine to how physicians make decisions.

The fundamental aspects of what concluded as being the main tenets of ***Focusing*** emerged early in the process of development. The main aspect in the maturation of this category however was the discovery of the specific function of the "Centred Catalogue" that was produced.

During sorting and further memoing many of the properties, concepts and relationships of Cataloguing were used in development of ***Self-Referencing***, ***Surrogating*** and ***Shifting and Focusing***. This movement of ideas was crucial in the completion of the integrated theory. Further details on the development of ***Focusing*** are available in Appendix Fifteen.

2.14.4 The Emergence and Rejection of Controlling as a Sub-Core Category

At an early stage in theory development the category of Controlling emerged and was subsequently selectively coded for because of it's apparent importance to the core category. As the process continued however, it's significance began to reduce until

under the core category that was chosen (as two potential ones appeared to emerge) it was reduced to a sub-category of ***Surrogating*** (Duty Bound). See Appendix Sixteen for details of this process.

The development of ***Surrogating*** was found to incorporate some of the properties and concepts of Controlling (especially Knowledge Controlling). As sorting continued these concepts were found either not to fit or they contributed to a sub-category of ***Surrogating***

Duty Bound ***Surrogating*** therefore contained the properties and concepts from Controlling that were related to the core category. It is a sub-category that is expected to become more important as more control excerpted within the NHS. Currently however with the independent self employed nature of GP's and Consultant lead hospital ward, these concepts remain a small part of the integrated theory.

These developments, if they occur may lead to modifications being made to ***Trading Off***, this flexibility is a criteria for evaluating a grounded theory.

2.14.5 Summary

A brief diagrammatic and written presentation has attempted to illustrate the complex and often hidden world of theory development. A far greater level of detail is available in the Appendixes.

The selective categories chosen were done so to because of their ability to demonstrate crucial breakthroughs and processes of the theory development that occurred. Controlling is included as one example among numerous of ideas that did not pattern out as was first thought they might.

2.15 Conclusions

This chapter has detailed the method applied during this research project. It has elaborated on the specific procedures used and highlighted a number of deviations from Glaserian approach to grounded theory detailed in chapter 1. These will be discussed where appropriate during this conclusion section.

The theoretical sensitising procedure followed is believed to have been successful in opening the author's awareness to conceptualisation and theoretical structure. This was crucial after the stagnating environment worked in previously. The use of literature that was related to the production of a PhD but distinct from the specific are under scrutiny was thought to be a useful tactic in combining two necessary tasks.

The data collection methods used in this study showed mixed success based on the type of data that was sampled. The primary data collected was successful essentially because of its ability to provide detailed examples of behaviour and data from how these examples were rendered by the physicians. In addition to the explicit detail provided on the options considered, tone, pacing, "asides" and non-verbal language provided invaluable data on the process used to solve problems. This was seen particularly when requests for general examples were given and the physicians immediately discussed specific cases and then introduced the relevant options into the answer.

The lack of success using secondary sources is thought to be due to the same reasons. The data analysed involved outcomes and predetermined properties that the researchers believed could cause this. Whilst this data was being used to develop the role of pharmaceutical company activities on decision-making, it was unable to provide information on their decision-making process. It did not contain sufficient information on the individual interactions to shed light on the cognitive process that had emerged as the core category.

The emergence from the data of prescribing decision-making from the area of new pharmaceutical launches, demonstrated Grounded Theories ability to detect the concerns of the subjects. This was discovered early in the collection of primary data and remained unchanged until the final version of the theory was written and discussed.

The returning to sampling points and discussion of a draft version of the theory proved to be important collection methods. This allowed clarification and probing of issues that had either been unclear or more data was thought to be necessary. A further technique that assisted data collection was turning off the tape recorder at the end of the "formal discussion" but continuing to discuss areas of interest. A number of political and controversial points of view were elicited in this way. These benefits support the use of individual depth discussions as the primary method of data collection used in this study.

The use of tape recorders is a further area that this study deviated from the views of Glaser. Glaser expounds that view that a researcher should listen and observe while researching and write up field notes after the event. He believes that the use of a tape recorder inhibits the respondent and decreases the ability of the researcher to conceptualise.

It was felt however during the planning stage of the research that a tape recorder would be useful in capturing a complete record of the verbal communications from the discussion. This would leave the researcher free to concentrate on theoretical sampling and recording non-verbal data in addition to areas that struck as important. This tactic proved successful in allowing these facets of data collection to take place. The previously mentioned turning off of the device at the end of the discussion was used to allow data to be expressed that may have been inhibited.

The issue of reducing conceptual ability is debated, particularly in the novice researcher, because of the number of tasks faced. Conceptualisation during data collection is

reduced by the management tasks of the discussion and this is reduced further if more detailed notes are required. It can be argued that using field notes and post discussion write- ups leaves the research open to memory bias and the intrusion of preconceptions on the indicators and resulting concepts. In short, relying on memory and notes may reduce the correct grounding of the study. Therefore, it is believed that the use of a recording device, when used in conjunction with other tactics can help ensure quality data collection and theory development.

The theoretical sampling pathway used covered primary care, secondary care and health board professionals. Despite the different working environments, the core category of ***Trading Off*** was found in the approaches to prescription decision-making used by these groups. This is thought to be due to fundamental similarities in patient problems and constraints that exist in proposing a solution.

Whilst this research produced a substantive theory, it's scope to include other types of medical decision-making can be investigated with further sampling. It is tentatively believed however that the ***Trading Off*** process should have a close fit to that used for wider treatment decision-making. This is based on a number of factors. First, data was presented on decision-making used in other forms of treatment, these demonstrated the same concepts as the far more common pharmaceutical examples.

Secondly, the same need for individual consideration and the situational constraints of time, money, available techniques, skills and patient opportunity exist when referral, surgery etc are considered as options. These options also possess their own benefits and costs that need to be examined when decisions are made. Therefore whilst ***Trading Off*** is presented as a theory of prescription decision-making, it may possess wider applicability. However, whether this research should perform this development, because of aforementioned preconceptions is open for debate!

During the initial phase of data analysis a deviation was taken from the Glaserian method due to a literal interpretation of " to analyse the data line by line, constantly coding each sentence" (Glaser, 1978) p57. This resulted in an over-fracturing of the data where all incidents were labelled, coded and memoed. This coding was conducted however using the Glaser's coding rules (Glaser, 1978) and corrected using the constant comparative method. The use of these rules and the method overcomes the criticism, based on lack of comparison, directed at Corbin and Strauss's assertion that the data should be fractured in this way (Corbin and Strauss, 1990).

This initial phase was continued because in addition to arguments given above, it was proving useful in developing a full understanding of the data, being able to locate indicators and producing an initial memo fund from which to further develop concepts. The issue of consistency also influenced this decision. The remaining coding phases proceeded in accordance to the Glaserian model.

The wealth of memos produced were sorted over a considerable period of time using a large room containing white boards and substantial desk space. It allowed the capturing of ideas and exploration of relationships crucial to this stage, without this space, the proximity of data would have been restricted and hence ideational flashes to be investigated. The conclusion drawn from the success of this area is that whichever method used (floor space, desk space or computer program[4]) is that it must offer fast, simple access to and management of data and allow rapid crystallisation of ideas. Without this speed and simplicity, the "moment" and ideas can be lost and the sorting process undermined.

The draft version of the theory was reworked after comments from the writing group and supervisor by returning to the data to solve problems and add density to the categories. The final draft was then presented to one of the respondent and further developments

[4] For example Atlas Ti (www.atlasti.de)

drawn from this data and the original data. The completion of this task then saw decisions made as to the areas of literature to be reviewed.

The need to review expertise and its development demonstrates the ability of grounded theory to take research into areas outside the knowledge of the researcher. This supports therefore the assertion that this study was conducted in a largely unpreconceived manner. This conclusion is drawn with the understanding that it is impossible for a researcher to be completely free of this or as " (Blumer, 1979) argue the Glaser and Strauss "tabula rasa" view of inquiry is open for serious doubt"

The remaining areas were chosen to provide a ***Focusing*** on decision-making theory from the general area to the specifics of pharmaceutical choice and its influences. In each chapter the literature is used to develop and frame ***Trading Off*** and to explore areas where it is able to integrate published thinking. The Introduction to this thesis provides a more detailed explanation of the literature reviewed.

Overall, the method used in this research proved successful in producing a substantive theory related to the original area of study. A number of modifications are supported during this chapter though the methods used remained true to the fundamental tenets of the Glaserian grounded theory approach. The theory developed will now be presented.

3 Chapter Three *Trading Off*

3.1 Introduction

This chapter presents ***Trading Off*** as an explanation of prescription decision-making discovered during this study. This chapter will detail the process and core category of ***Trading Off***, and the supporting categories.

Trading Off is an explanation of vicarious Expert-Laymen consumption behaviour based on the pharmaceutical decision-making process of physicians. The process that has emerged from this study gives an explanation of physicians behaviour in the choice of medical treatments for their patients.

The choice process explained is primarily concerned with the medical treatments required by the patient. Other treatment modes are occasionally used to illustrate the process but the main decision-making area that emerged from the coding process was that concerning the use of medical interventions.

It can be argued that referral behaviour, lifestyle advice and surgical interventions could also be explained by ***Trading Off***. These forms of treatment represent different options that possess individual strengths and weakness that may be ***Traded Off*** when deciding on their suitability within a particular patient situation. Investigation into these areas specifically would be necessary to determine to what extent ***Trading Off*** represented the decision-making process. The illustrations given during this study suggest however that the process is the same.

Trading Off also incorporates the decision-making process used for investigative behaviour, assessment of new information and use of information sources. These areas are viewed as supplemental decision areas that support treatment choice behaviour.

The BSPP of ***Shifting*** represents the outcome of decision-making concerned with the use of information sources and assessment of new information. This category can be seen as a core category in an explanation of these areas however, it represents a sub-process within ***Trading Off***.

The detailing to ***Trading Off*** provided in section 3.2 is based on its explanation of the core medical decision-making process. The sub processes involved are integrated into the story during the detailed examination of each in individual category and it's relationships.

3.1.1 Characteristics of ***Trading Off***

The crucial characteristics of this process are:

- The crucial nature of the many and varied characteristics of the situation in which the consumption takes place.
- The significant consequences of many of the actions and the uncertainty surrounding them.
- The often wide range of individual choices which represent parts of the wider plan.
- The ***Trading Off*** of feelings of confidence used to make decisions.
- Habitual behaviours performed by matching the situation to what normally works
- The preference for using internally held, actual patient case experience to solve problems.
- The ***Shifting*** from external sources of influence and information to internal ones

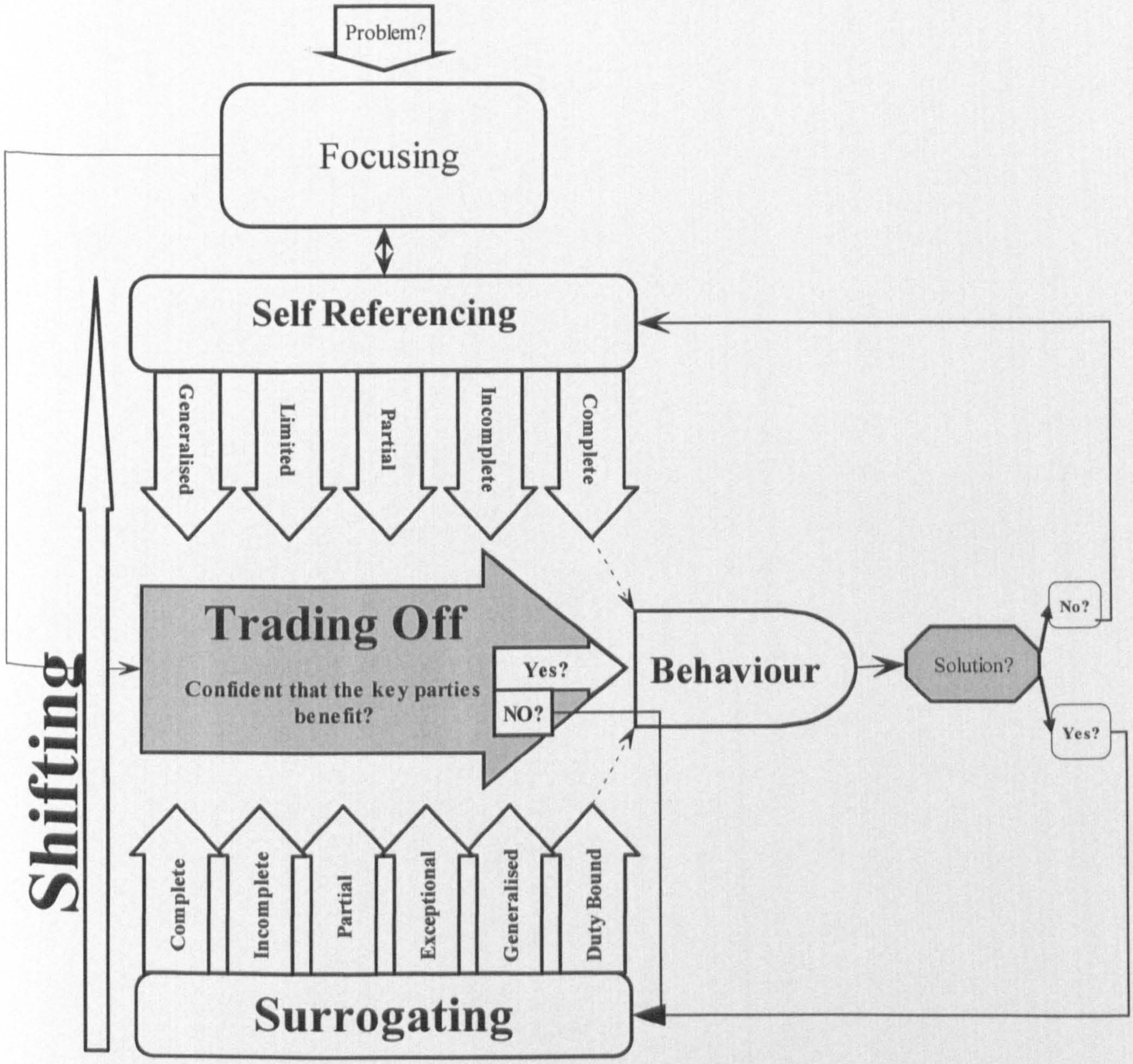
These characteristics interact to create a decision and consumption process that is based around the core category of ***Trading Off***. The exact situation and the potential behavioural alternatives for this situation, have ***Confidence Built*** for each option. These levels of confidence are then ***Traded Off*** against each other in order to ensure that the course of action that is chosen is trusted to fulfil the objectives of the problem.

3.1.2 The *Trading Off* Process:

A temporal ordering of the categories of ***Trading Off*** is demonstrated in the figure.

These are now explained in the order they occur.

Figure 1: Trading Off Process



3.1.3 Problem:

The presentation of a patient to the physician with a problem initiates the overall decision-making process. This can be for the first time or "nth" time with the same problem. ***Trading Off*** is also initiated if new information is discovered or presented to the Doctor concerning the patient, situation, treatments (including new treatments) and diagnostic procedures. These factors lead to ***Focusing.***

3.1.4 *Focusing*:

This is the discovery and ***Focusing*** on the critical properties of the problem as it is presented to the doctor. It involves a detailed look at the problem situation. The ***Focusing*** process highlights the areas that need to be treated and in what particular circumstances. In doing so, it produces a wider and deeper view of the problem than purely diagnosis of the disease. This process leads to the performance of ***Self-Referencing*** and if necessary ***Surrogating, if the process is initiated by new information then Surrogating is performed on it.).*** These categories are conditional on the outcome of ***Focusing***. During ***Focusing*** and ***Self-Referencing*** the outcome criteria for ***Trading Off*** are determined.

3.1.5 *Self-Referencing*:

This is the self analysis phase that determines the physicians knowledge concerning the problem as discovered during ***Focusing***. It also involves decisions on whether there is sufficient confidence held in the possible solutions so that the problem can be dealt with by this experience and knowledge. If not, external advice is required.

The decision as to whether the problem can be dealt with internally is made based on the criteria set out during ***Focusing*** and ***Self-Referencing.*** If it cannot be dealt with

internally, then ***Surrogating*** is used. ***Self-Referencing*** is used initially because of the preference to use internal experience and information.

There is a two way process between ***Focusing*** and ***Self-Referencing*** as personal knowledge directs the discovery of information from the situation and decides on the centre to focus on.

Having determined the source of information and confidence concerning the behavioural options **Trading Off** occurs as the central decision-making process.

3.1.6 *Trading Off*:

Trading Off is the process of decision-making where the confidence held in the important factors for choice are taken into account and traded against each other to ensure that the key parties benefit from the behaviour. Most frequently, it is the direct patient who is the centre of this action with this centre being defined during ***Focusing*** and ***Self-Referencing.***

If the behaviour's constituent parts are ***Traded Off*** (and against other behavioural options) and it is confidently felt that the option will fulfil the desired outcomes then the behaviour will be performed. If the ***Self Referred*** behaviour fulfils these criteria the behaviour is performed with no reference to outside source.

Trading Off can be performed consciously or sub-conscious depending on how routine the problem is. In the case of routine problems, it becomes a subconscious act as the ***Trade Off's*** have been worked out and the outcomes observed during encounters. In this case, the cognitive effort is reduced to a matching process between the problem and the behaviour that usually works.

This action is represented in the diagram as going straight to "Behaviour" bypassing the conscious ***Trading Off*** action. It is drawn onto the **Complete *Self-Referencing*** category because this is the type of ***Self-Referencing*** that is most likely to be under habitual control.

If the ***Self-Referent*** behaviours are not able to fulfil these criteria within the specific ***Focused*** situation then the Doctors **Surrogate**.

3.1.7 *Surrogating*:

Surrogating is process whereby outside sources are looked at in order to surrogate other individuals experience in the problem area. ***Surrogating*** is used to develop the levels of Confidence needed to treat. The mismatch between the ***Self-Referencing***, ***Focusing*** and ***Trading Off*** shows the areas of experience and information that needs to be ***Surrogated*** for the behaviour to be tried.

This ***Surrogated*** behaviour is then ***Traded Off***, and if it fulfils the criteria then the behaviour is performed. When ***Surrogated*** behaviours are unable to fulfil these criteria then a further search is made.

Duty Bound ***Surrogating*** (a category of ***Surrogating***)- does not involve this confirmation process as the behaviours ***Surrogated*** in this classification have to be followed. Therefore a further line is drawn from Duty Bound ***Surrogating*** to behaviour.

3.1.8 ***Behaviour***:

The behaviours that are performed after ***Trading Off*** involve a large number of decisions concerning the treatment that go beyond the active ingredient. Other aspects of the behaviour involve what length of treatment, presentation, level of dosage and in

combination with what other treatments. Decision are also made concerning the role the treatment will perform and place within a treatment plan

3.1.9 *Solution*:

The outcome of the behaviour is tested against the criteria set out during ***Focusing*** and ***Self-Referencing***. The level of success dictates the effect on ***Surrogating/Self-Referencing*** and the ***Shift*** of location of influence. Success shifts the use of evidence and location of behavioural influence internally. Failure however loops the Doctor back to ***Self-Referencing*** as a starting point and other options are examined with same process as before. The level of internal knowledge is now is developed by this failure and a ***Shift*** has taken place.

3.1.10 *Shifting*:

Performance of behaviour regardless of the outcome builds the level of knowledge/experience held internally. Success (partial or complete) then shifts the location of behavioural influence from ***Surrogating*** toward ***Self-Referencing***. As experience develops and because of ***Self-Referencing*** there is a ***Shift*** from the use of ***Surrogating*** to ***Self-Referencing***, it also changes the usage of evidence by the Doctor.

When the Doctor is faced with new information/options/experiences there is a temporary movement back toward external sources. These are used to Surrogate the necessary experience/knowledge to integrate the new information etc. This then builds the personal level of experience/knowledge and shifts evidence and influence usage back toward the ***Self-Referencing***.

Having presented the process of ***Trading Off*** and outlined its individual categories, this grounded theory write up will now detail these categories and the connection between them.

3.2 Trading Off

3.2.1 Introduction

Trading Off is a decision-making process where the factors used for choice are taken into account and traded against each other ensuring that the key parties benefit from the behaviour. Most frequently it is the direct patient who is the centre of the action, this centre is defined during ***Self-Referencing*** and ***Focusing.***

A number of other beneficiaries also need to be taken account of, these include the wider society, patient supports groups and other patients. Central to ***Trading Off*** is that one party must benefit from the action and that the cost to the other parties must be acceptable.

The confidence held in experiences and knowledge from ***Self-Referencing*** and ***Surrogating*** are ***Traded Off***. These processes produced properties and variables (both positive and negative) that the Doctors trust and are confident in (to varying degrees) concerned with the ***Focused*** problem. These are then ***Traded Off*** against one another to see if the patient and the wider patient group will **benefit** from the behaviour being performed.

Trading Off is the process where the positive and negative properties of the potential behaviours are looked at and balanced off against each other. This is performed in order to decide whether the patients particular problem (discovered during ***Focusing***) are likely to benefit from performance of that behaviour.

Trading Off is the area of the treatment decision process where the most cognitive effort is made. As one GP mentioned, it is **"Where they live"**.

Trading Off is centred on the situation of the patient not the disease and is an interactive process between the **Patient** and the **Treatment.** The benefits of the actions decided on during ***Trading Off*** are centred on the efficacy of the treatment. I.e. what it does for the patient's problem though there are a large number of other types of benefits.

The increased benefit to the patient includes curing, relief, and increased quality of life. The increased benefit that is possible with new or different treatments must show an increased benefit over the existing treatment, independent of the form that takes. It must also be beneficial enough to overcome the intransigence that exist in staying with tried and tested, trusted treatments.

It is often crucial that the advantage over existing treatments is in an area of importance to the problem and its situation. This advantage though, only needs to be relative.

As individuals have personal reactions to pharmaceuticals and treatment generally, the treatment has to be tailored to the individual. The consumer has a personal relationship with the product (reactions etc) and its use has to be tailored around this. This individualising procedure includes a customising of the dosage and the actual drugs that are used.

Trading Off accepts the situation that treatment cannot be performed without some party losing out (however trivially). These negatives are mainly seen in the side effects that treatment causes, it's interaction with other treatments, it's effect in overdose and other characteristics (such as the nitrate tolerance effect that must be worked round). It also covers financial and opportunity cost.

The development that is looked for when new treatments are being considered is a reduction in negative effects, for example, for fewer side effects than the treatment being replaced. This again should be proven. The desired effect of treatment is a balanced

benefit to the patient, therefore the specifics of the negative effects in comparison to the benefits need to be assessed.

Further details on these properties are provided in this section.

3.2.2 Causes of *Trading Off*

The performance and need for ***Trading Off*** in all instances and at all levels of medical decision-making behaviour is based on the integration of five factors.

1. Commonly a number of treatment options[5]
2. The risk involved in treatment,
3. The uncertainty attached to this risk
4. Physicians responsibility to their patients
5. The consequences of a number of issues concerned with risk within the Patient/Doctor interaction.

3.2.2.1 Risk

The risk within the patient/physician relationship can be expanded further:

- Risk of not giving beneficial treatment,
- Risk of poor outcome from drug,
- Risk of extra work for the physician.
- Risk to the doctors reputation
- Risk of litigation

[5] For many diseases, there are a number of alternative pharmaceuticals and other treatment options available. Certain diseases such as Multiple Sclerosis where the number of medical interventions is small there remain other options available to the physician.

3.2.2.2 Responsibility and Protection

Doctors are concerned primarily about patients though they have responsibility to a number of parties. Patients are their responsibility and are protected and treated accordingly. They are ***"My patients"*** this gives the medicine and ***Trading Off*** a paternalistic/materialistic feel.

The patients in turn, rely on physicians and trust them, therefore they need to repay this trust by doing what is best for them. A behaviour that this involves is not exposing them to harmful treatment. Therefore physicians are often happy to let other patients be experimented on and will wait until they are happy with the safety of drug.

"Well I am prepared to let other peoples patients be the guinea pigs."

This may be related to the importance of confidence between the two parties being essential for the optimising of treatment efficacy. I.e. the placebo effect seen in patients who have confidence in the doctor's treatment. This confidence may be reduced by poor experiences with drugs that have caused side effects or not fulfilled their expectations.

"and potentially destroy the patients confidence in their own doctor and the doctor himself is a drug "

The very nature that they are to be "protected" suggests that treatments are seen as having inherent danger. Therefore treating a problem actively must be seen as preferential to doing nothing before a decision is made as to which specific active treatment to use. This leads to the situation where the Doctor may prefer to manage a problem without active treatment.

These issues manifest themselves in as a fear of and avoidance of treatments where possible not only where little or no experience is possessed. This is compounded by the

individual nature of reactions to drugs where one person can take a drug safely and another is killed by it.

"Aspirin is a drug I have been rather frightened of for many years... on Friday morning and took two aspirin on an empty stomach and he arrived into the hospital sometime mid afternoon ...I got back on Sunday night I found his car to one side he had died, he had taken a further massive haemorrhage"

This experience has had wider consequences for all the drugs used by this physician.

This fear of the unexpected can develop into a fear of the unknown and thereby contribute to the conservatism that underpins much of the behaviour of Doctors. This in turn can be seen in the distrust of generics, foreign drug (non-western European) and the fear of litigation. This fear and need to protect, leading to conservative behaviour is often based on lack of knowledge about aspect of quality and research.

"It is a bit of a subjective view. I know they are not all made by typhoid carriers in back-street flats in Naples and things, but you know."

The realisation and acceptance of these risks and their potentially severe nature coupled with the responsibility that the Doctor has for the patient, leads to the doctors wanting to protect their patients. This is independent of the whether the risks are real or imaginary and or experienced personally or vicariously. The **Trading Off** process is a way of reducing risk and achieving the goal of protecting their patients.

3.2.3 Parties Performing *Trading Off*

So far in this write up, the focus has been on the individual physicians performing the task. However, ***Trading Off*** is also performed in groups to decide on, for example formularies and guidelines.

Trading Off for formularies and guidelines is a process where the advantages and disadvantages are discussed in a far wider context than the drug itself. The procedure is also more transparent than when undertaken individually. The actual objectives for setting up formularies and using guidelines and the ones confessed to during the process may be different however.

Whilst many parties can input into formulary and guideline decisions, consultants and general practitioners currently retain the right to prescribe the options they want. It is thought that this right will disappear overtime.[6] The advice of these parties is therefore easier to accept if the physicians are ultimately able to ignore it.

"Although they will take some advice from specialists in the individual fields, but a lot of things will be clinical pharmacology decisions because certainly the "ME TOO" its going to be some little kinetic difference or some formulatory difference, in general terms they can keep things off the formulary "

3.2.4 Categories of *Trading Off*

The overall ***Trading Off*** process contains a number of sub-categories, these are:

- Option
- Influence
- Beneficiaries
- Overriding.

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[6] The formation of PCG's which was discovered during the literature search provides a concrete example of how the GP's will be find it necessary to prescribe from a limited formulary

The ***Trading Off*** that occurs for the behavioural options, is the compensation of the properties of the options and the compensation of the overall option versus the other options available. The common nature of many diseases and the experience that develops in dealing with them ensures that treatment habits are formed. This forms a sub category of Option ***Trading Off*** and demonstrates subconscious and matching aspects.

Trading Off also occurs at a deeper level and looks at the basis upon which the behaviour's properties are discovered and evaluated. This corresponds to ***Trading Off*** of the sources of influence. The sources of influences are compensated against one another because of the often conflicting nature of the information they provide. For example, a clinical paper may show one level of side effects but personal experiences showing a different view. These two will be balanced against each other to see where greater confidence lies. As will be discussed in detail later, there is a general preference to use personal experience when making decisions.

Trading Off also occurs between the potential beneficiaries and losers in the performance of the behaviour. A wider view of treatment behaviour often has to be taken to ensure that the benefit to one party does not cause unacceptable costs to another.

These three levels of ***Trading Off*** occur as the core processes when medical decisions are made. The physicians accounts for the options at their disposal, the trustworthiness of the information on these options and who is to benefit from the action. In doing so the physicians is reducing the level of risk and increasing the likelihood of performing a beneficial act.

A further level of ***Trading Off*** exists that corresponds to particular situations that regularly occur. Overriding ***Trading Off*** occurs when one particular factor in the process out weighs all others, this is normally due to the importance of situation.

3.2.4.1 Option *Trading Off*

The ***Trading Off*** of behavioural options is itself performed on a number of levels within and between each of the alternatives. These levels are:

- Treatment types (surgery vs. drug vs. rest, etc),
- The specifics options of these types (i.e. Beta Blocker Vs Ace Inhibitor),
- The options within the subtypes (Lisonopril v.s Enalapril)
- Various presentations of the chosen treatment (pill vs. IV).
- Dosage regimen

The choices made within these levels are based on the individual properties of the treatments. Whilst ***Focusing*** and ***Self-Referencing*** develop the important properties and combination needed in each clinical situation the process is most often based around efficacy, side effects and financial cost.

A larger group of variables can be added to these in order to fully address the situations individual needs. These add to the subtlety and complexity of ***Trading Off*** as do the volume of data and its level of uncertainty. The information and confidence in these variable is determined by either ***Self-Referencing*** or ***Surrogating***.

Once efficacy, side effects and cost (in the particular situation) have been discovered these often constitute main factors used in ***Trading Off***. It is important to remember however that the hierarchy of influences and variables is a fluid one dictated by the patient's situation.

"so you know there is two same side ...same drug two different conditions but one is acceptable and one is not them you know the conditions themselves because of the way you are using them"

The likelihood of the option containing these properties or the property occurring is a further piece of information that is ***Traded Off***. The importance of a particular property is clearly linked to the perceived likelihood of it occurring. For example in the case of efficacy, will it work completely in all cases all of the time or work with 80% efficacy in 50 % of cases? This is then compensated against the costs of the treatment.

The importance of both benefits and costs in ***Trading Off*** is that the outcome shows a relative advantages against other behaviours. In this way the advantages or reduction in disadvantages only have to be relative to the other options available in areas that are important in the situation.

A final aspect of Option ***Trading Off*** is that the benefits can be seen in combination or via one important factor. The dominance of one factor is seen most clearly in the Overriding category.

In this way behaviours are performed where they do not possess, for example any efficacy advantages but in the overall assessment they show a relative benefit in areas that are important in the situation.

This can be seen in the case of the SSRI's. This class of drug possesses an equal level of efficacy as its predecessors, is considerably more expensive but has in comparison a hugely beneficial side-effect and safety profile.

"they are equally as efficacious as any of the commonly prescribed antidepressants their side-effects profile is so much cleaner and there safety profile in overdose is phenomenally better".

3.2.4.2 Habitual Behaviours

A major subcategory of the ***Trading Off*** of options is the performance of habitual behaviours. Physicians often prefer this type of behaviour because it uses less cognitive effort in making a decision and behaviours are used in which they are confident about the outcomes.

When situations are presented in which the physicians has sufficient experience of solving, the habitual behaviour will be performed by matching these two elements. The ***Trade Off*** has been performed previously and the outcomes have been checked against the objectives. This leaves the physician confident in the matched situation and treatment.

The use of habitual behaviours extends further to include the habituation of parts of the option ***Trading Off*** process. For example, habits may be formed for the use of a medical treatment for hypertension and for the use of Atenolol as the beta blocker of choice. However, because of particular patient circumstances dosing decisions may be consciously ***Traded Off***. Habits are therefore used to solve whole and part of ***Focused*** problems.

The preference for habit can be effectively demonstrated by the continued use of Beta-Blockers. This also provides a good example of the ***Self-Referencing*** basis for behaviour and the ***Trading Off*** processes.

Beta-blockers were mentioned in conjunction with various reasons for their usage, most important among these were the long-term usage data and large amounts of personal experience.

"BETA BLOCKERS which have been very, very widely used"

Individual beta-blockers have had high quality research performed with them. This has lead them to be seen as cardio-protective for improving mortality in Post MI situations. They have also been well marketed with physicians commenting on the marketing messages and the gimmicks used.

The habits formed over long period of personal usage and experience compensates for the poor side effects profile and the availability of other more effective agents in the areas.

Habits are also seen in the use of diagnostic questioning and information usage. The preference for habits and for reducing cognitive work load are reasons for the preference in using ***Self-Referencing***.

Having introduced the properties of the ***Trading Off*** of options, the properties involved in all levels of the decision-making process will be looked at in more detail. These can be classified as **Benefits** and **Costs**.

3.2.4.3 Benefits of Treatment

3.2.4.3.1 Efficacy

Of all the benefits of the behavioural options, it's efficacy is at the centre of the ***Trading Off*** process and in many instances it can be an overriding influence.

"if a patient absolutely needs a medication then we would have to put up with minor side-effects but if they don't really need it then the may need it borderline need the medication and they've got significant side-effects then you'd stop it."

The ***Trading Off*** of the positive effect of the medication is clearly seen in contrast to its likely side effects. This example is also an ideal demonstration of the individual nature of each problem and patient that ultimately dictates the solution to each problem.

3.2.4.3.2 Speed of Action

The benefit of the behaviour is also looked at in terms of the speed with which it will act. In a number of situations, for example pain relief and control of acute infections, this becomes an important property. There is a relative and actual dimension to this aspect and it should be demonstrated via clinical studies or experience.

3.2.4.3.3 Mode of Action

The mode of action of a medication can have an effect on the choice of treatment. The specific nature of the effect may be understood by the physician as having benefits. This understanding can help the physicians accept the likely effect and side effect profile of the drug. These benefits are particularly seen for new drug classes.

The manor in which the effect works is not always important, if the drug is performing to expectation. In addition to this, the Placebo effect is welcomed and encouraged.

3.2.4.3.4 Dosing

The benefits of the treatment are also helped by the dosing regimen. Compliance is a crucial issue, as the effect of the drugs may only be seen if the patients take the drugs in the manner in which they are prescribed. Treatments therefore that have regimens that help the patients take their drugs will be benefits to that drug and the patient.

Motivation to comply with taking the treatment diminishes with time and therefore there is advantage to prescribing shorter courses containing fewer doses.

3.2.4.3.5 Presentation

The presentation of the treatment should enhance its chances of being used by the patient and therefore the physician. For example, delivery mode and the size of the doses are important. Many delivery characteristics can benefit the patient. These include:

- Easy to use packaging
- Specific delivery devices (inhalers, insulin pencils)
- Patient information leaflets
- Long acting versions (once or twice a day versions),
- Range of delivery options (liquid, pill, capsule).

The importance of the presentation and the problem with compliance is again dependent on the individual patient and situation. For example, there are some patients who are unable to follow instructions accurately and whose use of drugs dangerous in this situation must be restricted.

Patients may be forgetful and others may deliberately hide compliance issues from the GP. Therefore, the presentation of the treatment must be compared to personal characteristics of the patients in making a decision. This demonstrates the importance of ***Focusing*** on the ***Trading Off*** process.

3.2.4.4 Behavioural Costs

3.2.4.4.1 Side Effects

Side effects are a major aspect of the risk involved in drug usage. Their prevalence within medicine means that physicians expect them to exist. Further to this, companies are expected to claim that new products have lower side effects that their competitors and these claims are treated sceptically.

Side effects can be divided into "nuisance" and "life threatening". It is not possible however to dismiss the "nuisance" or say that they are relatively unimportant because of the interaction with the patient situation.

Nuisance side effects are important for example when combined with diseases whose characteristics are asymptomatic. In this instance the patient will be apparently worse off taking the medicine as the disease is not presenting them any problems.

"but the nuisance side effects if you are well and the risk of you having a problem with your condition are low become more important "

"If the disease is however life threatening then even severe side effects become less important, and you would expect the weight gain perhaps the mild diabetes that you might get from it serious conditions in fact caused by the drugs you are taking but they keep you alive em whereas used say for perhaps arthritis that is osteo-arthritis you know you'll certainly get rid of the pain but the side-effects of the drugs are totally unacceptable,"

This second example demonstrates ***Trading Off*** based on the specific problem of the patient and how the same treatment is a legitimate option in one instances but not in another.

How the treatment deals with negative properties of its effect is an important aspect in reducing its effect on the ***Trading Off*** comparison. For example, in the case of overdose with Paracetamol, the use of clear warnings on the packet and the use of Parablex (liver protection agent) will reduce the cost effect of the potential to overdose on it.

The side effect issue or negative treatment outcomes are complicated by side effects that occur when compliance to drugs is poor as well those that occur as the drug builds up.

3.2.4.4.2 Interactions

Interactions occur when the drugs react with and against each other causing known and unknown effects. Further to this, they can occur between the treatment and other diseases. These effects can range form being very harmful to the patient to no effect perceived.

Beyond the issue of interaction between prescription pharmaceuticals, medicines can interact with common substances such as alcohol. For example, penicillin interacts with alcohol to potentiate the effects of the alcohol. To prescribe this antibiotic the physician should take a wider view of the patient to determine whether they are likely to abstain from drinking while completing the course.

The issue of interactions becomes more important when prescribing for patient receiving therapy for more than one problem. For groups such as the elderly or patients whose problems can be managed with a cocktail of drugs interactions can restrict the use of certain preparations.

"and you've got to watch that the drugs aren't interacting because you don't just treat every disease with a different pill, that you know you could just give them a pill for this and this and this and give them a pill for every different thing that is wrong with but then they would all just interact and em..."

3.2.4.4.3 Financial Cost

The issue financial cost is seen as a major aspect and factor that has to be compared. Most commonly cost of the drug is not looked at from a lowest cost perspective. What is looked for is value (which itself can be viewed the outcome of a trade off) and increasingly, cost reduction.

Price alone is not felt to be a legitimate reason for changing a patients medication. Change involving price should be based on a balance of benefits/costs. A lower cost drug must usually be the same/ better in terms of efficacy and side effects (and evidence is needed for this) before it will be swapped to.

The financial cost is also not supposed to be a reason for refusing a medication. The need of the patient should override this. Cost is allowed however to be a deciding factor though ultimately not when it effects the treatment of the patient.

"if someone for instance needs intravenous Ciprofloxicin (which is about £200 a go I think) and that is an antibiotic you don't say I'm not going to give them that because it costs too much, you just have to give them it, you would just have to give them that if that is the only thing it's sensitive to".

This property of the ***Trading Off*** of cost is supported by other claims stressing the all importance of cost. These claims reduce in strength however when probed further for specific ideas.

"***We're not a fund holding practice where cost is obviously all important.***"

3.2.4.4.4 Justification and Evidence

If the drug is higher priced than the alternatives there must be evidence and benefit for the additional costs. This can lead to the marginalising of drugs if in the majority of patients the benefit is not big enough. The more expensive drug will then be used in a reduced number of cases. The roles that treatments performed such as this are detailed in Behaviour (section 3.7)

"since only one in four gets a cough anyway you wouldn't automatically rush to Cozaar, you would start with you usual bog Standard Ace inhibitor and then if the

guy gets a cough you'd say oh hang on I remember now lets switch you to this one and see if you cough goes away."

3.2.4.4.5 Minimising

Often Doctors will look for the cheapest drug that is able to fulfil the goal of treatment with the fewest negative outcomes. This minimising of one outcome of treatment (the having to pay for it) is seen in other areas. For example the level of efficacy that is needed to achieve the treatment goal is often kept to a minimum. I.e. physicians may use a drug that will lower blood pressure by 5 % before using one that will lower it by 10% even though the 10% is guaranteed to do the job.

3.2.4.4.6 Cost Tactics

The use of product reformulation to maintain price is a recognised tactic of pharmaceutical companies. As with other price issues, these must be compensated for by additional benefits being shown. Products at reduced cost claiming the same efficacy (for example generic versions) must also provide evidence for their claims.

3.2.4.4.7 Other Treatment Cost

The cost of prescribing goes further than the financial cost attached, time cost and opportunity cost, are also important.

3.2.4.4.7.1 Time costs

The time that a Doctor spends with a patient is time that is lost to other activities if it does not produce the expected result. The repeated presentation of patients whose treatment is not effective or requires intensive monitoring is therefore costing the Doctor. Treatments that demand more of the Doctors and patients time than expected or

in comparison to other treatment options are therefore cost negative in the ***Trading Off*** process.

3.2.4.4.7.2 Opportunity Costs

The opportunity cost issue is caused by the limited number of medications that a patient can tolerate at a given time. By treating a patient in a particular way and with a particular drug, the opportunities to use other options are blocked at that time.

The treatments used therefore should be more beneficial to the patient overall than treatments for other conditions. This situation is seen most clearly in the elderly who often have a number of concomitant diseases.

3.2.4.5 *Trading Off* of Sources of Information

The sources of information used in ***Trading Off*** are themselves factors that are traded off. The information that is gained from these differing sources concerning the important properties of the options is therefore effected by the source. This becomes a feature of its credibility when the options and properties are analysed

Information can come from personal sources internal to the physician and external sources classified as Professional, Formal and Marketing. A personal continuum exists in the credibility afforded these sources by physicians, that is dependent on the problems being confronted. This continuum and these sources are analysed further in ***Surrogating*** and ***Self-Referencing***.

The causes of these differences in credibility and trust in sources are the differing levels of independence and quality of the information that they produce. These factors will be examined further in ***Self-Referencing*** and ***Surrogating***.

3.2.4.6 *Trading Off* for Mutual Benefits.

The preferred actions taken allow a wider range of people to benefit from the behaviour than purely the patient. The wider range of beneficiaries can include:

- Other patients,
- Patient interest groups
- The Doctor,
- Local Secondary care physicians (specifically the local eminencies),
- Company representatives (and companies that the Doctor may have relationships with)
- Wider interest bodies, for example the CRC[7] or the BHF[8].

Wherever possible the action that is taken for the patient is dependent on it not having a negative effect on the other parties that outweighs the benefit to the individual patient in that specific situation. For example, the benefits of treating patients with Multiple Sclerosis with Interferon, a drug that is described as:

"you are dealing with a drug for which the information that it works is extremely scanty...and if you spend £10m extra you have to find £10m from somebody else's budget"

It is therefore ***Traded Off*** against it's wider effects on other parties. Preferably, all sides **benefit** from the interaction, however the benefit to the patient and the wider patient good that remains central.

This is shown less dramatically with the description of the Doctors justification for improving the business side of the practices.

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[7] Cancer Research Campaign

[8] British Heart Foundation

"At the end of the day it must all boil down to two things improved patient care and better quality of environment for your staff and possibly yourself as well".

When considering the patients objectives as the central beneficiary it is noted that patients may not be primarily interested in his or her well being. Patients often have their own agendas which may be abuse or overdose on a drug, or remain "ill" to allow them to claim social security benefits.

The ***Focusing*** procedure may highlight these objectives and therefore changes the doctor's decision-making to avoid certain drugs. The patient's illness or problem is therefore being detached from the patient themselves.

3.2.4.6.1 Need for Mutual Benefit Trading Off

The need for ***Trading Off*** for mutual benefit is based on Doctors working within a situation of limited resources. These limitation include opportunities for treatment, financial cost to the physician, their practice, the health board, the country, physician and the patients time, hospital resources, consultant time, time window for curing/treatment of disease. As such physicians must balance these limitations with their responsibilities in order (ideally) to provide the best overall solution.

3.2.4.6.2 Benefits of Mutual Beneficiary Trading Off

A benefit of ***Trading Off*** to provide mutual benefits is the development and maintenance of successful relationships. This is true for the relationships with eminencies, colleagues and company representatives. The benefits for relationships are also seen by the pharmaceutical companies.

The reason for doctors preferring to deal with friends (both professional and social) in a situation of limited resource is because friends are seen as more trustworthy and will perform favours without ulterior motives. Actions that benefit relationships are seen as a legitimate reason to choose that behaviour.

The professional friend may be understood to be performing favours for other fundamental reasons (sales) and therefore this reduces the value of the action.

3.2.4.6.2.1 Benefits of relationships with Colleagues and Eminencies

The benefits for the GP's with relationships with the Local and National eminencies include:

- Trust in the treatments that other parties are using,
- Support when using new therapies
- Support against litigation
- Education via formal and informal dissemination of information i.e. letter based teaching, tutorials or phone discussions,
- Advice and performance of interpretation of developments in the area,
- Beneficial treatment, for example faster access to the consultant and his waiting lists etc.

These benefits can be classified into aspects that provide emotional and social support, an increase in the speed of treatment and further education for the doctor. These can be further conceptualised into improved patient care by increasing speed of treatment and also reduction in physicians work load and stress load!

In terms of litigation support, the test that applies for defence in this situation is that a number of other medics would do the same thing. Therefore following advice has wider implications than attempting to provide quality treatment.

The speed of treatment benefits can for example be achieved by a consultant treating more quickly the patients of those GP's with whom they have good relationships. Speed can also be increased by the GP learning sufficiently to treat the patient without sending them to the hospital. In this way they are increasing their use of Initiation ***Surrogating***.

3.2.4.6.2.2 Benefits of Relationships with Pharmaceutical Companies.

The benefits to the doctors on having relationships with the companies are based on confidence, fiscal benefits and friendship. Long-term relationships and the provision previously of good treatments, gives a halo effect to the current drugs promoted by the company.

There are also fiscal benefits to the doctors with pharmaceutical companies donating medical and practice equipment that could not be otherwise afforded. This equipment should however be useful and of benefit to the patient, it is not sufficient for it to be expensive.

"Yea the supply of nebulisers and eh spirometer which are investigation equipment which really as a non-fund-holding practice are out with are budget to buy and service ourselves and they will do that"

3.2.4.6.2.3 Benefits to Pharmaceutical companies

Overall, these benefits to the company from the Doctors can be described as prioritising and access. These relationships are based fundamentally on the treatments provided being of benefit to the patients.

The company benefits from the mutually beneficial relationships include:

- Being able to introduce new products more easily,
- Reintroduce and develop messages concerning old products
- Increased attention paid during calls.
- Reduction of perception that meetings are "sales calls" leaving the physicians more open to suggestions.
- Reducing opportunities for competitors to sell products

Relationships also allow a further differentiating factor in choice to be added. In situations where there are no perceived differences in the products, the strength of company/physician relationship can act to differentiate between options. Its changes therefore interaction of influences and how other influences are interpreted and acted upon.

The company also benefits from the barrier that a relationship creates around the area. This makes it harder for the competition to infiltrate and gain prescriptions from the doctor.

This is not to preclude new relationships being built up. It is however a time-consuming process but if the treatment, gifts and other influences are beneficial for the patients, doctor and the wider audience, then they can be built.

3.2.4.7 Overriding Trading Off.

A final category of ***Trading Off*** occurs where there is one property (occasionally more) of overriding importance that is strong enough to dominate the process. The need for ***Trading Off*** multiple factors may be eliminated by the obvious strength of these prime factors. The strength of the outcome of this ***Trading Off*** can dramatically reduce the time usually taken to adopt a product.

For example, the adoption of Streptokinase and Ace inhibitors for congestive heart failure (CHF) are examples of drugs that were taken onboard very quickly. This is because the benefits shown by the evidence from clinical trials were so clear cut that there was considerable amount to be gained from a quick change in behaviour.

"the clearest examples I can perhaps think of off the top of my head. Perhaps the ace inhibitors as well over the over eh frusemide alone in the treatment of cardiac failure, as soon as you got the early studies with captopril it became clear that these things should be prescribed"

3.2.4.7.1 Conditions for Overriding Trading Off

These examples demonstrate the conditions within which Overriding ***Trading Off*** occurs. One condition that can cause this is there being very few treatment options and a poor prognosis for the disease.

In these circumstances a new treatment that remains unproven in general practice and is viewed as risky may be introduced earlier than usual. In this instance, the situational and market conditions provide overriding factors.

Indeed, for diseases with poor outcomes and very few treatments, evidence beyond that required for its launch, need not exist before its availability and the chance it represents override and allow it to be used. This is demonstrated by Flosiquine which was said by manufacturer to not be as good as an Ace inhibitor and had very little evidence to support it's use. It still represented an option for CHF and this was used for those people who could not tolerate an Ace Inhibitor.

"but it was such a poor, the outlook was so poor it is like the really bad or dreadful when you've got cardiac failure that if you can't take an ace inhibitors then so a new drug comes onto the market you know it is claimed to do this"

This example shows how proof of efficacy which is normally the cornerstone of usage can be outweighed by the situation. It is interesting to note that this drug has been removed from sale because it was found to have a negative effect of mortality.

Factors are also allowed to override when the behaviour is to be performed in a way that reduces risk for the doctor. For example, the patients treated with Ace Inhibitors for CHF were swapped onto this therapy as they presented themselves to the physician. This was rather than the doctor instigating the presentation by bringing them in to special clinics. In this way, a mini personal trial was conducted to allow any unforeseen problems to effect as few people as possible. Hence, risk to physician for litigation and providing dangerous treatment was reduced.

The production of results that shows very strong evidence for a treatment can lead to Overriding ***Trading Off*** partly because of the fear of litigation. For example it was felt that the clinical evidence (not supported by experiential) for Streptokinase was so strong that not to use it may lead to litigation. Hence the lack of experiential evidence was overridden to allow it to become standard therapy within a year. This one year is seen as quicker than would be expected with other compounds.

"the other example would be streptokinase in the treatment in the treatment of MI you know the evidence was so great that eh it is reaching the stage now that if you didn't get it you would probably be able to sue the hospital for not giving it you"

3.2.5 Summary

Trading Off is the core category found during the study of pharmaceutical decision-making. It involves the ***Trading Off*** of levels of confidence held for numerous properties, in order that the behaviour chosen is likely to produce a mutually beneficial

outcome. This is done to ensure as far as possible that the outcomes determined during ***Focusing*** are satisfied.

Trading Off is a consequence of the risk and uncertainty that is present throughout medicine and the importance of Doctor/Patient relationship. It is also a consequence of the complexity of medical situations that partly cause the uncertainty and risk.

This is the area that the most cognitive effort is used when decision are made. The sub categories of ***Trading Off*** are Options, Sources of Influences, Beneficiaries and Overriding. ***Trading Off*** is performed in each of these categories on a number of levels as decision are made on the type, class, compound and presentation of the treatment.

The use of habitual behaviours reduces the amount of cognitive effort used by matching successful behaviours to particular situations. In these behaviours the ***Trade off's*** have been performed previously. Habits are also used for individual levels of ***Trading Off*** within the overall decision.

Trading Off is a relative process that is based on the options that are available. It is also a process that is performed both individually by the physicians and in groups.

Having detailed the core category discovered the sub core categories will presented in the temporal order which they are performed.

3.3 Focusing

The ***Trading Off*** process starts with the problem faced by the patient being discovered and defined. ***Focusing*** is the discovery and ***Focusing*** on the critical properties of the problem as it is presented to the doctor. It involves detailed and interactive examination of the problem situation and is performed by questioning, investigations and observations. ***Focusing*** hence directs the informational needs of the ***Trading Off***, which are satisfied via ***Self-Referencing*** and ***Surrogating***.

Focusing then acts as the base for the ***Self-Referencing*** of information to see if a solution is held with confidence internally, and hence the whole ***Trading Off*** process, if not then ***Surrogating*** is used. ***Self-Referencing*** and ***Focusing*** are to an extent simultaneous as ***Self-Referencing*** will direct the discovery of properties during ***Focusing*** (i.e. the questions that need to be asked, tests etc to get the full picture). ***Focusing*** is not a process that occurs once per problem, it is a process where the information sources returned to and **Re-*Focusing*** occurs.

This takes place when new information becoming available concerning the patient, i.e. new information about symptoms, disease development, the results of tests and relevant history.

A critical property of ***Focusing*** is that it goes beyond a diagnostic view of the core physical and mental signs and symptoms of the disease. It involves a detailed look at the patient, doctor and wider community characteristics and the personal and social situation within which the interaction takes place.

It incorporates the discovery and registering (either mentally or physically) of the highly specific nature of the assessment that is individual to the patient at that particular time. It includes therefore patient history and the wider context that can direct treatment

decisions. It is performed in order to ensure that confidence is ***Traded Off*** based on the important issues that can effect decisions beyond purely identifying the problem.

This detailed ***Focusing*** allows the matching of behaviour to the problem to occur from a base of greater knowledge and trust. This in turn allows the Doctor and the Patient to have more trust in the treatment/solution to the problem/s.

The ***Focusing*** process in addition to being performed by individual physicians is carried out by the various prescribing committees and less formal guideline and formulary bodies. Their decisions are typically made on an assessment of efficacy, comparison, relative advantage, and eventually cost.

The ***Focusing*** by committee is an example for the influence of politics in ***Focusing***. There is an acceptance that politics comes into the committee decisions though this can be seen to enter all levels of decision-making (where there is more than one interested party).

This represents a restricted approach to ***Focusing***. Further details on the continuum on which ***Focusing*** is carried out will be provided in section 3.3.2.

Focusing explains why influences that are important in certain circumstances will be overlooked in others. There is no overriding centre that is ***Focused*** on though, as is true throughout ***Trading Off***, it must commonly ***"boil down"*** to the patients care. For example, medicines will be prescribed despite cost if the patient needs it.

Focusing is a reaction and adaptation to the complex, uncertain and restricted (financially and medically) situation that physician practice within. This complexity and uncertainty goes further than those surrounding the core disease and the issue of correct diagnosis and therefore a wider and deeper assessment is needed.

Focusing is also an adaptation to another main characteristics of medical care (especially evident in geriatric medicine) where commonly the patient suffers from a number of problems. Close assessment of the situation is therefore needed to determine the relative importance of the problems and how they may influence each other.

For example, beyond the multiple specific diseases faced by the elderly, they may suffer from memory and functional impairment that are a part of old age. These issues should be known because treatment with a high number of medications may mean that they are not remembered or that they cannot be swallowed. Specific choices of medication are therefore required to overcome these problems.

3.3.1 Specific Areas ***Focused*** on

It emerged that there are two main areas that are ***Focused*** on, these are the Individual Patient and the Wider Population. The experience of having dealt with the core disease in conjunction with this wide range of patient and wider population issues characterises expertise and individuals who are able to self refer in order to treat the situation effectively.

The potential complexities also demonstrates why ***Self-Referencing*** of personal experience is preferred because greater levels of detail are remembered than are available from clinical trials and through discussions with colleagues. These "other" issues can be crucial in the success or failure of treatments. These will now be detailed.

3.3.1.1 Individual Patient

The individual patient of the assessment can be further divided into Physical and Mental categories. The physical and mental characteristics of the patient go further than those that are the focus of the presentation (i.e. the core disease/symptoms).

3.3.1.2 Physical Characteristics

The physical properties ***Focused*** on are based on the disease, complications, other health issues and demographics of the patient. The most obvious centre for ***Focusing*** on is the problem/s that the patient has. These will define initially the treatment types that will be considered. Other centres such as wider population involvement then act upon this base, before the final decision is made.

The capabilities of the patient also need to be assessed. An example of the level of detail that can be appropriate is once again given by elderly. Relevant characteristics include the level of frailty, manual dexterity, ability to swallow, liver impairment, renal impairment and brain sensitivity. Certain of these problems lead to dysfunction's that are inherent in the disease, others however are associated with age but cannot be assumed hence the need for ***Focusing*** on an Individual Patient basis. The presence of these problems can then have a direct effect on the treatment decision.

The importance of this level of assessment is demonstrated by the interactions these issues have with many aspects of treatment. These include the type and form of the drug and the concomitant drugs that can be used. These characteristics then provide directions and settings for care supplied by the health care provider and also can be is taken into account by the manufacturers.

The demographics of the patient also provide factors that may effect the overall treatment process. The sex, body mass index, socio-economic grouping, location and type of housing, level of education and intelligence may be important in the specific situation beyond the immediate impact on the core disease. For example, medical intervention for hypertension may be more suitable than dietary and lifestyle advice when patients because of their socio-economic status may be subjected to strong behavioural norms that make following such advice difficult.

"But here because of the weather they can only go to the bingo where even if they don't smoke 350 other people are puffing away."

3.3.1.3 Mental Characteristics

Critical factors in prescribing behaviour can also be the mental abilities, intelligence, memory skills, personality, trust, pressure and the agenda of the patient. These features can direct the types and form in which treatment is provided for a problem.

The patient's agenda and motivation needs to be looked at because the compliance and involvement of the patient often determine treatment success. Patients are expected to be active partners in their treatment, especially in primary care. It is clear however, that in many cases the patients do not always behave in a way that will help their specific condition and their general health.

The obvious manifestations of this are smoking and poor compliance. Poor compliance may be due to the patients not believing in the treatment or may not want to improve for some reasons such as benefit fraud or work avoidance. These are extremes, but patients often do not help the doctor in working to improve their own health. The discovery and ***Focusing*** on these problems will therefore become crucial in directing effective treatment.

Characteristics of treatment can therefore be looked for to minimise the difficulty of usage so that a high level of patient motivation is not needed. It can also be designed in such a way to reduce the involvement of the patient or involve them in a way that they are motivated to do. I.e. pills rather than exercise.

The level of trust that the patient has in the treatment and doctor is also important and needs to be assessed. Patients may avoid behaviours that are designed to be of benefit to them because they do not trust them or the diagnosis.

"and it is surprising I didn't realise quite how many people don't take their drugs properly until I came into general practice".

There is also a degree of pressure placed on the physician from the patients themselves and needs to be looked at. This is the case in chronic illnesses where the patients are on drugs for a period of time designed to alleviate as well as cure problems. For example with the use of NSAIDS and H2 receptor antagonist, patients may have favourites and moving them off this therapy or onto something cheaper/different can result in them asking for the old drugs to be re-supplied.

The patient pressure can come via asking for the drugs or by telling the doctor about the re-emergence of symptoms that are only helped by their favourite drug. The ***Focusing*** of the patient's personality and results with past treatment is therefore important.

This patient pressure goes further to include the population of patients with the same problem i.e. the HIV community. This is therefore linked to ***Focusing*** on the wider population that is looked at later in this section.

3.3.1.4 Wider Population Involvement

Focusing on the involvement of the wider population is necessary because of the number of sources that can influence the treatment process beyond the primary Doctor-Patient relationship. It is also important because involvement from a wider range of individuals and groups can increase the likelihood of a positive outcome of treatment.

Wider group involvement involves looking at the situation in terms of the three populations concerned with health care, the health care providers, the patient community and the wider society. These populations effect treatments on cultural, political and

social level. ***Focusing*** is also important here, as by integrating together these three communities, the widest range of solutions (long-term and short-term) become available.

The effective treatment of problems is helped when there is an integrated effort by the various divisions of the healthcare community. The primary and secondary areas should involve each other, for example the GP should be made aware and be part of the hospital care of the patient.

This interaction needs to go further than the physicians working in these areas. It should involve a wide range of healthcare professional including nurses, pharmacists and health promotion officers.

On a societal level, often the wider community is involved in healthcare decisions by providing a normative framework for deciding what their problems are and what are the best ways to solve them. This lead to a need to assess and catalogue the feelings, knowledge, levels of motivation, support and resources of the wider community. This assessment demonstrates the information gathering aspect of ***Focusing*** that is conducted via each patient interaction and interaction with society more generally.

It is not claimed that physicians in medical decision-making discuss issues concerning the well being of society. ***Trading Off*** claims however that these issues do need to be understood because they may have an important role in a particular situation.

An example of community involvement and the need for understanding of the wider situation is the attitude toward and attempts to influence community health issues in the first and third worlds.

There is a political aspect to the ***Focusing*** on wider group involvement that involves national and local government, their policy decisions and attempts to influence these.

This is demonstrated by patient interest groups that are lobbying for resource, research and treatment for the sufferers.

These groups and the extended interests groups can exert considerable pressure on Doctors and Healthcare workers, as seen in Women's health issues, HIV infection and Cancer. This along with the health-board, its policies and restrictions (monetary etc) show the political situation of the problem assessment.

"Fifthly you are dealing with a very vociferous patient group in society who can excerpt considerable pressure on the doctors who are looking after them, as can the patients because they are extraordinarily unfortunate. And while it is not that difficult for people sitting in a little group away from patients to say that we don't think that that is an appropriate way to spend our money. It is not necessarily terribly straight forward for an individual doctor to make that decision and when there is somebody at the other side of the table whose is clearly getting worse year by year"

The wider group assessment also involves the culture of the community as well as the culture of the wider society and the behavioural norms that are interrelated with the situation and the culture. An examples of this is cultural influence on social behaviour where in the East-End of Glasgow the behavioural norms involve sitting indoor (ruled by the weather) and performing activities that are integrated with smoking and drinking alcoholic drinks.

3.3.2 Categories of *Focusing*

The amount of ***Focusing*** behaviour performed by doctor's manifests itself between a scale anchored by Restricted and Wide ***Focusing***. The extent of ***Focusing*** on the areas outlined in section 3.3.1 depends on a number of issues. These are the resources available, medical culture/training, political considerations (as detailed previously), patient/doctor relationship, physician characteristics/knowledge and experience.

In situations of restricted resources the physician is obliged to take a wider view of the problem in order to discover clues as to possible solutions. Where there are many readily available solutions a more restricted view predominates.

A longer term patient/doctor relationship and a deeper knowledge of the area that the doctor is practising in, is a further indicator for wide ***Focusing***. The depth of knowledge developed by this type of relationship will bring further relevant information to the decision-making process.

Physicians perform ***Focusing*** according to habits. For example when one physician is the symptoms "tired all the time", the patients notes are marked "TATT" and immediately conducts a predetermined set of tests. A wider view of the patient problem is taken after the results have been obtained. This demonstrates ***Focusing*** driven by experience and the habits evolved during diagnostic questioning and testing. It also demonstrates the link between ***Self-Referencing, Focusing*** and ***Trading Off.***

3.3.2.1 Restricted *Focusing*

Restricted *Focusing* is characterised by physicians taking a conservative insular, non-creative and short-term view of the patient's problems and its possible solutions. A restricted view of the situation is then taken without accounting for many of the issues that if addressed may improve the quality of treatment decision and therefore care of the patient. As a consequence of the reduced range of information focused on, restricted ***Focusing*** leads to a constrained use of information sources in order to solve relevant problems.

Examples of this restricted ***Focusing*** include not attending to the real world complexities during training or the experiences of wider experts. This is shown by aspects of the UK training of Doctors where critical reading and lack of community

based training characterise the teaching of community care. This leads to a restricting of the experience field of influence and a narrowing of the view that is taken when deciding how to treat a particular problem. This is changing however to a more action orientated problem solving approach.

3.3.2.2 Wide *Focusing*

The other anchor on the ***Focusing*** scale is Wide ***Focusing*** and involves the extended consideration of the situation, characteristics (personal and wider community), influences and therefore solutions. ***Focusing*** that is performed in this way is charecterised where possible by discussions and two way communications between the physician and patient. It also involves a greater degree of importance placed on the patients history.

A wide situational view of problem diagnosis should involve a number of aspects beyond the patients personal characteristics, demographics, diseases mental state and competencies as detailed in section 3.3.1. It should also include the cultural and behavioural norms of the wider and the micro-society (ies) with which the patient lives in and interacts.

An example of this is the to the third world model that is described where a wider view of treatment is taken, wider sources of influences used, more partnership sought with patients and the community.

3.3.3 Summary

Focusing is the discovery and ***Focusing*** on the critical properties of the problem as it is presented to the doctor or committee. It involves a detailed and interactive look at the problem situation performed by questioning investigations and observations that goes further than the information required of diagnosis of the problem.

It is the essential operation for deciding on the objectives and targets of the ***Trading Off*** process. Critical in this role is that it directs the analysis of personally held information during ***Self-Referencing*** (and hence the need for ***Surrogating***).

Focusing comprises looking at the Individual Patient and Wider Group involvement in the interaction. Within these areas, the physical and mental characteristics of the patient are reviewed in conjunction with issues that may arise from the multiple problems that may be present.

The wider group involvement comprises the detailing of societal, political and cultural influences on the health care providers, patient community and the wider society as these may effect decision-making. These groups are also ***Focused*** on because of the importance on wider involvement to provide better health care.

The amount of ***Focusing*** performed corresponds to a point on a continuum anchored by Restricted and Wide ***Focusing***. The actual amount carried out is dictated by the situation, available resources, medical culture/training, political considerations, patient/doctor relationship, physician characteristics/knowledge and experience.

Having performed ***Focusing*** corresponding to the above continuum as directed by self referred knowledge, further ***Self-Referencing*** and ***Surrogating*** occurs in order to find a solution to the problem. ***Self-Referencing*** occurs first and will now be detailed.

3.4 Self-Referencing

Self-Referencing involves referring to internal knowledge (primarily actual patient case) to match it to the properties of the problem discovered during ***Focusing***. This behaviour is caused by a preference to use internalised experience and information for making decisions. Of this information, personally experienced actual patient cases are favoured when a problem is encountered.

There is a two way process between ***Focusing*** and ***Self-Referencing*** because personal knowledge directs the discovery of information from the situation and decides on the centre to focus on. A number of categories of ***Self-Referencing*** exist that correspond to the amount and how this personal experience is used.

Self-Referencing is used to decide whether the Doctor has sufficient personal experience and ability (personal and outside resources) to treat the patient. If this is not the case, decision will then be based more heavily on external sources such as clinical studies, guidelines the opinion of hospital and other colleagues.

The self knowledge which matches the ***Focused*** context is then referred to ***Trading Off.*** This is to see if sufficient confidence exists in the behaviour after it has been ***Traded Off*** against other options and the ***Focused*** situation. The responsibility, risk, uncertainty and consequences of medicine and treatment decisions dictate the need for confidence to be held in behaviours before it will be performed.

If sufficient confidence does not exist, then in order to fulfil these criteria the Doctors **Surrogate** and build the confidence this way. Determining whether self knowledge is used can be under conscious or sub-conscious control depending on the level of experience in the area. The movement between ***Surrogating*** and ***Self-Referencing*** as

sources of information involves a process of ***Shifting*** which is outlined in the next section 3.5.

Central to ***Self-Referencing*** is the phenomenon where the individual experiences of the physician are seen as the best and most appropriate. These personal aspects of experience and situation are promoted to a position of importance and relevance over those of third parties.

This is due to personal experience being more vivid and containing more details concerning a ***Focused*** situation. The need for clinical studies to aggregate data and the limited time that can be spent discussing cases with colleagues means that these sources may not able to provide all the information that may be relevant in a situation.

Personal experience is able to represent the subtle differences between cases that may be crucial for success or failure of a particular treatment strategy. It is therefore held with more confidence that these behaviours will do what they are expected to do in the particular encounter and hence be used more readily or avoided.

"I would try and avoid the Tricyclics. I've seen to many people overdose on them, with serious consequences while working in A and E"

In this example, personal experience provides the Doctor with more vivid, comprehensive details of the use of this class of drug. The outcome is that despite it being very popular and well documented these are overridden by personal experience.

The preference for the internal source is also caused by the ease with which information can be retrieved and used. The time constrained nature of the medical environment means that making decisions rapidly is important. Indeed, in certain situations rapid decision-making is often necessary to save patients lives or reduce suffering, accident and emergency wards are a good example of this.

The use of this strategy is supported by the routine nature of much of medicine, this is the case in general practice. One of the primary roles of general practitioners is that of gatekeeper to ensure that only those people who need more specialised help receive it. In these instances, using personal experience to make a decision quickly enables more patients to be cared for and it is likely that personal knowledge will be sufficient.

Self-Referencing represents a form of personal conservatism and involves egocentrism and personal independence. It is conservatism that manifests itself by the view that what you have done is seen as the best and is a model that others should follow.

An example of this is given by an Angolan trained Doctor who was required to retrain in order to be allowed to practice in the UK. In discussing the parts of her medical training that she was forced by the UK authorities to re-sit, she promotes these areas as being more effectively dealt with by individuals from a similar background to her.

The fact that she had to retrain is also an indicator for this property. The authorities were necessarily saying to her that her experience and training are not good enough and needs to be checked before she can practice in the UK.

This conservatism is also seen in the fact that the evidence sought is preferred if it contains elements similar to the Doctors situation, culture, characteristics, training and physician's environment. The national culture involving the UK class structure and the national characteristics such as wealth and level of development are looked for within evidence. Personal aspects of training such as primary and secondary medical schools and the further community based training involved in a physicians development are also important.

Evidence, knowledge, experiences and sources displaying these characteristics are promoted to a higher level of importance when information is provided and obtained in order to determine it's use.

An example of this is given on the comments made concerning a series of lectures on community health given by a UK speaker and a Sudanese. The lectures delivered by the Sudanese were seen as more useful by the Angolan trained physician as it was full of her experiences. The lectures by the UK physicians on the other hand were hedged by a reluctance to try to change UK citizen's attitudes and were seen as less beneficial.

Self-Referencing may be prompted by not only the patient presentation but by new information becoming available. This situation leads the doctor to look initially internally to see if their levels of experience and knowledge are able to cope with understand and use this new information. If not, explanations and further information are sought from external sources.

Self-Referencing can explain elements of the adoption process used by physicians for new products. It explains the observed need for personal use and experience before treatments are accepted and why initiation of new treatments is commonly done very cautiously. This is often despite wider scale evidence for their usage. The example of Mobics demonstrates this. A GP who while admitting that it was supported by a high volume of printed discussion and evidence, only two patients had been initiated and a "wait and see" strategy adopted. The role given to this drug was therefore "work in progress".

Self-Referencing leads to perpetuation within that person or culture of the mistakes and benefits that it has created. It acts to dictate how information is used and searched for in the solving of problems. If the information and experience held is not representative or insufficient analysis is made of the outcomes of ***Self-Referenced*** behaviours then mistakes may be continued.

3.4.1 Categories of *Self-Referencing*

It would be preferable, from a physicians perspective, for all presentations of a particular problem to be dealt with internally using ***Self-Referencing***. This would negate the need to look outside for the knowledge to solve problems and therefore would save physicians time and effort. Achieving this situation is the development of expertise in the particular area.

The reality of medicine is that while the majority of cases are dealt with by internally held knowledge a large number require external assistance. The very large number of relevant and interacting circumstances (internal and external to the patient) that can be discovered during ***Focusing*** results inevitably, in situations where outside assistance however small is required and sought.

Self-Referencing therefore exists in a number of forms differing in the amount of the problem that is dealt with internally and habitually. As detailed in section 3.2.4.2 the physician may use habits to solve whole or parts of particular medical decisions. As habits are internally held patterns of behaviour that are performed without conscious deliberation, they can form part of any of the categories detailed in this section. They are more likely to be used in categories where greater amounts of expertise exist, i.e. Complete and Incomplete.

Categories of ***Self-Referencing*** refer primarily to the amount of the decision that is made via ***Self-Referencing*** and they therefore correspond to categories of ***Surrogating***. These relationships will be developed in the relevant sections.

A further property is the development of expertise that is seen as physicians use ***Self-Referencing*** for a greater number of problem areas. Expertise development, as

charecterised by use of *Complete* ***Self-Referencing***, develops in specific problem and may move eventually into mastery of a disease area.

3.4.1.1 Complete *Self-Referencing*

Complete ***Self-Referencing*** is the development of sufficient expertise and confidence in ones own experience and knowledge that effectively all presentations in this area are dealt with internally. It refers to the development of expertise where internal sources are able to address completely a particular problem.

Complete ***Self-Referencing*** also refers to the situations where new information, new therapies etc present themselves, the doctor is able to analyse these and Surrogate from the information without reference to colleagues. These forms can exist together or individually.

"I am basing quite a bit of my practice on at the moment is a thing that is published in the BMJ which was called the North of England evidence based guidelines for the management of angina."

"I wouldn't have to go and read a paper about it because I find these papers quite difficult to read unless you know how to do it."

Complete ***Self-Referencing*** develops in small specialised areas initially and broadens as experience develops. One of the outcomes of this behaviour is the formation and use of habits to make responses routine. These habits may be in the form of treating a patient, using certain tests or referring to a higher authority.

This kind of ***Self-Referencing*** can occur on many levels which correspond to the developing and growing confidence and expertise in wider situations. The **Complete** ***Self-Referencing*** of a particular drug or treatments usage (i.e. Zantac) tends to be on a

smaller scale than the ***Self-Referencing*** of a particular sub area of a disease (Peptic ulcer disease) or whole disease (Gastro-intestinal medicine). Complete ***Self-Referencing*** can be seen as widening (more areas understood) and deepening (more treatment options) as it develops.

"em I actually em in the hospital setting I would always enalapril just because I am use to using enalapril em I also use quite a bit of perindopril if I am starting patients on it at home and the reason for that is that there is a wee bit of data to suggests that it causes less problems with hypotension starting it than the other ones It is a newer one yea but it has got this advantage that it doesn't cause so much hypotension something as often"

This example demonstrates a depth of knowledge and experience concerning the manifestations of a disease and the use of different treatments in order to match these areas to the treatments. It also demonstrates the ability to integrate study information into decision-making and practice.

3.4.1.2 Incomplete *Self-Referencing*

This is the level of ***Self-Referencing*** that occurs when the majority of the situation is dealt with by the doctors own experience and knowledge. However gaps exist that need to be filled in order for them to be sufficiently confident in the behaviour. It is used as a small confidence booster in the particular situation.

"Well I look up everything except things I write out lots of times a day because I want to be able to sleep in my bed at night knowing that I wrote the dose that is written in the BNF and not something I thought was the dose that was written in the BNF."

Incomplete ***Self-Referencing*** is mirrored by **Partial** ***Surrogating*** as the process that is then used to fill in these gaps. The behaviours such as referring to the relevant product

dictionaries (BNF, MIMS) and textbooks can be seen as **Partial** ***Surrogating*** as a consequence of **Incomplete** ***Self-Referencing*****.**

"We changed to trimethiprin only which was quite effective in killing the vast majority of E coli urinary infections for example the bacteriologist in PRI told us just a few years ago that in fact Nitrofurantoin which is a relatively old drug was remarkably effective in killing off the E coli, more so than Trimethoprim"

This example demonstrates the longitudinal aspect of the process as over a period of time ***Incomplete Self-Referencing*** leads to information being sought and received which develops the expertise in the area.

3.4.1.3 Partial *Self-Referencing*

This occurs in situations where the Doctor has less confidence in his experience and knowledge but still has a level of expertise to draw upon. This expertise will direct their efforts to manage the lack of confidence. This behaviour is mirrored by **Incomplete** ***Surrogating*** as the process that is then used to fill in these gaps.

"I would probably stick to the ones I have been brought up with in hospital first before I tried that or I'd probably wait and see if it was coming out of hospital a bit more if they were tending to use it if they were discharging people on that,"

This example shows how the limited experience of the physicians in treating angina has lead to *Partial* ***Self-Referencing*** with the comparison of a new compound with the current treatment. ***Surrogating*** is then used for the further confidence needed to start using the drug.

"I follow the kind of paediatric advice which is you give them an ordinary inhaler and a spacer and when they are adults they can deal with an ordinary inhaler and I only give special things really to elderly people who can't cope with the timing"

Other potential outcomes of Partial ***Self-Referencing*** include referral to greater authorities and or usage of the treatment.

3.4.1.4 Limited *Self-Referencing*

Limited ***Self-Referencing*** occurs where a low level of confidence, knowledge and experience are held. These may be sufficient to diagnose the problem or narrow the area down but second opinions (from Professional, Formal and Marketing sources) are required. This behaviour may therefore require a considerable amount of ***Surrogating*** (complete and partial) to be performed in order for a decision to be made.

The reasons for the lower levels of confidence and knowledge include lack of exposure to certain diseases during practice and training, inconsistent results from previous treatments, junior status and role.

"and you think well Oops because as a GP we are a generalist we can't possibly have the time or the knowledge or ability even to read enough papers to make a decision ourselves but we can't know all the papers in every area otherwise there would be no need for the hospital specialists but we can't"

This indicator demonstrates a further property of ***Self-Referencing*** and ***Surrogating***, in that it is not possible for GPs to attain high levels of expertise in certain areas because of the nature of their roles. They can however become expert generalists.

3.4.1.5 Generalised *Self-Referencing*

The conservatism, volume of problems and situations that are possible, combined with the desire for ***Self-Referencing*** leads to experience and internalised data being generalised to similar problems as they arise. This form of behaviour is *Generalised* ***Self-Referencing***.

Generalised ***Self-Referencing*** is the use of existing experience to cope with in similar circumstances. It therefore reduces the volume of experience that is needed to cope with an area, speeding up the ***Shift*** from ***Surrogating*** to ***Self-Referencing***. It occurs when the circumstances are felt to be similar enough to allow the confidence in one experience to be generalised to this other situation.

"I know all, a lot of the studies have been done on Simvastatin but other statins I am fairly happy in my mind are have read some of them unusually are you know going to turn out to be about the same you know they reduce cholesterol the same that kind of thing"

It is an important tactic for reducing the amount of work a doctor needs to do to when dealing with problems as without it far more ***Surrogating*** would have to be performed to fill in the experience gaps. It can be seen therefore as a further tactic used by physicians to reduce the time and effort used in making decisions. It does however constitute a risk because the physicians cannot be sure that the individual ***Focused*** details of the patient will cause an idiosyncratic reaction to the treatment.

It can work for and against a treatment as is demonstrated by the biases that are shown toward drugs in classes that have given the doctor bad experiences in the past.

"but as a group we are very hesitant about putting new NSAIDS onto the formulary because there tends to be no information as to whether they are more effective than what is already available and we are pretty nervous about the group because of the experiences regarding Opren"

3.4.2 Summary

Self-Referencing is the preference and need to use internalised experience and information when a problem is encountered. It involves referring to internal knowledge of actual patient case to match it to the properties of the problem discovered during ***Focusing***.

There are a number of categories of ***Self-Referencing*** that represent the levels of confidence and knowledge the doctors have in that situation. A large number of situations are dealt with by using a level of personalised knowledge that is incomplete, a distinction therefore drawn between the desired situation of Complete ***Self-Referencing*** for all problems and its actual attainment.

Once ***Self-Referencing*** has been performed the information and confidence is then ***Traded Off*** to see if this information provides a solution to the problem. If it does not then ***Surrogating*** sources are looked at. An important category that is integrated to both these is ***Shifting***. This category explains the movement between these sources and will be turned to next.

3.5 Shifting

Shifting is the process where the most important influences for treatment selection moves from external ***Surrogated*** sources (hospital, experts, more experienced GP colleagues, reps, journals books) to internal ***Self-Referenced*** ones (own knowledge of disease, case history, experience, further training). It also occurs on a second path which is the ***Shift*** along the categories of ***Self-Referencing*** and ***Surrogating*** as the physicians becomes more expert in specific areas.

These shifts lead to behavioural ***Shifting*** where the behaviours performed in the same or similar situations, move from being what others tell, suggest, recommend being done to being based on personal knowledge and experience (habit, personal, more cognitive decisions).

This process happens as the confidence of the practitioner in themselves increases. This confidence is based on trust that in turn is based on levels of experience and knowledge of the treatment, diseases, patients and the opinions and actions of experts and colleagues.

Self-Referencing and the developing of experiences are the causes of ***Shifting***. As personal experiences are seen as the best influences, the development of experience will allow the doctor to move toward this preferred internal source from external ones. Initially the ***Surrogating*** sources are more trustworthy but the development of experience allows them to move to the personal ones.

"DB More and more you know say I was guilty in the past of prescribing what was eh. It is difficult they are not your patients they are your consultants patients and if your consultant likes a given drug you know you are under certain bit of pressure to prescribe that drug.

IB and if you are taking decision that is away from his habits?

DB Well I would always... I would increasingly go on evidence based

IB And do they ever challenge you on that do they ever say

DB I've never really had that yet I thing that will happen increasingly as I get more... stand up for myself more as you get on more."

The processes that underlie ***Shifting*** and its outcomes represent expertise development in physicians as characterised by a growing ability to deal with problems internally.

The default direction for ***Shifting*** is the desired and general move from ***Surrogating*** to ***Self-Referencing***. However ***Shifting*** also occurs back and forward between the two categories within problem specific areas. This occurs as experience and knowledge increases (***Shifting*** them toward the internal) and new information, new therapies, different patient situations arise, which cannot be dealt with via ***Self-Referencing***.

Therefore the ***Shifting*** continuum allows Doctors to move backward along it if situations arise that they cannot deal with internally.

"sceptical people like myself in terms of lipid lowering are having to re-look at the whole thing recently because there has been two major studies that have come out that have really changed our thinking. The 4 s study show that s is beneficial is 2nd prevention in reducing all cause mortality and its the first study ever that has really shown that."

It takes a sufficient amount of force (in the form of knowledge, experience and trust) to ***Shift*** the Doctor along the continuum. This force is demonstrated by the conservatism of physicians. This manifests itself by the lack of willingness to change from a drug that they know and has been tried and tested. The preferred behaviour appears to be to avoid change when other more familiar options are available. Information (either formal or informal) is a key to creating the movement in ***Shifting***.

"I think they mostly tend to stick to what they know unless something really wonderful comes out that persuades them to change"

3.5.1 Path One: ***Shifting*** between Sources

As mentioned above, ***Shifting*** occurs on along two paths, the first of these is the movement between ***Self-Referencing*** and ***Surrogating*** sources of knowledge and experience. This continuum involves the physician moving from the use of professional colleagues to external formal data (referred to and looking for external analysis of it) to internal use of data and finally personal experience.

The more experienced doctors are followed in their prescribing because of the levels of experience and knowledge they have. By following what they do they are gaining from this experience and can be more trusting in the treatment. The expression "***word of mouth***" is used which indicates that this influence is developed partly by an informal process.

As it is the trust in others experience that is fundamental to the use of external influences, this continues until the physician's knowledge is sufficient to trust in making the decision. This occurs problem by problem and treatment by treatment. The first autonomous areas are likely to be the common and less severe that are seen often, and that they are empowered to treat earlier in their careers. ***Shifting*** therefore occurs according to these areas.

Whilst the use of personal experience is the preferred source and represents the end point in this ***Shift***, it may lead to decision-making based on an unrepresentative sample of cases. Therefore, clinical data in addition to clinical experience should be used. There is a concerted effort within medical education to move physicians further toward this situation.

A crucial point of ***Shifting*** on this continuum, is the use of formal evidence in the form of clinical papers, reviews, books etc. The Doctors as they become more experienced, use evidence that they personally analyse more frequently in their decisions. This is at the expense of basing their practice on Professional colleagues.

"you know if you go in the coffee room and have a drug and a few of them say I have never heard of that and somebody says I have used it is quite good, it is that kind of way that influences prescribing, but generally they are cautious until they know a bit more about it and know that it works."

"DB Well I would always... I would increasingly go on evidence based
IB And do they ever challenge you on that do they ever say
DB I've never really had that yet I thing that will happen increasingly as I get more.. stand up for myself more as you get on more."

3.5.2 Path Two: *Shifting* between *Surrogating/Self-Referencing* Categories

As the physicians become more expert in specific areas, they are able to use more Self-Referencing in their decision-making. This is mirrored by a decrease in the amount of Surrogating they perform. The therefore represents a second ***Shift*** within Trading Off that is based on the amount of use made of the sources in decision-making.

"Well I look up everything except things I write out lots of times a day because I want to be able to sleep in my bed at night knowing that I wrote the dose that is written in the BNF and not something I thought was the dose that was written in the BNF."

3.5.3 Categories of *Shifting*

Shifting on both paths occurs at varying speeds that are dependent on the level of confidence that is built by ***Surrogating***, personal experience and the quality of information available. Two distinct categories can be identified within the varying speeds and represents the end points on a continuum.

3.5.3.1 Cautious *Shifting*

This is where the movement to internal sources is slow and done cautiously. They stick to external influences for a longer time to allow problems and fears to be worked out.

"whereas GP's aren't using Simvastatin very much at the moment that will come in a few years time I think perhaps em I would say I am starting maybe 5-6 patients on Simvastatin a month at the moment."

The areas that Cautious ***Shifting*** is seen within tend to be the more complex and where side effects and problems can be dangerous. This is the more common form of ***Shifting*** and is more likely to occur during **Partial *Surrogating*** and **Incomplete *Surrogating***

There are a number of causes of this behaviour that include internal and external issues. The personal experiences of the physicians that warn against rapid changes in practice and personality types can slow the movement between sources. Lack of understanding of the area and training deficiencies are also causes. Finally, national and medical cultures can also contribute to this behaviour.

3.5.3.2 Rapid *Shifting*

This is the rapid movement from external to internal sources and to increasing amounts of ***Self-Referencing***. This occurs where the Doctor has a good grounding in the

knowledge of the specific area and is often seen in areas of special interest for the Doctor.

New information and situations within the problem area can be dealt with by looking at external information sources such as colleagues and journals, briefly. The new information is therefore assimilated into their existing schema and decisions are made based on internal sources more quickly.

For Example, one doctor felt she was knowledgeable about depression because of a training rotation. She was confident in being able to make her own decisions in this area. Of the pharmaceuticals she uses for the problem there is one group - the tricyclics which are dangerous in overdose and whose use must be carefully considered.

"I've seen to many people overdose on them, with serious consequences while working in A and E".

This demonstrates how knowledge and experience with these drugs has lead to the internalisation of their usage. There lack of safety and her first hand experience of this has given her a need to search for alternatives and develop trust in them.

For Rapid ***Shifting*** to manifest itself in behaviour an alternative must be available, through current awareness or becoming aware of it. Extending the example given above, the physician was aware of next group of drugs (the SSRI's), and can remember the relevant reps calling to talk about them. This in conjunction with expert usage, leads her to confidently and rapidly ***Shift*** toward the use of internal knowledge.

"If the consultants were using them in the hospital, if they had less side effects, it they got the patient feeling better faster things like that."

3.5.4 Summary

Shifting is the movement from ***Surrogating*** to ***Self-Referencing*** for influences and sources of behaviour. Within this, ***Shifting*** occurs between professional and formal sources of influence as the experience of the doctor develops. ***Shifting*** also represents the movement toward using more ***Self-Referencing*** and less ***Surrogating*** in decisions. It therefore represents the development of expertise within medicine.

The speed with which this change occurs is represented by a continuum between Cautious and Rapid categories of the behaviour. The level of confidence, knowledge and trust in the area under scrutiny, determines this speed.

3.6 Surrogating

"when they gave it in the starting doses that were recommended to begin with then lots of folk fell about with a profound blood pressure response now the feel for that and the general usage's of that you only get through experience"

"and <u>I tend to gain from their experience really as to what they use</u>".

Surrogating is the use of other influences and information sources to compensate for the physician's lack of experience in an area by using other influences and information sources <u>as their own</u>.

The preferred basis for behaviour is personal experience because it is easier for the doctors to trust and feel confident in this type of behaviour hence ***Self-Referencing*** is used initially. ***Surrogating*** is a way of obtaining this personal experiential knowledge for either part or the whole of the problem without experiencing the patients themselves. In this way they "Surrogate" other sources of experience and therefore confidence and trust. They can condense the time needed to gain personal experience and building up their internal catalogue by obtaining it from other sources.

Physicians therefore look to use external sources that provide as much confidence and trust as their own experiences do. The outcome of ***Surrogating*** on the use of treatments depends on the content and recommendations of the sources and the ***Trading Off*** that is performed with them. These external sources are categorised as Formal, Professional and Marketing Sources.

Surrogating can occur directly via communication with other physicians to provide specific case details. It also occurs indirectly when the patient experience is buried within consolidated information such as clinical studies. It therefore involves the

physicians using this data as it refers to the "n" individual cases. Clinical evidence is a strong influence on the doctor's opinion partly for this reason.

Surrogating is caused by physicians dealing with patients individually (as detailed in ***Focusing***) and using their experiences to provide information for solutions to the problems as they arise. The highly complex nature of patient problems means that the use of actual case experience is a more accurate method of representing a patient's problem than statistics.

Statistical representations of patients necessarily leads to a loss in the individuality of each case and hence reduce their applicability for individual patients. In this way physicians prefer to use individual experiences rather than statistics which are often used incorrectly.

These aspects are combined with the lack of time and opportunity to experience wide ranges of patient cases in a large number of problem areas to resulting in a need to Surrogate these experiences from other sources.

A further contributing factor are the fundamental properties of ***Self-Referencing*** where the individual experiences of the physician are seen as the best and most appropriate. Hence information is sought that reflects this when it is not available internally.

Currently, experience is the strongest influence in this process though there is a feeling that younger physicians will prescribe more from a base of evidence than experience in the future.

Negative reactions to the treatment will colour the drug despite the level of global use. There is a need therefore for ***Surrogated*** information and the decisions based on it, to pass through the personal experience tests before it will be accepted fully by the physician.

Physicians worry about treatments and evidence reduces this by helping to ensure that it is used in the right people in the right dosage. This anxiety is reduced further by their own experience and evidence providing a basis for trust and therefore knowing the consequences of the behaviour chosen. Whilst personal experience is stronger than the trials but the trials often provide sufficient trust to initiate the adoption process.

Different categories of ***Surrogating*** exist whose performance depends on the experience of the Doctor and ***Self-Referencing***. As even the most frequently occurring trivial complaints occasionally throw up circumstances that cannot be dealt with via ***Self-Referencing***, advice or information is required from third parties. On the other hand even the most inexperienced doctor has knowledge and training to base decisions on and can do so in certain circumstances.

Two important properties of ***Surrogating*** develop from this. Firstly, in the majority of cases, despite advice being taken eminent, reliable sources, the ultimate decision rests with the individual with clinical responsibility. This is irrespective of the location of the influences.

"Certain things, his experience by far and also at the end of the day there are his patients and he is ultimately responsible for them so you have got to be responsible to him and be prepared to carry out his wishes. They are his patients and you are seeing them on his behalf so the buck stops at him"

The second is that all behaviour is ***Surrogated*** to some extent. This is the case because training involves ***Surrogating*** and clinical research is based on the work of previous researcher.

Surrogating has been found to contain the following categories: Complete, Incomplete (with sub-categories of Maintenance and Initiation) Partial, Exceptional, Generalised and Duty Bound.

Complete, Incomplete, Partial, Exceptional ***Surrogating*** represent a continuum of ***Surrogating*** that is based on the amount of information that is needed. The remaining categories represent specific areas of use or ***Surrogating*** from specific sources.

The properties of the sources of ***Surrogating*** will now be looked at followed by its categories.

3.6.1 Sources for ***Surrogating***

Surrogating is performed on three main groups of influence, these groups vary in the amount of credibility given to the information taken from them. There is a general preference for ***Surrogating*** to occur on professional sources though as previously discussed, the use of formal sources is growing in popularity.

Professional *Surrogating* is the use of other healthcare professionals including Hospital doctors, GP's, pharmacists and prescribing advisors. Whereas **Formal *Surrogating*** involves taking the experience from formal data such as: Clinical papers, books, pharmacological information, review articles, meta analysis, formulary documents, BNF and MIMS and documents prepared by professional and interested bodies.

The final source is **Marketing *Surrogating*** which involves the use of company produced marketing efforts, this is the least influential reference point.

3.6.1.1 Professional *Surrogating*

This is the specific following of the advice and practice of other Physicians, Experts, Pharmacists and Pharmaceutical advisors where they are deferred and referred to. These sources are followed with their experience and knowledge ***Surrogated*** by the Physicians. This advice and practice maybe formally or informally provided and may or may not be at the request of the physician.

It is based on the experience and information that the Professionals can provide and the relationships that are founded. Through the experience and knowledge, the experts have, they are thought to be more able to determine the correct course of treatment. Further benefits of these relationships have been documented in more detail in section 3.2.4.6 (***Trading Off*** for Mutual Benefit).

The experience of Professionals means that they are likely to have seen a wide range of circumstances around which the core disease is based. I.e. they have a wider and deeper internal catalogue of experiences. They will have seen a wider range of reactions and interactions and will posses more experience on how to modify treatments to situations. Even if a professional source does not possess a larger catalogue of experiences they may possess experiences that are different and therefore can provide legitimate assistance.

Professional sources are also be able to assess whether information is reliable and hence interpret it into a meaningful set of recommendations that will benefit the physicians and their patients. The knowledge of experts etc can also be used to weed out those poor studies and the ones that may have been analysed in a biased or incorrect way.

3.6.1.1.1 Consultants

The Consultants, (individuals with the most knowledge and experience) are a particularly important source for ***Surrogating***. As patients in hospital are the

responsibility of the Consultant and the juniors treat on their behalf, Consultants seen as the most important medical professionals in secondary care.

The consultant's usage patterns are more important than the their recommendations, though this remains a very strong influence. This is evidence for medicine as a practical art, it is practised and experienced. It is what is seen to be practised by more experienced and trustworthy others, that is the important influence. The prescription that patients are given when they are discharged back into the community provide a strong influence to primary care physicians.

The influence of hospital physicians is a central external influence. It contributes to personal experience by observing and demonstrating what is being performed by experts to the doctor's patients. The hospital setting is recognised as the setting where the more serious patients who will need a higher level of care are seen. These cases have less margin for error and this acts a further reason why the treatments used are a strong influences.

3.6.1.1.2 Colleagues

The experience and information that Colleagues within a practice or ward provide is often informal and can have a considerable effect on practice.

"and what started me off on that was discussing it with people and that was just colleagues and somebody said do you know the cost just look them up in the BNF just see the cost difference "

Colleagues, however, do not necessarily influence physicians to behave in similar ways.

"so the fact that my colleagues are using a certain drug doesn't persuade me one way or another not at all"

This quote also demonstrates ***Shifting*** where the GP feels he is more experienced and can solve the problem internally.

Issues that determine whether colleagues have an effect or not include the relative levels of experience, personal factors and clinical responsibility. It was found that differences exist in the willingness of physicians to accept the advice of colleagues or whether they prefer to follow their own practice.

3.6.1.1.3 Guidelines and Formularies

Guidelines and formularies produced by experts and committees are further sources of **Professional *Surrogating*.** These are often produced based a disease area and therefore contain self help and doctor directed suggestions based on experience that extends beyond medical treatments. For example dietary advice, fitness advice and breathing exercises. By following the guidelines of consultants and other experts leads therefore to a following of a far richer behaviour than purely the use of a particular medicine.

3.6.1.2 Formal *Surrogating*

Formal *Surrogating*, is the use of Formal clinical evidence and published information to fulfil the ***Surrogating*** role. The evidence is used in combination with their own experience etc on which to base treatment decisions. Formal ***Surrogating*** explains the desire for scientific rigour because with it they can have a higher degree of trust in the data and the experiences that it represents. These properties will be detailed later in this section.

"I know it's not formally abstracted but you know we get a paragraph to say there are two papers published on this product the first was a placebo controlled trial on 253, ages such and such and such and such, and the outcome was as follows I mean you get a reasonable feel for it."

Formal evidence is used and weighed up to help ensure security in the drug used. There is a movement toward basing medicine on hard, published data. This is moving away from the experiential lead evidence that practice was previously based on.

This development has been proceeding for 30-40 years and is still being talked about as a movement. It is slow partly because of the time Consultants can remain in their positions. This movement is helped by the increase in good studies being produced, therefore increasing the security of the decisions.

As discussed previously, evidence is used when the physician has too little experience and knowledge to trust completely their own judgement in a specific case. This may be due to a lack of studying, time or opportunity in the case of treatments that have been available for some time. The level and volume of the data ***Surrogated*** depends on the degree of lack of confidence that needs to be addressed. In addition to this the situation where the Doctors are working (either primary or secondary care) is important and is directed by ***Self-Referencing***

The need for ***Surrogating*** with new drugs is even greater because it is likely that the Physician will have no experiences so evidence is required to give an indication of the treatments use. The proliferation of new drugs in the last 20 years has meant that doctors cannot have sufficient experience of all new drugs on the market. Therefore, studies are useful to separate the "wheat from the chaff". New treatments are subject to strict regulatory requirements meaning that a large volume of evidence is available. However, the usefulness of this volume of data is questioned.

Litigation is becoming more prevalent and study evidence is used in this situation to show why drug x has been used here. This is supported by the claim that there are more good studies now being performed.

3.6.1.2.1 Preferences within Formal Surrogating

Preferences exist for the type of data, the source of data and study design of the clinical evidence used in decision-making. Overall, these build a picture of the preferred type of information. There is a need for the information to be reputable, show benefit over existing treatments and justify the risk that is taken with new drugs.

There is also a need to show whether the benefits are those of the individual drugs or the drug types. The work done must also be conducted in the relevant population and the sample size should be relevant to the size of the disease.

Physicians appear to want a close correspondence between the target population and the study population. There is a need to improve the research that is done to match these needs.

"For example NICORANDIL has been produced as an anti Anginal compound. NICORANDIL the problem about it is that virtually all the work has been produced in Japan. You know the question is whether observations on that population is easily applicable to our population. Because you know certain things they have a much lower incidence of coronary heart disease, much higher incidence of hypertension die more of strokes than heart attacks a lot of them die of gastric cancers. You know there are different observational things in these population"

The evidence provided can be applicable to only a very specific area and this will may become the niche that the product can start to fill. The indications can be small areas as well as very large ones where major diseases become treated as standard with using the data.

The onus is on the company to produce evidence that shows that a change should occur. Good evidence (to a certain extent) can be negated however by the cost differential of the product vs. its replacement. These are also examples of ***Trading Off***.

Trials are however not always available for the full ranges of questions that the doctors would like answers to. For example, the process of Drug Assessment by the CSM (Committee for the Safety of Medicine) is based on the checking of a treatment safety and efficacy against Placebo. This safety check though is not grounded in sufficient numbers to reassure practitioners or committees.

This scepticism is based on a number of occasions where "safe medicines" have gone on to kill or harm patients when released into the wider patient population. This has lead to a general lack of complete trust in new drugs and a situation where they must prove themselves in the patient population before the results are accepted.

There is also a desire for direct comparison in trials between the new and the disease standard treatment shows that the physicians prefer to avoid change and need strong reasons to do so. Once again, the C.S.M. procedures do not provide this.

It is admitted that getting this information is difficult because the companies would prefer to "out sell" each other than take the risk of negative results from comparative research. This is an example of ***Trading Off*** from the company's point of view.

3.6.1.2.2 Data Type

The specific type of data produced has an important role on the level of influence of formal data. The following types of data were found to have a particularly strong effect on decision-making:

3.6.1.2.2.1 Prognostic data

Prognostic data showing increased life expectancy is a particularly strong source of influence. It can allow a drug to be used far more widely despite problems. An example

of this are the drug class of Beta blockers, where side effect problems are tolerated because of the demonstrated benefits of saving the patients life. This also demonstrates the relationship with ***Trading Off***.

This kind of data can also produce benefits to other drugs that have similar actions, these are developed to give more treatment options in case of reactions etc. (Same benefits-more options). This is an example of Generalised ***Self-Referencing*** and ***Surrogating***.

3.6.1.2.2.2 Comparative data

There is also a desire for comparative data because this allows physicians to check scientifically the sort of experience they are likely to have. For example the performance of the old drug vs. the new (or potential) drug and their use simultaneously.

Comparisons are an area where the current studies production could be improved and provide further evidence. This would provide Doctors with a further short cut to changing behaviour more quickly. Currently comparisons are performed based on experience or separate studies. The comparison therefore lacks scientific accuracy. If comparative studies were undertaken then the drugs could be accurately assessed. This would provide physicians with a further instrument with which to reduce areas of inaccuracy in drug choice and therefore increase patient welfare.

"all that the companies have to put in is information as compared to placebo not compared with other drugs so we would be more interested in relative efficacy rather than absolute efficacy"

3.6.1.2.2.3 Meta-Analysis

Meta-analysis and review articles are liked because of the volume of data and hence patient cases that they analyse. There is however varying amounts of effort put into

reading and understanding this type of data. They may be analysed and the constituent results explored in depth or they may be used as a convenient short hand and accepted.

This latter form of the behaviour is likely to be accompanied by acceptance of the review provided by eminencies and colleagues. The form used by individual physicians depends on their level of expertise, confidence and motivation.

Again, there is a desire for more studies of this type to be performed and made available.

"I must say that I don't review that many papers or read that many trials you know, you know any drug that has been on the market has maybe been in one hundred studies or something like that so we really need met analysis or reviews to, to look at them."

3.6.1.2.3 Data Source

There is a gradation in the preferences for the source of formal data that is ***Surrogated*** from. This continuum is, once again, based on the level of trust and confidence that can be placed in it. The clinical work carried out by the Doctor themselves influences the strongest, through to that which is produced but not formally published by the pharmaceutical companies.

"No I think I am a most influenced by the research that I have done"

Use of this source means that they do not have to worry about the interpretation and the quality of the evidence as they are fully aware of its design implementation and analysis

The continuum develops next into the referred papers in good journals, the symposium issues, pharmaceutical company meeting papers and finally information held on file by the company.

"For example there is obviously a refereed paper in a good journal is much better than a symposium issue, that is, you know, non-refereed but might be might appear to be in a reasonable journal but what happens there is you get there is a wee editor who just looks at the thing corrects the English and puts it in. So it's not really sent out to the referees..."

"Then the final thing is information in house from the pharmaceutical company"

The journals with refereed papers have their own pecking order, which are understood formally and informally by the profession. It is the independence and review process of better journals that is critical for the information to be held in more confidence. This added to by a competent review board.

"I would prefer to see something to see more independent"

3.6.1.2.3.1 Study Design

Physicians have an ideal study evidence format which serves as an influence itself and a process for accepting a study. The influence created by the design of clinical studies can be enhanced by a review process. This review is most influential when performed by local and national eminencies. It provides support in the case of litigation and a comfort blanket of what they think and do, is endorsed by others.

The basis for the process of acceptance of the studies and hence their evidence is good scientific practice. This includes studies being randomly and placebo controlled, double blind and performed with large numbers of subjects.

"it is absolutely mandatory nowadays that they are double blind or at least against a placebo ideally or against something else"

These factors act not only to increase trust that the results are likely to be correct (the level of accuracy is known) but also having these study design aspects will act as heuristics for good work. Again, there is a desire to see more work of this quality performed.

However, from the perspectives of a pharmaceutical company this work is more costly and more risky. The main risks that are involved are the production of results that show no benefit from the drug or show unacceptable side effect profiles. It may also make public knowledge of problems that the companies are keen to suppress.

Good study design and evidence can promote a drug from a situation of general usage to a situation where because of evidence produced it allows them to surrogate experience for wider indications. Simvastatin is given as an example of a drug whose usage has been greatly expanded in this way.

3.6.1.2.3.2 Examples of Formal *Surrogating*

A good example of the effect of **Formal *Surrogating*** on prescribing is the effect of the 4 S study (Pedersen, 1994) using Simvastatin in patients with existing Coronary Heart Disease. This paper is also a good example of the benefits of good study design, good refereeing, and publishing.

Before this paper was published, Simvastatin was used regularly as a cholesterol management product. Its level of usage was restricted though by worries concerning the long-term benefit of treatment. The 4 S study demonstrated in large numbers the life saving long-term benefit of the drug and as a consequence prescribing has greatly increased.

The evidence is statistically strongly significant and shows considerable life saving benefit for a particular patient group. Therefore, it has considerable benefit to the patients as it demonstrates that usage can save lives, increase survival times, reduce life threatening events and increase quality of life.

The production quality of this piece of evidence is important and the significance levels are quoted; placebo control and double blind as properties that appeared in this study. It is was also published in a highly regarded medical Journal-The Lancet.

The influence and outcomes of **Formal *Surrogating*** are often less dramatic than the Simvastatin situation. The use of Nicorandil in hospital and evidence for it has lead to a far more cautious approach to its adoption. This can be explained by the fact that it is a new drug and the vast majority of Doctors do not have personal experience of it. The data produced in support of it also does not provide a perfect match to the information required. This is demonstrated by a quote used previously.

"an anti Anginal compound, NICORANDIL the problem about it is that virtually all the work has been produced in Japan you know the question is whether observations on that population is easily applicable to our population."

"I would probably stick to the ones I have been brought up with in hospital first before I tried that or I'd probably wait and see if it was coming out of hospital a bit more if they were tending to use it if they were discharging people on that,"

3.6.1.3 Marketing *Surrogating*.

The role of the company in influencing medicine is enigmatic and often conflictory. On one hand, many pharmaceutical company activities including direct mail and journal advertising are seen by physicians as having very little influence. Conversely company

representatives and educational support are seen as useful sources of experience and are ***Surrogated***. These activities will be detailed later in this section.

The level of influence of company activities is a further example of the need for trust and confidence in information that is ***Traded Off*** to make decisions. It also demonstrates further the importance of the individual decision context and the relationship between physicians pharmaceutical companies, treatments and patients.

3.6.1.3.1 Company Representatives

There is an acceptance of pharmaceutical company representatives, indeed many individuals are seen as influential and useful resources. A reason given for this is that pharmaceutical companies would not spend the money they do if representatives did not make a difference! It is also admitted that some (often older) representatives can be very persuasive

The importance of the individual representative and treatments also adds to the varying perception of company influence. This suggests that company influence needs to be viewed on an individual basis. This is further added to by the reluctance of physicians to admit that companies and representatives do influence them.

For example:

"It doesn't matter, it (reps) has virtually no influence on me"

Representatives are often necessary but not sufficient in attempts of pharmaceutical companies to change the behaviour of physicians. They act as the conduit through which company messages are accepted but often, they require other support to convince physicians to change. These conjunctive activities include provision of books and

literature, journal articles supporting the companies product and promotional activities designed to ensure the physicians know the relevant messages.

The influence of the marketing effort of a company is limited by a fear of it's bias. It is felt that company activities are potentially bias in they may be used to cover up unfavourable side effects and interactions and unreasonably promote it's potential benefits. The profit motive of pharmaceutical companies underlies this fear. A further contributing factor is the number of pharmaceuticals that have been launched only for severe side effects to be discovered

3.6.1.3.1.1 Educational Support

A mentioned earlier educational support appears to be a successful marketing tactic for the pharmaceutical companies in conjunction within representative activity and good products. The methods used by the pharmaceutical companies include the provision of books and educational resources (these can be used as legitimate access items) and sponsorship of educational meetings. It is expected that these items support the marketing messages proposed the company.

This form of marketing is seen as the most useful and hence influential tactic used by pharmaceutical companies. This is because it provides trustworthy patient experiences to the physicians or allows further contact to reliable colleagues.

One of the main roles for the company in providing educational items is that access to physicians is often dependent on supplying these items. The bribery factor that this can be said to be an example of is also seen in more blatant forms. For example funded trips to Monte-Carlo or paying for dinner or lunch.

It is claimed that tactics such as overseas trips do not or cannot influence physicians because of their obviousness. The influence of paying for lunch or dinner is seen in their

ability to build relationships rather than the "bribe" of providing free food and entertainment.

3.6.1.3.1.2 Marketing Messages

The codes and memos concerning marketing, demonstrated that the marketing message can affect the doctors if it is clinically correct. The phrase ***"struck a cord"*** concerning a marketing message is important because it shows that a successful message can encapsulated what the doctor feels about the treatment or disease and maybe demonstrates that the company understands the situation. If they understand then they may be seen as more trustworthy and can provide weight for ***Trading Off*** favourable to the companies position.

The idea of a ***"Super marketing Message"*** is related to this. This is a message where the company is able to encapsulate the problems of the disease area with the pictures and phrases and in doing so creates a message that "sticks" with the physician. This experiential encapsulation provides further support for the central tenet of ***Surrogating*** that physicians use information in a way to represent actual patient experiences.

3.6.1.4 Summary:

The reasons that outside information and influences are ***Surrogated*** is because of the EXPERIENCE with the product that they represent. The influences can be broadly categorised as **Formal** (clinical and scientific evidence and data) **Professional** (other health care professionals) and **Marketing**.

The Professional influences can be further divided between the specific advice they give, the treatments they use and the relationships that are formed. Formal data is a vital component in building trust and is often used a starting point for this process. It is used as a starting point where the treatment is new and experience cannot be found internally

or from other external sources. It is also used as a checking point to add trust to their own advice and that of other professionals.

3.6.2 Categories of *Surrogating*

There are a number of categories of ***Surrogating*** that vary in the amount of experience that needs to be ***Surrogated*** and in the freedom the doctor has to perform preferred behaviours. A number also correspond to categories of ***Self-Referencing*** which holds the other pieces of information needed for building confidence and performing ***Trading Off***.

3.6.2.1 Complete *Surrogating*

This occurs when the Doctor has no experience of the situation on which to build confidence and hence trade off. This occurs when new drugs classes are launched or treatments that are new to the physician are seen filtering through from Hospitals or other sources.

"if he is happy to prescribe it then there is no great reason why we should eh be too critical of that"

Complete ***Surrogating*** is described with the property that Doctors training gives them a foundation to be able to understand the disease and the treatment. Therefore, in a strict sense they do not require to Surrogate all relevant information. However, training can also be seen as ***Surrogating***.

"For example when Lisinopril came out marketed by Zestril by ICI. I remember going to a meeting in Edinburgh run by a Doctor Padfield who is a recognised expert in Scotland in hypertension and he was extolling it's virtues um over and above other

Ace inhibitors and other things so that was certainly quite a strong influence to go for it. I felt quite confident in going for it, and wasn't disappointed as it happens"

This example demonstrates complete ***Surrogating*** from a professional source and therefore highlights the interaction between sources and categories of ***Surrogating***. Complete ***Surrogating*** is far more likely to occur from Professional sources than from Formal ones, those this does occur.

Specific rules showing the source and the category of ***Surrogating*** that it is used in, did not emerge from the data. However generally the most credible sources such as Professional and Formal can be ***Surrogated*** from more completely than those such as marketing sources that which are not held with as much trust.

Complete Professional ***Surrogating*** when performed on accepted experts is often accompanied by an uncritical analysis of the information provided. This property is demonstrated by the following indicator.

"and if I'm sharing care with a consultant on a very basic drug like that I would find it churlish in the extreme if I was to refuse to do that"

3.6.2.2 Incomplete *Surrogating*

Together with Partial ***Surrogating*** this the more common from of ***Surrogating*** and occurs where the doctor has a level of experience in the field. It is performed where the levels of confidence and experience are low and considerable amounts of information etc are needed. It mirrors **Partial *Self-Referencing***.

It refers to the situation where nearly all the experience and knowledge needed to decide on a course of action are taken from external sources. An understanding of the situation

exists because of experience, training and extra reading but more is needed in the specific situation.

It occurs in situations where the combination of factors discovered during ***Focusing*** fall outside the experience of the physicians and their knowledge is not felt to be sufficient. These factors may be due to unusual patient circumstances, product development (i.e. new presentations) or situations where confidence has been built from other sources but more is needed.

"I think that after I'd two or three patients coming back like that I would ring the guy back and say look I am interested that you are changing to Amplodipine can you just tell me what your thoughts are on this so that I'm with you on this"

This example shows the **Incomplete *Surrogating*** performed when new practice develops from a secondary care setting. The example below demonstrates its occurrence when new drugs are used and a minimum of knowledge is held on them.

Two sub-categories of **Incomplete *Surrogating*** exist that are based on physicians reactions to recognised experts. The first involves maintaining the treatments suggested and started by eminencies and the second is initiating treatment based on their recommendations. These sub categories represent the ***Surrogating*** of information for specific types of behaviour that occur in certain situations.

3.6.2.2.1 Maintenance Surrogating

The maintenance manifestation of this behaviour takes place when a patient returns from hospital on a certain treatment and then care is shared between the consultant and the GP.

Rather than the GP changing the treatment and following their own treatment regimen, the expert's treatment is stuck to and **Surrogated**. Information is sought concerning the drug that they are maintaining to further understand it's usage.

3.6.2.2.2 Initiation Surrogating

This involves starting treatment for new patients in a way that follows the consultant known practice. This behaviour demonstrates a higher level of confidence in the treatment than by maintaining the therapy of the expert.

"but as a more junior doctor you were hugely influenced by your consultant
A) because you didn't know very much and
B) because you thought consultants were gods so would just prescribe very much what their habit was you would prescribe those drugs"

Maintenance and **Initiation** ***Surrogating*** are both characterised by the personal aspect of the ***Surrogating*** in that it is an individual expert that they follow not a department. The colleagues whose preferences are ***Surrogated*** also include senior partners and general practice colleagues.

3.6.2.3 Partial *Surrogating*

This behaviour occurs where the Doctor has a good level of experience in the field and requires only a few pieces of information to develop the confidence, once ***Traded Off***, needed to make a decision. It is performed in response to **Incomplete** ***Self-Referencing*** and fills in the gaps which are missing from the Doctors knowledge and experience.

"and what started me off on that was discussing it with people and that was just colleagues and somebody said do you know the cost just look them up in the BNF just see the cost difference and I had never really realised that codeine could be prescribed

nowadays it has just fallen just so far out of fashion that I just didn't realise that it was, it was always used a anti-diarrhoea but I never really just clicked"

It may only involve a very small amounts of experience and information that is required and can be delivered in a formal or informal way. What is importance is that it is a piece of confidence that is wanted as well as needed for the Doctor to prescribe.

3.6.2.4 Exceptional *Surrogating*

This is a minor category of ***Surrogating***, at one end of the continuum that occurs in fields where the doctor has considerable levels expertise and knowledge. This expertise is sufficient to deal with the vast majority of circumstances that arise, however from time to time an exceptional situation arises and the Doctor needs to Surrogate from another source.

Exceptional *Surrogating* is best shown in the sub-specialities that exist within teaching hospitals and centres of excellence. For example the paediatric cardiologist in Edinburgh's Royal Infirmary who is deferred to in very specialist cases by other cardiologists.

Exceptional *Surrogating* occurs in primary care in common situations that are often dealt with automatically but certain circumstances arise triggering further investigation and advice. An example of this (that has been previously mentioned) is when a patient presents with being “tired all the time", this prompts the reaction of certain blood test being ordered. The notes are written up as "TATT" representing “tired all the time”. The results of these tests are then used to see if further help is needed or whether, as is the case in the majority of the time, it is the lifestyle of the patient that is the cause.

3.6.2.5 Duty Bound *Surrogating*

This refers to a further specific form of ***Surrogating*** which takes place mainly in hospitals where the juniors are ***"Duty Bound"*** to follow individual consultants practice. It also occurs in general practice where a GP trainee is present and is duty bound to treat according to the trainer's wishes.

"Well yes it is an interesting one because when you are in the hospital you are duty bound to do what the consultant wants and in fact one of the main differences between being a junior doctor in a British hospital and being a junior doctor in a place like south Africa is that you get far more freedom elsewhere to prescribe"

Treatment of patients on behalf of the consultant means that the juniors are **Duty Bound** to treat the patients as the consultant wants. They are being forced into ***Surrogating*** the senior doctors experience for their own. This ***Surrogating*** can occur wherever the clinical responsibility for the patient does not reside with the Doctor administering the treatment.

The clinical responsibility for the patients in hospitals depends on the day and week of admission, as all patients taken in during a week tend to be the responsibility of one consultant. A consequence of the changing consultant responsibility is that the practice in the department may change week on week depending on the consultant is charge.

"if you are working for a particular consultant who has a particular preference for a particular drug you tend to follow his practice because you know he wants his patients to be on it..."

Duty Bound ***Surrogating*** also leads to drugs being used that the doctor would not use if they were free to prescribe their choices.

"Well for example we are trying to change everyone from Ranitidine onto Cimetidine at the moment...I tend to use omeprazole you sometimes see Lanzoprazole used but it tends to be Losec that we use".

The experience and evidence that is ultimately listened to is from the area that is thought to be more trustworthy and can be used more confidently.

Duty Bound Surrogating can be seen as a controlled form of teaching and as a controlled form of **Complete *Surrogating***. The difference between them is the freedom they have not to pursue the form of behaviour.

3.6.2.6 Generalised *Surrogating*

This is ***Surrogating*** where the experiences taken does not refer directly to the specific behaviour where it will be used. It takes place on influences from the three sources discussed in this section. **Generalised *Surrogating*** explains why information is used in situations that it is not designed for and hence represents a risky strategy.

It occurs in two forms, the first of these is where experience is being used as a crutch for the Doctors preferred action. For example clinical evidence being generalised to a class effect and therefore being used to justify the use of a favourite, similar drug.

The feeling is that confidence exists for a particular treatment and that the risk in changing to the specific treatment is greater than the risk of generalising. This behaviour demonstrates the conservatism of physicians and their desire to use tried and tested treatments that they trust.

Generalising also occurs when "exact" experiences are not available. In this instance, a sufficiently close case or piece of information is generalised to build confidence. For

example, data produced in a different population for a particular disease being generalised to the physician's population.

There can be positive and negative outcomes for the treatments of this behaviour. The outcome of similar treatment if generalised may support or restrict the use of the actual treatment. Cost differences may be assumed, as are side effect profiles.

"and we are pretty nervous about the group (NSAID's) because of the experiences regarding Opren in other words when you use it that class of drug when you start using it in hundreds of thousands of people it is quite possible that you turn up dangerous side effects that weren't actually the knowledge about wasn't actually available when they were actually doing the studies"

This behaviour in addition to Generalised ***Self-Referencing*** represent tactics to reduce the cognitive effort and time spent on discovering information for decision-making. This desire to reduce effort and time is seen throughout ***Trading Off***.

3.6.3 Outcomes of ***Surrogating***

Surrogating supplies ***Trading Off*** with information and confidence which is then analysed according to the objectives of the process set out during ***Focusing/ Self-Referencing***. It can therefore supply sufficient confidence to base a decision on or a further search is needed and the ***Trading Off*** process is initiated again. A number of levels of behaviours are decided on during ***Trading Off*** process (as set out in section 3.2.4.1), it addition to these the outcomes include a number of roles that treatments can fulfil.

3.6.4 Summary

Surrogating is the reaction to a lack of personal experienced discovered during ***Self-Referencing***. It is the process of using the actual clinical experiences of external sources as if it were their own. It's purpose is to act as a source of experience and information for building confidence that can be ***Traded Off*** to decide whether a **behaviour** should be performed.

It is a process that diminishes as expertise in a particular field develops and the location of influence shifts toward ***Self-Referencing***. ***Surrogating*** is performed on Formal, Professional and Marketing sources, the first two of these correspond to the strongest sources of surrogated behaviour. There are a number of categories of ***Surrogating***, within these there is a continuum dependent on the amount of information that is needed from external sources. The remaining categories correspond to the use of certain sources or in specific situations.

3.7 Behaviour

The Behaviours performed using the ***Trading Off*** process encompass a wide range of actions including treatment choice, investigations and assessment of information. As described in the introduction to ***Trading Off***, this process is primarily concerned with decision-making used to decide on treatment behaviours and the behaviours outlined in this section reflect this fact. The outcome of the ***Trading Off*** of investigative behaviour is also looked at whereas the assessment of information has been addressed throughout ***Self-Referencing*** and ***Surrogating***.

Individual behaviours are most often constituents of a plan, for example either during a plan for investigations, treatment plans or wider health care issues. The behaviours have a specific role to play and this along with likely interactions is a further condition that is ***Traded Off*** in making decisions.

3.7.1 Treatment Behaviour

Trading Off is primarily concerned with the treatments prescribed by physicians. Its applicability to **services rendered** (either physically or mentally) to the patient and **lifestyle changes** may be shown with further theoretical sampling.

Beyond the choice of a treatment within a treatment plan, ***Trading Off*** provides specific roles for treatments within a physician's armormentarium. For example, the data may suggest that the therapy being used in this circumstance represents an option that should be used in conjunction with another.

3.7.1.1 Roles

Most treatments do not enjoy a standard therapy role and are limited in their level of usage, as a treatment becomes more trusted however its use may ***Shift*** toward this position.

3.7.1.1.1 Standard

A Standard role is the pinnacle level for a drug to obtain and is involves the acceptance of the drug as the standard drug for a particular indication. This standardisation often needs formal data and empirical usage, however empirical experience remains the strongest influence. The actual drug used in this role may not be the only one that can do the job but it may be the only one with the data to give the doctor sufficient confidence.

"Oh yea yea so it has become a standard drug in treatment in gastro eh oesophageal reflux it is very free of side effects well tolerated by the patients it doesn't seem to interact with other drugs which is quite important and it can be used in all ages"

Self-Referencing categories are the more important source of this role however formal based ***Surrogating*** can also be crucial.

3.7.1.1.2 "N"th line role

Where options allow, physicians often maintain lists of treatments that they use in case of problems with their standard therapy. They can be described as being used 2nd 3rd or 4th line. As the majority of problems have a number of options the development of these roles is common.

The actual length of these sequences depends on the disease, ***Focused*** problem, physicians experience and knowledge and input from the patient.

This laddering occurs whenever there are treatment options available to the physician and through experience and formal studies an order forms for their usage. The need for such sequences are due to the idiosyncratic reactions of patients to treatments ensuring that 100% efficacy cannot be guaranteed.

These sequences may be strongly adhered to due to personal preference built on experience and or formal data. In this case the 3rd line drug will not be used until the 2nd line one has been tried. Conversely the positions on these ladders may not be fixed and can be interchangeable with small variations in the situation leading to different outcomes of ***Trading Off***. Patient preference and personal indifference can cause this latter behaviour.

"OK have a go on Tagamet but a few of them will come back and say I want to go back on Zantac,it has got fewer side effects than Tagamet"

These orders are often based around classes of medication/treatment and within the classes individual compounds. For example, Omeprozole (Proton Pump inhibitor) may be used as Standard therapy for Gastro-oesophageal reflux, then 2nd line to this Lanzoprazole (also a PPI) may be used. If this too fails then H2 Antagonists may be turned to in a sequence of Ranitidine then Cimetidine. Finally, surgery may be indicated.

"if someone had the symptoms of reflux or is known form an endoscopy to have evidence of reflux then then I wouldn't use a an H2 receptor antagonist first I would use a proton pump inhibitor"

An important property is that these sequences are dependent on the specific ***Focused*** problem diagnosed.

"IB. But you don't go Zantac Omeprozaole.

RG No not necessarily they are different drugs they work in different ways although they overlapping in many ways if someone had the symptoms s of reflux or is known form an endoscopy to have evidence of reflux then then I wouldn't use a an H2 receptor antagonist fist I would use a proton pump inhibitor but if they just had peptic symptoms/ ulcer then I would probably use a h2 receptor antagonist"

These roles are created by ***Self-Referencing*** and ***Surrogated*** sources.

3.7.1.1.3 Extension

Drugs acquire extensions to their areas of use if new information (from formal, professional or marketing sources) supports an increase in its areas of usage. This may be a formal extension granted by the CSM, supported by trial evidence or via informal one suggested by results of generalised usage.

While performing this role, the drug benefits from the experience held for it in other areas. Greater usage in the new area is therefore likely to occur more quickly.

While the main recipient of new information and license development is the named drug. Results are often a generalising of the effect to other similar types of drug. For example, other "Statins"[9] benefiting from the Simvastatin Survival "4S" study (Pedersen, 1994)

Once again, all categories of ***Self-Referencing*** and ***Surrogating*** can cause this behaviour though clearly the Generalised forms of these behaviour are particularly important.

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[9] HMG Co-enzyme A Reductase inhibitors

3.7.1.1.4 Conjunctive

Drugs can offer a conjunctive role within therapy where they provide an option if the disease proves to be resistant. This role is especially welcome if the norm for a disease is to be treated with increasing doses of drugs.

The standard drugs in these types of area (hypertension, anti-angina) will be used initially with the conjunctive treatment used in case of failures or resistance. The standard drugs are used because of experience and proof of their worth.

The development of this role can be due to all categories of ***Self-Referencing*** and ***Surrogating***.

3.7.1.1.5 New Option

A further role is performed by medications that are a new Option of treatment being used for a disease. This role exists in areas where there a number of other treatment options and where only a few exist. In this way it may be used after a number of failed attempts to treat the patient using the traditional therapies. This gives the drug opportunities to gain experience and to move up the ladder i.e. from fifth choice to fourth and so on.

Usage may therefore remain at a low level and grow if the treatment demonstrates consistent success over the existing options. However, because of the higher price often seen with new products and the conservatism in decision-making New option treatments can take a considerable time before they are used first line. The following example, as previously used to illustrate the justification needed before products are used, demonstrates this role.

"anyway you wouldn't automatically rush to Cozaar, you would start with your usual bog Standard Ace inhibitor and then if the guy gets a cough you'd say oh hang on I remember know lets switch you to this one and see if you cough goes away."

New options are often seen as interesting, especially in areas where there are few options for treatment. In this case their promotion is likely to more rapid. It is also likely that the greater negative and smaller benefits will tolerated.

This role is likely to be based on ***Surrogating*** or on Complete ***Self-Referencing*** where the physicians is able Surrogate new information without reference to other sources.

3.7.1.1.6 Work in Progress

Work in progress represents the lowest level of usage a drug is put to. Here, the drug is being used at trial level and is under close scrutiny. There is a feeling that the newer drugs of this type will have fewer side effects, will be slightly more efficacious and will be more expensive. A wait and see strategy is used.

A lack of formal evidence and experience is typical here though because of the situation it is required to be used. Therefore Professional sources and Generalised **Surrogating** and **Self-Referencing** are likely basis for this role.

Drugs fulfilling this role are felt to be more vulnerable to problems such as undiscovered side effects and are monitored carefully. A reaction of this kind is likely to severely restrict the use of this drug in the future. Conversely good results are likely to see the drug used more often.

3.7.1.2 Investigative behaviour

The investigative behavioural outcomes of ***Trading Off*** covers the testing and questioning of the patient to discover the ***Focused*** problem. It can involve tests being carried out by the doctor themselves or by sending them on to the other departments/doctors etc.

It does not represent the process of differential diagnosis, only the development of behaviours used to this end. ***Trading Off's*** applicability to differential diagnosis is again an area for further theoretical sampling.

The questioning aspect of investigative behaviour opens the process up to the development of diagnostic expertise. As experience develops, the asking of certain questions and performing certain tests in response to symptoms becomes more refined and there again develops a ***Shift*** from ***Surrogated*** questioning behaviour to a ***Self-Referenced*** set.

The testing procedures develop with the subtle development of added/reduced tests and decision-making tree. This happens as the discriminative powers of the doctors develop so they are able to see differences during the ***Focusing*** process.

Therefore the development of the doctor allows them to see more differences in the individual patient's problem, they have more tactics to discover these differences and act upon them.

3.7.2 Conclusion.

The behavioural outcome of ***Trading Off*** is primarily concerned with the use of medical interventions. The behaviours associated with investigative behaviour have also been outlined. As the consequences of the ***Trading Off*** of information and it's sources are

thoroughly intertwined within the ***Trading Off*** process and its constituent categories these outcomes do not require to be detailed in this section.

Beyond the decision to treat with a particular medicine, ***Trading Off*** produces various roles that they can fulfil. The role that a medication performs is dependent on the ***Focused*** problem and the outcome of previous Trade Off's. These behaviours are also likely to be part of a wider treatment plan and their position in this plan is a further aspect that is ***Traded Off***.

The integration of this process with the literature written on this subject will performed during the literature review chapters and in the conclusion and recommendation chapter 11. This review will now be presented.

It is noted that because of the size of the relevant fields the integration was not possible using footnotes as preferred by Glaser in Theoretical sensitivity (Glaser, 1978). Instead the suggestion provided in (Glaser, 1992) is followed and separate chapters are used. The greatest level of this organisation and integration will occur in the conclusions and recommendations chapter.

4 Chapter Four Decision-making

"When I use a word it means just what I choose it to mean-nothing more nor less" (CARROLL, 1961).

4.1 Introduction

This introductory chapter of the literature review will provide an overview of the field of decision-making including its principles, theoretical perspectives and developments. It is designed to ensure that the reader has sufficient knowledge of decision-making in order to understand its application to a medical context, it is not designed as a comprehensive review of decision-making research. It will provide therefore a framework within which medical decision-making and ***Trading Off*** can be understood within the wider decision-making literature.

It will examine the decision-making theories proposed from a Normative and Cognitive perspective. In particular the models of how decisions should be made (Normative theories) will be developed with those ideas that introduce the "inescapable role of intuitive judgement in decision-making" (Einhorn and Hogarth, 1981).

The review of the cognitive perspective will also examine choice strategies and heuristics used to simplify the evaluation task within decision-making. This review will therefore outline theoretical progress toward explaining observed decision-making behaviour. These perspectives are examined in detail because of their importance within current medical decision-making research and ***Trading Off***.

This chapter is designed as a framing document, from which many specific applications of it contents will be detailed in chapters 5 to 9. Therefore, details and conclusions on the factors that develop ***Trading Off*** and the use of ***Trading Off*** to synthesis these

literatures will be elaborated in these later chapters. This is order to highlight these issues where they are more specifically relevant to the objective of this study. However, where appropriate brief discussion of these issues will be held within this chapter.

4.1.1 Definition

Decision-making can simply be defined as "the selection of an option from two or more alternatives" (Schiffman and Kanuk, 1997). It is a field that is studied by disciplines as diverse as economics, psychology, marketing, management science, and philosophy.

4.1.2 Basic Process of Decision-making

The basic process of decision-making can be broken down to contain the following steps:

1. **Information Acquisition**
2. **Evaluation**
3. **Action**
4. **Feedback and learning**

(Einhorn and Hogarth, 1981)

These steps can be seen in the decision-making theories suggested from Normative and Cognitive and Consumer Behaviour backgrounds. The Normative perspective is to constructs a framework on how, rationally these steps should be performed. Cognitive theories develop these steps by applying cognitive factors that are able to account more accurately for the actual performance of decision-making and in doing so provide a more realistic concept of decision-making.

The basic consumer behaviour model then provides a variation on this generic process specific to decisions made when acting as a consumer.

The basic steps will be looked at initially within the study of the different models proposed for the whole process. For example the information acquisition step can be contrasted between the Expected Utility Theory perspective (Von-Neumann and Morgenstern, 1947) and the Theory of Reasoned Action (Ajzen and Fishbein, 1980) as the work on these two theories is developed.

4.1.3 Principles of Decision-making

4.1.3.1 Interaction

The generic steps of the decision-making process cannot be seen as independent as they involve interaction with each other as the process is performed (Einhorn and Hogarth, 1981). The degree of cognitive effort that is used in each of these steps is also dependent on the context of the choice and the individual involved. The diagram representing ***Trading Off*** (Chapter Three) demonstrates this interaction and co-dependence.

4.1.3.2 Alternatives

A decision requires that there must be at least two alternative actions that can be taken. This may be a choice between two products or it may be a choice between behaving in a certain way and choosing not to (Plous, 1993). For example, choosing to prescribe antibiotics (for which there are many different kinds) or deciding to wait and prescribing nothing.

4.1.3.3 Uncertainty

Judgements are very often made under conditions of uncertainty and in this instance people are often wary of ambiguous situations and will choose options where probabilities are known over the unknown ones (Hogarth and Kunreuther, 1992) . This

work and that of (Heath and Tversky, 1990) can be seen to support ***Self-Referencing***, as these authors found that people prefer their own beliefs over those of others when they feel skilled in that domain. The situation discovered during ***Trading Off*** is also one of considerable uncertainty.

4.1.3.4 Probability Judgements

Within these generic steps, the judgement of probabilities concerning the occurrence of events becomes a crucial element of making a decision (Plous, 1993). This is the case for whether the decision is being made according to a normative or cognitive perspective. ***Trading Off*** involves a subjective probability assessment concerning a number of issues surrounding the choice among alternatives.

4.1.3.5 Context

The individuality of each decision task context is a crucial finding of ***Trading Off*** (outlined in ***Focusing***) and is reflected in many aspects within the decision-making literature (Mellers et al. 1998), (Simonson and Tversky, 1992), (Erev et al. 1994). The importance of the individual task reflects the need for each decision to be evaluated within its own context and not against pre-set goals.

4.1.3.6 Personal Factors

One of the main aspects of this section of the literature review and the literature review in its entirety is the effect on decision-making by the individual making the decision (Plous, 1993). Normative theories (to be outlined in more detail below) are based on a picture of a rational decision-maker who is furnished with all relevant information for the situation and is willing and able to calculate the most rational outcome. This suggests a role for the decision-maker as a glorified calculator who works out the path to be chosen according to a pre-set goal. This path would be the same as the one chosen by the next person and so on, if the same goal is chosen.

However individuals differ in a number of ways that have been shown to effect the outcome of decisions. They differ on how they perceive the information used in the situation, they differ in how effectively and comprehensively their memories perform information searches. They differ in the attitudes and beliefs that they hold toward information sources, features and outcomes relevant to the task at hand.

The discussion of these personal issues will be made within the framework of behavioural inconsistencies compared to a normative perspective. They remain a fundamental aspect of the need to consider decision-making in individual contexts.

4.1.4 Approaches to Decision-making

4.1.4.1 Normative Theories

Historically the main decision-making paradigm has been that of the normative theories. This is seen clearly in the approach taken by medical decision-making reviewed in chapter 6. These theories also have roles to play in the education of decision-makers, to provide frameworks for the development of decision aids and artificial intelligence and as work to develop ***Trading Off***. The underlying tenets of these theories are therefore reviewed here.

These theories state that decisions are made rationally in order to maximise the expected utility of a choice. This type of theory proposes that the choice made represents the highest predicted payoff from the options available. The most famous example of this paradigm is the Expected Utility Theory (EUT) by (Von-Neumann and Morgenstern, 1947). This is set out as a normative model that represents how people **should** choose rather than how they actually do. This class of theory is detailed in section 4.2.

It is clear that in many instances of decision-making the rational choice as predicted by normative theories is not made. Biases and errors have been shown experimentally (Tversky and Kahneman, 1973), (Tversky and Kahneman, 1982), (Tversky and Kahneman, 1981) and can be seen empirically in decisions made in every day life. For example the use of habits to buy the same loaf of bread from the same shop as previously, may rule out finding the same loaf at a cheaper price or one that is fresher etc.

The study of these of these errors and biases (Tversky A. and Kahneman D, 1974), has added to the practical understanding of decision-making and has been used to help reduce the occasions when these problems occur. It has also lead to theory development that is detailed throughout this chapter.

4.1.4.2 Cognitive Theories

The cognitive perspective on decision-making views problem solvers as contemplative adaptable beings who apply a level of thought to decision-making situations. This view reflects ***Trading Off***'s position of non-habitual decision-making. Theories conducted from this perspective have been able to account for behavioural violations of rational theories such as the effect of framing, context and attitudes of the decision-maker.

This has lead to variations of rational choice theories such as Prospect Theory (Kahneman and Tversky, 1979). This theory represents a more general movement toward management of observed behaviour by incorporating individual differences and contextual richness into decision-making models.

The utility maximisation maxim of EUT assumes that the decision is independent of the context. Work however has shown the importance of the task environment to the individual making the choice (Von-Neumann and Morgenstern, 1947), (Flynn et al. 1994), (Ellsberg, 1961) .

A fundamental difference between the normative and cognitive theories is the importance placed on task structure by normative theories compared to the task content and personal factors of the cognitive approach.

The study of how decisions are made has also lead to the development of rules and strategies describing actual choice tactics. These strategies, cognitive decision theories, errors and biases will be outlined after normative theories have been reviewed in more detail.

4.1.5 Summary

This section has outlined the generic process and principles of decision-making. It has identified as crucial in decision-making research, the context of the decision-making task and the importance of the individual making the choice. These aspects of the decision-making are supported and detailed throughout this literature review and where found within ***Trading Off***.

Of particular interest is the similarity the view of the decision-maker from a cognitive and ***Trading Off*** perspective. The basic principles and process of decision-making can also be seen within ***Trading Off***. This similarity is developed in section 4.4.

The identification of Normative and Cognitive approaches as the key perspectives within decision-making research shows the medical decision-making bias of this study. These approaches will be detailed and the movement from how decision should be made to how they are made will be followed.

The Normative, "how it should be done" approach will now be reviewed.

4.2 Normative Theories

The expression "Normative Theory" is used to explain that these models were designed to represent how people would make decisions if they behaved rationally. They are not descriptions concerned with the reality of actual decision-making. Normative theories of choice are based on the principle that the choice made will be the one that provides the individual with the highest expected utility.

Utility here is seen as the benefit to the individual by making that decision and is based on particular desired outcome or combination of outcomes chosen by the individual. The expectation aspect of these theories is represented by the objective probability of an event happening or the object having that attribute. It suggests that a decision is arrived at by the subject initially systematically gathering all relevant information concerning the choices. The probabilities of the events are then weighed up and finally a choice made based on the calculation of the option providing the highest utility (Yates J F, 1990).

Indeed from a structural perspective this is similar to the findings of ***Trading Off*** however the execution was found to be very different. There is no suggestion in ***Trading Off*** that all relevant information is gathered, only that sufficient is in order build confidence in the behaviour.

4.2.1 Expected Utility Theory

(Von-Neumann and Morgenstern, 1947)'s Expected Utility Theory is the most famous example of a normative, rational theory of choice. It attempts to discover a subjects preferred outcome among alternative from a process using Standard reference gambles. (See Appendix Seventeen and Eighteen for explanation of Standard Reference Gamble and the process of EUT).

The authors specified six principles that underlie the rationality in expected utility theory, these principles are used in varying combinations in developments of the theory.

The title "Expected Utility Theory" is now used to describe a family of theories which includes work by (Coombs, 1975) and (Karmarkar, 1978). They provide extensions and refinements to Von Neuman and Morgenstern's work, which are based (to varying degrees) on the same principles. These principles are:

4.2.1.1 Principles

Ordering of alternatives: A rational decision-maker should be able to compare alternatives. There should be a preference for one of the options or indifference.

Dominance. A particular choice will not be made if there is another option that is superior in the eyes of the subject.

Cancellation: Choice should only be made on those aspects between which the options differ, the similar aspects cancel out.

Transitivity: If option A is preferred to option B and B is preferred to C then A will be preferred to C by a rational decision-maker.

Continuity: A gamble between the best and worst outcome should be preferred to a sure outcome that lies in between these two extremes if the odds of the best outcome are good enough.

For example a vaccination should be taken if it has a 50% chance of preventing Asian Flu even if the vaccination has a 1in 10 million chance of killing you. This should be a

preferred gamble to a vaccination with a 1 in 20 chance of prevention and no chance of death.

Invariance: Decisions should not be effected by the presentation of the alternatives (Plous, 1993).

It has been shown mathematically however by (Von-Neumann and Morgenstern, 1947) that if these principles are violated then the benefits of a decisions are not maximised.

4.2.2 Summary

An outline of the objectives, process and principles of normative theories has been provided. This has been illustrated by detailing the Expected Utility theory of (Von-Neumann and Morgenstern, 1947). This theory provides a list of principles which if adhered to will ensure that the choice made represent the option with the highest benefit to the decision-maker.

As a class of theories representing how decision are made, the normative perspective can be criticised from a number of standpoints. Indeed there are a number of studies (supported by intuitive evidence) that demonstrates that utility maximisation or the other principles of EUT are not adhered to. The objective of normative theories however to demonstrate how decision should be made, render criticisms from an observed standpoint unfair.

These criticisms and demonstrated inconsistencies do however provide directions for decision-making research to address in attempting to model this class of behaviour. A number of these inconsistencies will therefore be outlined before detailing theories whose objective is to account for observed behaviour.

Normative theories do remain a useful teaching model and as data and information technology develops (particularly with medicine) they could become models of observed

behaviour. This may occur as many of the problems with implementing EUT style models will be removed and decision will be able to be made according the principles they espouse.

4.3 Behavioural Inconsistencies of Normative Theories

The principles outlined above have been shown to be violated in a number of studies and indeed these violations have been shown to be enduring in some cases. These breaches and inconsistencies will be examined in detail because they form the basis of theoretical developments in decision-making research. These infringements provide the background for cognitive developments in decision-making and its increased respect for contextual information and psychological processes. ***Trading Off*** offers further cognitive model that is able to explain some of these inconstancies.

A number of inconsistencies have been found with the acquisition and evaluation of information. The use of choice criteria when decisions are made has also been shown to be inconsistent. Once the discrepancies relevant to these generic decision-making steps have been discussed, models proposed to develop EUT will be looked at.

The differences found between ***Trading Off*** and the process of medical decision-making suggested by (Sox and Blatt., 1988) that is based on a normative approach will be detailed in chapter 5.

4.3.1 Rationality

The concept that there is only one rational decision that can be made has been questioned because of the individual differences that are brought to choice situations and differences in task structure and content.

The single correct rational response assumption has been shown to be incorrect because different answers can be correct, depending on the normative theory applied. For example, if specifying the likelihood of extraterrestrial life being discovered, from a Frequentist point of view, no answer would be possible. From a Bayesian perspective however, an answer would be placed between 0 and 1. Both of these would be correct from their respective positions (Mellers et al. 1998). Within a medical context more than one treatment is capable of achieving the objectives set and can therefore be chosen via ***Trading Off***.

Rationality within EUT is seen as grounded in, "internal coherence and logical consistency within a system of beliefs and preferences" (Mellers et al. 1998) p449. This suggests that decisions made will be consistent with beliefs and preferences across situation and over time and therefore the content of the task is unimportant

This has been the basis of criticism and work showing the importance of the content of the decision task (Gigerenzer and Goldstein, 1996). (Mellers et al. 1998) suggests that good decisions are made when the content of the decision task is looked at, not just when laws and principles are applied. Not to do so leaves the individual un-adaptive to the environment (Cosmides and Tooby, 1996). These findings support the importance of ***Focusing*** on the ***Trading Off*** decision-making process.

An additional situation-based criticism of rational choice theories is that rationality is not necessarily independent of the status of the actors. It can instead be seen as a personal issue. For example, a task may be set by an experimenter and designed to reflect a certain situation with certain objectives leading to a rational outcome. It is unlikely however to be able to reflect the full range of beliefs, motivations and perceptions that the subject brings to the task and hence reflect their perception of rationality (Frisch and Clemen, 1994).

Further to this, the objective of a study may for example be to test the coherence principle. It may be the objective of the subject nevertheless to finish as quickly as possible to allow them to collect their participation fee and get on with more personally important tasks. Instead of acting as intuitive statisticians, the respondents may therefore be acting as intuitive politicians (Tetlock and Boettger, 1998). In this instance, the subject may behave "irrationally" as defined by the experimenter but is behaving perfectly rationally according to their own motivations and objectives. Once again a physicians choice of a particular behaviour can be viewed simultaneously as irrational and rational, i.e. the prescription of antibiotics for a viral complaint in order to terminate the consultation.

4.3.2 Likelihood Judgments

Likelihood judgements are the building blocks of decision-making, independent of whether they are subjective or objective. It is these judgements that provide the cognitive units upon which a decision will be made (Plous, 1993). This is independent of the objective of the decision-maker.

A major issue within EUT is the dependence on objective probabilities to calculate the optimal decision. It is obvious from reviewing the steps involved in EUT that this type of calculation is unrealistic in everyday decisions. This is because of the arithmetic difficulty in performing these calculations, the mental effort required, and the reliance on a statistical data bank on which to base these decisions.

The data needed for these calculations may not be available to the subject and if it is, it may not be accurate. An additional intuitive reasons against this use of probability data is that it cannot be available for unique events.

These problems have lead to the use of subjective weightings in expected utility based theories. (Savage, 1954) developed this idea with "Subjective Expected Utility Theory".

This answers many of the issues raised previously, in particular the point concerning unique events. For example, subjective probabilities can exist for the chances of your personal survival during an epidemic of a previously unknown disease though that cannot be calculated objectively.

Subjective probabilities are not without problems themselves. This can be seen in the lack insight into the subjective weightings that individuals hold and an inability to produce a comprehensive model of the reasons for their behaviour. A more detailed review of subjective expected utility theory is provided in chapter 5.

Related to likelihood judgements is the issue of confidence in these judgements. The research into over confidence in ones own abilities has lead to disagreements over its existence. For example, work by (Brenner et al. 1968) suggest that is does. However (Erev et al. 1994) assert that overconfidence is the result of regression to the mean or is the result of non-random sampling. The notion of overconfidence in ones abilities does however provide a possible cause of ***Self-Referencing*** and the problems caused by it.

4.3.2.1 Base Rates

Base rates refer to the prevalence of the object in the general population. How and if base rates are used when developing likelihood judgements has been subject to debate however. (Slovic et al. 1977) showed that base rates were ignored and is thought to happen because of the representativeness heuristic. Heuristics are detailed at the end of this chapter.

(Koehler, 1996) however thought that base rates are frequently used, the degree to which depends on task structure and representation. This again is evidence for the dominance of the environment in decision-making.

This insensitivity's is of importance to Marketing and Medicine. I.e. disease A may be thought of as more likely than disease B despite the prevalence of disease B being far greater because of the symptoms are seen as more similar to disease A (Kahneman and Tversky, 1972). This is good illustration of the maxim that (Sox and Blatt., 1988) report: "if you hear hoof beats think of horses not zebras" p25. This area is discussed further in chapter 5.

4.3.3 Context

The context within which the decision are made has been shown in previous sections to have a profound affect on choice, indeed the specific context is seen at the very heart of ***Trading Off***. Work on specific contexts will now be expanded.

In choice situations, the specific context entails a local stimulus context, which involves the attributes within the choice set, and a wider stimulus context that involves the attributes from all the choice sets presented (Mellers et al. 1998).

4.3.3.1 Local Stimulus Context

Local context effects include the increase in the values of certain options when they are displayed in sets of three compared to when they are compared in sets of two. This has profound consequences for new product development and marketing communications. It also represents a violation of the invariance principle.

(Simonson and Tversky, 1992) develop this idea of the ***Trading Off*** of a products attributes being dependent on the other products surrounding it in the choice set. These effects also mean that it is not possible to compare objects on just the attributes that they differ. The differing attributes mean that the similar attributes are perceived differently that in turn violates the principal of cancellation.

The addition of further options to the choice set can also lead to a compromise effect where the middle options become more popular. A related effect is seen when a middle option is added and preferences can polarise so one of the extreme options becomes more preferred (Huber et al. 1982). For example if the product trade off concerns high price and high quality vs. low price and low quality, the addition of a mid price and quality option can increase the desirability of one of the original options. This type of behaviour contravenes the dominance principal outlined previously. Again, this phenomenon has important consequences for new product development and marketing communications.

4.3.3.2 Wider Stimulus Context

Global stimulus contexts have been shown to effect the weights given to attributes (Tversky and Simonson, 1993), this is a further argument supporting the importance of the individual environment and individual in decision-making. These findings have also strong implications for product portfolios and marketing communications specifically.

(Simonson and Tversky, 1992) believe that context effects are the norm rather than the exception and that by taking into account comparative characteristics of alternatives, people are motivated to **try** to find the best solution.

These authors state categorically that the findings outlined above show that the principal of value maximisation is false and they call for the effects of context on choice to be outlined further.

These results on context effects and the use of heuristics as methods of cognitive effort reduction suggests that the objectives for a decision are determined by a combination of the situation and the individual. It also suggests that the method used to solve it depend on these two aspects.

Further to this it suggests that individuals use different methods to solve different problems and even different methods to solve the similar problems. This area will be detailed further in the choice strategies section.

The individual factors and heuristics will be looked at in future sections whereas next a brief look at problems with how information concerning decisions and attributes are communicated will be made.

4.3.4 Communication

The communication issues that affect normative theories can be divided into two sections. These sections are the meaning of the information and how it is framed, these issues once again combine the context of the decision and the individual differences of the parties involved.

4.3.4.1 Meaning

Communication of information between the parties involved in decision-making should be unbiased, provided in language that has a shared meaning and is complete. This then allows a shared understanding of the situation and information, in turn this permits the decision-maker to make a rationally based choice.

The exchange of information to allow decisions to be made and compared is however subject to a number of biases (Ramsey, 1931). (Bryant and Norman, 1980) found a wide range in objective interpretations of common expressions. For example, the objective score of the meaning of "possible" was found to range between .2 and .6 with a mean of .4.

This finding is of crucial importance when objective information is being translated to a third party such as doctors discussing the chances of operative success to a patient. In case where their understanding of "possible" varies to the extent found by (Bryant and

Norman, 1980) this could lead to objectively and subjectively poor decisions and ones which leave both parties with very different expectations of the outcome.

For example, a doctor may talk about "a possibility of serious side effects" with the understanding that this refers to a .6 chance whereas the patient understands this to mean a .2 chance. These differences can conceivable lead to alternative courses of action and even medico-legal issues arising from the patient accepting a course of action based on misunderstanding.

This lack of shared meaning also makes learning from experts difficult "we can take full advantage of expertise only is we can discover their true opinions (Yates J F, 1990). This problem would not arise if there were valid and reliable statistics for all outcomes possible in a given decision task. In this instance, communication from the experts could be performed mathematically. However this volume and quality of information does not exist and therefore the use of objective models which are then translated into subjective language leads to biases and errors. In these terms the use of ***Self-Referenced*** information is legitimate because the person using it they know what they think it means!

4.3.4.2 Framing

Framing concerns "the variations in the presentation of decision situation" this can lead to the decision-maker holding a different view of the situation than other parties (Yates J F, 1990). It can effect how information is stored and can be used to manipulate preferences for certain options. Therefore framing can be used to work against the choice of the rational alternative (from either an EUT or personal perspective) and hence violate the invariance principle. It can also be seen as a reason why similar situations in medicine are treated in different ways. The effect of framing on ***Trading Off*** is explicit in the theory via ***Focusing***.

The wording that the data is framed within and the sequence with which it is presented are two examples of how the presentation of information can effect how it is acquired and (Levine and Plott, 1977). (Tversky and Kahneman, 1981) showed that changing the wording in a decision scenario can lead to the subjects changing their choices despite the structure of the scenario staying the same.

It has been found that the form in which information is received tends to be the form in which it is used. I.e. if the probability of an event is described as 1 in 10 then this tends to be how it is remembered (Slovic, 1972). Framing has been shown to be very effective way of manipulating preferences based on this. (Johnson et al. 1993) showed that preferences for insurance can be changed if the premiums are described as rebates or deductibles. Many other authors have found framing effects of this sort.

Framing can be seen as a crucial component of marketing communications for the construction of messages that will enhance the communicators message. It can also be seen however, as a phenomenon that works against unbiased communication where the objective is to provide information without promoting one outcome over another.

The effect of framing can be reduced however if the outcomes of options within the task are made explicit and it is not left to the individual to fill in missing detail (Kuhberger, 1995). This is also the case if the outcomes are manipulated rather than the reference point. I.e. describing something as 98% fat free or 2% fat changes the perception of the product, it does not however reduce the consistency of the product (van Schie and van der Plight, 1995).

4.3.5 Cue Redundancy

The use of cues and specifically cue redundancy show the tendency to reduce the amount of effort expended when making decisions. Despite being able to handle large amounts of information, when deciding on the form of an incident, people only pay

attention to certain cues. This leads, for example, to doctors making decision by regarding only a few of the symptoms of a disease (Phelps and Shanteau, 1978). This tendency also contradicts the EUT approach of defining and considering all the possible alternatives.

The adaptive benefits of cue redundancy have been shown that it allows searches to be limited without great reductions in predictive accuracy. This appears to be a skill that is closely related to developing expertise. It protects against information overload and can help the decision-maker discover unreliable cues as it provides them with multiple measure for the same cue (Einhorn and Hogarth, 1981).

(Phelps and Shanteau, 1978) found that experts are able to attend to a large number of cues and are capable of using this information in their decisions. This suggests that there is a personal aspect to the use of cues and as such cue usage will vary by context. This leads to a further behavioural inconsistency compared to EUT.

However, non-experts do not use cues as effectively, for example they pay attention to, but cannot use certain cues. They are also prone to attaching incorrect weighting to those cues that are not attended to because of the relationship to cues that are used. This weighting may be too little or too much (Einhorn et al. 1979).

These aspects of cue redundancy are seen specifically during the *Focusing* process and *Shifting* as physicians become more expert and diagnose using more refined questioning strategies. They also add support to the view of physician decision-making involving a desire to reduce the volume of cognitive effort expended.

The selective attendance to cues does raises the question of whether the cues attended to are important or not. This may be a further area where errors develop in decision-making. In the case of medicine, if important symptoms are ignored or related ones attended to too heavily, then incorrect diagnosis and treatment may occur.

This work has been the base for comment that a model of decision-making that does not allow for cue redundancy will be incomplete (Einhorn and Hogarth, 1981). This is because it is important when making decisions and when teaching it, to understand how evidence is used and under what circumstances biases and errors occur.

4.3.6 Risk

The decision-makers perception and attitude of risk has been looked at recently as an important source of variation in choice. This research adds to the importance of dealing with each situation individually.

Risk is perceived differently depending on cultural and background aspects of the subject. Cultural differences were found between Asian and Western subjects when the perception of gambles was looked at by (Bontempo et al. 1997). Asian subjects were more concerned with the size of losses compared to Westerners who weighted the probability of losses higher.

A combination of cultural and background aspect effecting perceptions of risk and hence personal decisions was demonstrated by (Flynn et al. 1994). They showed that well educated, white, conservative men saw environmental hazards as less risky. Experts have also been shown to be less willing to extrapolate toxicology studies than members of the public (Kraus et al. 1992).

Further work on risk develops the importance of the decision task. People's attitudes toward risk are reported to be different depending whether the gamble is in the loss or gain domain. Subjects tend to be more averse to risks when the task is in the gain domain and risk seeking when in loss i.e. they will take a risk when they are already down from previous gambles. (Kahneman and Tversky, 1979). This research suggests

that during ***Trading Off*** physicians may behave differently if the patient is viewed as having something to gain from treatment or something to lose.

4.3.7 Emotions

Emotions have been shown to have powerful consequences on decisions making before, during and after the decision task. Their effect is via their effect on learning, memory, creativity and integration of information. This personal issue again involves an interaction between the individual and the context, this in turn leads to variations from rational decision-making.

The effect of emotions before and during the choice situation suggest that positive affect is beneficial in harder tasks. This conclusion is drawn from research showing emotions leading to more efficient integration of information, a reduction in the amount of anchoring (detailed later in this chapter) and allowing individuals to display more creativity in their thinking (Estrada et al. 1994). The benefit of positive emotions on decision-making is also shown by (Kahn, 1993) who found it leads more variety seeking behaviour

Negative affect on the other hand appears to be beneficial on easy tasks. It has been shown to narrow attention, lead to faster and less discriminative use of information and leads to more attribute based comparisons (Mellers et al. 1998).

The post decision consequences of affect involve the reaction to the outcome and from that learning for subsequent decisions. (Gilovich and Medvec, 1995), studied the common feeling of regret after a decision has been made. Their work demonstrated that action is regretted more in the short-term but less so in the long-term.

Post purchase cognitive dissonance which (Gilovich and Medvec, 1995), work equates to is a well known phenomenon in consumer behaviour (Schiffman and Kanuk, 1997).

It refers to the purchaser feeling uneasy about the purchase just made and is thought to be caused, in part, by the action of making a purchase being seen as closing off all other alternative actions. This feeling then leads to concern over whether the right decision was made.

The emotional reaction to decision outcomes forms part of our memory of the experience which in turn is brought to bear on similar decisions in the future. This in turn forms part of the personal background brought to a decision as described earlier. These memories have been shown by (Kahneman et al. 1993) to be biased and insensitive to the length of the experience. For example by adding diminishing emotional pain to the end of a painful experience the memory of it can be manipulated in a more positive direction. This finding can be seen as the basis for marketing communications which give a solution (product or service) for a problem that the authors suggest.

This timing aspect of emotions and decisions is more evidence for the need for a specific focus on the situation to truly understand and predict decisions made in it. It is also evidence against the use of rational choice theories as methods of educating decision-makers.

The importance of emotions in decision-making is recognised in marketing and consumer behaviour with appeals to emotions is marketing communications being common. This could be seen in the communication "it could be you" for the National Lottery, (Brassington and Pettitt, 1997). This is an influence on decision-making that was not discovered during ***Trading Off*** and therefore is used to expand the model, specifically the personal antecedents of how influences are viewed and their consequences.

4.3.8 Conclusion

The inconsistencies found and outlined in this section that contradict the normative theories in general and EUT specifically have undermined these approaches as both instructive tools and as methods prescribing how decisions should be made.

Numerous finding confirming the role of individual differences, context and communication on the outcome of decisions have been outlined. This points to decision-making as a situational bound activity that requires detailed individual study to understand why one option has been chosen, therefore supporting ***Trading Off*** as explanation of decision-making.

Underlying many of these studies is an interaction between the context and the individual that leads to the situation changing the individuals reactions. This may manifest itself as inconsistent or irrational behaviour when compared to past behaviour or from a highest utility standpoint, but the context surrounding the situation may provide reasons for this. It is vital therefore to study the context of the decision in detail.

Attempting to quantify decisions and to predict them using formula such as the standard reference gamble is not able to account for the complexity and variation that has been shown. The use of normative theories in education therefore may be limited to providing an understanding of the generic steps in decision-making and as a focus for which behavioural developments and refinements can be introduced.

By providing these steps and in combination with detailed contextual studies they may provide a useful outline for the development of computer decision aids and artificial intelligence. These aids will be discussed in the next chapter within the context of medical decision-making.

To account for some of these inconsistencies, cognitive models of decision-making will now be looked at. These add cognitive elements to the generic decision-making steps that in turn are able to explain some of the behaviour outlined previously.

Trading Off as a substantive theory of prescription decision-making provides the contextual richness around a structured process. The discussion in this section has demonstrated the need for this form of decision model. Further conclusions will be drawn between decision-making and *Trading Off* in chapter 5,6 and 7 because of the greater specificity in these chapters accounts on decision-making.

4.4 Cognitive models

The criticisms of normative theories and the studies showing behavioural inconsistencies have lead to the development of models in order to address these issues. Prospect theory, Satisficing and Regret Theory are included as deliberate attempts made to develop expected utility theory in order to account for apparent behavioural inconsistencies. Prospect theory in particular will be used to detail how a number of these behaviours can be explained.

Beyond these deliberate developments, the Theory of Reasoned Action (Ajzen and Fishbein, 1980) is presented as an important theoretical development that adds to the ability to explain behavioural variations beyond those predicted by normative models. It is detailed here as a model that is able to account for observed behaviour rather than an attempt to explain specific normatively inconsistent behaviours. It is also connected to section five which discusses choice strategies specifically as it represents a weighted additive compensatory rule for choosing amongst alternatives.

As mentioned previously ***Trading Off*** can be viewed as a cognitive method capable of explaining many of the behavioural inconsistencies seen against normative theories. It would be legitimate therefore to include ***Trading Off*** in this section. This section will further define the kind of cognitive model ***Trading Off*** is.

The Theory of Reasoned Action (TRA) and Prospect theory are both expected value theories. This type of theory in various formulations have been used widely in medical decision-making research, further adding to the need to frame them here. In keeping with the role of this chapter these theories will be outlined in this section whereas actual applications in medicine will be outline in chapter 5.

4.4.1 Prospect theory

Prospect theory was proposed by (Kahneman and Tversky, 1979) as a development Expected Utility Theory. In it, they replace the concept of "utility" by "value" which is defined in terms of gains and losses. This theory has become a widely accepted development of Expected Utility Theory though issues still remain concerning its use.

Prospect theory asserts that both the size of outcomes and their probability effect choices. "Prospects" (alternatives) are inspected and subjective values and decision weights are constructed from their possible outcomes and probabilities. These values are then combined to produce a subjective value for the prospect as a whole. Choice is then made based on the "prospect" with the highest value.

This view is similar to that of EUT but Prospect theory differs in how the values are calculated. The crucial distinction is based on the differences between the value placed on gains and losses.

The authors contend that losses are felt more strongly than gains, i.e. a loss of $50 is felt more strongly than a gain of $50 (Kahneman and Tversky, 1979). They also contend that large losses or gains are valued proportionally less than small ones. Further it states that evaluations are made relative to a reference point, the most common of these being status quo. These principles have lead to Prospect Theory being able to explain a number of apparently inconsistent and irrational behaviours in decision-making.

4.4.1.1 Inconsistent Behaviours explained by Prospect Theory

The principle of loss aversion can explain the use of habits and maintenance of the status quo because the potential harm from a change is perceived as greater than the benefits. It also clarifies why in negotiations the aspects conceded are weighed more heavily that the gains that are received from the other party. This is referred to as the Buyer-Seller bias (Quattrone and Tversky, 1988).

The endowment effect is another consequence of loss aversion and explains apparently irrational behaviour. This effect manifests itself in the value of a good increasing when it becomes part of an individuals possession. This is seen where the selling price for a common object in your possession is placed higher than what you would pay for an identical item (Thaler, 1980). The history of ownership also affects value with duration of ownership increasing it. This effect supports the contention that personal knowledge is held more strongly and trusted more than that from external sources.

How objects are gained, i.e. via exemplary performance or luck effects value. Objects are rated higher when gained through excellence and hard work. (Arkes et al. 1994) showed windfalls are spent more rapidly than other types of asset. This again leads to decisions that are irrational from a EUT perspective but supports ***Self-Referencing***'s view.

Prospect theory also differs from Expected Utility Theory in its ability to predict a "certainty effect". This refers to the value of a reduction in probability (of the same amount) is higher when the outcome is certain compared to when it is probable. i.e. you would pay more to have the last bullet removed during a game of Russian roulette than having the number reduced from 4 to 3. This is despite the probability reduction being the same (Kahneman and Tversky, 1979).

A development to the certainty effect is the pseudo-certainty effect which shows that the certainty effect holds true in conditions when the certainty is fictitious. This was demonstrated by (Slovic et al. 1982).

Work on Prospect Theory also demonstrates the importance of the task environment in decision-making and highlights the issue of irrationality. The following task was set up by (Kahneman and Tversky, 1979):

Alternative A: A 50% chance of gaining a $1000

Alternative B: A sure gain of $500

In this paring 84% opted for option B. However using the pairing

Alternative C: A 50% chance of losing $1000

Alternative D: A sure loss of $500,

70% choose alternative C.

In probability terms these two games are equal and therefore subjects should be consistent in their choices. However in reality we understand how much $500 represents in terms of hours spent working and saving this amount or the benefit a windfall like this could bring. Avoiding a loss and keeping your windfall then appears rational. This is also the case for paying more to have the last bullet removed in Russian roulette!

Two further development of Expected Utility Theory are:

4.4.2 Satisficing

One of the earliest developments of EUT was proposed by (Simon, 1956; Slovic et al. 1982) who suggested that people "Satisfice" when decision are made rather than maximise. By this, it is proposed that certain important needs and wants are satisfied rather than choosing the option with the highest overall utility. This kind of behaviour was also seen in ***Trading Off*** where choices were made that would satisfy the objectives but were not necessarily the best available.

4.4.3 Regret Theory

(Loomes and Sugden, 1982) suggested that anticipated feelings of "regret and rejoicing" are taken into account when decisions are made. These become separate reference points used when options are being evaluated.

4.4.4 Summary

Prospect theory, Satisfycing and Regret theory provide useful development of EUT and by using the concepts of value, satisfying and feeling of regret and rejoicing are able to explain a number of behaviours that appear irrational.

Prospect theory with losses and gain's having different value functions has been shown to be of particular use in explaining behaviour. It has also shown the importance of contextual and individual factors. For example the increased worth of having the last bullet removed from Russian roulette and the buyers-seller bias.

It remains however, a theory based on the quantification of alternatives and therefore suffers from problems of translation and the loss of depth and richness that keeping the factors in their original form avoids. It is also criticised because of ambiguity and lack of depth from a statistical viewpoint. It does however support ***Self-Referencing*** and the importance of the task environment.

Having outlined deliberate variations of EUT the review of cognitive models will now move to a model that is able to explain and predict behaviour but was developed from work on the attitude-behaviour causal pathway.

4.4.5 Theory of Reasoned Action

The Theory of Reasoned Action has been used extensively in psychology, marketing, consumer behaviour and medical decision-making to analyse and explain behaviour. (Manstead et al. 1983; Shimp and Kavas, 1984) (Bagozzi et al. 1992; Sutton, 1987). It and its precursor the Behavioural Intention model (Fishbein, 1967) have been used in a number of studies in medical decision-making. These are reviewed in chapter five.

It provides an important model for explaining and predicting actual behaviour. It uses in this area, and more generally, the use of expected value theories in medical decision-making research requires this model to be detailed.

The Theory of Reasoned Action is an expected value theory that proposes that actions are taken after a reasoned thoughtful process based on the decision-makers evaluation of the consequences of undertaking the behaviour. ***Trading Off*** therefore demonstrates similarities with this approach.

It was developed over a decade of theoretical research from Fishbein Learning theory(Fishbein, 1963) through the Behavioural Intentions model (Fishbein, 1967) to the Theory of Reasoned Action (Fishbein and Ajzen, 1975). It is designed to measure behavioural intentions from which behaviours are expected to follow, when the behaviour is under volitional control.

The clear and concise nature of the TRA has lead to impressive levels of prediction of actual behaviour such as a correlation of .84 between intention to stop smoking in the next 2 months and the actual rate of cessation within this period (Fishbein, 1982).

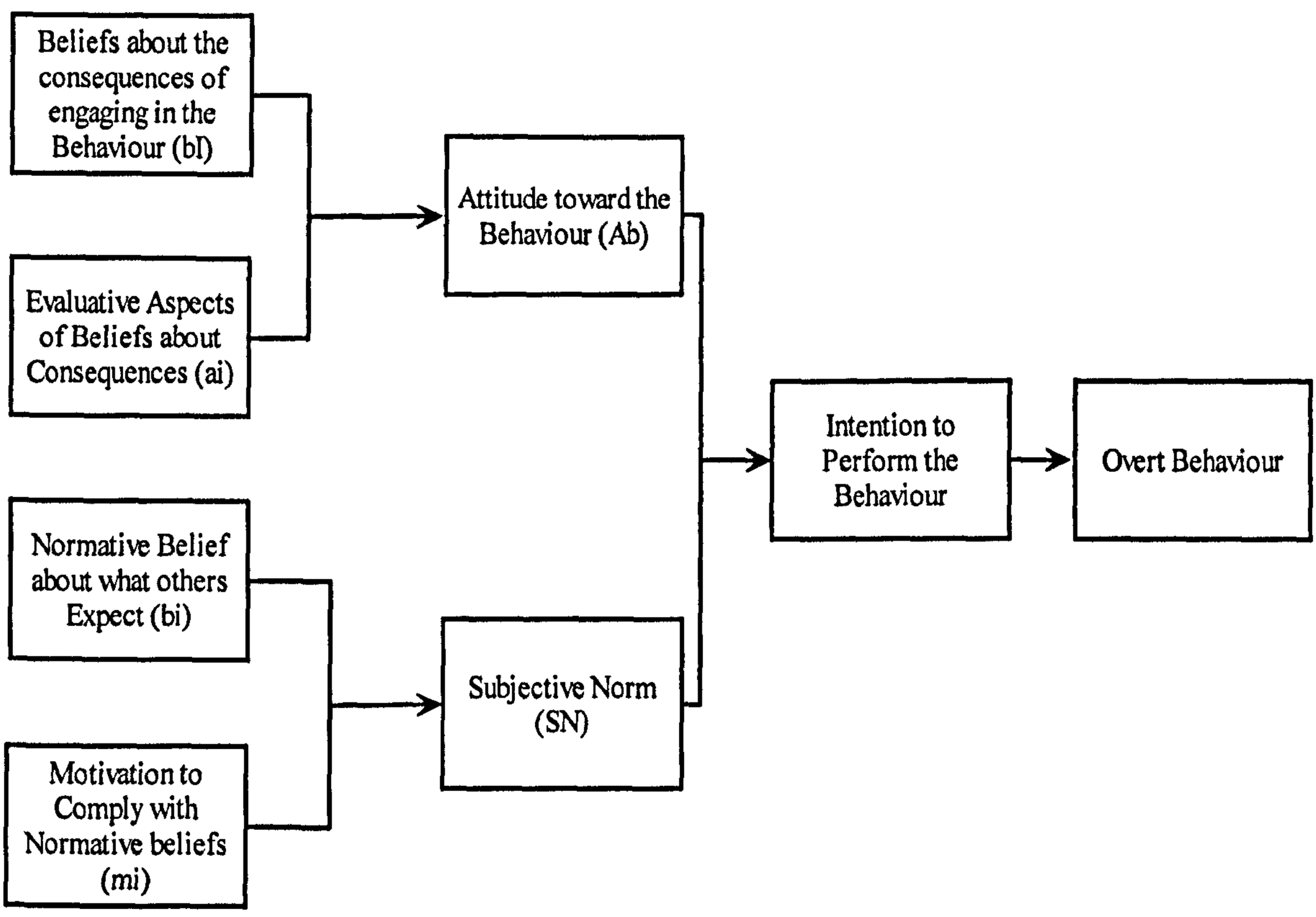
The theory states that in order to accurately predict whether a behaviour will be performed, the individuals intention to act should be measured. This intention is itself comprised of two using two components: one attitudinal and one normative. The attitudinal component comprises the sum of a number of relevant personal attitudes toward the own performance of the behaviour. The normative component or the "subjective norm" is the sum of the social pressure the individual feels under to perform or refrain from performing the behaviour.

It is possible for two individuals who posses the same attitudes and subjective norms to form different intentions based on the relative importance that each determinant is given.

4.4.5.1 Diagram of the TRA

The Theory of Reasoned Action (TRA) is represented by the following diagram:

Figure 1: Diagram of the Theory of Reasoned Action.



A brief explanation of the Attitude and Normative components of this model and their precursors, will now be given.

4.4.5.2 The Attitude component

4.4.5.2.1 Attitude toward the behaviour

The attitudinal component of the TRA forms one of the two main cognitive antecedents of intention. Ajzen and Fishbein state:

"A persons attitude represents his [or her] evaluation of the entity in question".
(Ajzen and Fishbein, 1977)

Great care must be taken when predicting behaviour from attitudes based on direct experience because the knowledge set tends be larger with subtle differences. It is therefore difficult to measure the respondents true attitude about a given object or behaviour unless the attitude is defined specifically. The area of definition and measurement within the TRA is explored in detail later in this section.

4.4.5.2.2 Antecedents of the Attitude toward the Behaviour

This Attitude toward the behaviour is in turn a sum of the actor's appraisal of the outcomes associated with the behaviour (or beliefs about the object's attributes) and the strength of these evaluations.

The number of beliefs held about each object can vary considerably depending on factors such as whether they are based on direct experience or the complexity of the attitude object. The most important beliefs will be the determinants of attitude.

4.4.5.3 The Normative component

4.4.5.3.1 Subjective Norm

The subjective norm is the social pressure felt by the subject on the behaviour. This component recognises that certain behaviours are strongly influenced by social pressures.

4.4.5.3.2 Antecedents of the Subjective Norm

Similar to the attitude component, the subjective norm is also the sum of two components, the first of these are the Normative Beliefs, the beliefs on what "specific significant others" think about performance of the particular behaviour. The second factor is the subject's motivation to comply with these significant others. These factors are once again summed to produce the subjective norm influence for the respondent.

The importance of dealing with specific behaviours when using the TRA was stressed by Ajzen and Fishbein and has been mentioned on a number of occasions. In order to ensure that the behaviour described in the measurement of the normative and attitudinal components equates to the overt behaviour that is being tested. The authors provide strict criteria for this measurement that will be looked at next.

4.4.5.4 Measurement Elements

The applicability and accuracy of the TRA is considerably enhanced by the detailed description of how to attitudes and behaviour should be measured to enable behaviours to be predicted. The authors identified four elements that needed to be present in descriptions of attitudes and behaviour. These are **Target, Action, Time,** and **Context.**

The attitude, subjective norm and behavioural components should be defined using these four elements so that they correspond closely to each other. It was made clear in the theory that correspondence can occur either when attitude, subjective norm and

behavioural elements are defined generally or specifically, as long as the definitions allow them to correspond. These elements are:

4.4.5.4.1 Action

The definition of the "Action" or behaviour must include information on whether the behaviour represents a multiple or single act, it's outcomes, the goals and behavioural categories

The multiple act criteria is defined as an index of behaviours peculiar to the individual as observed in repeated observation. The authors admitted that where observation is impractical then self report is acceptable as long as it is used with it's limitations in mind. It is important to note that the theory was only designed to predict multiple act behavioural categories. It is unrealistic to expect that attitudes can be used to predict individual single behaviours because of the variation context can cause.

4.4.5.4.2 Target

The second of the elements that must correspond in the definitions of both the attitude and the behaviour, is the "Target" element. The target element is toward what the "Action" is directed. An exact definition allows the individual to reflect on all the specific influences on intention and behaviour that are available to him/her. This reflection would not be possible if the definition was wide. For example, It is easier to answer a question on attitudes towards Zantac ™ brand of H2 Receptor Antagonists than all drugs used for this purpose because the evoked memory set is smaller and more easily reviewed.

4.4.5.4.3 Context and Time

The predictive quality of the model is also increased if the **Context** is specified e.g. prescribing Simvastatin in a general practice consultation. The **Time** element is also

important, as prescribing in the above context is different if this is the first reading of high cholesterol or whether it is the third taken at two monthly intervals.

The importance of **Context** and the other elements used in description add weight to the importance of the ***Focusing*** and the pattern recognition approach to choice that is suggested in ***Trading Off***. However, with ***Focusing*** only general guidelines can be given as rules contradict a core concept of this behaviour.

This importance was demonstrated effectively in an analysis of attitude-behaviour studies performed by Ajzen and Fishbein in 1977 that looked at the level of correspondence between these elements in measurement and behaviour. The results of this study will now be detailed.

4.4.5.5 Correspondence between Measurement and Behaviour

The importance of the close correspondence between these elements was demonstrated in an article written by Ajzen and Fishbein in 1977. They reviewed studies in the area of the attitude behaviour link and attempted to explain why some of the studies support the causal pathway of attitudes predicting behaviour while others did not. These findings supported strongly the need for detailed measurement of the specific situation being investigated.

The authors themselves described the importance of correspondence:
"To obtain high attitude-behaviour correlations in studies in which the context is systematically manipulated, it is essential to ensure not only correspondence in target and action elements but also correspondence in the contextual elements" (Ajzen and Fishbein, 1977) p892. Further details on this study and area are available in Appendix Nineteen.

4.4.5.6 Development of the Theory of Reasoned Action

Despite the high levels of correlation found between the intention to perform a behaviour and the subsequent measurement of the behaviour when the TRA is implemented correctly, further work has been undertaken to develop it. This work has been based on the issue of control over the performance of the behaviour.

The subject's intention to act is described in the TRA as the strongest predictor of behaviour, however for this to hold the behaviour must be under volitional control. If this is not the case then it is possible for external factors to interrupt the belief-attitude-intention-behaviour pathway.

It can be seen therefore that intention to act may not be enough to predict behaviour because there may be incomplete control over many of our goal directed behaviours. For example, a doctor may want to prescribe Viagra but as it is only available on private prescription in the UK and that supplies are limited.

Two broad categories of such barriers can be seen to exist, internal barriers such as personal skills and external barriers such as time and availability of resources. The TRA was expanded in order to take account of the existence of these barriers with the formulation of the Theory of Planned Behaviour (Ajzen, 1985).

This model adds a measure of the respondents perceived control over the performance of the behaviour. This incorporates beliefs on the presence or absence of the necessary resources and opportunities to perform the behaviour. This theoretical development has been shown to add to the predictive ability of the TRA. For example, (Parker, 1992) found that the addition of a measure of perceived control added between 7 and 21% to the accuracy of predictions of behaviour.

4.4.5.7 Summary of the TRA

The Theory of Reasoned Action has been described in some detail because of its ability to explain and predict behaviour beyond that predicted by normative theories. A number of the characteristics of this theory are similar to those in *Trading Off*, these are highlighted below. Further to this it is included because it has been used in medical decision-making research and is an example of the wider category of expected value models that have also been used. These applications will be reviewed in chapter 5.

1. TRA supports the idea of a decision-maker as a thoughtful, reasoned actor.

2. It demonstrates the importance of internal and external influences on behaviour and further to this the importance of the perception of these factors. These issues will be developed in chapter 5.

3. The TRA and ***Trading Off*** demonstrate how the same information can be used in different ways to cause different behaviours when the above influences are applied.

4. The TRA incorporates rules of the measurement of the context and stresses the importance of corresponding description of the behaviour under scrutiny and the tools used to predict it. The need for this correspondence supports the wider conclusions from this chapter that decision-making is a context and individual specific process. Therefore, in order to study and model decision-making it is necessary to incorporate the context and individuality.

The addition of weighted characteristics to form an intention score seen in this model means that it can also be classified as a weighted additive compensatory choice strategy. This and other types of choice strategy that have been proposed represent a further development and adaptation of research into decision-making behaviour. These strategies concentrate on the decision-making stage performed once information has been gathered and evaluated. These will be detailed in the next section.

4.4.6 Conclusions

The models detailed here are examples of Expected Values theories that have been used extensively in medical decision-making. These cognitive models are able to account for a greater amounts of observed behaviour than Expected Utility theory outlined earlier. Prospect theory specifically has been shown to explain certain violations from the normative principles set out in EUT. *Trading Off* can be classed as one of these models.

In addition to this, the Theory of Reasoned Action has been shown to provide a model of behaviour that includes the cognitive antecedents to the behaviour. By demonstrating an accurate process of behaviour, this model therefore provides a theory for decision-making. This occurs where the individual options are assessed and compared to find the strongest held intention and hence a decision is made.

These models both represent decision-makers by the use of an numerically based process of choose between alternatives. The findings from studies such as (Bryant and Norman, 1980),(Slovic et al. 1977) contend however that people struggle to use numbers correctly. This is supported by ***Trading Off*** and intuitive findings that assert that this numerical approach is not how decisions are made in reality. Therefore while these Expected value models are improvements on normative models they still lack descriptive power concerning the nature of decision-making. ***Trading Off*** can be said to provide a model which has structural similarities to Normative and Cognitive models but is able to more accurately describe the behaviour decision-making process.

The theories of decision-making outlined in this section are supported by specific choice strategies that are also characterised by a numerical representation of the decision task. These strategies are able to account for a number of choice behaviours that occur because of variations in the decision context. These are therefore developed in the next section.

4.5 Choice Strategies

The normative and cognitive models set out previously provide a framework as to the overall process and possible goals of decision-making theory. These also include instructions on how decisions are made once relevant information has been collected and evaluated. This section will outline a number of strategies that have been proposed to explain how choices are made under various circumstances once information has been collected and evaluated. They therefore provide a cognitive comparison to the core process of ***Trading Off*** of confidence.

Heuristics, to be detailed in the next section, have also been explored as mechanisms used to estimate the probability of events that in turn are used as the basis for decision-making. These represent a behaviourist view of these activities.

4.5.1 Introduction

The majority of choice situations require decisions to be made based on a number of objectives. Those in turn require a number of attributes to be considered. For example, the objectives for the use of a drug may involve a fast rate of effect with minimal cost to the patient and the health service. Therefore, the attributes considered may include price, efficacy, side effects and interactions.

Consequently, choice strategies are required to respond to these situations. It is thought that people posses and use a number of choice strategies depending on the contextual and personal factors that are present during the particular problem.

For example, a choice between two alternatives is likely to be dealt with by a simple compensatory strategy (Payne, 1982). Alternatively, in more complex situations where

a number of alternatives are presented a non-compensatory strategy is more likely to be used. These types of strategies will be detailed later in this section.

The various strategies for choice that have been proposed and studied, leads to the question as to whether there are overriding principles that can be applied across all levels of choice. Work by (Christensen-Szalanski, 1978), (Einhorn and McCoach, 1977) suggested the performance of a cost benefit analysis as an overriding principle. This idea is compatible with ***Trading Off*** as the core choice procedure discovered in this research.

(Einhorn and McCoach, 1977) raised the questions of the definition of "cost-benefit" and therefore the context dependency surrounding this idea. This idea also has the advantage that it recognises conflict as inherent within choice.

It is this researchers contention that conflict and context dependency of "cost benefit analysis" add to its quality as an explanation of decision-making. The concept of decisions being bounded strongly by the situation in which they take place, and therefore the need to study and evaluate them within their context, has been suggested throughout this section of the literature review. This is required in order to understand them fully and therefore supports the findings of this research.

4.5.2 Compensatory strategies

Compensatory strategies correspond closely to the strategies discovered during ***Trading Off***. Compensatory strategies state that attributes evaluations are traded off with each other according to the goals of the behaviour. These strategies allow alternatives to "compensate" for deficiencies by strength on other attributes and therefore can be thought of as confronting and dealing with conflict. ***Trading Off*** though suggests that confidence in the attributes of the behaviour or object is the commodity that is traded.

Two types of compensatory strategy can be identified, the simple and weighted additive. A simple compensatory strategy involves the addition of the favourable evaluations of the important criteria. The alternative with the highest score is then chosen (Engel et al. 1993). This type of strategy is used where motivation or ability in the decision task are limited.

The more complex weighted additive strategy (including the Theory of Reasoned Action) involves the weighting of the importance of each criteria in the decision according to personal choice, the addition of the score and choice based on the highest score (Payne, 1982). The critical issue in the use of this type of strategies is getting the weightings correct for the attributes (Armstrong, 1978). The higher levels of cognitive effort needed for the use of this rule ensure that is used in tasks where motivation and involvement are greater.

Essentially therefore compensatory strategies of both types are subjective expected evaluation theories used for choice among alternatives. Their subjectivity leads to inconsistencies in the application however (Hammond and Summers, 1972) showed this in decision-making in similar situations.

These inconsistencies may be due to a lack of clarity or understanding of the situation within which the decision is being made. It may also be due to even very small differences in situation and personal circumstances at the time of decision having effects on the evaluations of the features. This in turn will effect the outcome of the compensation and therefore decision.

Traditional compensatory strategies can, similar to normative and cognitive theories, be criticised on their representation of decision-making as a numerical process. This numerical representation is undermined from an intuitive standpoint, studies showing the poor use of statistics in decision-making (outlined earlier) and the findings of this research.

This researchers findings concerning the importance of confidence in decision-making provides a phenomenon for compensation that can account for the effect of situational differences on decisions. The confidence construct also accounts for the importance of personal cognitive factors such as perception, attitudes and motivation within decision tasks.

4.5.3 Non-compensatory Strategies

Non-compensatory strategies offer a more simplistic and less flexible approach to making choices. They do not allow trade offs between attributes but are instead based on various rules that eliminate options that do not posses certain characteristics or qualities. Four non-compensatory rules are well known in psychology and consumer behaviour and are outlined in Appendix Twenty (Engel et al. 1993), (Schiffman and Kanuk, 1997).

4.5.4 Conclusion

The Compensatory and Non-Compensatory choice strategies represent cognitive rules for making decisions under conditions of multiple alternatives and uncertainty. Individuals have been shown to posses and use more than one strategy depending on the decision situation.

This again supports the theme of the interaction of the individual and context determining decision behaviour and is contradictory to the normative approach.

Trading Off can be seen a compensatory strategy that is based on confidence in the attributes of the options under scrutiny. The large numbers of treatment options available to doctors in certain areas of medicine does however suggest that non-

compensatory style cut-off rules are used to reduce the number of options to be evaluated.

The final section in this chapter framing important work and aspect of decision-making will provide an overview of work by (Tversky A. and Kahneman D, 1974) on cognitive rules or heuristics.

This approach develops a more accurate description of decision-making as it moves away from the use of numerical representations in decision tasks. These heuristics use the language of probability however the internal representation of this mathematical concept can be seen as linguistic.

These rules have been extensively used in medical decision-making research and will therefore be framed in this chapter and detailed in chapter 5 (formal decision-making).

4.6 Heuristics and Biases

(Tversky A. and Kahneman D, 1974) and (Tversky A. and Kahneman D, 1974) described specific rules or "Heuristics" that they propose as the cognitive tactics people use when estimating probabilities used for making decisions. These heuristics have become a widely accepted view of how decisions are made.

Whilst these heuristics generally provide good estimates of probability in decision-making, the authors also associate a number of common errors and biases with the use of these rules.

It is thought that rules are created, followed and maintained in an attempt to reduce cognitive effort in decision-making and to increase consistency of behaviour. The reduction in cognitive effort can be seen with behaviours that involve difficult trade offs. For example, it is difficult to trade off subjectively the outcomes of taking exercise vs.

watching television when these are the choices being considered in an evening. In this instance a personal rule to do exercise 3 evenings at week allowing at least 4 nights for television is useful in reducing the effort used in this situation (Tversky and Kahneman, 1981).

The rules are however, "may have involved trade offs at one point" (Mellers et al. 1998) p459-460. The role of rules expressed by these authors goes wider than that of habits and is thought to express social, personal or moral identity (Fiske, 1992).

These heuristics along with the errors and biases associated with them will now be outlined.

4.6.1 The Representativeness heuristic

The representativeness heuristic states that people often base probability judgements on the degree of similarity between the two objects or events (Tversky and Kahneman, 1982). This aspect is seen in the use of information sources in ***Trading Off***.

This rule was tested using a descriptive vignettes to outline a character and then asking respondents which other factors they would associate with them. One of these vignettes involved described a character called "Linda" and her activities for social causes. The respondents were then asked which was more likely, whether Linda was a bank teller or a bank teller and an active feminist.

Nearly 90% of the subjects in this experiment suggested that she was the latter despite no objective evidence for this. This finding also breaks the rule where co-occurring events cannot be more likely than a single event. Linda as a feminist bank teller is seen as more likely because her profile is thought to be representative of someone like that.

This heuristics leads unfortunately to a number of errors and biases including, stereotyping, insensitivity to predictability, misconceptions of regression to the mean and insensitivity to base rates (Tversky A. and Kahneman D, 1974).

4.6.2 Availability heuristic

The availability heuristic is used to assess the probability of a event by how easily it is brought to mind. This rule is adaptive because large classes of events are usually thought of more quickly than smaller ones. There are problems associated with this rule though.

The effectiveness and accuracy of the memory retrieval process can cause errors based on this rule. (Tversky and Kahneman, 1973) for example found that subjects thought that there are more letters with "r" as the first letter than the third. This is believed to be because it is easier to search your memory by first letter than by the third.

This heuristic has also been attributed to the formation of a "salience effect" that manifests itself when an action just witnessed (i.e. particular disease just diagnosed) increases the likelihood that this event will be judged to happen again. Choices made under the effects of this bias may overestimate the real chances of it occurring (Tversky and Kahneman, 1973).

4.6.3 Adjusting and Anchoring

Anchoring and Adjusting is a two stage heuristic used to develop through further information a more accurate probability estimate. The "anchor" refers to an initial value chosen for the probability in what is thought to be the correct domain. This value is then "adjusted" as more information becomes available.

This heuristic is beneficial when confronted by situations that contain large amount of information and some way of making initial sense is needed. In this situation, use of available information to form a preliminary opinion and then adapting this as more information is encountered is a reasonable tactic.

However, as with the other heuristics outlined, bias and errors occur based on it. A consequence of the subjective nature of Anchoring is that these evaluations can be too high or low, the adjustment are often insufficient with final value remaining too close to the anchor (Tversky A. and Kahneman D, 1974).

(Northcraft and Neale, 1987) demonstrated the biases associated with anchoring when they studied house prices and the valuations given by estate agents. The experiment involved the manipulation of the list price for particular houses and studying the subsequent valuations given by estate agents. It was found that one piece of information could shift the initial appraisal of a houses worth by $10,000.

Anchoring and Adjusting is seen as a robust heuristic, this is illustrated in work by (Quattrone et al. 1984). These authors gave subjects incredibly high initial values for probabilities and prices and then asked them to adjust from it. For example, one task involved estimating the cost of the average college text book where the original cost given was $7128.53! The findings showed that the subjects performed insufficient adjusting despite these plainly ludicrous anchors!

4.6.4 Learning and Feedback

The maintenance and development of the rule described in this section requires a mechanism for people to learn from the results of their application. This necessary experiential learning is complicated however because of a lack of realisation that errors and problems exist. This is further complicated when realisation of these issues is coupled with a lack of knowledge of how to correct them (Brehmer, 1976).

The use of feedback is complicated because of the need for the quality of the outcome to depend on the quality of the decision with no intervening factors. This pathway cannot be guaranteed however, for example prescribing an antibiotic for an infection that subsequently clears up may feed back the effectiveness of the drug. The correct explanation for the success however may be due to the disease trajectory.

Learning and the development of rules is therefore a difficult task that is fraught with inconsistencies and problems. This adds further to the reasons why heuristics are associated with biases and errors.

4.6.5 Conclusion

This section has looked briefly at three heuristics used to simplify problems solving whose use and associated problems have been researched extensively. The rules represent a further development in attempts to explain decision-making. In doing so they have produced a number of strategies for estimating probabilities (though not in the mathematical sense) that are then used to make decision.

This approach does not therefore represent an integrated theory of decision-making rather delineating cognitive rules that are used in everyday life to simplify this task. This movement to simplify where possible is a well documented feature of ***Trading Off***. The features of these heuristics can be seen in use of information sources.

4.7 Chapter conclusions

This chapter has provided an overview of the fundamental principles of decision-making and given an introduction into the main paradigms in this area that are relevant to ***Trading Off***. It was discovered from the outset that it conforms to the basic decision-making process and principle.

The Normative approach typified by the Expected Utility Theory, was set out and evidence presented that demonstrates the inconsistency of observed behaviour to these models. This acted as a starting point from which relevant models and theories were developed that were able to represent observed decision-making more effectively. Similarities in the structure of normative models and that of ***Trading Off*** were noted.

As Normative models are proposed as theories of how decisions should be made, they cannot be criticised too heavily for being unable to explain observed behaviour. They are useful in providing a framework for decision aids and the attempts of artificial intelligence to improve the quality of decision-making. The production of studies into prevalence and improvements in presentation and manipulation of this data, will see normative approaches becoming representations of actual behaviour.

The cognitive models reviewed as attempts to account for observed behaviour fell into two areas, the first including Prospect theory were proposed as direct developments to Expected Utility Theory. Prospect theory and the concept of gains and losses possessing different values is able to account for behaviours such as the buyer seller bias and loss aversion. This theory supports concepts within ***Self-Referencing*** such as the dominant position held by internal knowledge.

The second, which looked at the Theory of Reasoned Action in detail, demonstrated research based on the attitude-behaviour causal pathway. The TRA was detailed review

because of its extensive use in medical decision-making research and its demonstrated ability to predict and explain thoughtful behaviours including decision-making.

The TRA in particular demonstrates the importance of defining the decision context in order for predictions to be made as the outcome of the task. Indeed the theory contains stringent rules for its application and measurement. It is therefore similar in these aspects to ***Trading Off***, these similarities frame ***Trading Off*** as a cognitive, subjective evaluation style theory. It differs however in its behaviourist approach to the performance of the cognitive tasks.

Specific strategies for choosing among alternatives were looked at in order to frame ***Trading Off*** and to demonstrate the number of ways that choices can be made. These strategies suggest that different situations are dealt with using variations of similar approaches. ***Trading Off*** provides the approach which is the refined by the outcome of ***Focusing***, ***Self-Referencing*** and ***Surrogating***

Finally important work on the use of rules or heuristics was reviewed, these heuristics are used as cognitive shortcuts when constructing an evaluation of an events probabilities. These short cuts highlight the behavioural approach of reducing cognitive effort where possible, the habits is a further example of this.

Taken as a whole this chapter has provided the necessary information to frame the more specific review of medical decision-making in the following chapters. It has also provided strong support for ***Trading Off*** 's view of the importance of studying specific decision-making contexts individually.

It has developed the concept of context and decision-maker importance in the decision task and has provided many examples to support this. A further area that has emerged is the representation of the decision-making process as a mathematical exercise which is contrasted with peoples demonstrated inability to use numbers accurately. The

importance of the context and decision-maker however ensure that it is crucial that these attempts should incorporate contextual richness and individual differences into their design.

The next chapter will continue the necessary framing of medical decision-making by detailing importance aspects of the context and boundaries in which it takes place.

5 Chapter Five Principles of Medical Decision-making

5.1 Introduction

This chapter will provide the information necessary to understand the effect of the medical context on decision-making. In doing so it will also develop areas discovered during ***Trading Off***. Specifically it will introduce ethical principles of medical decision-making, it's characteristics, the overall process, types of decision, and it's outcomes. These aspects will be reviewed and their importance to the decision-making process highlighted. In achieving the above aims this chapter acts as an introduction for the review of the medical decision-making literature in chapters 5,6,7.

The details in this chapter concerning the problematic outcomes of medical decision-making (classified as variations in treatment usage and inappropriate medical care) provide justification for decision research in this area. These sections are not used however to justify the research that discovered ***Trading Off*** as a process of medical decision-making. ***Trading Off*** emerged from research into the prescribing of new products and does not require defence of this kind. These sections do however support the potential importance of its findings.

These problematic outcomes (as detailed in this chapter) and the need to reduce them also form the basis for specific research into modifying medical decision-making. This work and the interpretation of it from a ***Trading Off*** perspective will be summarised in this chapter and developed in detail in chapter7.

5.2 Definition

Medical decision-making can be defined simply by narrowing the context of Schiffman and Kanuk's definition of a decision "the selection of an option from 2 or more alternatives" (Schiffman and Kanuk, 1997) p558 within a medical context. The field can be classified further to cover decisions made in the diagnosis and treatment of patients. Section 1.5.2 (Types of Decision Involved in Medical decision-making) expands these classifications further. Pharmaceutical decision-making is therefore a further subset of this area.

(Sox and Blatt., 1988) see medical decision-making as an attempt to match the current store of medical knowledge to the complaint of the patient. This is done to achieve a number of goals of treatment. It is constrained by a number of fundamental principles of medical ethics and by the context within which medicine is practised.

5.3 Ethical Principles

The area of medical ethics has a profound effect on the medical decision-making process. This effect is based on providing the objectives and boundaries for physicians within which they practice. Three main principles of this area will be outlined here to illustrate this effect. These will be looked at here but without moving into areas of ethical dilemma.

5.3.1 First, do no harm.

Medicine is underpinned by the essential principle (sine qua non) of "first do no harm". Physicians have a duty to care for the patients under their supervision and in doing so their actions should not harm them (Edmunds and Scorer, 1967).

This primary factor leads to decision-making that is paradoxically conservative yet demonstrates a preference for action. This manifests itself by doctors preferring to prescribe a course of action but the actual options chosen tend to be those with which they are familiar. This can lead to situations where the introduction of new and potentially better treatments is delayed because of this conservatism.

The preference for action, the vast increases in the last 30 years of treatment options and the increase in medical litigation has lead to the dictate above being developed into "first do something" (Haney CA, 1975).

5.3.2 Responsibility to Wider Society

Medical decisions makers have a responsibility to treat patients within the norms and group standards of society and to make decision that account for the consequences of the decision in a wider societal context (Grenier, 1997). This leads to conflict where decisions that are legitimate and rational for the individual patient may burden society with a price that it unwilling, or unable to pay.

An example of this is the current concern over cost to the NHS from treatment with Viagra ™ for impotence and the use of Interferon ™ for Multiple sclerosis sufferers (Ruddock, 998). This social responsibility is a developing principle of medical decision-making as the numbers of expensive, highly specialised treatments grow within a publicly paid for system such as the NHS. The issue of constrained resources and its effects will be detailed later in section 5.4.5. This property is clearly seen within the ***Trading Off*** for mutual beneficiaries.

5.3.3 Consent

The right of the patient to choose and refuse treatment is a critical issue within medical decision-making. The doctor-patient relationship is therefore a partnership that, if to be

successful must involve co-operation. The doctor has to listen to patients concerns and objectives and should base treatment around these. Patients have to give their consent (direct or implied) to be treated, this adds further to the need for decisions based on the will of the patient.

5.3.4 Conclusion

This brief section has outlined three crucial elements in medicine that profoundly effect how decisions are made. These principles direct medical decision-making by providing objectives and boundaries within which practitioners practice.

These principle have helped create a medical system that is conservative yet has a preference for action. To complicate this situation further, these actions need to incorporate the objectives and norms of the patient, physician and the wider society.

To further develop the context within which medical decision-making is practised, this chapter will now turn to look at the common characteristics of medical situations.

5.4 Common characteristics of medical situations

There are a number of common characteristics that contribute strongly to how decisions are made in medicine. The uncertainty, limited level of resources and multiparty nature of medicine that will be reviewed here conspire to create a decision context where conflict is frequent. This conflict exists internally due to the uncertainly that pervades medicine and externally because of the differing objectives of the parties involved. All these characteristics were found to be causes of ***Trading Off***.

5.4.1 Uncertainty

The most important of these characteristics is the level of uncertainty that surrounds all aspects of medicine. Its ubiquitous nature means that it is vital for theories and models of medical decision-making to show how this uncertainty is dealt with.

Medicine has famously been described as " a science of uncertainty and an art of probability" Sir William Osler 1904 in (Bean, 1950). Uncertainty is ever present in medicine, for example, in the uncertainly of the diagnosis, what the results of diagnostic tests mean, the stage of the disease and how the patient will react to treatment (Diamond and Forrester, 1983).

Underlying this uncertainty is the situation where individual diseases manifest themselves in a wide range of signs and symptoms and that patient react idiosyncratically to treatment. The individuality of disease presentation leads on to a wide range of test, history and physical examination results that can point to the same disease. For example, a high reading from a test may indicate a normal reading for one individual or a positive test for another (Sox and Blatt., 1988).

This uncertainty is then compounded by the individual reactions of the patients to treatment that leave the physicians uncertain as to the outcome of the intervention. These issues will be expanded on in chapter 6 concerning the medical decision-making literature.

Detecting and differentiating between these variations can be dealt with by formal statistical methods and is also a factor in medical expertise associated with diagnosis and treatment (Eddy, 1990). This area will be looked into further in the chapter 10.

The importance of ***Focusing*** is driven by this characteristic, by discovering the important factors of the patient and their situation this may suggest reasons and interaction that cause individual reactions.

5.4.2 Parties involved in Medical Decision-making

Medical decision-making is primarily a process that takes place between doctor and patient. However, other parties that are involved with the payment for, provision and supply of health care are increasing their influence on the individual decisions made.

These third parties include collaborating health care professionals, health care providers (such as the NHS, HMO's and private insurers), the government and the suppliers of health care products (pharmaceutical and medical supplies industries). This is in addition to the involvement of the patient's family, patient interest groups and society as a whole.

This long list of interested parties contributes to conflict within medical decision-making due to their different objectives. There has been a growth in the last 15 years of the number and importance of these other parties.

A cause of the conflict is the greater level of control being placed on decisions because of the differing objectives. This is set to continue. For example, the creation of Primary Care Groups (PCG's) will bring with it the development of strict formularies containing positive list of treatments in order to fulfil the governmental and NHS objective of controlling cost.

Whilst hospital prescribing has been controlled in this way for a period of time, the extension of this to primary care in this format is new. It creates a situation where the GP will have clinical responsibility for the patient yet may not be free to treat them by the means they see fit.

This change has become necessary because of the dramatic increase in number and cost of treatments provided by the pharmaceutical and medical equipment industries. For

example the cost of medicine to the NHS has grown from one billion pounds in 1980 to 5.6 billion pounds in 1997 (ABPI, 1998). This supply issue has lead to demand issues from patient, patient pressure groups and families. These groups apply pressure on a number of levels to help ensure that their problems are treated with the available medical advances.

The care providers within these numerous concerned parties differ in the levels of expertise they possess and the roles they perform when acting individually or collaboratively. These issues have important implications for medical decision-making.

5.4.3 Differing Levels of Expertise and Medical Roles.

The numerous care providers within medicine perform different roles within the system and vary in their levels of expertise. These differences are demonstrated in the structure of health service provision and effect the performance and quality of decision-making. This section will provide a number of illustrations of these effects whereas a more detailed review of how expertise effects decision-making is provided in chapter 10.

Physicians possess different levels of expertise in clinical areas independent of their role in primary or secondary care. This is due to differing case load experience, levels of competency and education (Ericsson et al. 1993; Kassirer et al. 1982; Starkes, 1990). These aspects combine to effect on the quality of decisions made and care received.

For example, GP's deal with 85-90% of their patients themselves, in addition to this they act as a gatekeeper for access to further, more specialised medical care (Knottnerus, 1991). They also attend to a broad range of problems and the earlier presentation of the fewer serious diseases that they see. Examples of how this effects the decision-making process is the greater use of general diagnostic questions (Dinant, 1991) and the more frequent diagnosis of psychosomatic disorders (Williamson, 1985).

In contrast, specialists see a pre-selected caseload that contains more serious and advanced cases. This leads them to formulate rare and serious hypothesis for possible diseases more frequently than generalists do (Gerritsma and Smal, 1982). It also requires them to use specific diagnostic tests.

The hierarchical structure of the NHS and the role of the GP as gatekeeper are an important method of providing access to expertise to as high a number of patients as possible. It also allows those patient who require the knowledge and ability of experts to manage their conditions to gain access to them. The benefit of this has been shown by (Hassebrock and Johnson, 1993) and (Norman et al. 1992). These authors demonstrated that experts diagnose more accurately than non-experts particularly in difficult cases, similar to findings in ***Shifting***.

A final characteristic of medicine and the parties involved in it that will be looked at, is the collaboration involved in many decisions.

5.4.4 Collaboration

A large number of medical decisions are made in collaboration with other health care professionals and therefore an understanding how this affects decision-making is important. (Christensen and Larson, 1993) p339 define collaborative decision-making as "whenever two or more individuals contribute their diverse knowledge and expertise to the decision-making process". Examples of it include morning rounds, case conferences and referrals.

The effect to this group decision-making situation on medical decision-making has been looked at by (Christensen and Larson, 1993). These authors showed that the use and dissemination of information is a crucial aspect of ensuring that the group process provides high quality conclusions. They found that distribution of knowledge within the group and the understanding of the other participant's talents and knowledge influences

the type of information that is disseminated. This in turn influences the decisions that are made.

These authors concentrated on the collaboration between health professional. Their results can also be expanded to help explain the majority of medical decision-making situations where the patient is involved in the decision. These situations are similar because of the imbalances in the roles performed and this leading to differing amounts and types of information being brought to the situation.

The final characteristic of the medical context that will be detailed in this framing chapter is that of limited resources.

5.4.5 Limited resources

The limited nature of resources within medicine has a strong and growing effect of the practice of medical decision-making. Financial, Physician and Patient resources are all limited and will be outlined in this section. These confinements are a prime cause of conflict within the system as the resources are fought over by the numerous parties outlined previously.

5.4.5.1 Financial Resources

Financial resources are the most apparent of the restricted resource within health care globally. This may manifest itself in the large but limited budget of the NHS[10] or the limited liability of private health insurance for the full range of health care. Indeed, the limited budgets provide a definition for a form of inappropriate prescribing. This occurs where the drug chosen is the more expensive alternative without real benefits of efficacy or reduction in side effects (Lilja J, 1976).

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[10] The NHS cost 44.3 billion pounds in 1997(ABPI, 1998)

This restriction is becoming more apparent as health care becomes more costly to provide due to a number of factors such as an ageing population, more diseases becoming treatable and higher prices being charged for new medicines. An example of the higher cost of medicines is seen with Viagra ™ which costs 4.84 pounds per tablet and expected to cost the NHS 50 million pounds annually as the first of a new class of treatments for impotence (BBC Online Network, 1998). These increases have resulted in strong cost pressures being placed on health care providers at all levels and the introduction of strategies to increase the amount of health care that can be purchased for the budget allocated (Soumerai et al. 1987).

The pressures to act in this way are helped by the belief of the majority of GPs' that it is possible to make savings in prescribing costs without affecting the level of care to patients (Avery, 1997). A further justification of budgets is given by (Segal, 1980) who confirmed that prescribing does increase where there are no financial deterrents.

The advent in the UK of Primary Care Groups as a development of Fundholding and Health board trusts is an example of the reaction of the NHS to this situation. This initiative will provide budgets for the provision of health care on a geographic basis that is regulated by financial penalties if they are exceeded.

It is in turn expected that pharmaceutical companies for example, will have to demonstrate increased cost effectiveness as an integral part of their product offering (Lewis, 1998). Indeed reaction to this pressure forms a central strategy for the pharmaceutical industries marketing effort. These efforts are reviewed in chapter 9.

These pressures have caused conflict between the parties involved in the NHS. For example, the restriction of funds for nurses pay has caused a recruitment crisis has been highlighted recently. The Nursing unions are therefore lobbying for a larger share of the NHS budget to remedy this situation (Rogers, 1998). However extra money is also being sought for example to treat patients with Viagra ™ and a number of other new and

expensive treatments (Ruddock, 998). The need for Trade off in these situations is clearly demonstrated.

5.4.5.2 Health Care Provider Resources

The time and expertise of health care providers is a further category of resources that is limited and that effects decision-making. The clearest example of this is the limited number of GP and hospital appointments available to patients which in turn leads to NHS waiting list. This shortage also shows regional and speciality variations for example 87,500 people waiting for hospital treatment in Scotland in December 1997 with particular shortages in mental health resources (The Scottish Office, 1998). This is exacerbated when access is needed to a particular specialist.

This limitation is closely related in many instances to financial restrictions however training and research issues also contribute. For example, with the discovery of a new surgical technique, the numbers of surgeons able to perform the treatment will be limited by the time needed to train in it's use.

The structure of the NHS can be seen as an attempt to accommodate this lack of availability to expertise. The GP's role as a gatekeeper (outlined previously) the structure of health boards and individual wards can all viewed as a filtering mechanism. This allows the most precious medical commodity, the time and knowledge of the experts to be available to those that require it. Less difficult or interesting cases are dealt with by individuals with lesser degrees of expertise so shepherding the experts.

5.4.5.3 Patient resources

A final restricted resource within health care is concerned with the patient. Patients are themselves restricted by their motivation, and physical and mental competency. For example, there may be a lack of motivation to comply to the care prescribed to them,

that in turn effects the choice of treatment to drug that is easier to comply with but less effective.

Their level of mental competency will also effect this issue. Physically patients differ in their ability to cope with side effects and interactions of treatments prescribed, this may manifest itself in surgery being avoided because the patient is thought to be at greater risk because of their physical condition.

5.4.5.4 Summary

The financial, healthcare provider and patient resources constitute an important characteristic of the context surrounding medicine. These aspects clearly restrict what can and cannot be used to treat patients. This leads to conflicts between the parties involved with health care.

Restricted resources provide further boundaries within which medical decision-making must be undertaken. The effect of these restrictions as influences on this process are discussed in chapter 7. The use of financial restrictions as a strategy of modifying behaviour is discussed in Chapter 8.

5.4.6 Conclusion

This section has looked at a number of important characteristics that shape the boundaries and context within which medical decision-making is performed.

The uncertainty that surrounds medicine requires the decision-maker to use subjective and objective judgement in determining the probability of the event. Unfortunately, as was discussed in Chapter 4 many studies have shown that this process is prone to error (Balla et al. 1983; Kahneman and Tversky, 1972). Uncertainty is therefore a factor that

contributes to the variation of decision-making whether inappropriate or not. This will be discussed in detail later in this chapter.

The numerous parties that are involved in health care and the differing objectives they have, bring a degree of conflict to medicine. The limited financial, health care provider and patient resources that are available, exacerbate this. This is due to attempts to persuade the decision-makers to adopt differing agendas than purely patient and well being within society.

The most pressing objective in health care and one whose importance is increasing, is the need to improve the cost effectiveness of care. Whilst this does provide a common target for the parties involved, it can lead to further conflict and political pressure. This occurs when tactics used to achieve cost effectiveness restrict the availability of care that has a legitimate role in the management of patients. For example Viagra ™ being not being available from GP's due to concerns over cost.

The complexity of the characteristics discussed in this section and their interaction with each other, adds further weight to the conclusion from this literature review that research into medical decision-making needs to include a detailed and wide ranging review of the situation surrounding it. The absence of this contextual richness means that subtle interactions and relationships that have a profound effect on the decision may be lost.

This is not to say that theoretical representations of medical decision-making are invalid. It suggests however that models such as ***Trading Off*** and others developed throughout this literature review provide frameworks around which the contextual richness of the situation should be developed.

A key advantage of ***Trading Off*** in this area is that it provides a wider and more detailed conceptualisation of the process that goes beyond the basic steps seen in other work.

This basic approach will be demonstrated in the following sections which will outline the medical decision-making process within which individual decisions are made.

5.5 Process and types of medical decision-making

Individual medical decisions are made within an overall diagnosis and treatment process to achieve the goals relevant to the patient and the situation. This process, along with examples of the types of decision made as part of this, will be outlined in this section. In terms of this overall process, ***Trading Off*** provides an explanation of how the individual pharmaceutical decisions are made within this process.

5.5.1 Medical Decision-making Process

Work carried out during the 1960's and reissued in 1976 by (American Institutes for Research, 1976) outlined what was found to be the critical components of how the overall medical decision-making process takes place. These are:

1. **Identify initial pertinent hypothesis.**
2. **Test all pertinent hypotheses.**
3. **Re evaluate hypothesis in light of new findings.**
4. **Recognise when sufficient data has been obtained and don't jump to conclusions.**
5. **Integrate data into one or more meaningful conclusions.**
6. **Select appropriate management.**

These stages then involve further decisions concerning how to perform each of the stages. Typically however, the process is divided into **Diagnosis** and **Treatment** of the defined problem. The types of decisions to be made within these two areas are set out below. These areas are not independent however as treatment response can be used as a diagnostic test (Lusted, 1968). This can be seen in the empirac prescribing of antibiotics

(Hepler et al. 1982). The core category of ***Trading Off*** incorporates how physicians make decision in one specific area however as discussed in chapter 1, its substantive findings could be widened with further theoretical sampling.

5.5.2 Types of Decision Involved in Medical Decision-making

The types of decision involved in decision-making can be categorised as diagnostic decision and treatment decisions.

5.5.2.1 Diagnostic decisions

- The type of history to elicit
- What questions to ask to do this?
- Issues surrounding the physical examination of the patient
- Which "para-clinical manoeuvres" to order i.e. lab tests?
- How to interpret the data that is discovered?
- Within the set of data that has been gathered, how should the elements be weighted?
- How should conflicting data be resolved?
- Whether to investigate further?

(Werner, 1995)

5.5.2.2 Treatment decisions

- Whether to act or to wait to see how the problem develops?
- How long to wait?
- Whether to refer to a specialist?
- Which specialist to refer to?
- Which type of treatments to use: drug, lifestyle advice (dietary advice, stress management, exercise regime, medical device (surgical collar etc)?
- Within each of these treatment types which specific options to prescribe?
- What course length and intensity to prescribe?

- Which combination of options to try?
- What options to use if the first set of decisions (and nth following) is not successful?

(Werner, 1995)

5.5.3 Conclusion

This section clearly frames ***Trading Off*** as a subset of decisions with medical decision-making and the medical decision-making process. The process and categorisation of decisions shown here demonstrates the volume and complexity of decision-making that occurs within medicine and therefore hence highlights a possible reason for the large number of errors that occur within it. These aspects in conjunction with the constraints detailed earlier demonstrate the practical need for shortcuts and rules in order to deal with patients effectively.

Self-Referencing can be viewed as the most obvious shortcut used by physicians as it details the preference to rely on imperfect internal sources of information in making decision when access may be available to more reliable sources. The literature detailing the use of rules and shortcuts in medical decision-making will be looked at in chapter 6.

The preceding sections have outlined the context and characteristics of medicine and medical decisions. The final section in this chapter will review the outcomes and problems associated with making these decisions in this context. In doing so, the need for decision-making research is highlighted.

5.6 Outcomes of medical decision-making

The outcomes of medical decision-making are characterised by variations in the usage patterns of care and a volume of decision that can be described as inappropriate. This section will detail these outcomes. These results are due to a number of reasons that include the complexity, urgency and uncertainty of the task in conjunction with the number of options that are available to the physician (Redelmeier and Shafir, 1995).

Clearly, these sub-optimal decisions are in addition to the majority that are **appropriate** and contribute positively to the patient. Two issues develop from this however. First as this section will demonstrate there are unacceptably high levels of inappropriate decisions made. Secondly, amongst the decisions that are not defined as inappropriate there will be a further volume that can be described as satisfying rather than optimising within it's context. The restrictions surrounding health care and it's importance demand that better decisions be made that use the available resources more effectively for the patient and the providers.

These issues provide a rationale for research into accurate representations of medical decision-making. ***Trading Off*** provides such a representation and therefore can be used to suggest corrections to the approach that is causing these problems. Specifically, the normative theories explained in chapter 4 in conjunction with the behaviourally accurate ***Trading Off*** can be used to modify prescribing behaviour. The implementation of normative procedures is limited currently by the use lack of prevalence data and physician expertise, though work described in chapter 6 is being performed in these areas.

Trading Off has exposed a number of specific reasons for inappropriate and variable behaviour (see section 11.3.2.4) and these can be targeted independently. For example the preference for use of ***Self-Referencing*** can lead to errors if the physicians experiences are biased or have not been controlled via feedback. Modification of these areas and those exposed by independent research can then be achieved using techniques and strategies reviewed in Chapter 8.

5.6.1 Variations in Treatment Usage

Variations in the usage of treatments between physicians and between areas would be expected to exist according to variations in disease patterns. This section will address

briefly the size of the observed variations, whether this is greater than would be expected whether is has any significance for the patients. This will be followed by a explanation of these findings from a ***Trading Off*** perspective.

5.6.1.1 Size of Variations

A number of authors have demonstrated variations in treatment usage rates over a number of classes of treatment and within both primary and secondary care settings. (Chassin et al. 1986) found in a study of Medicare beneficiaries that of 123 medical and surgical procedures, 67 showed a 300% variation between the highest and the lowest using sites. They also showed no consistency in the level of usage across procedures at a particular site. I.e. being a high usage site for one procedure did not mean that high levels of usage were shown for all procedures.

(Leape et al. 1990) in a study of the causes of geographic variations in use, looked at three surgical procedures and found large differences in usage within the same county in the USA. For example, the use of coronary angiography varied from 13 to 158 patients per 10,000 Medicare patients. The rate of hospital admissions has also shown variations (Roos, 1992).

5.6.1.2 Outcome of Variations in Medical Care

The outcome of these variations on medical care is unclear. If, as is suggested by (Leape et al. 1990) that the differences were not due to inappropriate usage then the outcome of this variation may be unimportant. It may merely reflect the usage of a number of legitimate options that are acceptable in those treatment situations.

Chassin et al however, stated that the level of variation found in their study "was too large to ignore" (Chassin et al. 1986) p285 and in a later article reported that this variation is due inappropriate use (Chassin et al. 1987). In this instance variation of

usage patterns can be said to contain examples of care that are at best sub optimal and at worst, dangerous to the patient. The specific types of inappropriate care will be discussed in section 5.6.2.1.

5.6.1.3 An explanation of variations from a *Trading Off* perspective

Trading Off can be used to suggest reasons for these variations. Variations can be seen as legitimate preferences for different forms of treatment based on patient need once the ***Focusing*** has been performed. ***Focusing*** may have discovered small but important differences in the context of the problem that requires different care. This explanation is likely to account for a percentage of the variation, one that can be very difficult to quantify because of the complexity of the medical decision-making context.

Similar to this, a number of treatments may have practically identical outcomes and their usage whilst leading to variation of treatment for the same diagnosis may not be associated with inappropriate use. For example, there are currently 11 Ace Inhibitors licensed for use in hypertension in the UK and whose efficacy can be argued to be a class effect. Variation in patterns of use can legitimately occur therefore.

A further explanation that again is likely to account for a percentage of the remaining variation concerns ***Self-Referencing*** and ***Surrogating***. Individual personal experience and education will have created different level of confidence concerning treatments held internally and therefore used for ***Self-Referencing*** within individual physicians.

This will lead therefore to similar situations being resolved differently depending with what the physicians feel confident. These differences can be exacerbated into geographic variation (as found in (Chassin et al. 1986)) by the choices of local experts which are then ***Surrogated***, either volitionally or by being *Duty Bound* to do so.

The findings that have shown variation in both primary and secondary care suggested that this ***Self-Referencing-Surrogating*** explanation account for a further percentage of variable treatment usage, that which is inappropriate to the situation. Simply put, physicians do make mistakes in treatment choices. Further to this, the published cases on eminencies providing substandard and even dangerous "care" indicates that experts are included in this (Anonymous1998; Anonymous1998). Where they are involved and ***Surrogated*** from variation due to inappropriate care may be more prevalent and show geographic patterns.

The reduction in inappropriate variation is therefore based on the identification of these areas and then building the physician's confidence in those behaviours agreed as representing appropriate care. The extension of *Duty Bound* ***Surrogating*** from secondary care to primary care would be effective in the reduction of resistant inappropriate variations.

However the removal of autonomy seen in *Duty Bound* ***Surrogating*** would also necessitate the removal of patient responsibility from the GP. The unpopularity of this step results in the use of *Duty Bound* ***Surrogating*** in primary care to reduce variation, requiring the building of the pseudo from of this behaviour. This occurs where the outcome of completely following of the eminencies instructions is seen, but without the obligation to do so.

5.6.1.4 Summary

Variations in care have been shown across a number of contexts including medical and surgical procedures. The outcome of this variation on patients is debated however. No research was identified that was able to categorise variation discovered into decision that have a detrimental effect of health or that represent legitimate variations according to patient need. A conclusion can be drawn however that within this divergence is a level of usage that either harms the patient or provides sub-optimal care.

5.6.2 Inappropriate Medical Care

This section will address the size and nature of inappropriate care that has been observed throughout medicine. It will also look at the outcomes of this problem and suggest reasons for it. Finally it will summarise literature that is reviewed in chapter 8 that looks at the issue of modifying medical decision-making in order to reduce this problem. This will be looked at according to the published literature and ***Trading Off.***

The outcomes of inappropriate care will be addressed as the importance of this serve as the central reason for improving knowledge of medical decision-making. In relation to the previous section, inappropriate medical care exists within the variable patterns demonstrated and within consensual patterns.

5.6.2.1 Forms of Inappropriate Care

A number of forms of inappropriate care have been identified, these include care chosen:

- When side effects are likely. (Bates et al. 1995)
- When interactions may occur. (Segal and Hepler, 1985)
- When contraindications are present. (Segal and Hepler, 1985)
- Is more expensive than alternatives. (Lilja J, 1976)
- That is not efficacious for the patient problem.
- Without firm diagnosis. (Hepler et al. 1982)
- Incorrect treatment chosen.
- Dosing errors. (Segal and Hepler, 1985)
- Potential for clinical importance. (Lesar et al. 1997)
- Hospital stay of incorrect duration. (Restuccia, 1982)

These definitions demonstrate the wide range of possible errors that medical decision are prone to. A careful examination of some of these definitions also shows that they could produce extremely high levels of care deemed as inappropriate.

Using the first three definitions on this list necessarily describes the vast majority if not all pharmaceutical interventions and hence could be used to describe all pharmaceutical care as inappropriate. Clearly these definitions must contain an element of comparison to other options available and be relative to the benefit they will bring to the patient. This kind of process is integral within ***Trading Off*** as explanation of prescription decision-making.

5.6.2.2 Prevalence of Inappropriate Care

The problem of inappropriate care is produced by it's prevalence in combination with it's outcomes, this section will look at the first of these. Findings from work on the prevalence of the problem are dependent on the form that is being studied. (Lesar et al. 1997) found 3.99 errors per 1000 medication orders in a teaching hospital when they used "potential for clinical importance" as a definition. This figure fell to 1.3 errors per 1000 when potential for causing adverse reactions was used. This low figure can be compared to the findings of (Bates et al. 1995) and (Bates et al. 1997) which reported error rates of 5.3% and 5.5% respectively when all dosing and frequency errors were counted regardless of their potential outcome. (Lilja J, 1976) supports this prevalent account of errors by reporting that 65% of drugs chosen for a patient with pneumonia were unsuitable when cost factors were introduced.

These results and a number of authors demonstrating sub-optimal use of medications show that inappropriate prescribing is a particularly common form. For example (Avorn et al. 1992) studied the level of psychoactive medication in elderly patient and found them to be used frequently despite well known side effects in this population. This prescribing is also found to be resistant to measures designed to change it. This

persistence is also found in (Ross-Degnan et al. 1993) who reported on the continued use of Zomepirac despite warning letters as to its dangers.

The findings from these studies shows that the problems of inappropriate medical care though dependent on definition used, it is undoubtedly a large problem in volume terms. The apparently less important cost aspects however become important when the limited budgets of the NHS (and other care provision systems) are taken into account.

For example, using a drug that is more costly than an equally efficacious alternative option may appear only to be inappropriate from cost point. However this added cost diverts money from areas of care that cannot be provided because of lack of resources. I.e. the money saved through appropriate prescribing at a level shown in (Bates et al. 1997) could be used to provide more nursing staff, more accurate diagnostic equipment or pay for more operations.

5.6.2.3 Outcomes

The effect of this volume and forms of inappropriate care is seen in both monetary and patient terms. Drawing firm conclusions on the levels of harm that overly expensive care has on the level of health provision is difficult. However, the government white paper "The New NHS" outlines the NHS response to variations in cost of providing the same treatment in different hospitals. This response is designed to reduce these differences and effect cost savings. It can be concluded therefore that these variations have a sufficiently large negative effect to warrant deliberate intervention (Secretary of State for Health, 1997).

The harm to the patient is however easier to show and has been found to range from the inconsequential to death of the patient. (Bates et al. 1995) found that 1% of medication errors in their study resulted in adverse drug events. The importance of adverse drug event (ADE's) was demonstrated in a large dual centre study where they found that:

- 1% of ADE were fatal.
- 12% Life threatening.
- 30% Serious.
- 57% significant.

An important finding in this study was that ADE caused by inappropriate prescribing and therefore preventable were more likely to be serious. In further support to Bates et al, (Brennan et al. 1991) found that nearly 4% of patients in New York hospitals suffered an ADE during their treatment. The volume of harm caused by this has been extrapolated to equal 180,000 deaths annually in the USA. Of greater concern to medical decision-making is the figure of 69% of these ADE's being in some way due to "errors in management" (Brennan et al. 1991) p29. (Leape et al. 1993) supports this majority finding.

Inappropriate care in a surgical setting has also been shown to have grave consequences with 10% of 4500 deaths of surgical patients in Scotland being attributed to errors or poor after care (The Royal College of Surgeons of Edinburgh, 1996).

The cost of ADE in financial terms has been reported as $76.7 billion in the USA related to the costs of morbidity and mortality (Johnson, 1995). (Bates et al. 1997) found that for preventable ADEs, 4.6 days were added to the length of stay in the hospital with an overall cost of $4685 per patient. This figure is thought to means a total annual cost of preventable ADE's as $2.8 million in the 700 bed teaching hospital studied. They add that these costs are thought to be conservative because they do not include malpractice costs. A figure of $1939 with the addition of 1.9 days to the length of stay is reported by (Evans et al. 1993).

Again, the cost, in this instance financial, is found to be very high. The characteristic of growing cost pressures on medicine outlined previously in this chapter, demands that this figure be reduced. The accurate modelling of medical decision-making and the

strategies for reducing error that can be taken from it, provide a mechanism for achieving this goal. The application of ***Trading Off*** to this issue will be outlined at the end of this section.

Prior to this, the causes of inappropriate care will be looked at followed by a brief review of strategies proposed in the literature for reducing this problem. A more detailed examination of work on changing and modifying medical decision-making is provided in chapter 8.

5.6.2.4 Causes of Inappropriate Care

In research by (Lesar et al. 1997) it was found that knowledge was the key component of errors made in medical decisions. Lack of knowledge of the drug and it's application accounted for 30% of all errors whereas lack of knowledge of and use of patient factors accounted for 29.2%. To this can be added the 13.4% of errors caused by incorrect use of the name of the drug. Clearly according to these results, the education of physicians is an important factor in reducing this problem

This pessimistic view of healthcare providers efficiency in prescribing matters is supported by (Bates et al. 1995) who found that 56% of errors occurred at the ordering stage and 34% at administration. These findings indicate that administrative strategies to intercept these errors and correct them would be successful in reducing the impact of lack of knowledge.

(Soumerai et al. 1989) provide a wider ranging and more detailed summary of the causes of inappropriate care. These are:

- Failure to keep abreast of developments.
- Over-promotion by pharmaceutical companies.(Avorn et al. 1982).
- Oversight or simple errors. (McDonald, 1976).

- Ignoring Cost issues.
- Insulation from cost by other factors.
- Patient pressure. (Schwartz et al. 1989).
- Over reliance on experience.
- Need to provide treatment where no clear one exists.
- Pressure from health workers.
- Using prescriptions as a termination strategy.

(Soumerai et al. 1989)

To this list can be added the complexity and volume of decisions that need to be made, the medical decision-making process detailed in section 5.5.1 and the practice of this process detailed in ***Trading Off***. This provides a number of opportunities for incorrect or sub-optimal decisions to adversely effect the outcome of the treatment.

The multiple causes of inappropriate care highlighted here require a multifaceted approach to solving or reducing the problem. The large body of literature found to refer to this issue is reviewed in chapter 8 in addition to a detailed appraisal of how this work can be interpreted and developed using ***Trading Off***. This literature is summarised below.

5.6.2.5 Modification of Inappropriate Care

The literature concerning the modification of medical decision-making can be categorised into Educational, Administrative and Financial strategies. These classifications also encapsulate the areas of influence that ***Trading Off*** found that are used to form and change behaviour.

A wide variety of educational strategies can be used to improve the physician's knowledge of treatment and their use in addition to the process of decision-making

employed. Methods that have shown to be effective include one to one tutorials, lectures and mailed information (though only where it is in conjunction with these other methods) (Schaffner et al. 1983) (Evans et al. 1986; Plumridge, 1984). It was found that the methods such as one to one tutorials that were most flexible and focussed to the needs of the health care providers had the greatest effect.

The ***Trading Off*** position concerning the need for *confidence* can be used to synthesises the above findings. As *confidence* is a personal entity based on specific area experience and knowledge, to develop it, the delivery method must be flexible to the specific needs of the physician. Therefore, one to one tutorials from sources recognised as expert and preferably based on clinical experience are likely to modify behaviour most effectively.

The use of administrative strategies for example formularies, (Abramowitz, 1984) and mandatory second opinions (Myers and Gleicher, 1988) provides an effective means of restricting the use of certain treatments and providing means of examining treatment orders for mistakes. The development and application of these strategies has become simpler as information technology has advanced and medicine is moved toward more centralised control.

The Administrative methods used are seen in ***Trading Off*** primarily as developing ***Surrogating*** as the location of influence for treatment confidence, i.e. the patient experience and knowledge encapsulated in the formulary decisions is what followed. This therefore supplies an understanding of the specific type of information that when used in conjunction with educational efforts can be an effective method of changing behaviour.

The use of administrative strategies to strictly control use of certain treatments corresponds to *Duty Bound **Surrogating***. This category of behaviour is being expanded from it's traditional place within hospitals to control (and therefore modify where applicable) behaviour in a wider spectrum of medical contexts.

The final group strategies that can be used to modify inappropriate behaviour are the use of financial incentives/disincentives. The application of budgets controlled by financial penalties e.g. fundholding in UK general practices has been shown to have an effect on prescribing (Wilson et al. 1996).

Financial strategies modify behaviour primarily by increasing the importance of cost as a factor that is ***Traded Off*** and increasing cost effectiveness as an objective of treatment. In doing so changes to decisions on which treatments to use may be made because of their cost and cost effectiveness.

In conclusion, the most effective of these strategies to modify inappropriate medical decision-making involves the use of flexible and targeted educational methods. If this fails however strong administrative and financial strategies will work but may develop resentment amongst the health care providers and their effectiveness may last only as long as they are in place. In the long-term, the use of education in conjunction with these strategies is the best method of change.

Trading Off has been used to add further understanding on how to modify this inappropriate behaviour by providing the physicians confidence as the psychological component that needs to be changed. It also demonstrates the importance of clinical experience as the type of information that is important when attempting to develop this confidence.

5.6.2.6 Summary

Inappropriate care, because of its prevalence and the importance of its outcomes provides a central rationale for the study of medical decision-making.

The actual prevalence of the problem depends heavily on the definition used to describe it. For example when "potential for clinical importance" was used .4% of decision were found to be inappropriate, (Lesar et al. 1997) this is compared to 65% when cost factors were introduced (Lilja J, 1976). These differences combined with definition such as "care used when side effects are likely" (Bates et al. 1995) leads to the view that inappropriate care depends on a comparison between the options available and the problems caused relative to the benefit gained. Such comparisons and relativity lie at the heart of ***Trading Off***.

The negative outcomes of inappropriate care can be categorised into the effects they have on the patient and cost issues. The effects on patients show a wide range of severity, from minor side effects to death. The reported number of surgical deaths attributable to poor care in Scotland (The Royal College of Surgeons of Edinburgh, 1996) demonstrates eloquently, the need to improve decision-making .

A figure for the financial cost to the NHS of inappropriately prescribed drugs is currently unavailable. It can be expected to be a very high absolute figure (considering that in the USA $76.7 billion was attributed to the costs of morbidity and mortality associated with ADE's (Johnson, 1995). This figures can be expected to be proportionate to the problem in the UK

This issue combined with the restricted financial resources available to the NHS has lead to the reduction of this figure becoming a key objective of the government and to a degree the pharmaceutical industry. The creation of the prescribing advisors role and the PCG's are a governmental response to this. It has also lead to cost effectiveness data from pharmaceutical companies becoming an integral part of their communications to decision-makers.

The causes of inappropriate care appear to be based on a lack of knowledge that is compounded by the characteristics of the medical context. The consequences this has

for reducing these behaviours is the need for education and availability of reliable data in the form that physicians use. Administrative strategies to act as a safety net for errors that continue to be made are also appropriate.

The overall conclusion that can be drawn from this section is that the size and importance of inappropriate care necessitates the study of medical decision-making. By producing accurate models of how it is performed, errors and gaps can be identified. In turn, either strategies can be designed to modify the errant behaviours at source or procedures designed to intercept it before the patient is effected. A number of these strategies are reviewed in chapter 8. ***Trading Off*** provides such a model and the implications it proposes for these strategies are provided in chapter 8.

5.6.3 Conclusions

This section has examined the outcomes of medical decision-making primarily from the perspective of its negative consequences on patient care and cost and using data from the USA and UK. It must be remembered however, that a majority of medical decisions in these countries lead to diagnosis and treatment that benefit the patient and provide a very high level of care.

This does however leave a proportion of these decisions that do not provide this high quality of care. The actual levels of variation and care described as inappropriate are dependent on the definitions used to describe them. For example inappropriate care has been shown to range from .013% (Lesar et al. 1997) to 65% by (Lilja J, 1976). Whereas 300% variations in usage of some medical and surgical procedures were found by (Chassin et al. 1986). These figures contain a number of decisions that represent a range of outcomes for the patient that extend from no consequences for all the parties concerned to sub-optimal care, added cost to the healthcare providers and even death.

These problems and their prevalence are unacceptable in a system that provides a fundamental human right and where causes of the problem known. Studies have shown that a lack of knowledge on a number of factors such as drug information, patient information and the correct treatment name are the major cause of inappropriate prescribing (Lesar et al. 1997), (McDonald, 1976).

The information to correct many of these problems (and many of the other causes as detailed in section 8.4.2) is however readily available, for example the correct name, dosage, indications and contra-indications are known for all available pharmaceuticals. Despite this inappropriate and sub-optimal care continues to occur.

This can be explained by ***Trading Off*** and particularly ***Self-Referencing-Surrogating*** and ***Shifting***. This explanation for modifying medical behaviour is detailed in chapter 8 which sets out the findings of ***Trading Off*** within current literature on decision modification. Essentially, however ***Trading Off*** found that the preferred location of medical knowledge used as the basis for action is internal and it is experiential and pattern recognition based. In this case, the continuation of errors can be seen as a problem of the form in which information is provided to the physician, the context within which medicine is practised and the education methods used to improve physician's knowledge.

Trading Off suggests further that to develop improved knowledge into a change in practice, the information provided must make the physician feel confident in the behaviour. Further to this the information should be in the form in which confidence is most easily built i.e. experiential, pattern based supported by experts and provided by an interactive medium.

Beyond improving physician's knowledge and methods designed to modify behaviour based on this, administrative strategies (also detailed in chapter 8) can be used. For

example, simple computerised ordering systems can identify inappropriate indications and doses.

Indeed the problem of inappropriate care and the need to reduce it may be strong enough to justify the introduction of compulsory administrative and peer control strategies to health care provision on all levels where it is found to be deficient. These strategies such as compulsory peer assessment similar to that found to be effective in changing doctors behaviour (McAuley et al. 1990) and substitution (Weintraub et al. 1991) could be used to this end.

The imposition of these kinds of strategy on those physicians found to be deficient would however involve a reduction in clinical freedom that the physicians may find unpalatable. Careful imposition of these controls would therefore be necessary. This extension of control corresponds to the widening of duty bound ***Surrogating*** which is detailed in chapter 3 and developed within chapter 8.

Structural changes in the provision of health care may indeed be justified throughout medicine as the complexity of each of the decision stages in the medical decision process (corresponding primarily to diagnosis and treatment) increases. Separation of these roles may be a way of developing expertise and reducing errors due to lack of knowledge.

5.7 Chapter conclusions

The objectives of this chapter were to provide the necessary information to frame decision-making as it is performed in a medical context and conclusions regarding this are drawn together in this section. A further objective was to detail the outcomes of medical decision-making. This involved a specific review of the variations and errors that exist.

The variations outlined in this chapter will contain decisions that represent legitimate variation due to patient need and circumstance, they also however contain variation that masks a sub-optimal level of patient care. Indeed the volume of errors found represents a spectrum that contains instances where decisions have caused no harm to the patient as well as ones that have killed them. The volume and importance therefore provides the justification for research into this area

Throughout this section conclusions will be drawn as to the nature of causes of these problems and potential answers for it. More detail on strategies and ideas suggested to reduce the volume of medical errors (and the modification of decision-making more generally) are presented in chapter 8.

5.7.1 Uncertainty

Arguably the most important characteristics of the medical context as regards it's impact on medical decision-making is the uncertainly that surrounds each situation. The management of this uncertainty has created a paradox in practice, where action is often favoured but the actual choice is conservative. It also explains the use of various information sources upon which to base decisions.

5.7.1.1 Confidence

Conservatism is a manifestation of the physicians need for confidence in a behaviour in order to perform it. This research explains the preference for internally directed behaviour as partly due to the vivid, experiential nature of a physician's memory that can often be trusted to a greater extent than external information. This preference however opens the doctor to the perceptual and memory biases that surround an individuals knowledge and hence can be seen as a potential reason for the volume of errors in medicine.

Objective statistics from clinical trials and the use of opinion leaders in collaborative decision-making are further tactics used to manage uncertainty by providing information that can build confidence. Further, conclusion concerning confidence, the location of knowledge used for decision-making and the implications for decision-making quality and are provided in chapter 7.

5.7.2 Conflict

The modern medical context is also characterised by conflict due to the differing objectives of the parties involved in the provision and receipt of healthcare. The restricted resources available to provide healthcare and most crucially, growing financial restrictions exacerbate this factor. Increasingly this is developing a system where the decision-maker is forced to consider the objectives of a number of parties including the NHS, health insurance companies (or party paying for the care) and patient interest groups rather than purely the wellbeing of the patient.

Conflict is clearly shown where the financial restrictions placed over medical practice are being placed under greater stress by the continued product development within medicine. This development has drawn an increasing number of diseases and therefore patients within the bounds of what can be treated. It has also added to expense by the development of pharmaceuticals that perform more effectively than older preparations but also cost more.

The health care provider is therefore being asked to provide care for their patients but is restricted financially to whom can receive which treatment. This situation has seen conflict between a number of parties as decision-makers are effectively being asked to prioritise patient care. It has also lead to the emergence of cost effectiveness as an added and important criterion for decisions.

The conflict and prioritisation may however provide a further explanation for the large volumes of variation and inappropriate care that have been reported. Depending of the focus of the definitions for these errors the physicians may have been acting appropriately from the perspective of the objectives they were following but inappropriately according the definition used in the study. For example, a prescription of a cheaper less effective medicine may appear inappropriate from the perspective of the individual patient but appropriate from the wider, cost effectiveness perspective. The opposite may also be true.

5.7.3 Variation, Inappropriate care and *Trading Off*

The preceding discussion highlights effectively the complexity of the medical decision-making context and adds further weight to the argument calling for ***Focused*** and wide ranging situational analysis of medical decisions when they are researched. This scope of investigation is needed whether it is designed for marketing research purposes or from a medical decision-making perspective.

Taking the discovered need for ***Focusing*** and the variation in treatments together, ***Focusing*** suggests that a large proportion of this variation is due to patient and contextual variation. It may be that the definitions used in deciding on levels of variation were not sufficient to deal with legitimate treatment variations due to variable patient/physician circumstance

5.7.3.1 Complexity

The complexity of the medical decision-making process and the number of decisions that constitute the treatment of one patient is a further cause of the errors found during this study. This chapter outlines simply the main categories of decision (diagnosis and treatment) and further details decisions that need to be made within these groupings. This volume and their individual complexity give rise to the use of mental short cuts in

the form of over-reliance on internal sources of knowledge and the use of heuristics which contribute to the volume of errors.

5.7.3.2 Knowledge

The main cause of these errors has been shown to be a lack of knowledge in a number of forms. This can be partly attributed to the use of the physician's memory without adequate support, which is available from a number of sources.

Self-Referencing provides potential answers to why this lack of often simple and readily available knowledge is the cause of so much inappropriate prescribing. ***Self-Referencing*** states that there is a preference for using internally held information (which is represented importantly as mental imagery of patients treated) because it is often held in higher confidence than externally information. This restricts the physician search for external information to solve the problem and therefore reduces the likelihood that up to date and correct information will be discovered and used. Even if the "correct" information is known it may not be held in sufficient confidence to break the patients prescribing patterns.

This misplaced confidence may be reinforced if the treatment prescribed is successful in achieving its objectives though it may still cause unnecessary side effects or cost more than the "appropriate" drug.

The rejection of external information may also be caused partly by the information being provided in a form that is not fully understood and does not represent the form that is readily used by the physician. Physician use of statistical information has been shown to be prone to error and it may not provide the physician with the situational understanding that they require to build confidence. This provides a further reason why relatively simple knowledge based errors are a continuing source of medical errors. It also

suggests that provision of information from a patient orientation rather than a statistical one may improve practice.

The simplification of the medical decision-making process is a potential method of reducing the rate of errors seen in medicine. This could include dividing the process into diagnosis and treatment decisions, each being performed by separate specialists. This would reduce the number of areas physicians are required to be proficient in and allow greater specialisation. In turn this specialisation would allow greater volumes of experience and knowledge to be gained and may reduce errors.

The imposition of administrative strategies on physicians found to be treating inappropriately is a further and potentially very effective way of reducing errors. These strategies are well used on a number of levels health care provision and research into their effectiveness is detailed in chapter 8. This has shown the effectiveness of strategies such as peer review and therapeutic substitution, in changing behaviour.

The imposition and monitoring of more stringent, tailored strategies according to the practice of individual physicians is a potential method for reduce errors but would pose questions of clinical responsibility and the quality of the guidelines being worked from.

This chapter has provided an overview of the context of medical decision-making and the outcomes from it. It has also suggested reasons and potential answers to the problems caused by this context and decision-making within it. The review of literature will now proceed with a review of literature providing models of medical decision-making as it should be performed and how it is performed. The following chapter goes further and provides details on a number of aids designed to assist individual parts of the medical decision-making process.

6 Chapter Six Medical Decision-making Research

6.1 Introduction

This chapter presents the literature concerning research into medical decision-making. In doing so, it concentrates on research produced from a positivist perspective and the quantified representation of the behaviour, as this approach is the dominant one used to study this area.

It is not this reviews intention to provide a wide-ranging and in-depth study of the techniques themselves for example, critiquing the Standard Reference Gamble. Instead, it is used to review medical decision-making research and develop and integrate ***Trading Off*** into this literature. Conclusions will also be drawn on the differences in methods used.

Trading Off provides a well fitting, workable model of the behaviour of prescribing decision-making. The behaviour it represents can however be improved by integrating into it the quantifiable aspects proposed and discovered by other methods.

For example, this study suggests that the core category of pharmaceutical decision-making is ***Trading Off***. ***Trading Off*** involves feelings of confidence about certain actions and the existence (and performance) of certain attributes being constructed by the doctor. These are then ***Traded Off*** against each other based on a specific set of goals set out during ***Focusing***. The objective of this is to make a decision on which action to action and using which objects.

As discussed in the previous chapter, the performance of medical decision-making would be improved if normative models and procedures replaced the error prone practices currently used. For example, instead of using personally constructed

probabilities assessments that are susceptible to error (as highlighted in chapter 5, probabilities should be available from reliable and valid data sources.

The chapter provides greater detail on the procedures that are being used and others that could be used to improve medical decision-making (and specifically pharmaceutical decision-making) reviewed in light of ***Trading Off***. It therefore explores ***Trading Off***'s integration within current literature and its ability to integrate it.

Following an introduction into medical decision-making research, the review will be structured around the model of Differential Diagnosis (Pauker and Kassirer, 1987). This cyclical model is reported in (Sox and Blatt., 1988) and the expansion and developments this book provides to the process are used to structure further this chapter.

The work by (Sox and Blatt., 1988) is then elaborated on by research from relevant authors, as this proceeds "formal" techniques of decision analysis will be introduced. Their contribution to the objectives set for medical decision-making research will be also be evaluated

6.2 Objectives of Medical Decision-making Research

The objectives of medical decision-making research can be broken into four areas.

1. Provide a model and insights into how medical decision-making should be performed
2. Provide a framework from which to teach medical decision-making
3. Provide decision aids for medical decision-making.
4. Provide insights as to how is it actually performed

The work reviewed within this chapter is principally concerned with how medical decision-making should be performed. This review however contains literature that is

concerned with all of the above objectives. Indeed much of the work here answers several of these objectives, for example the work by (Sox and Blatt., 1988) provides a normative and educational handbook for students and practitioners.

The literature that looks at how decisions are actually made is reviewed within the developed model of differential diagnosis section 6.5. The contribution of medical decision-making research to the understanding of how decisions are actually made by doctors, is the area where it makes its weakest contribution. However, the research reviewed has been useful in the study of medical decision-making according to the three remaining objectives.

6.3 Benefits of Quantitative Methods

The major benefits of methods used to study this area can be seen as the validity, reliability, and structure with which answers can be produced. These benefits underpin the use of quantitative methods in addressing the issues of inappropriate and variable decision-making highlighted in chapter 5.

Specifically, they can be used to satisfy the objectives outlined in section 6.2. For example, a valid, reliable decision process can be used to highlight where doctors actual decision processes may be causing errors. Decision aids, which contain the ability and probabilities required to structure the problem and perform sensitivity analyses, can then be designed to correct the problem

The valid and reliable decision models that these methods provide for educators and practitioners can then be used to design new educational programmes and form the objectives for new studies. I.e., it has been found doctors do not use base rates correctly when estimating the likelihood of a disease in a patient (Elstein et al. 1986). Educational programmes can therefore be designed to help ensure that base rate information is used correctly in the future.

Having introduced the methods used this review will now turn to their findings within medical decision-making. As mentioned earlier this review uses the structure of MEDICAL DECISION-MAKING by (Sox and Blatt., 1988) to guide this chapter.

6.4 Medical Decision-making

The book MEDICAL DECISION-MAKING by (Sox and Blatt., 1988) is recognised as a seminal work in the area of how doctors should make decisions and provides a teaching guide for medical decision-makers. This book provides a model for the decision-making process and then expands on the necessary aids and techniques that are needed to complete the steps they suggest.

The fundamental process that these authors provide on medical decision-making is the exercise of "Differential Diagnosis" (Pauker and Kassirer, 1987). This represents the generic decision-making process within medicine, designed to solve the problems presented by patients. The book continues by examining the individual actions within this process and expands and develops these stages with additional research.

The errors within medical decision-making can occur as a result of the differential diagnosis process not being followed or the errors within the individual steps. The diagram in section 6.5 demonstrates the simple, common sense nature of the overall process, this can be contrasted with the complexity of the individual stages. It is likely therefore that errors in medical decision-making are due to failure to perform the individual steps correctly.

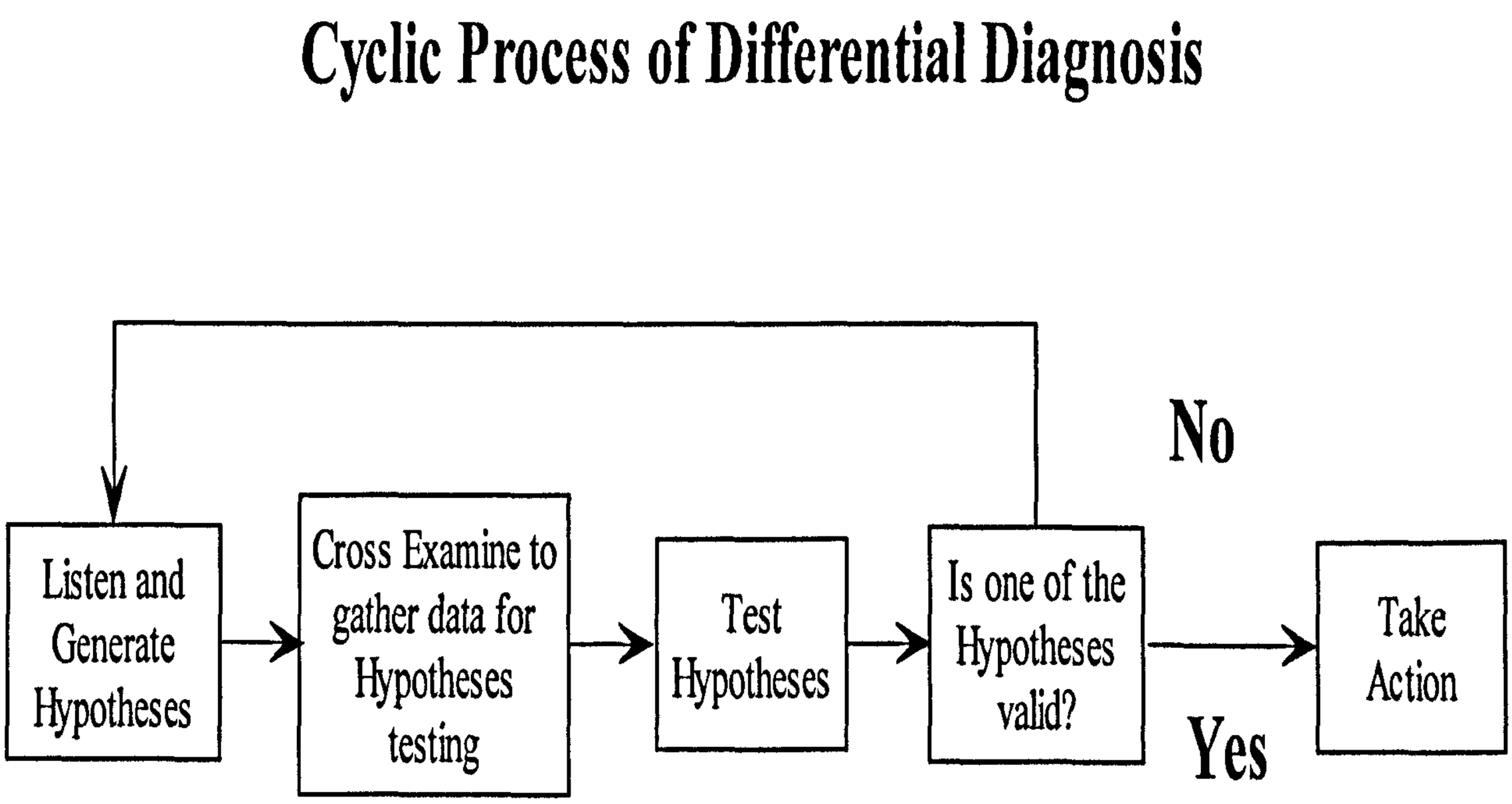
6.5 Differential Diagnosis

The differential diagnosis process involves decisions beyond the diagnosis of the nature of the problem possessed by the patient. It also looks at decisions that are made

involving the treatment of these problems. The process discovered by (American Institutes for Research, 1976) and the decisions made within the sub-areas of Diagnosis and Treatment were detailed in chapter 5. It should be remembered however that Diagnosis and Treatment cannot truly be separated because of instances where treatment is used as part of diagnosis.

The differential diagnosis process presented here, while fundamentally the same, demonstrates the process involved and the relevant questions and decisions that are required at each step.

Figure 7: Differential diagnosis



This process will be analysed initially by outlining the steps within it in and then the methods prescribed as how to perform its tasks. The formal methods categorised by (Pauker and Kassirer, 1987) are used throughout this book to develop the themes of this process (see section 6.6.1.6).

The fundamental tenet of this model is that data gathering is hypothesis driven. This is the same relationship that was found in ***Trading Off*** especially between ***Focusing*** and ***Self-Referencing*** then ***Surrogating***. The authors mention that while this diagram stresses the acceptance and rejection of the hypotheses generated, the exact cognitive processes used in completing this task are not known.

6.5.1 Listen and generate hypothesis

The first stage of diagnosis is to listen and observe the patient and to start to hypothesise about the problem. This listening stage will trigger off a set of hypotheses that will be narrowed down as history, physical examination and testing are performed. In this instance, the hypothesis that should be tested first is the most common. A further important factor to consider from the list of hypotheses is which of the diseases that it could be is too important to miss.

6.5.2 Cross examine to gather data for hypotheses testing

To further reduce the number of hypothesis being considered, questions and examinations are performed which are specific to each idea. This will result in some ideas increasing in apparent likelihood and others decreasing.

Here the cost of the information should be considered both on an economic and patient benefit, basis. Using tests and investigations whose outcomes will not effect the treatment of the patient can escalate medical costs and should be avoided.

6.5.3 Test hypotheses

The hypotheses that remain should be evaluated considering the relative prevalence in the particular population. It should also be remembered that evidence or a pattern of evidence against one disease increases the chance that the other is correct.

Here the authors suggest ranking the remaining hypothesis and listing the evidence for them as an aid to deciding between them.

6.5.4 Is one of the hypotheses valid?

The testing procedure should then lead to an evaluation of the results and findings to see whether they are completely consistent with hypothesis. At this stage a small number of active hypothesis will still remain which are ranked in the mind of the doctor and a number of actions can be considered.

6.5.5 Take Action.

Action can be taken on how or whether to treat the patient, what further information to gather and how to achieve these objectives This stage is clearly where pharmaceutical decision-making is based, though the title demonstrates the large number of potential actions that can follow.

6.6 Development of the model of Differential Diagnosis

Sox and Blatt expand on this basic process of diagnosis and treatment by looking at the following areas.

1. How to assess information that is gathered in light of medical uncertainty
2. Understanding New Information
3. Assessing the Accuracy of clinical data
4. Decision Analysis
5. Decision-making (Expected Utility and Expected Subjective Value Decision-making).

These areas do not correspond exactly to steps differential diagnosis, they represent skills and aids that are relevant throughout the process. They provide further instruction on how medical decision-making should be performed, suggests the tools with which to

perform it and highlight methodological issues that need to be considered. In doing so this section provides the structure for the review of medical decision-making research, and its findings, that is the central objective of this chapter.

6.6.1 How to assess information that is gathered in light of medical uncertainty

Probabilities are attempts to quantify the uncertainty surrounding the patient and can be based on the personal experience of the doctor and on published data. As expressed earlier, doctors deal with uncertainty constantly when dealing with patients. This leads therefore to a need to understand and use the probabilities that are borne out of this uncertainty.

Unfortunately, as detailed in chapters 5 and 4 this process of estimating probability is prone to error. This uncertain picture is compounded by doctors themselves differing in the level of uncertainty they are prepared to tolerate when making a decision (Allman et al. 1985).

The use of personal and published experience will be discussed, followed by how to improve the probability estimates made using these sources.

6.6.1.1 Personal Experience of the Doctor

As (Sox and Blatt., 1988) point out "Personal experience is and will continue to be the principal factor influencing a physicians probability estimates" p34.

This use of personal experiences as the main origin of probabilities is reflected in ***Self-Referencing***, as the first source looked at by the doctor when attempting to find a solution to the problem presented. This reliance on internal information and the ease

with which it is biased (as outlined earlier) contributes heavily to the issues of medical errors and variation.

6.6.1.2 Published Experience

Published studies are suggested by (Sox and Blatt., 1988) as a useful starting place from which to estimate probability if the differential diagnosis process is to be performed correctly. Published data sources are seen as "the second important influence on estimates of probability" (Sox and Blatt., 1988) p52. This coincides with the ***Trading Off*** concept that ultimately all clinical knowledge comes from ***Surrogated*** sources. It also corresponds to the function of this source being a database that is relied on when gaps are found in ones knowledge.

At the heart of ***Surrogating*** is that externally held information is used in order to gain access to that sources catalogue of individual experiences. The data gained from them is treated as their own experiences (hence ***Surrogated***). This is done when the doctor cannot produce a solution that is held confidently enough and additional data is needed.

(Sox and Blatt., 1988) support this view when the say "a published report about an uncommon disease usually reflects a larger collected experience than even the most senior clinician can". The larger collected experience represents a number of individual patients from which probabilities concerning the doctor's patient problem can be estimated.

Published data also often contains specific statistical information designed to help medical decisions. For example, prevalence, incidence of side effects and data on efficacy can all be used to produce estimates of probability of disease and treatment effect. They can be developed further into clinical prediction rules that are investigated in more detail later in this chapter.

There are issues however with the availability, quality and use of clinical data and the effects of this have been looked at by a number of authors. (Poses et al. 1995) (Wennberg, 1990) found that practice variation is partly due to a lack of understanding, knowledge and availability of statistics such as prevalence and the effect of treatment on population groups.

6.6.1.3 Errors

The use that is made of the information from these two sources is associated with a number of errors. The cognitive rules (Heuristics) shown to be used to help solve decision problems have a number of associated errors

(Sox and Blatt., 1988) present in detail a number of specific medical examples of these errors. This can be seen as an attempt to promote the use of methods of computing probabilities and to educate readers as to these problems so that they can be avoided or reduced.

6.6.1.3.1 Representativeness heuristic

This rule refers to the probability of an event often being based on how closely the two objects or event resemble one another. For example, the probability of a patient having a disease may be based on how closely the patient resembles the class of patient with the disease who have been seen recently. This heuristic is at the centre of ***Trading Off*** 's explanation of decision-making. This can be seen as the pattern matching approach to decision-making that has been argued for by (Werner, 1995). This leads to the development of expertise being viewed as experts possessing more and varied instances for the doctor to compare patients with (Werner, 1995). However pattern recognition (and hence ***Trading Off***) as a method of problem solving explains why there are a number of errors associated with the use of this heuristic. These errors include:

- Ignoring the prior probability (prevalence) of the disease.
- Using clinical cues that do not accurately predict disease.
- Being too sure of a diagnosis when redundant predictors are present.
- Mistakenly using regression-to-the-mean as diagnostic evidence.
- Comparing a patient to a small number of unrepresentative experiences of patients with a disease.

(Sox and Blatt., 1988)

6.6.1.3.2 Availability heuristic

This is defined simply by (Sox and Blatt., 1988) as the "process by which recall is enhanced by repetition" P47. This heuristic leads to estimation of the probability of an event being dependent on how easily it comes to mind. The ease with which events comes to mind is to an extent a good rule of thumb as memories of frequent events are easier to remember than infrequent ones. How interesting an event is, also positively effects how available it becomes in memory. This effect is called Vividness.

The availability heuristic provides an explanation for why feedback and particularly feedback from recognised experts is an effective component of learning. Repeated exposure concerning positive outcomes will increase the availability of the outcomes and the mechanism used to achieve them. Information from authority figures is often seen as more vivid and interesting and hence feedback from these individuals or groups will be easily available in memory. It will also have more impact on probability judgements used to decide on behaviour (Raisch, 1990). Errors associated with this approach are:

- Overestimating the likelihood of a complaint being present after education has been received.
- Overestimating the likelihood of a disease because a patient with the disease has been seen recently.
- Overestimating the likelihood of a rare disease. (Sox and Blatt., 1988)

6.6.1.3.3 Anchoring and Adjustment heuristics

The anchoring and adjusting rule describes the process where an initial estimate (the anchor) of the probability is made and then adjusting to take account of individual features. This heuristic is used in medicine to deal with the large number of hypothesis that can be generated in the initial interview with patient. Biases and errors that have been found with this heuristic are:

- Anchoring the probability of a disease too high or too low.
- Attaching to much weight to the doctor's initial view of the prior probability of the disease.
- Not adjusting the initial probability appraisal of the disease by sufficient amounts.

(Sox and Blatt., 1988)

6.6.1.3.4 Over Confidence as a cause of errors

Many of the errors and biases described previously can be seen as evidence for doctor's being overconfident in their judgements. For example, attaching too much weight to the initial view of the prior probability of the disease or being too sure of a diagnosis when redundant predictors are present.

This overconfidence has been explained as an example of "illusion of validity" (Einhorn and Hogarth, 1978) where people have a tendency to posses too much confidence in highly fallible judgements. This illusion can be seen as a development of overconfidence in internally held information.

It may however have a legitimate role in medicine particularly in contexts where it is important to act quickly, for instance Accident and Emergency wards. This research showed that colleagues also see confidence as a measure of a doctor's ability and

patients may share this view. In this instance it may help develop trust and a relationship between the both parties and through the compliance and placebo effect may help in the treatment of patients.

However, overconfidence has potentially serious learning and treatment issues. For a need for learning to be established it has to recognised by the actor, in situations where the doctor is overconfident this may not occur and hence learning from experience is less likely (Faust and Ziskin, 1988).

This theme is developed by (Arkes et al. 1986) who said "One of the dangers of overconfidence is that one feels that no assistance is needed. If one assumes that his or her judgement is quite good, decision aids would be entirely superfluous".

Overconfidence has also been shown to be associated with premature closure of the search for alternatives (Arkes et al. 1986). This in turn may result in the doctors not being aware of, or considering a wide range of treatments for the patient.

Overconfidence is an issue that was also found in ***Trading Off***. Confidence was discovered as the psychological construct that is developed and ***Traded Off*** during this process to decide which behaviour to perform. Misplaced confidence and over-confidence can therefore work against the introduction of new or different therapies, for example drug A is used because ***Trading Off*** has decided that this behaviour is confidently expected to cure the patient. As a result of this, the search for alternatives is reduced and alternatives found are seen as more risky than the current treatment. In these instances, it can be very difficult for improvements in treatment to be accepted.

6.6.1.4 Improving Probability Estimates

Techniques for improving probability estimates is complicated by research that suggests that physicians do not in fact use them in strict mathematical form. (Poses et al. 1995) (Elstein et al. 1986) and ***Trading Off*** all suggest that medical decisions are not based on this type of assessment. ***Trading Off*** claims that levels of confidence are used whereas (Poses et al. 1995) say that the treatment is likely to be decided by referring to previous similar instance and following what was performed rather than updating probability techniques. In this way subjective probabilities as to the similarities of patients are made.

These conclusions were borne out of research into the effect of improving physician's probability judgements on treatment decisions (Poses et al. 1995). They found that better judgements about the probability of certain bacteria being present did not lead to fewer antibiotics being prescribed for throat infections. They also found that marked variations between doctors remained. This work supports earlier findings by (Elstein et al. 1986) who found that objective probability information concerning Estrogen therapy did not change decisions.

Therefore the initial stage for improving the assessment of information involves improving the methods that are used rather than providing correct objective probabilities and techniques for using them. To this end improving the use of heuristics becomes important and (Sox and Blatt., 1988) suggest that educating doctors with regard to their possible errors and the use of Bayesian theory may be techniques for achieving this. Overconfidence can also be included in this awareness.

Beyond improving current methods, physicians must be encouraged to use objective probability data, no research was identified that addressed that problem specifically though (Poses et al. 1995) showed that improving physicians knowledge of the data was not sufficient. The issues surrounding the pathway from information, belief and change

in behaviour as a basis for changing doctor's probability estimates will be investigated in more detail in section 6.6.6 dealing with expected value decision-making.

However, the causes of ***Self-Referencing*** supply characteristics of the data and source that should be promoted in order to achieve this. These include information that is trusted, readily available, vivid, and available for a large number of factors.

The actual teaching of the information is a more straightforward activity (Poses et al. 1995) suggest the use of structured feedback, availability of and exposure to computerised data bases, statistical training and increasing doctors awareness of the importance of predictive accuracy. A detailed discussion on how to modify physicians behaviour is provided in chapter 9. Bayes theorem is proposed by Sox and Blatt as a method for using the new information regardless of source, to make decisions.

6.6.1.5 Summary

Information concerning the probability of disease is provided from two sources, personal and published experience. This information is often assessed incorrectly by the physicians and this can lead to poor diagnosis and ultimately poor pharmaceutical decision-making. Incorrect usage of heuristics and difficulty with statistics are causes of this.

Work including ***Trading Off***, suggests that in order to reduce these errors physicians should be instructed in the use of heuristics and be made aware of common errors. Information on the use of statistics is unlikely however to improve the physicians use and knowledge of them. This source of data is also limited in its availability and quality.

Initially physicians must be encouraged to utilise this type of information rather than the subjective probabilities currently employed. The causes of ***Self-Referencing*** suggest which features of the data and source are important and therefore can be used to achieve

this goal. Further instructions on how to use information and other techniques to modify physicians behaviour are supplied in this chapter and chapter 8.

Before a review of use of new information to refine probabilities can take place it is necessary to define and outline "formal decision techniques" (Bockenholt and Weber, 1992). This is because these techniques become incorporated into the development of the differential diagnosis process

6.6.1.6 Formal Methods

Formal decision techniques used in medical decision-making involve:

" adding to intuitive decision-making techniques for incorporating quantitative information in an organised and logical fashion" (Bockenholt and Weber, 1992) p290. They can provide valid and rigorous support mechanisms therefore for the intuitive (and flawed) decision-making approach used by doctors

The following methods were classified by (Pauker and Kassirer, 1987) as "formal" into:

1. Methods using the updating of probability information e.g. Bayes theorem
2. Problem Structuring using decision trees.
3. Sensitivity Analysis
4. Utility Assessment (measuring patients preferences)
5. Decision Automation e.g. flowcharts and expert systems

In their assessment of the use of these formal methods (Bockenholt and Weber, 1992) found that 1) Methods using updating probability information and 2) Decision Automation were the predominant ones reported in clinical journals. This was within a set of findings that concluded that whilst increasing the use of formal methods in practice was still very low. This low level of usage is in contrast to the need for methods to improve the decision-making of physicians.

6.6.2 Understanding New Information

Bayes Theorem.

Bayes Theorem is proposed as the method that should be used in assessing new information concerning the patient. A number of quantitative methods develop from Bayes theorem for assessing the effect of new information on the likelihood of a disease. These methods, including tree diagrams and 2*2 matrix, are however, unwieldy in the context of the time restricted medical environment. Indeed (Sox and Blatt., 1988) admit that Bayes theorem is difficult to use without a paper and pencil or calculator. The issue of skills and facilities for using quantitative and formal methods is highlighted by the recommendation of this theory in medical decision-making.

Bayes Theorem does however contain useful ideas for dealing with clinical information. Significantly, it states that the meaning of new information depends on what is already known about the patient. Indeed Sox and Blatt said this idea was "perhaps the most important idea in this book" (Sox and Blatt., 1988) p98.

Whilst Bayes theorem serves as an accurate if somewhat impractical method for integrating new information, it has to be remembered that data in medicine from either published or personal sources is often inaccurate. It is important therefore to assess this accuracy if the data is to be used to base a decision on.

6.6.3 Assessing the Accuracy of clinical data

The accuracy of clinical tests and the data they provide is an additional area for uncertainty in medicine. It is vital to establish whether the test is providing a false positive, false negative, true positive or a true negative picture of the disease. Action or inaction based on one of these types of finding can have very serious consequences for the patient and the doctor alike. For example, if a false negative result is received for breast cancer screening and no action is taken, this may well have fatal consequences for the patient.

Sox and Blatt suggest a number of ideas and formulas for investigating the test performance and the accuracy of the information. These include the use of ROC curves, true positive rates and false positive rates calculations.

Measurements and tests are provided to determine the accuracy of clinical data in a strict quantitative format. For the tests to be accurate and for the results to be discriminative they must be used with patient's whose characteristics match those of the population used to originally validate the test. This matching process (albeit performed mathematically) is based on the same ***Focused***, correspondence principals that the pattern recognition aspects of ***Self-Referencing*** and ***Surrogating*** are.

These strict rules provide a rigorous approach to the teaching of medical decision-making and theoretical principles for the development on clinical aids. They do not however provide useful, practical aids to the highly idiosyncratic, time pressured environment of current medicine.

6.6.4 Decision Analysis (Problem Structuring and Sensitivity Analysis)

Decision analysis allows decision-makers to further understand the problem that they are faced with. It can also help in the choice of the alternatives that are objectively most likely to benefit the patient. Decision analysis should be highly focussed to the problem at hand to ensure that it provides the doctor with the information needed to understand the problem. Work by (O'Meara et al. 1994) and (Llewellyn-Thomas et al. 1996) has stressed the importance of using the patients own values when analysing decisions.

Sox and Blatt suggest the use of decision trees and performing sensitivity analysis (to test the conclusions drawn) to fulfil the objectives of decision analysis. Whilst this provides a useful educational tool showing the step by step approach to the analysis, it represents an unwieldy tool for everyday usage.

6.6.4.1 Decision Trees

The creation of a decision tree involves a detailed mapping out of the problem area and the possible clinical alternatives. Probabilities are attached to each of the possible outcomes of the alternatives and then values for the most desired outcomes are calculated. For example, if quality of life is seen as most important outcome by a patient then the expected quality of life scores are calculated for each treatment and its possible outcome results. Appendix Twenty One holds an example of a decision tree comparing medical and surgical treatments.

The data on probabilities and alternatives should ideally come from reliable published data, however this may not exist or be available and the doctors evaluation of probability may have to be used. This therefore reflects the use of data from ***Surrogated*** and ***Self-Referenced*** sources. The subsequent choice based on a patients preferred outcome is in itself similar to how ***Trading Off*** proposes clinical decision are made.

6.6.4.2 Sensitivity Analysis

A further complication with the objective probabilities used in decision analysis is that there is likely to be a range of equally reasonable values that can be used. Sox and Blatt describe this as values that can be used "with nearly equal confidence" (Sox and Blatt., 1988) p162. This leads to the need for Sensitivity Analysis

This reflects a test for the stability of the conclusions drawn from a decision tree when other reasonable probabilities are used. It relies on the use of a number of probability values within the reasonable range and checks by calculating the expected value to see if the decision is sensitive to that factor and for that range.

6.6.4.3 Problems with Decision Analysis Proposed By Sox and Blatt

The use of decision trees and sensitivity analysis as described above will provide an objective calculation of the alternative to be chosen. This method is however restricted in the combination of outcomes that can be represented and the depth of information that can be displayed. For example, a particular patient may want a treatment that provides her with a high chance of survival for a minimum of 5 years. If this is not possible she wants a high quality of life for at least two years.

Decision trees are complex in their structure and time consuming in production, the development of diagrams for multiple desired outcomes and the ranking of alternatives by the patient leads to this method becoming too complex and difficult to use.

6.6.4.4 Developments in Decision Analysis

The key to future developments in decision analysis and increasing it's clinical usage is being able to reduce the time taken to produce the decision tree, perform a sensitivity analysis and to carry out the complex calculations. These tasks must however be performed while retaining specificity to the problems at hand and adjusting the analysis to the values of the patient

To help with the use of decision analysis, computer programs have been used to remove the computational burden from the doctors and to help with the design process (Pauker and Kassirer, 1981). Decision analysis of this kind can be a practical clinical tool and have been used to analyse decisions in a number of areas including: Estrogen replacement therapy (Elstein et al. 1986), Streptokinase and Heparin usage in deep vein thrombosis (O'Meara et al. 1994) and Coronary artery surgery (Pauker, 1976).

These authors suggest that using these programmes will deal with the need for rapid assessment of different outcomes suggested earlier as a requisite for making Decision Analysis practical. Whilst these programs do speed up the process it has to be

remembered that a program to be practical itself will have to be reliable and easy to use within for example a 7 ½ to 10 minute GP consultation.

The issue of the quality of the data put in to the programs is also crucial. It was mentioned earlier that the published statistics might not be available for the particular problem with the particular patient type that is being faced by the doctor. In this instance, the statistics used might reduce the reliability of the answers produced. Therefore a further area for the development of computer aided decision analysis is the production of these numbers.

6.6.4.5 Conclusions

Sox and Blatt provide a mechanical method for analysing decision using tree diagrams and sensitivity analysis. These methods are difficult to use, time consuming and are prone to poor conclusions if the information used to produce them is not reliable and valid. Computer programmes have been used successful for a number of years to reduce the burden of production and calculation. Issues of time and statistics remain because of the length of typical consultation and the quality of data available.

These must be addressed if these techniques are to be used to replace intuitive decision analysis. The accurate analysis of problems provides a further area for reducing undesirable outcomes of all forms of medical decision-making.

The preceding sections have dealt with the issues and decisions surrounding the development of an accurate picture and understanding of the problem faced by the patient and the doctor. This has been looked at from a perspective of how decision-making should be performed, and how this has been taught to medical students. The next section will look at the theoretical representations of the actual process of making decisions based on the judgements formed during these earlier steps.

making should be performed, and how this has been taught to medical students. The next section will look at the theoretical representations of the actual process of making decisions based on the judgements formed during these earlier steps.

6.6.5 Decision-making

6.6.5.1 Expected Utility and Expected Subjective Value Theories

This section will look at the medical decision-making literature that has used Expected Utility and Expected Subjective Value theories in investigations of the decision-making process. The individual theories, their components and principles have been reviewed in chapter 4. Therefore this review will concentrate on the type of medical decisions studied and theoretical and methodological issues.

Following this, conclusions will be drawn on the following areas:

- The ability of these theories to explain and represent decision-making behaviour.
- Their use as methods of study.
- Their use as the theoretical basis for educating and changing medical decision-making.
- Recommendations for future developments.

This section contains examples of the use of formal methods to explain how medical decision-making is actually performed.

The term Expected Subjective Value Theory covers a number of well known and widely used theories that have been proposed to explain decision-making and behaviour. These include Prospect Theory and the Theory of Reasoned Action outlined in Chapter 4. These theories are based on the premise of Subjective Expected Utility first suggested by (Edwards, 1954) as a development of EUT. Simply put, this idea states that the outcome

chosen will be one that the decision-maker perceives will be most likely to provide them with the most of what they want. This is a similar position to that held in ***Trading Off***.

6.6.5.2 Expected Utility Theory.

Methods and principles from Expected Utility Theory have been used extensively in the study of a number of issues within outcome research and patient preference decision-making. For example, (Torrance G W et al. 1972) used EUT and specifically the principle of utility maximisation to propose a model to assess the effectiveness of treatment programs on the health states of a population.

Sox and Blatt propose EUT as a means of discovering patient's preference for an outcome amongst alternatives and incorporating them objectively into decision-making based on the maxim of highest utility. Whereas (Webb and Lloyd, 1994) used it to obtain information concerning the actions patients expected their doctors to make, i.e. write a prescription or refer them. EUT has also been used to obtain outcome preferences for specific diseases, (McNeil et al. 1981) used it to test hypothetical preferences for quality vs. quantity of life in cancer of the larynx.

The assessment of preferences needs to be focussed to the specific problems faced by the patient and has to be in a form that the patient can understand. An article by (Hazen et al. 1991) concluded that techniques used in utility assessment lead to questions being asked which are "unfamiliar to most patient...and do not reliably extend to the application at hand" P 294. This critique shows the problems of using techniques that are not ***Focused*** to the individual patient's situation.

If the EUT assessment is focussed to the specifics of the patient then it should accurately reflect the patient's preferences in the situation described and informed decisions should be calculated. It is debatable though according to ***Trading Off*** whether the level of detail available in the preference scenarios is sufficiently ***Focused***.

capture this sufficiently by a standardised, quantitative methodology is at best a poor way of trying to achieve this and at worst doomed to failure.

Summary:

EUT and it's principles have been proposed and used as methods of utility assessment designed to discover patient's preferences for treatment and using these to direct the treatment choices. It's success at achieving this is dependent on how closely it is able to match the situation it is trying to measure with the one constructed in its preference scenarios.

The step by step approach to performing EUT provides a useful model for educating decision-makers and as a framework for the development of patient preferences and clinical decision aids. Through it's use in education it can be used to make doctors aware of issues that should be taken account of. The technique is however, in line with formal techniques generally, time consuming and unwieldy to make decisions in clinical situations.

6.6.5.3 Standard Reference Gamble

The use of the Standard Reference Gamble, which constitutes a critical step in EUT, has also been employed in the area of patient preference decision-making. This method is able to provide the researcher with ordered and scaled information concerning patient preferences and more importantly, a common scale for outcome evaluations (O'Meara et al. 1994).

Similar to the use of EUT, the standard reference gamble (SRG) has also been utilised to discover patient's preferences for outcomes. (O'Connor et al. 1987) applied it to cancer sufferers to discover their preferences for quality and quantity of life. (McNiel et al. 1982) had previously used it in the area of oncology to discover preferences for radiation or surgical therapy.

6.6.5.4 SRG and Developments in Preferences Assessment

The preferences of patients for a particular outcome/s of treatment are a fundamental goal for treatment that the doctor should take into account when therapies are chosen. It is important therefore that research into patient preferences is reliable and valid. To this end, the SRG has been the focus of study and developments on how best to extract preferences.

(Llewellyn-Thomas et al. 1982a) looked at the SRG and found however that this method was internally inconsistent. They found that when the outcome of the gambles they put forward were altered these changed the values expressed by patients. This violates one of the principles of expected utility that states that the value placed on a particular condition should not be influenced by the gambles outcome. This therefore greatly reduces its use as a method of value measurement.

6.6.5.5 Probability Trade off Method

The previously discussed problem with utility oriented approaches has lead to the use of probability trade as an alternative method of outcome assessment. A number of authors (Ubel et al. 1996; O'Connor et al. 1987; Llewellyn-Thomas et al. 1996; Read et al. 1984) have used this technique and argued that it overcomes the lack of description in SRG approach.

(Llewellyn-Thomas et al. 1996) describe this technique as involving the use of clear descriptive and probabilistic information concerning alternatives that is presented to respondents in columns. It is then the patient's task to choose an option and via manipulation of the rejected options probabilities, the strength of the patient choice is tested.

This technique has been used in a number of areas of medicine including the study of lifelong hypertension and hypercholesterolemia treatment and the "Do not resuscitate" order (Percy and Llewellyn-Thomas, 1995; Llewellyn-Thomas et al. 1994; Llewellyn-Thomas et al. 1995).

Extensions

Its use has also been extended from two alternatives to three by (Llewellyn-Thomas et al. 1996). These authors, who have been very active in the area of patient preference discovery, used this technique to assess preferences between 3 treatments for benign prostatic hyperplasia (BPH). They concluded that this technique was able to generate meaningful preference scores for 3 alternatives.

This attempt to widen the number of alternatives considered is an important development as it exposes the method to more realistic contexts. The majority of problems in medicine have more than two potential treatment options that can be considered. This can be seen more easily when it is noted that watchful waiting and rest can be classified as treatments. In this case, methods for determining preferences should be able to deal with the full number of alternatives that would be considered in an actual decision-making situation. In many instances this is greater than three however.

The SRG and probability Trade off technique have been compared and tested in their ability to extract respondent's values. (Read et al. 1984) found that SRG ratings were higher than those using a Time trade off method when studying a group of physicians values for outcomes from Coronary Artery Surgery. These authors concluded that these methods were not interchangeable despite previous studies showing a relationship.

(Ubel et al. 1996; Read et al. 1984) tested and compared these methods against a number of rationing choices and found that the values obtained from SRG and Probability Trade off were inconsistent with those obtained from the rationing choices. It was suggested that these inconsistencies might have been caused by the Trade off

techniques being too difficult to perform, that individuals themselves are inconsistent or that the construction of these methods resulted in inherently different tasks being tested.

This explanation is likely because of the different focus either personal or social, on the situations i.e. what would you trade off and what third party group of patients would you prefer to see treated. The issue of personal inconsistency will be dealt with later in this section.

These authors concluded that Trade off and SRG techniques were effective in eliciting and scaling preferences but doubts were raised as to whether the relative values attached are accurate. I.e. they are confident that meningioma problems are seen as worse than cyst problems but not by how much.

6.6.5.5.1 Summary

Overall there are doubts over the reliability and validity of both the SRG and Trade off techniques as methods of eliciting preferences. There is a lack of contextual information and realism used in these methods therefore they fail to represent accurately the decision situations. The respondents are unlikely then to have the same level of emotional and cognitive involvement evoked as they would if they were confronted with this choice to make in a real life situation.

Despite using the term "Trade off" the work reviewed above represents a restricted form of the process discovered during this research. The development of the Probability Trade Off methods to include 3 pairs of alternatives does not represent the complexity of decision-making faced by physicians. It's further development to cope with the number of alternatives considered in a particular decision scenario is possible from methodological standpoint however it's practicality is restricted. Therefore it represents a useful experimental technique and one which can demonstrate to physician and

patients the process of ***Trading Off*** to achieve a preferred decision. The ***Trading Off*** process from this research however provides a more realistic and detailed teaching tool.

6.6.5.6 Further Reliability and Validity Issues in preferences measurement

The questions of reliability and validity of the measures is however complicated by number of factors. How the questions and statements are worded and framed are known to effect choice and this has been shown in a preference context by (Llewellyn-Thomas et al. 1992; Percy and Llewellyn-Thomas, 1995; Read et al. 1984). There is also debate over the ability of patients to produce rational decisions and the consistency of their preferences for outcomes (Llewellyn-Thomas et al. 1982b).

(O'Connor et al. 1987) showed consistency in patients choices before and 6 weeks after chemotherapy. (Llewellyn-Thomas et al. 1984) in a specific study of this issue using patients with laryngeal cancer concluded that preferences were stable in the short-term and unaffected by changes in the patients state.

However (Boyd et al. 1990) and (Christensen-Szalanski, 1984) suggest that preferences do change. (Christensen-Szalanski, 1984) showed that women preferences for anaesthesia during labour changed from pre-birth to one month post birth.

6.6.5.7 Conclusion

The conclusion to be drawn from this debate is again one of the importance of the context in medicine and medical decision-making. It is not surprising that patients who are dealing with the trauma of cancer and a high likelihood of death are constantly willing to deal quality of life issues for an increased chance of survival. It is not difficult to understand why the very painful memories of childbirth are likely to drive women to change their attitudes to anaesthesia!

The preceding sections have outlined the use of EUT, its principles and the SRG in the measurement of preferences within a range of medical contexts. It has also looked at the use of the probability trade off method that represents a patient value based development to this approach. The basic principles of the EUT and the development of the expected subjected value approach have also formed the basis of models used to explain how physicians choose drugs. This work will now be looked at.

6.6.6 Pharmaceutical Decision-making

6.6.6.1 Drug Choice Model (Segal and Hepler, 1982)

Segal and Hepler devised and tested a cognitive model of drug choice that is based on two principles. The first of these is that the prescriber forms beliefs about the probabilities of certain outcomes that would arise from various treatment choices. Secondly, the prescriber attaches personal values to these outcomes. This represents an expected subjective value approach to this problem, of the type that were reviewed in chapter 4.

In the original work Segal and Hepler tested whether this model was able to predict prescribing in a hypothetical case of a mildly hypertensive patient. They found that the model was able to predict 72% of drug choices and that both outcome values and the beliefs about treatment effect contributed to this level of accuracy. These results therefore supported both aspects of their approach.

Further work to test the model under actual clinical conditions was reported in (Segal and Hepler, 1985). In this study disguised case studies of fictional and actual patients suffering from hypertension or maturity-onset diabetes mellitus were presented. Outcome beliefs, the values attached and treatment recommendations were measured. The results showed that the model predicted prescribing intent in 81% of hypertension cases and in 87% of the diabetes cases and actual prescribing in 76% of hypertension

cases and in 70% of diabetes cases. However, unlike the earlier study only the beliefs as to the probability of outcomes contributed to these statistics.

The importance of beliefs concerning outcomes suggests that doctors prescribe to a pre-set goal and the likelihood that this goal will be met is a crucial part of choosing drugs. This is similar to the ***Trading Off*** explanation that suggests that goals for treatment are set during a period of ***Focusing*** and that building the doctors confidence in treatments to fulfil this goal dictates how the ***Trading Off*** process develops.

The authors suggest that the lack of contribution by the value placed on these outcomes may be due to a measurement issue. They suggest that it may be due to the doctors in this study (unlike those in the original) ranking the outcome values in a very similar fashion and therefore concealing their effect on choice. The methodological differences between these studies may also account for this.

The authors go on to discus their findings that showed that doctors beliefs concerning the effects of drugs differ from patient to patient within the same general disease group. This is very similar to the central points of ***Trading Off*** which says that doctors treat cases individually after a close and detailed examination (***Focusing***) and base their decisions on pattern recognition (***Self-Referencing*** or ***Surrogating***) based confidence (***Trading Off***).

This belief concerning the effects of drugs is a reflection of experience showing them that patient reactions to treatments and diseases are idiosyncratic, therefore patients have to be treated individually. This leads to the drawing up of a detailed picture of the patient and then when deciding on a treatment, looking to see the reaction of similar patients as guides.

The benefit of experience is the volume of cases and patient profiles that they have seen with a particular problem that gives them knowledge of a wider number of extremes and

variations that the disease may manifest itself. Their confidence in a treatment needs to be built on something and basing it on the reactions of similar patients they have seen is an accessible and reliable source. When this is not available then ***Surrogating*** this experience from others is undertaken.

The issue of prescribing intention is raised in the article by (Segal and Hepler, 1985), as the results show that intention to prescribe is not always followed through. This leads to speculation as to which factors interfere with this intention to behave. The suggestion is made that it may be due to near indifference between drugs. This issue of an intention-behaviour link opens further areas that need to be studied beyond the beliefs and values of outcomes. These areas will be developed as further expected subjective value theories are looked at as models of medical decision-making.

Segal and Hepler acknowledge that the results are limited by the design especially the convenience sampling. They propose (Knapp and Oeltjen, 1972) (Harrel G D and Bennet P D, 1974) (Lilja J, 1976) as support for their model overall however as these authors also found medical decision-making being performed according to a cognitive model. The cognitive basis used by these authors is in the form of behavioural intention models that will be reviewed at the end of this section.

6.6.6.1.1 Summary

The drug choice model proposed by Segal and Hepler is a useful model based on a expected subjective value approach to decision-making. Its applications have shown mixed results concerning the value placed on outcomes by prescriber, this may be due to the methodology used or the situations that it was tested in. It does however add weight to the argument behind the cognitive model of decision-making behaviour. The results concerning the intention-behaviour link also suggest that there are further factors that need to be added to the theory to explain more effectively medical decision-making.

The expected subjective value basis of this approach and the behavioural intention link are also seen in the work of Ajzen and Fishbein, particularly their Behavioural Intentions model and Theory of Reasoned Action (Fishbein, 1963) (Fishbein and Ajzen, 1975) (see chapter 2). The work using EUT, its principles and expected subjective value theories which was develop from it, does not refer to this similarity in basis between these two literatures. They both however share the characteristics of behaviour being based on expectation, a subjective nature and on the value to the individual not the objective utility. The work of these authors has been the basis of a considerable amount study on the explanation of the medical decision-making process and as the theoretical basis for intervention to improve it. The work concerning the explanation of medical decision-making will now be reviewed in depth, the use of the TRA as a causal pathway will be outlined and further develop in the chapter on prescribing influences.

6.6.6.2 Further Expected Subjective Value theories

Work based on the Theory of Reasoned Action.

The Theory of Reasoned Action (as detailed in chapter 4 proposes that in order to predict behaviour, the subjects intention to perform the behaviour needs to be accurately measured. In turn, this intention to behave consists of attitudes toward the behaviour and a normative component allowing for the concerns of 3rd parties to be taken into account.

This model and it's earlier versions provide a framework of factors (attitudes and normative effects) that have been shown to determine behaviour and also the constituent parts of these factors which are important for each behaviour. (Sutton, 1987) states that choice based on the TRA represents the option with the highest subjective expected utility where subjects will choose an option that brings them more of what they want and less of what they do not want.

(Harrel G D and Bennet P D, 1974) used the Behavioural Intention model and showed that there was a significant relationship between the attitudes toward the action of prescribing individual brands and intention to perform this behaviour. The results of this study did not show a relationship between the normative factors and behavioural intention or between intention and actual behaviour.

The results of this study lead to important points concerning the explanation of pharmaceutical decision-making and of the use of Behavioural Intention models. These authors provide evidence for the individuality of each decision context by showing that the different brands tested possessed individual attribute structures.

They also showed that prescribing for diabetes mellitus is driven by attitudinal factors, whereas other studies have shown different behaviours to be primarily under normative control (Epstein et al. 1984; Lilja J, 1976). This highlights the use of this model in directing interventions to change and modify behaviours. It can show whether behaviour is under attitudinal or normative control and within these factors which beliefs and normative elements direct the behaviour specifically. In turn work discovering the important factors in particular behaviours, can be used to design and target educational interventions more effectively.

For example, (Lilja J, 1976) showed that the effect of the drug was by far the most important belief concerning prescribing for adult onset diabetes and pneumococcal induced pneumonia. This information could be used by pharmaceutical companies in designing their marketing communications. {Soumerai & Avorn 1990 ID: 300} also found the importance of beliefs in their study of the use of pharmacists as drug informants. They used Fishbein's Behavioural Intention model and found that beliefs concerning the pharmacists ability to answer the questions and the type of question were the most important factors.

The variation and individuality of the factors controlling these behaviours is shown in work by (Epstein et al. 1984). This study showed that when studying actual prescriptions of anti inflammatory drugs, beliefs were not correlated to behaviour whereas the attitudes to cost were. This demonstrates not only that in this behaviour cost is important, but also that changing attitudes rather than beliefs toward cost is more likely to result in a change of behaviour.

The finding of (Harrel G D and Bennet P D, 1974) concerning the relatively low correlation between prescribing intention and actual prescribing (average r= .40) highlights once again the issue of further intervening factors that are not accounted for by this approach. It is suggested (and supported by ***Trading Off*** and particularly ***Focusing***) that this is partly due to the actual prescribing situations differing from the one that is presented in the study. This is despite the strict guidelines set out in (Fishbein and Ajzen, 1975) that describe how the behaviour under scrutiny should be described so it corresponds closely to the actual behaviour. These differences may lead to small but significant differences in patient conditions that may lead to alternative drugs being used.

(Harrel G D and Bennet P D, 1974) lend further support to the ***Trading Off*** recommendation for the ethnographic study of pharmaceutical decision-making. They state that "the behaviour response in the questionnaire is placed in a circumstantially different setting than the actual prescribing response demanded by a particular patient" (Harrel G D and Bennet P D, 1974) p276.

This finding concerning the need for ethnographic study is also supported by (Sutton, 1987) whom reviewed the use of the TRA in the study of addiction. During this review Sutton discusses the problem with questionnaire based approaches for studying behaviour. Specifically it is argued that a trade off has to be made between adding sufficient numbers of variables in order for it to construct a life-like picture and the questionnaire becoming too long and impractical.

Criticism are also aired concerning the TRA being unable to account for the role of past and current behaviour on future behaviour (which is so crucial for addictive behaviour). These factors lead Sutton to conclude that the TRA approach is a useful source of ideas in explaining and predicting addictive behaviours. However, questions remain concerning its overall legitimacy in addictive or habitual behaviours that are not under reasoned control. This is hardly surprising considering the title of the model and the areas of behaviour it was designed!

The work by Sutton also sets out an objective for developmental work for the TRA so that it is able to incorporate the effect of past behaviour and explain habitual and addictive behaviours. The use of the TRA is seen in it's use as a causal pathway for directing change and modification strategies. This area will now be addressed.

6.6.6.3 TRA as a Causal pathway

The Belief-Attitude-Intention-Behaviour pathway contained in the TRA showing how behaviour is formed therefore provides a pathway on how to influence this process and change it. Indeed (Soumerai et al. 1989) are explicit in using the Behavioural Intention theories as models around which educational interventions are based. This work on modification and change of medical decision-making will be reviewed in chapter 8.

Research has shown that this pathway does have a level of utility in directing behaviour. For example (Melville and Mapes, 1980) showed that higher levels of knowledge concerning a dangerous drug -Prolactol, lead to it being relinquished more quickly. (Schectman et al. 1991) looked at the use of memos and reminders to increase the usage of a particular diagnostic test and showed an increase over a 12 month period.

Further work showing the use of this pathway in education and how best to design is provided in chapter 8. As discussed previously however, a body of evidence exists that

suggests further issues that can disrupt this pathway. (Epstein, 1991) in an editorial article commenting on (Schectman et al. 1991) suggests a number of these factors. He mentions financial issues, social concerns, fear of malpractice suits, personality traits and patient preferences as possible factors that depending on the context may interfere. (Lomas et al. 1989) also showed the difficulty that education has with changing behaviour. These barriers were classified as Social, Administrative and Economic.

The TRA has been developed to include a measure of perceived control over the situation. This is designed to incorporate the perception of respondents concerning the worth of attempting this behaviour or whether they perceive barriers to it and therefore do not. For example, positive attitudes toward prescribing Viagra ™ may be formed and it may be seen as a behaviour supported by significant others. However as it is not widely available on the NHS and private prescriptions may be too expensive for a particular patient then the doctor may not prescribe it. This development is called the Theory of Planned Behaviour (Ajzen, 1985) and provides a useful development for the issues raised above concerning interruption of the TRA's causal pathway.
Unfortunately, this model does not appear to have been used in medical decision-making research.

6.6.6.3.1 Summary

The TRA and Behavioural Intention model have been studied as frameworks to explain medical and pharmaceutical decision-making and as frameworks to direct intervention into these behaviours. This research has shown that while they provide useful insights as to how decisions are made and how to intervene there remain further areas such as financial, social and administrative restrictions that need to be taken into account. This research also lends further weight to the individuality of decision contexts and the need to study them separately and in depth.

research also lends further weight to the individuality of decision contexts and the need to study them separately and in depth.

6.6.6.4 Conclusions on EUT and ESVT models in Medical Decision-making

This review has shown that the EUT and ESV theories provide a number of benefits for the study of medical decision-making. The fundamental basis of these theories, i.e. that you will choose an option that you believe will provide you with the most (or some) of what you want, provides a useful summary of the basis of decision-making. The development of EUT (and it's constituent parts) into ESVT (including Drug Choice model and TRA) has refined this representation further. The use of "value" to the individual is able to account for behaviours that would be deemed irrational by Utility based theory.

Trading Off can be viewed as a ESVT that is based on building feelings of Confidence concerning particular choices rather than subjectively calculating evaluations of their value. They are clearly similar, however Confidence emerged as a state that directs decision-making behaviour when studied from a sociological/psychological perspective. As such it can be viewed as a potential refinement to the EUT-ESV theories studied initially from an economic perspective. ***Trading Off's*** discovery from different research perspective provides it with a legitimacy as a potential refinement to the representations reviewed in this section.

These theories while providing an overall explanation for decision-making lack the ability to address the complexities of individual decision situations. This is demonstrated by the Probability Trade Off technique that despite having been extended to account for 3 pairs of choices, still falls short in being able to replicate the number of options assessed in most medical decision situations. The TRA and TPB have been formulated taking into account greater numbers of factors apparent in decision-making, and in doing so have been able to explain more decision-making behaviour. This supports ***Trading***

As a basis for studying medical decision-making the ESV theories especially those based on the Behaviour - Intention pathway provide a useful means of representing this type of behaviour. Improvements can still be made however by accounting for greater numbers of factors. The number of factors accounted for represents however only part of the necessary improvements. Techniques are needed that are sufficiently flexible to study the individual decision-making situation and adapt to what is discovered.

Therefore, the theoretical developments required for the TRA and TPB models (suggested by ***Trading Off***) are a flexible structure that is able to correspond to the individual factors found in an evaluation of the situation. It will remain though based on the overall principles of expected subjective value (or confidence).

Problems with decision-making concerning errors and variations in decisions, data sets, practicality, correspondence of subject to study population and personal issues of physicians has lead to work developing aids for decision-makers. These include the use of computer aids and decision rules; this work will now be introduced.

6.6.7 Computer Aids

The use of computer decision aids can be classified into two separate areas depending whether it is concerned with information provision or with assessing choice. The provision of information corresponds to aids for the initial two and final stages of the generic decision-making process (Need Recognition, Information Search and Feedback). (see chapter 4 for details) The area of assisting choice corresponds to Evaluation and Choice amongst alternatives.

The early use of computers to fulfil these roles appears to have been an attempt to tackle these roles separately. As computing power has developed though, so have the attempts to develop programmes that are of use throughout the process. The early provision of information approach will be looked at and how it has developed into a more analytic

The early use of computers to fulfil these roles appears to have been an attempt to tackle these roles separately. As computing power has developed though, so have the attempts to develop programmes that are of use throughout the process. The early provision of information approach will be looked at and how it has developed into a more analytic information management system. Work on computer aids to choice will then be reviewed

6.6.7.1 Information Provision

Computers have been used as databases in attempts to aid the decisions of doctors. Their storage power was utilised to hold patient information in the form of patient record. This was designed to allow faster access to the patient's details and to allow manipulation and easier cross referencing. (Rogers and Haring, 1979) looked at the impact of a program of this kind on length and incidence of hospitalisation. This work was developed in 1982, when they studied the influence of a computerised medical record system used for summaries in 3 disease areas. They concluded that these programs can help improve both care and outcome of care (Rogers et al. 1982). Work by (Garrett et al. 1986) also looked at the effect on quality of care.

This use of programs as databases developed into information management as computing power developed. (Chase et al. 1983) designed a "Medical Information Management system" that was able to "solicit, record analyse and distribute patient data". They then studied the ability of this program to aid in the identification and referral of high risk patients. They were able to concluded that an information management tool of this type was effective for improving pre-surgical care.

(Whiting-O'Keefe et al. 1985) compared a paper based and a computerised medical record system that summarised information for the doctor. They concluded that the summary system added information to that provided by the traditional method and that this could improve the clinical decision process.

effect preventative care such as mammographic screening, weight reduction and influenza. Reminders as methods of influencing medical decision-making will be examined in greater detail in chapter 8.

6.6.7.2 Assisting Choice

The rapid advance in computing power and its increasing ability to deal with greater and greater amounts of data have lead to increased use of sophisticated programmes to aid medical choice. The areas of choice that have been aided include diagnosis, signal detection and image processing (Miller et al. 1992; Rogers et al. 1994; Weinstein et al. 1994). However, the use of computers programs has been delayed by issues of dealing with problems inherent in medical information, these issues mirror some of the problems that interfere with doctors making correct decisions.

For a program to produce results that are at least as good as experts, it must be provided with an accurate data set and be able to deal with any imperfections in this set. Unfortunately the information provided in medicine (and the life sciences more widely) is often incomplete or flawed. They may be working with small data sets, missing information and categories of problems that have a low incidence. The information is often based on an incomplete understanding of the biological system and how concomitant diseases effect the problem under scrutiny. The information from tests also poses problems with common problems being a lack of certainty about the normal ranges of biological measures and test imprecision (Akay et al. 1997).

These issues combine to make the use of straightforward algorithms in computer programs difficult. This has lead to a number of different attempts to cope with these uncertainties. For example via pattern recognition (Patrick et al. 1974), knowledge based approach (Gorry, 1973), fuzzy logic (Akay et al. 1997) and neural networks (Penny and Frost, 1996).

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6.6.7.2.1 Neural Networks

Neural networks are an attempt to replicate the adaptive reasoning of human thought using computers. (Penny and Frost, 1996) reported on the type and level of use of these programs. They report a study by (Weinstein et al. 1994b) that found 386 applications of neural networks in biomedical science. This compares to a similar study by (Jackson, 1990) which found less than 20.

The areas where neural networks have been put to use include computer aided diagnosis, medical imaging and signal processing and cancer research (Rogers et al. 1994; Miller et al. 1992; Weinstein et al. 1994a).

The development of neural networks in medicine involves training the network with large numbers of cases involving a number of "input vectors' i.e. history or E.C.G findings. For example, (Baxt, 1991) used 351 cases and 20 input vectors in a net used for diagnosing myocardial infarction. In this instance when used to diagnose 331 cases, it was found to be more accurate for both positive and negative cases than clinicians.

The issue of the training set provides important backing for the idea of expertise and the preference to use ones own knowledge (as explained in ***Self-Referencing***). ***Self-Referencing*** is based on the doctor having an internal knowledge base concerning the problem at hand that is sufficiently large for them to have confidence in matching it to the problems and situation held by the patient. I.e. their experience of similar patients and scenarios has equipped them with enough knowledge that they can confidently predict that the patient being dealt with will react in a certain way to the treatment that

they will provide. Hence they use the treatments they are familiar with in this ***Self-Referenced*** source.

The reasons for the success of (Baxt, 1991) may be due partly to the high number of clinically important factors that it was able to take into consideration. ***Focusing*** suggests that accurate and reliable diagnosis and treatment depends on detailed, wide and deep look at the situation of the patient. This goes beyond the disease itself and into the socio-economic and family circumstances of the patient. This depth of look at the problem allows a number of cross checks to be made concerning missing of confusing data which in turn provides the doctors with more confidence to take a particular course of action.

This success is also partially dependent on the use of statistical techniques such as bootstrapping (Efron and Tibshirani, 1993) and cross validation (Stone, 1974) to deal with the data set issues outlined previously. Neural networks, in their attempt to mirror expert reasoning and their development of certain statistics to deal with data uncertainty, are in themselves a mirror of the issues of information management discovered during ***Trading Off***.

6.6.8 Decision Rules

Introduction

Decision rules are another form of decision aid that have as their objectives the reduction of uncertainty in medical practice. They can be used to guide decisions on hospitalisation, tests and treatment. They are produced by systematically observing clinical situations and deriving rules for how clinical findings in these situations should be used to make predictions (Wasson et al. 1985).

(Laupacis et al. 1997) sets out methodological standards for clinical prediction rules, these included the use of demographic variables, identification of predictive variables

and sound testing and validation procedures. These combine to produce a specific rule that is to be used in a particular population. This is very similar to the use of ***Self-Referenced*** information being used in a specific ***Focused*** problem.

Decision rules can therefore be seen as a quantitative representation to the process of ***Focusing*** and ***Self-Referencing***. Specifically, it is similar to the development and use of personal rules which doctors feel allows them to confidently predict the outcome of certain behaviours. The success or failure of these rules can be seen to be dependent on the specificity of the ***Focusing*** that occurs to define the area and problem.

6.6.8.1 Examples of Decision Rules

(Stiell et al. 1996) tested a decision rule for knee radiography and found it to be 100% sensitive in identifying knee fractures. The rule was also found to be acceptable to the physicians using it and was potentially able to save money by reducing the need for x-rays.

The success of this rule thought to be partly due to it being specific to a well defined population with strict inclusion and exclusion criteria. For example, "include adults, acute knee injuries and exclude paraplegics and injuries that occurred 7 days previously". The doctors involved in this study were experienced physicians who were able to apply the rule easily and rapidly, this is also thought to have contributed to the success of the rule.

(Shipp et al. 1993) successfully developed two models for predicting the outcome Non-Hodgkins's Lymphoma. This success again was thought to be due to the patient specific nature of the models (the second model involved an age adjustment of the first).

Conversely, negative results in the use of decision rules have been found. It is thought that this may be due to the rules being applied to populations that do not match the one it

used when constructing the rules. Comparability was also compromised by the percentage of African Americans being higher in the study groups compared to the development group. This ethnic group is associated with poorer outcomes of CPR.

6.6.8.2 Numbers of Factors in Decision Rules

The ***Focusing*** process involves a wide look at the specifics of the problem faced by the patient and leads to ***Focusing*** in on what are seen as the most important criteria in the decision. There are similarities in the numbers of factors used in constructing successful decision rules, successful neural network applications and this ***Focusing*** approach to defining a decision problem.

These similarities are based initially on the width and depth of factors used in looking at the problem areas. The similarity is maintained by the reduction of these factors to manageable numbers of cues used in the actual rules. These similarities can be seen as a supporting ***Focusing*** as a critical activity in successful medical decision-making.

The knee rule developed by (Stiell et al. 1996) involved using 23 factors and 1047 patients giving a wide focus of the problem and a large number of patients from whom to include variations. Twelve variables were included in the Non-Hodgkins lymphoma model by (Shipp et al. 1993), one for which was the tumour stage. This can be compared to work by (Carbone et al. 1971) that had previously used this as the only variable to predict survival. This can be seen as better ***Focusing*** on the problem leading to a better level of prediction of 5-year survival rates.

The number of factors taken account of is similar to the 20 used by (Baxt, 1991) for the development of a neural net. (Phelps and Shanteau, 1978) showed that experts were able to use 11 separate pieces of information when making judgements.

It may be therefore, that the number of factors that need to be taken into account when ***Focusing*** sufficiently on a clinical problem is greater than 10. Further to this the ability to cope with this number may be a characteristic of expertise development. This would result in information needs go considerably beyond what is understood to be the most important clinical finding (i.e. tumour stage or tenderness).

In both (Shipp et al. 1993) and (Stiell et al. 1996) these numbers of variables were reduced to produce the clinical rules depending on 5 clinical findings. Work by (Phelps and Shanteau, 1978) showing that doctors make decisions based on a few symptoms suggests this minimising approach is a reflection of the process used in intuitive decision-making. This work is supported by (Einhorn and Hogarth, 1981) who discussed the benefits to the decision-maker of reducing the number of cues attended to.

Decision rules and neural networks have the benefit of using computers and sophisticated statistics such as regression analysis to reduce the number of factors needed to produce them as workable models. This is not available to doctors when producing their own rules that are referred to in ***Trading Off*** and heuristics. The restrictions of human memory have lead to selective perception and use of cues (as discussed earlier) when making a decision, ***Focusing*** can be seen an example of this.

6.6.8.3 Conclusion

Decision rules can be useful aids to decision-making where they are used in situations that mirror specifically the situation that the rules were produced in. Their construction should involve a deeper look at the problem than just the most important clinical finding. The successful examples of decision rules take into account large numbers of factors from the problem area and refine these to produce rules based on smaller but critical number of cues. It has been shown that there is a similarity in the number and use of factors in constructing decision rules, neural networks and the approach discovered in

Focusing. In this way decision rules are similar in many respects to the relationship between ***Focusing*** and ***Self-Referencing/Surrogating***.

The making of decisions is not the final aspect of medical decision-making, it is crucial that the outcomes of these decisions are then studied to aid teaching and improve decision in the future. This area will be turned to now.

6.6.8.4 Health Outcomes:

The need for measurement of health outcomes stems from a number of factors. The most important of these is to see whether the objectives of the patient (as set out in their expectations and preferences) are being met by the treatments prescribed. These factors are related to the assessment of the treatments for efficacy in disease terms. Beyond the care outcomes of treatment, there is a need to objectively account for the vast sums of money that are spent on specific medicines, treatments and health programs.

Research into health outcomes provides objective feedback as to the success or failure of treatment on a number of levels. These levels include the individual patient-doctor interaction, the use of specific treatment modalities (specific surgical techniques, specific drugs), wider health initiatives (such as coronary heart disease prevention in specific locations) and health of the nation initiatives.

These initiatives can be assessed in a number of ways including life expectancy, functional status of the patient, QUALY (see Appendix Twenty Two), patient satisfaction with their own health and cost. The formal methods used to calculate these indicators can be used in isolation or in combination to test the success of a programme or treatment.

While they represent a blunt tool in capturing the detail and richness of individuals perceptions of their own health state they provide useful summaries of the use of

treatments and the success of programmes. They also provide important quantifiable checks for doctors whose own experiences may deviate from the norm. This use of formal data is being encouraged and is represented by the move toward evidence based medicine which is being encourage throughout the NHS.

According to ***Trading Off***, the feedback that is received by doctors from these techniques and studies is used to direct future behaviour by its effect on the doctors confidence in the treatment. The data however remains important to the doctor on individual patient basis, for example they are not using Simvastatin because it has been shown to reduce coronary events by 1/3 in the Scandinavian Simvastatin Survival Study of 4444 patients. They use it because this studies result allows them to confidently believe that this drug will allow the individual patient in front of them to live longer and with the likelihood of fewer coronary event. The importance of the numbers and percentages in studies is the ***Confidence Building*** that it allows and the volume of individual patients this study represents

6.6.8.5 Summary

The medical decisions that are made, independent of whether they represent decisions on individual treatments or on health policy, must be studied in order for doctors and wider health bodies to learn and improve future decisions. Formal methods such as calculation of QUALY's and representations of life expectancy are used to this end and provide useful summaries of the effect of such programmes. There is pressure being brought to bear throughout the NHS to base medicine on these forms of evidence and move away from personal experience.

6.7 Conclusions

The preceding sections have provided an overview of formal decision-making and the process of how medical decision-making should be performed. The book Medical Decision-making by Sox and Blatt has been used as a framework because it is recognised as an authoritative look at both this field and as a teaching resource. This structure has also allowed for a description of the formal methods described by (Pauker and Kassirer, 1987) to be performed.

The work reviewed has included the steps for differential diagnosis that represent a generic medical decision-making model. More detailed aspects of decision-making and tools to aid it have then been looked at to provide an insight into a number of the objectives of medical decision-making. These include developing a wide understanding of what medical decision-making is, how it should be performed, how it is taught and what aspects of this research can be used to reduce errors and biases. ***Trading Off*** is integrated into and used to integrate these literatures.

This overview has highlighted the following issues:

6.7.1 As Representation of how Medical Decision-making should be made:

Quantitative medical decision research has been used to represent the process as it should be performed accurately and in detail. Working from a structural rather than contextual background it is able to characterise the steps and calculations necessary to ensure that the option chosen will be the one the provides the highest utility to the patient.

In the context of medicine where uncertainty is ubiquitous and the conversion of this uncertainty is a crucial exercise in decision-making, these steps provide a transparent

guide to reducing uncertainty. It also provides objective methods of calculating which management option should be taken to achieve the pre-set goals of treatment

In doing so it has to make a series of assumptions concerning the goals and abilities of the decision-maker and patient and concerning the information available on the alternatives. These assumptions can be summarised by referring to them as ensuring that there are no restrictions placed on the correct calculation of the option with the highest utility using all necessary information.

In providing a structurally correct method of medical decision-making it sacrifices reality on a number of issues that will be summarised below. It also provides a framework and set of calculations that even if information, ability goals were as assumed would still represent a process that would be difficult to implement under the constraints of the current health care system. A number of support techniques to allow the use of normative processes are being developed. In the medium and long-term, it can be expected that medical decision-making and pharmaceutical decision-making will therefore be performed in this way.

Trading Off provides a legitimate explanation of prescribing decision-making and as such highlights areas, such as ***Self-Referencing*** where errors and poor practice occur. As such it can be integrated into the literature as a starting point from which normative aids can be designed and implemented.

6.7.2 As Methods for Educating Medical Decision-makers

The processes and methods set out by Sox and Blatt developed by other authors provide a logical and sound approach to the issue of educating medical decision-makers.

The training objective is to provide medics with a template for how to perform medical decision-making and to provide them with the skills and aids to perform this. The

current work does provide a logical template for medical decision-making but the actual techniques suggested to perform these steps such as EUT and Bayesian probability updating whilst being clear and well known are impractical to use in clinical settings.

Aids to help perform these difficult calculations are available but are restricted by the availability of specific medical data. Currently therefore doctors can follow the correct steps but must do so using their own flawed cognitive abilities in situations of uncertainty.

The research reviewed in this chapter has provided an understanding of the likely flaws in doctors reasoning as well as methods of dealing with uncertainty. They are therefore providing further benefits for teaching doctors by showing them how to avoid and work around these problems.

The benefits of formal methods in teaching are therefore providing doctors with ability to use the correct procedure and an understanding of the likely errors and biases they will produce using their own cognitive power and heuristics.

6.7.3 As Methods for Aiding Decisions

The formal methods set out by (Pauker and Kassirer, 1987) were found by (Bockenholt and Weber, 1992) to be perceived as being not very useful in helping doctors make decision and are not currently widely used. Reasons for this include a lack of time, ability and information. Procedures such as EUT, decision tree analysis and Bayes theorem are too time consuming and difficult to implement as part of a differential diagnosis in an everyday clinical setting.

These procedures can be of use if incorporated into aids that are quick, easy to use and have shown to work accurately. Computer programs and decision rules have been produced which attempt to aid decision-making in areas such as signal detection or knee

radiography. Aids and rules that have been found to work show a tight ***Focusing*** on the problem area and a strong match between the population used to design the rules and the one it is used for.

The areas that need to be improved to increase the use and usefulness of formal methods as decision aids include speed of delivery, ease of use and reliable clinical information. The development of computer technology and the increase in the volume of quality outcome studies produced (McAlister et al. 1998) will ensure that the logical and accurate framework and procedures will be used more readily in practical medical decision-making.

They capture the structure of decisions at the expense of the content. ***Trading Off*** suggests that it is the situational details of a clinical decision that is primarily used by doctors to make a decision and aids to improving medical decisions should be based on this area.

6.7.4 As representation of how Medical Decision-making is performed

There are a number of levels on which the actual performance of medical decision-making can be assessed. In looking at these levels, the research reviewed in this chapter can be said to be an accurate reflection at the higher levels though does not provide an accurate insight into the psychological process used at a lower level.

On the procedural level the differential diagnosis process represents how medical decision-making is performed in the majority of cases. Deeper than this, the work reviewed concerning the use of Expected subjective value theories represents an accurate picture of the criteria used to make decisions within the overall process. The choice of the option that is evaluated to posses certain desired attributes can be seen therefore as a criteria often used in decision-making. However, the use of theories such Bayes theorem to represent how these criteria are fulfilled and "value" calculated is

clearly false and has been shown to be so by a number of authors. The research reviewed in this chapter does not therefore represent how choice is made amongst alternatives.

Trading Off does provide an answer to this question by suggesting that physicians trade off levels of confidence that have been built (via numerous sources) concerning alternative behaviours. This ***Trading Off*** is performed within a ***Focused***, flexible, individual approach that allows for relevant internal and external factors (as relevant to the decision-maker) to be included in the process. It is therefore different to the Probability Trade Off technique.

The individual influences that are ***Traded Off*** to build Confidence provide the topic for the next chapter.

7 Chapter Seven Factors influencing Treatment choice

This chapter will discuss the individual factors that have been studied and found to effect physician's choices during the individual stages of the differential diagnosis process. It will concentrate on the choice of treatments and specifically pharmaceutical decision-making. Comparisons will be highlighted throughout the chapter with the factors found ***Trading Off*** to be influences.

The literature reviewed in this chapter (chapter 3) discusses the importance of certain factors such as efficacy and side effects in medical decision-making. This develops the discussion in the previous chapter concerning the need for a flexible, individual approach to the influences on decision-making. This individual approach is necessary, however there are a number of factors that are likely to be important in all decisions. These factors will be discussed where appropriate.

As discussed in chapter 5 medical decision-making can be seen as an attempt to match the current store of medical knowledge to the patients problem (Sox, 1987). The physician's beliefs and attitudes used to perform this task are derived from a number of sources including their education, experience and the advice of third parties.

These sources posses a level of influence intrinsic to them that manifests itself in a willingness to use information from certain sources more readily than from others and different degrees of confidence held in the information from them. The discussion of the influences in this chapter will therefore contain an appraisal of these factors and are used to illustrate support for the central role of confidence in ***Trading Off***.

Initially the role of the disease, patient and the characteristics of the treatment will be looked at. A review of physician, colleagues and pharmaceutical company influences will follow this. Finally, the structural influences of the health care delivery system will be discussed. Chapter 8 will then look at how these influences are then used in varying combinations in a number of strategies and programmes to change and modify treatment choice. These programmes will then be reviewed including the efforts of pharmaceutical companies.

7.1 Complaint

The most direct influence on the treatment prescribed for a patient is the complaint that is diagnosed. In some instances it is not necessary for a treatment to have been granted a licence from the FDA or similar government regulatory body or for it to have proven efficacy for doctor to use.

This may occur in areas where there are very limited treatment options such as Multiple Sclerosis where there is use of Interferon despite limited data on its efficacy. It may also happen through intuitions by the Doctor being acted upon, for example the use of NSAID's to relieve period pain or prior to license Cozaar ™ being used to treat congestive heart failure. Empirical usage of this kind is therefore based on the physician's perception of its likely benefits rather than proven actual benefit.

7.2 Patient Characteristics

A number of characteristics of patients beyond the problems suffered have been shown to effect medical decision-making. These will be reviewed under the headings of Demographics, Expectations and Preferences. These aspects are also examined because they support the findings within ***Trading Off***, for the need for wide ***Focusing*** on the problem. They also demonstrate the wide range of factors that are potentially ***Traded Off***.

The review here of demographic variables looks at the variations in practice and outcomes beyond what would be expected from these factors as part of the diagnosis. It looks at the negative effects that have been found in practice and the support this gives for ***Focusing***. A number of the studies reported here make the point that the variations may be due to patient preferences or disease severity however they conclude that they suspect that these variations are due to inequalities (Donovan, 1995; Wenneker and Epstein, 1989; Burstin et al. 1992).

The importance of patient preferences and expectations are based on the positive effect that patient involvement can have in compliance (Donovan, 1995) and the placebo effect. It is therefore an important aspect of influence that the doctor takes account.

7.2.1 Demographics

The age, sex, race and economic status of a patient have all been shown to have effects on treatment choice beyond diagnostic need.

7.2.1.1 Sex

(Ayanian and Epstein, 1991) concluded from a study into the levels of usage of procedures for coronary heart disease that men may be receiving to many procedures or women too few. (Steingart et al. 1991) also found gender based differences in this area of medicine.

7.2.1.2 Ethnic Origin

The ethnic origin of the patient has also been shown to effect treatment choices. (Wenneker and Epstein, 1989) found that in a study of Massachusetts hospitals, black patients were significantly less likely to have angiography of coronary artery bypass grafts. (Yergan et al. 1987) revealed that the intensity of use of hospital services also varied according to the race of the patients. The differential effect of race has not been found in all studies however (Burstin et al. 1992).

7.2.1.3 Age

Age has been shown to vary treatment options for both surgery and chemotherapy. (Bennett et al. 1991)'s findings that older patients (over 75 year olds) received less surgical and radiation therapies compared to younger cohorts add weight to the idea of an age bias in cancer medicine (Greenfield et al. 1982). (Webb and Lloyd, 1994) also found older patients more likely to receive a prescription than younger one.

Trading Off suggest that these differences may be due to the patients ability to tolerate certain treatments, life expectancy and quality of life issues. The work by (Greenfield et al. 1982) and (Bennett et al. 1991) proposes that the contrasts go further than the different clinical needs of patient of varying age.

7.2.1.4 Economic Status

The economic and insurance status of a patient has been shown to have significant effects on the likelihood of medical injury. It has been shown that uninsured patients in New York are twice as likely to suffer from negligent care (Burstin et al. 1992).

7.2.2 Summary

Age, gender, race and economic status have been shown to characteristics of patients that can adversely effect the treatment received. There remains a debate however whether these differences are as consequence of ageism etc or whether the differences are caused by the issues linked to being old or male, interacting with the disease. Overall, it is thought that the effect of these characteristics goes beyond what would be expected from interactions with the disease.

Having looked at physical and fiscal characteristics, the area of mental characteristics of the patient that effect treatment decision will now be looked at.

7.3 Patient Expectations and Preferences

The expectations of the patient have been shown to have a profound effect on decision-making. (Webb and Lloyd, 1994) found that where 51% of patients expected a prescription, 55% received one and that where 13% expected a referral 10% received one. These authors concluded that patient expectations effected prescribing and referral behaviour. The varying levels of this influence may account, in part, for variations in the provision of medicine outline in chapter 5.

These effects on physician's choice may be due to the benefits of compliance and the placebo effect derived from patient involvement in the decision-making process. ***Trading Off*** of patient expectations and preferences was found in areas where there was considerable choice in potential treatments, i.e. large numbers of similar drugs such as NSAID's used for arthritis management. This suggests that this influence is of relatively minor importance and can manifest itself when patient preference will not undermine more important choice criteria.

This section demonstrated that patient preferences change according to the context they are confronted with. Patient preferences are an important goal of treatment that should be respected where possible. This is particularly the case in situations where there are important long term outcomes or the patient has particularly strong preferences for certain outcomes (Kassirer, 1994). This again supports ***Trading Off's*** view of the consultation process as an exercise in initially ***Focusing*** on a wide range of factors and then discovering the critical factors of the problem.

7.3.1 Summary

The effect on treatment decision-making by patient characteristics goes further than the influence these characteristics have on the disease process. Demographics of the patient have been associated with variations in use of surgical and medical procedures that have had negative effects on patient care. The effect of patient expectations is thought to be

based on the positive effect patient involvement can have on compliance and the placebo effect. Knowledge of patient preferences also aid in involvement and also supply the doctor with goals for treatment.

This look at patient characteristics has provided support for the wide-ranging look at the problem context suggested in ***Focusing*** and also the importance of attributes outside the symptoms of the disease. These attributes provide further properties that can be ***Traded Off*** after confidence has been built up in them.

7.4 Characteristics of the Physician

The characteristics of physicians that have been shown to influence treatment choice include levels of knowledge, expertise and personal responses to uncertainly in medicine and demographic variables.

The preference of physicians to use internal sources of knowledge to solve problems is fundamental tenet of ***Trading Off***. This review supports the finding that this is due to the vivid nature of personal experience being more capable of building confidence.

7.4.1 Levels of Knowledge and Expertise

The most obvious characteristic of a physician that influence treatment choice is their knowledge of the problem and treatment options. There is however a debate concerning the effect of greater knowledge of the physician concerning the outcome of this to the patient and how this greater knowledge is used in making decisions. This debate will be dealt with in detail in Chapter 10.

(Boshuizen and Schmidt, 1992) and (Patel et al. 1989) suggest that less biomedical knowledge is used in decision-making as expertise develops whereas (Lesgold, 1984) argue for the use of this knowledge in medical reasoning. This preference for

experience supports the idea of preference for internal experience over external academic knowledge. This may also be reason for the treatment errors discussed in chapter 5.

7.4.1.1 Expertise

This debate is complicated by conflicting results found in the outcomes and influence associated with greater expertise. (Poses et al. 1985) looked at experienced physicians and the accuracy of their probability estimates for streptococcal infection in sore throats. The found that the physicians overestimated the likelihood of an infection by 81%. This result has clear implications for the prescribing of pharmaceuticals. It is thought to be an example of base rate neglect and "value induced bias." This phenomenon appears where the probability of an event is linked to its clinical importance and is perceived to be more likely (Poses et al. 1995).

This bias is however congruent with the dictate in medicine expressed in Sox and Blatt (Sox and Blatt., 1988) which calls for diseases that the doctor cannot afford to miss being dealt with first. This is especially the case if an effective treatment is available. These conditions are both met in streptococcal throat infections and therefore it can be seen as rational to overestimate and treat in this way. It is also congruent with ***Trading Off*** that claims that this fear of missing an important problem becomes another factor that is ***Traded Off*** in favour of the treatment.

(Flood et al. 1984) on the other hand found in a study of nearly 500,000 patients that there was a strong and consistent relationship between higher volume of surgical patients seen and better outcomes for these patient. The results were mixed for medical patients however. These findings may be due in part to the physical skill element of surgery for which repeated and prolonged practice is necessary (Starkes, 1990).

A further issue in the level of experience of a physician and its potential effect on treatment is the finding by (Wilson et al. 1997). These authors showed that more experienced physicians were not able to infer patient preferences with any more accuracy than junior colleagues. This lack of accuracy may manifest itself in treatment decision directed by erroneous preferences.

7.4.1.2 Summary

There is debate as to the effects of clinician experience and knowledge on treatment decisions. Three issues have been raised here concerning how much knowledge is used as expertise develops, whether greater experience leads to superior outcomes for the patients and the ability of more experienced physicians to infer patient preferences. The debate indicates that the intuitive feeling that a more experienced and knowledgeable physician is of benefit is not as straight forward as this and again specific instances of the experience need to be looked at. This is feeling is reflected in ***Trading Off*** which suggests that experience and expertise are found in specific areas.

7.4.2 Responses to Uncertainty

As outlined in chapter 5 medicine is practised in an environment of uncertainty, derived from uncertainty surrounding the diagnosis and patient reaction. This uncertainty is dealt with in different ways by physicians and manifests itself in medical decision-making generally and pharmaceutical decisions specifically. It is also seen as a reason for the variation in levels of use of treatments (Wennberg et al. 1982; Wennberg, 1984).

Physician's tolerance for levels of the uncertainty in medicine differs (Lamberts and Janssen, 1984). This is based on how physicians are able to deal with the feeling that it can lead to i.e. the fear of making a mistake or loss of self esteem (Grol et al. 1990).

It is thought that this reaction is developed partly during training where physicians are taught to avoid taking risks (Shuvall, 19198). ***Trading Off*** suggests that this tolerance for uncertainty is also partly learned and is context specific. It found that unusual and dangerous reactions can lead to a reduce tolerance for uncertainty in similar cases. I.e. an example of one doctor who was very much against the sale of aspirin without tight statutory controls because of fatalities caused by this drug.

(Allman et al. 1985) compared physicians requirements for levels of certainty before and after they ordered tests into possible liver metastases. They showed that 50% of the doctors wanted higher levels of certainty after the test results had been reported than was initially requested. This allied to the desire of 31% of the doctors for absolute certainty suggest that doctors often require too much certainty which in turn leads to over use of diagnostic tests. This result supplies support for the importance of confidence in decision-making.

Risk taking was shown by (Grol et al. 1990) to have an environmental and cultural dimension. They showed that a significantly higher percentage of Dutch doctors are prepared to take risks compared to Belgian and English ones. The nature of the health care environment in Belgium and the location and focus of training in Britain can help explain this. It leads English and Belgian doctors to possess more defensive attitudes to risk and hence treatment usage.

7.4.2.1 Conservatism

A physician's reaction to uncertainty may manifest itself in a therapeutic conservatism. This conservative attitude toward prescribing has been shown in physicians in comparison to the attitudes of pharmacists (Holden and Wolfson, 1996). Conservatism is a property of ***Self-Referencing*** that promotes the continued use of treatments that the doctor is familiar with.

It is characterised in the literature by low levels of prescribing and a cautious approach to adding new therapies to their armamentaria, (Walley, 1993). (Griffin and Griffin, 1992) concludes that therapeutic conservatism as described above harms patients, a judgement disputed strongly by (Walley, 1993).

7.4.2.2 Bias toward Action

A contrasting personal trait to conservatism is the bias toward action reported by (Ayanian and Berwick, 1991). These authors replicated a study by (Bakwin, 1945) that looked at indications for tonsillectomies and the finding that a steady percentage of children (approximately 45%) were recommended for surgery. Ayanian and Berwick found that repeated screening of cases by different physicians (stepwise re-evaluation), lead to more and more patients being actively treated. These results are taken as an indication that doctors have a steady bias for action.

(Ayanian and Berwick, 1991) suggest that this bias may be seen more readily in low risk procedures and is a reflection of the doctors understanding of the prevalence of the disease. This explanation suggests that context and personal expertise may be its cause. In this case, it adds further weight to the importance of ***Focusing*** and ***Self-Referencing*** in pharmaceutical decision-making.

7.4.2.3 Overconfidence

Overconfidence in ones judgements is further personal factor related to uncertainty in medicine that influences prescribing. It can lead to treatments being based on poor (but confidently held) judgements of the likelihood of disease and the efficacy of the treatments. This issue was reviewed in detail in chapter 6.

7.4.2.4 Perceived threat of Litigation

A further influence on decision-making (that was also highlighted in ***Trading Off***) is the real and perceived threat of litigation for negligent behaviour. This is a growing issue within medicine in the UK and may contribute to the practice of defensive medicine. Aside from the fear of litigation influencing the choice of drug, it has been shown by (Reynolds et al. 1987) in the USA to affect treatment by absorbing a large percentage of the cost of medical service. These authors found that 15% of physician's income covered their professional liability. Therefore, less care is being purchased because of measures protecting against litigation

7.4.3 Demographic Variables

Characteristics of the physician such as sex and country of training have been shown to influence prescribing. For example, (Davidson et al. 1994) found that physicians who were classified as high prescribers were more likely to be male and trained in Canada. (Grol et al. 1990) also showed that nationality can effect prescribing behaviour.

7.4.4 Summary

The characteristics of a physician can have important consequences for treatment decisions. It has been shown that demographic and cultural variables such as sex and nationality can effect the medicines chosen. The issue of physicians expertise and knowledge on decision-making is a contentious one that will be addressed in greater detail in chapter 10. However, the brief review made here suggests that varying levels of knowledge and expertise do effect decisions and how these are then performed.

The uncertainty inherent in medicine leads to a number of characteristics of physicians that have wide implications for use of treatments. This uncertainty may manifest itself in a low level of tolerance for it and conservatism. In turn this may lead to the over use of diagnostic tests and under and constricted use of treatments. It may also show itself

in overconfidence in ones own judgements that may restrict the development of treatment options used by a doctor.

The characteristics of physicians that have been reported on, especially in how uncertainty is dealt with, have shown connections to ***Trading Off***. It supports many of the characteristics of ***Self-Referencing*** and physicians preference to use this data source.

7.5 Treatment characteristics

The characteristics of a treatment are a further area of uncertainty that is dealt with by the prescriber when choosing a drug etc. There are certain characteristics of a treatment that have been shown to be consistently found to be desired by physicians. The specific desired characteristics of a treatment depend on the particular patient problem and may not be available therefore drawing hard and fast lists of characteristics is difficult.

7.5.1 Efficacy

Belief concerning the efficacy of a treatment not surprisingly has been found to be the most important generic characteristic when choosing a treatment. As previously reported (Lilja J, 1976) found that curing effect was given most weight by physicians. They also mentioned the importance of side effects and financial cost. (Denig et al. 1988) also established that expectations concerning efficacy were more important in treatment choice than side effects. ***Trading Off*** discovered the importance of relative efficacy as further, important dimension to this influence.

7.5.2 Other Characteristics

Other characteristics of the treatment that were shown during ***Trading Off*** to be taken into account include, presentation (pill vs. liquid etc), interactions and packaging. It is important to note what is being considered are benefits and cost of the treatment to the

patient. The benefits are the efficacy, easy compliance and lack of interactions so other treatments can be used for concomitant diseases. The costs are in terms of side effects financial costs, interactions with other treatments and issues that make taking and complying to the treatment difficult.

This context based cost-benefit analysis is at the heart of ***Trading Off*** and is supported by the studies showing the importance of efficacy followed by negative aspects of treatments depending on the situation.

7.5.3 Symbolic characteristics of the prescription

A further aspect of the treatment are the symbolic characteristics of the prescription. This refers to what it does and can mean to both the doctor and physicians beyond access to treatment. (O'Hagan, 1984) reported on a number of perceptions concerning prescription that may act as influences for their production. He suggests that the prescription has a symbolic importance which signifies the healing power of the doctor and legitimises the complaint.

A prescription can also provide a quick and convenient method of terminating a consultation. This fact in conjunction with the work of (Webb and Lloyd, 1994) discussed earlier (51% of patients wanting a prescription from a consultation) means that writing a prescription can provide benefits to both parties (Webb and Lloyd, 1994). Indeed in situations where the physician's services are being paid for directly by the patient a prescription provides a tangible outcome to the consultation and may even make the charging of the fee more acceptable.

7.6 External Influences

The influence asserted on doctors by their colleagues, pharmacists and pharmaceutical companies is an area that has been thoroughly studied. This section will explore the influences of these sources including the social influence that other people excerpt.

The use of external sources is inevitable as physicians internal knowledge is unable to build confidence for all behaviours within medical decision-making. The strength of the influences from these sources is dependent on the trustworthiness and vividness of the information that the sources produce. The order that these external sources are reviewed in corresponds (broadly speaking) to a decreasing level of influence felt by the physicians.

7.6.1 Other Physicians

Other Physicians are used as sources of information, treatment ideas and to provide direct recommendations and instructions for treatments. (Weinberg et al. 1981) found that this informal advice and information seeking relationship between physicians is a regular and common occurrence. The strength of this relationship is used in a number of educational interventions that will be looked at briefly. The discussion concerning the use of these educational methods will be explored further in the section dealing with organisational influences on prescribing.

The influence of other physicians has shown a number of benefits to the outcomes of treatment. These include (Ruchlin et al. 1982) who showed second opinions to be cost effective mechanism for reducing the use of a surgical procedure. (Soumerai et al. 1993) demonstrated the benefit of specialist advice on the appropriate use and reduction of cost concerning blood products during surgery.

Whilst the benefits of following the recommendations of others physicians has been well documented, and it appears to be a strong influence, issues remain as to whether the

advice given is correct and will benefits patient outcomes. (Salem-Schatz et al. 1990) found a very strong effect of senior recommendation concerning the need for blood transfusion. These authors found that 61% of residents in their sample had ordered a transfusion that they believed was unnecessary because of advice from senior colleagues. This finding coupled with earlier work on the debate concerning the benefits of expertise, suggests that following colleagues may not always be a wise course of action.

7.6.1.1 Diffusion of Innovation

In a classic study of the social processes of adoption of new drugs, (Coleman J.S et al. 1959) showed that physicians who shared an office were quicker in adopting new drugs. It was also shown that this support was strongest in the early part of new drug adoption.

They suggest that this close social influence in medicine is potentially based on two factors. The first of these is the information that colleagues and members of social networks are able to provide. This information may be in the form of technical data concerning dosage, interactions, side effects and results of clinical studies, or in the form of experience from personal or second hand usage. Indeed in very strong support of the idea for ***Surrogating*** Coleman, Menzel and Katz state: "he has surrogates to carry part of the burden of finding out about new developments" (Coleman J.S et al. 1959) p8.

The second factor that is provided by the social network of a physician is support either real or subconscious for the experimental and developing usage of the drug. It is thought that being part of a network can provide reassurance when new drugs are being used. This is important because physicians do not have a fund of personal knowledge concerning likely reactions and problems when treatments are new. It is ***Trading Off***'s contention that the ideas concerning ***Surrogating*** information on new developments are expanded to incorporate the ***Surrogating*** of reassurance and support that are also crucial in the use of treatments.

This work by (Coleman J.S et al. 1959) provides strong evidence for the diffusion of innovation process (Glaser, 1978). In Coleman and Menzel's study the drug under scrutiny was adopted more quickly by those doctors who were large users of similar types of drugs corresponding to Innovators and Early Adopters. Also individuals who maintained larger social networks developed usage more quickly.

In further work which supports the Diffusion of Innovation process in treatment decisions (Stross and Bole, 1980; Stross et al. 1983) found that the use of opinion leaders as educators was an effective way of changing physicians behaviour. They used a small number of physicians, who had been identified by their peers as influential in their local medical community, to deliver medical education in community based hospitals. The results showed an improvement in care of arthritis without support from traditional academic opinion leaders.

7.6.1.2 Opinion Leaders

(Lomas et al. 1991) studied opinion leaders in comparison to audit and feedback as methods of implementing practice obstetrics guidelines. It was found that education from opinion leaders improved the quality of care for mothers who previously had had caesarean section.

This use of opinion leaders supports findings of within ***Surrogating*** particularly in it's categories of Duty Bound, Complete and Incomplete ***Surrogating***. In these situation the physicians rely heavily on individuals they respect for guidance on a informational and confidence background to the treatment.

This work on opinion leaders and diffusion of innovation leads the discussion from the importance of other physicians in decision-making onto the use of this influence in education.

7.6.1.3 Social Influence in Education

A strong indication concerning the importance of social influences is the number of methods that have been developed using physicians in the education of their peers.

These methods include one to one tutorials, lecture style meetings, consultant devised guidelines and peer feedback. These will be explored in detail in chapter 8 but are outlined here showing their positive effects and indicating the reasons for the benefit of physicians based education and change mechanisms.

Physicians tutorials were used in (Klein et al. 1981) to improve antibiotic usage and it was found to be effective in increasing the prescription of favoured drugs and decreasing usage of the out-of-favour ones.

The use of tutorials was integrated into a wider programme by (Soumerai et al. 1993) who studied the use of face to face education as a method for improving blood transfusion practice in Massachusetts. A transfusion specialist was used for a program of education that involved attending physicians receiving a lecture, educational guidelines and brief one to one meetings concerning red blood cell transfusion. The results showed that this type of programme was successful in improving the cost effectiveness and appropriate use of transfusions. The focused nature of these interventions is suggested as a reason for its success.

The use of peer comparison feedback to in an attempt to change behaviour was performed by (Parrino, 1989). In this study automated feedback was provided to doctors who were in the top 50% of antibiotic usage, conveying to them their position relative to their peers.

Their results showed no effect for the use of this impersonal social influence, however the authors suggest that this method may be of use if opinion leaders were identified and their statistics provided as feedback. The results are explained in context of ***Trading Off*** and the (Coleman J.S et al. 1959) study due to a lack of focus. The feedback does not provide the physicians with information, reassurance of confidence for the ***Focused*** use of individual antibiotics or for specific problems.

The benefits of face to face personal contact in formal educational programmes can also be explained in light of ***Trading Off*** and (Coleman J.S et al. 1959). These methods provide a flexible, reactive methods of education where the physicians are able to interact and develop the information and support needed for their specific practice context and needs. This is because for example questioning and case study appraisal is easy in this scenario. This allows ***Focused*** communication between the parties that in turn can be used to build up confidence in the treatments being looked at.

In support of this, the use of local physicians that are identified by the recipients as opinion leaders helps ensure respect and trust for the information source. This may be partly based on a previously successful relationship and also a greater understanding of the local practice context and culture.

7.6.1.4 Continuation of Treatment

The previous examples have developed the concept of other physicians as providers of information and confidence for treatment choices. This influence can be expanded to involve cases where choice is a continuation of others treatments, both formally or informally. In this case formal continuation represents treatments prescribed on behalf of a more senior colleague who retains clinical responsibility for the patient. Informal continuation involves the prescription of treatments that have been recommended or started by colleagues, but where there is no obligation to use or continue.

(De Vries et al. 1996) found in an audit of prescribing of cardio-vascular medications that 66% of drugs used in this area were originally prescribed by specialists. A closer look at the proportion of specialist continuation shows that it varies considerably by the particular cardiovascular disorders. For example, uncomplicated hypertension leads to continuation of 29% whereas with chronic ischaemic heart disease, 93% of prescriptions are specialist initiated and continued. The authors call for further studies to be performed to see if this pattern is repeated over other drug groups. This finding develops Initiation ***Surrogating***.

A common sense conclusion that can be drawn from these results is that the more complex and serious the disease the higher proportion of following the specialists recommendations. This study adds weight to ***Surrogating*** as a base and form of information usage and the ***Shifting*** that develops between it and ***Self-Referencing*** as expertise develops.

7.6.2 Summary

The influence on treatment choice by other physicians is a well-recognised phenomenon in the medical literature. The influence is thought to be based on the technical and empirical data that it communicated as well as feelings of support and reassurance that it develops. Various educational methods have used physicians as tutors, lecturers and influencers. These methods have been shown to have beneficial effects on costs, quality of care and appropriateness of use. This area will be looked at in more detail in the section 8.4 in chapter 8.

This section has demonstrated rich support for ***Surrogating*** and it's categories as an explanation of how information is used from 3rd parties. It also provides support for the feeling of confidence as the important property that is ***Traded Off*** when decision are made.

7.6.3 Pharmacists

The role pharmacists whether in a community or hospital setting or as part of health care provider (NHS, HMO) have been shown to have a strong and beneficial effect on treatment choice especially pharmaceutical choice. There has been a shift in recent years in the role of the pharmacist, which has seen them move from a technical product role to a greater patient orientation. This change has lead to a pharmacist's roles including education, consultation and agents of change for both patient and physicians within the above settings.

The need for these roles, their objectives, the strategies employed to achieve these objectives will now be looked at in order to assess the influence of pharmacists on treatment choice. Further detail on mechanics of pharmacists as educators will be provided in chapter 8.

The need for pharmacist intervention in treatment choices is based on the level of sub-optimal prescribing and poor patient compliance described in chapter 5.

To help reduce these mistakes there is a role for pharmacists as educators, consultants and as agents of change between the physicians and the pharmaceutical experts. Pharmacist work toward these ends within the health service to improve the use of resources and to improve patient compliance and outcomes (Christensen et al. 1981). In these circumstances the pharmacists can also be seen as opinion leaders (Rogers, 1983).

Pharmacists are well placed to fill these roles in medicine as they can occupy many of the criteria that have been shown in learning research to be important in change. These criteria include being perceived as credible and up to date sources of unbiased information that can provide both sides of an argument and suggest alternative behaviours. This is supported by an ability to use repetition and reinforcement so that the learning is maintained (Soumerai and Avorn, 1990; Kupst et al. 1975; Long, 1983; Rogers and Kincaid, 1981).

Work has shown the effectiveness of pharmacists as educators and consultants. For example (Covinsky, 1981) found that doctoral level clinical pharmacists were effective in teaching pharmacological knowledge for both medical students and junior doctors. Their role as educators extends to developments in medications from therapeutic categories to individual compounds and in the use of diagnostic tests (Berbatis et al. 1981; Berbatis et al. 1981; Soumerai et al. 1989).

7.6.4 Summary

Studies have shown an important need for methods of improving sub-optimal treatment usage. Pharmacists are able fulfil a number of roles which can be deployed to reduce this volume of poor prescribing. The educative and consultative roles that they now hold have been shown to be effective if conducted in a personal concise and targeted fashion. In showing this research supports ***Trading Off*** view of information usage and the need for ***Focused*** communication. Pharmacist are also used in setting up and maintaining formularies to be used in a wide range of settings, in many of these instances these are used to influence decision-making directly by restricting access to certain treatments.

7.6.5 Pharmaceutical Industry Influence

The level of influence of the pharmaceutical industry on treatment choice is contentious issue within the medical community but is one the industry spends billions of pounds world wide attempting to exploit. This brief look at the pharmaceutical companies influence will involve outlining the methods used, their objectives, and then a discussion on the existence of this influence. Suggestions will be made according to ***Trading Off*** and the literature as to how the industry is able to influence physicians and the drawbacks it faces. A qualitative analysis of efforts of pharmaceutical companies to modify treatment choice will be performed in chapter 9.

There are many methods used to influence physicians including Sales Representatives. Sponsorship of Continuing Medical Education (CME), Journal advertising, Direct mail, Patient education, Post Marketing Trials, Incentives and gifts. The last of these highlights the important ethical issues that are involved with pharmaceutical marketing. These methods have a number of objectives that primarily revolve around sales. Objectives used to this purpose include relationship building, communication of product information, disease education, direct persuasion and increasing patient numbers.

7.6.5.1 Level of Influence

It has been calculated that pharmaceutical companies in the USA spend $10,000 US dollars a year on each physician (Gotthelf, 1996). This figure in conjunction with the number of methods and research carried out into them suggests that pharmaceutical companies have an influence over the prescribing of physicians. However the statement that the "companies may influence other doctors but they don't influence me" was common in the field work for this study and is well known elsewhere.

In comparison, one GP in ***Trading Off*** stated that is the he was not naive enough to believe that all this money and effort were gone to without some effect on him. This opinion is borne out by the literature (Avorn et al. 1982; Freeman and Kaatz, 1987). A further issue that this leads to is if they are able to influence does it have a negative effect on patient outcomes?

(Lexchin, 1993) in a meta-analysis of studies looking into the effect of company-physicians relationship concluded that the 3 main methods used (funded clinical trials. Sponsorship of CME and information from representative) all affected prescribing behaviour. In the case of information from representatives this affect was less appropriate prescribing. (Bowman and Pearle, 1966) had found this relationship with sponsorship 27 years earlier and also by (Orlowski and Wateska, 1992). These authors showed that the rate of increase in use of a featured IV antibiotic by attendees at a

sponsored symposia was 10 fold compared to 3.5 fold in the general physicians population.

The effect was also seen in (Chren and Landefeld, 1994) who found that physicians who asked for specific additions to formularies were more likely to do so if they had met the manufacturers representative. This research showed a number of relationships between pharmaceutical company activities and subsequent requests for formulary additions. These relationships were strong, consistent, independent and specific.

However an alternative interpretation adds an important personal element to pharmaceutical company influence. It may be that the sort of person who accepts pharmaceutical hospitality is the sort of physicians who requests additions to formularies. This interpretation adds the element of personal difference to this debate, some physicians are influenced in this way more than others. The pharmaceutical industry is not able to control all physicians through its activities.

The pharmaceutical industry has an important role as sources of information, for example (Peay and Peay, 1988) found that 68% of physicians first heard about Temazepam from a commercial source. While this source is important (Lexchin, 1993) and the findings of ***Trading Off*** suggest that there is a lack of respect for this information.

7.6.5.2 Ethical concerns

This lack of respect and credibility is caused by their sales motivation indeed a number of tactics used by the companies may border on the unethical. There is feeling of unease concerning the effect of pharmaceutical company influence which is shown in the debate that continues over what is ethically acceptable in pharmaceutical marketing.

(Thomson, 1988) provides a number of action points that can be used by the pharmaceutical industry to improve the perceived quality of it's information and wider marketing activities. This list can also be seen as list of the dubious marketing practices and the some of the reasons why physicians are sceptical about the quality of pharmaceutical company information. The action points include:

- Allow studies to be published if results are unfavorable
- Ensure Drug trial results are be in peer reviewed journals
- Uncontrolled studies should not be quoted as fact.
- Equal weight given to drawbacks
- Ensure indications for use are not extrapolated out
- Ensure editorial autonomy
- When gifts are made – no real or implied obligations should be asked

7.6.5.3 Reasons for Influence

It is thought that pharmaceutical companies are able to develop relationships with physicians and through this, trust and the social benefits of human influence (as outlined previously) create influence. As sources of information they are easily accessible, well presented and brief. There are links therefore to adult learning theory in their approach (Long, 1983).

From a ***Trading Off*** perspective, they provide benefits that are attached to particular drugs in the form of friendship, gifts, practice programmes etc that become further benefits that are ***Traded Off*** when decision are made. ***Trading Off*** suggests that the influence of pharmaceutical marketing is limited by the importance of efficacy and side effects. In this situation it becomes important as an influence in decision contexts where there are a number of closely matched products, here the pharmaceutical company benefits may tip the balance in favour of one companies products. This is in addition to the information they provide as sources for ***Surrogating***, albeit ones whose

recommendations are not generally highly trusted and as such Confidence Building is harder.

7.6.6 Summary

In summary, the pharmaceutical industry uses a number of methods to influence physicians in order ultimately to sell its products. The effect while not admitted to by some physicians has been shown in a number of studies looking at a number of methods. This effect is thought to be due to a) The information provision representing a ***Surrogated*** source and B) a number of other benefits such as friendship, being used as variables that are ***Traded Off*** when a decision is being made. The effect of the industry while strong is still dependent on perception of core product variables. This accounts for doctors influenced by false claims concerning the treatments proven abilities.

7.7 Health Care delivery system

A final sphere of influence on the choice of treatments is the administrative system within which the physicians work. The activities of the NHS which are directed at modifying and changing treatment choices will be looked at in the next chapter, in this section the structure and financial restrictions of the UK healthcare system will be discussed.

7.7.1 Administrative Structure

The primary and secondary care system in the UK provides, via a series of semi-autonomous regional health authorities, the structure within which the majority of UK physicians work. This structure provides the type and speciality of physicians, support services and staff, the number and types of beds and the available finances within which doctors work. This ensures that a number of problems are dealt with by a generalist who

when it is felt appropriate will refer the patients to more specialist care. The treatment choice of the generalist is therefore directly effected by the care delivery system.

The particular resources available within each level of this structure i.e. the local health trust or in a particular health centre will effect physicians when treatment choices are made. For example if your local trust hospital has a paediatric cardiologist available then the choice concerning treatment for a child with heart problems may be different if this was not available.

(Wilson et al. 1996) looked further into the influences of individual practice characteristics on prescribing in fund holding and non fund holding practices. They found that differences in prescribing practice were attributable to characteristics such as level of deprivation, whether they were a training practice and the status of their partners. Fund-holding status was related to differences in prescribing costs. This study demonstrates the importance of the particular work environment on treatment decisions and the width of factors that can influence prescribing.

7.7.2 Summary

The health care delivery system in the UK imposes financial and resource restrictions on physicians that can strongly affect treatment choices. The structure also influences choice restrictions by providing roles for primary and secondary care which use each other symbiotically to deliver care. The actual programmes and strategies that are used by the NHS at all its levels to direct and modify treatment choice will be looked in the next chapter.

7.8 Conclusions

This chapter has provided a review of the factors that influence physicians when making decisions. It studies therefore the elements that are ***Traded Off*** when medical decisions are made. These elements are used as both influences on differential diagnosis and for the actual choices made within this process. Specifically, this chapter has highlighted the influences for choice among pharmaceutical alternatives.

Whilst the individual medical context dictates the influences used, it has been possible to identify some characteristics that are important in most if not all decisions. The first of these is the specific complaint that the patient is suffering from. Beyond this, the efficacy and side effect profiles of the possible treatments have been shown form a number of sources to be of central importance. These issues represent the most relevant positive and negative aspects of the behaviour.

The beliefs concerning the diagnosis and treatments are created by personal and social factors. In addition to this, the importance given to these beliefs are influenced by their source where personal sources are preferred to external. Social influence is strong though, particularly when it is ***Focused*** to the specific situation and allows two way communications.

The varying degree of influence the pharmaceutical industry has, serves as support for confidence being the key to behavioural choice and a wide ranging ***Trading Off*** process. The crucial aspect determining whether the company or representatives have an influence is in the level of trust that the physician holds for their information and activities. This trust is used to build confidence that in turn will determine the performance of the behaviour desired by the company.

The industry spends enormous amounts of money attempting to influence physicians and in many cases is successful in doing so. Doubt can be raised though over whether this influence leads to the patients receiving appropriate care and it is even less likely that it leads to the "best care" possible. In these instances, lack of knowledge on the part of the physician contributes but other variables such as friendship, gifts and entertainment are also being ***Traded Off*** to make the decision.

The administrative environment of the NHS provides a final, wide ranging influence on physicians. The structure determines their role and the case load they see in addition to providing them with colleagues and budget constraints.

These influences form the building blocks of attempts from various sources to modify physician choice behaviour. This area will be now be reviewed.

8 Chapter Eight Modifying Treatment Choice

This chapter will review literature that has looked at changing physicians behaviour and specifically choice of treatments. It will consist of a review of the following

- The need to modifying behaviour
- Important components of a change strategy
- Models that have been proposed.
- Review of methods that have been used to change behaviour
- Conclusions and Issues concerning how to perform these effectively.

This review will also contain findings from ***Trading Off***'s view of modifying decision-making. Conclusions are drawn throughout this chapter comparing the views found in the literature and this researches findings on how best to effect change.

This chapter is written from the standpoint of the health care provider's attempts to change behaviour. There is however, a close relationship between the attempts of the health care providers and those of the pharmaceutical industry. The efforts of pharmaceutical companies using these methods to modify physician's (and other relevant target markets) behaviour will be reviewed in the next chapter.

These two chapters will then used to provide conclusions on how the literature suggests modification should be attempted and how this compares and develops the position held by ***Trading Off***.

8.1 Need for Modifying Physicians Behaviour.

The need for change and modification of physician's behaviour stems from the high number of preventable decision errors that are common with medicine. Chapter 5 provided a thorough analysis of this area, a summary is provided below.

The actual levels of variation and care described as inappropriate are dependent on the definitions used to describe them and the disease under scrutiny. For example inappropriate care has been shown to range from .013% (Lesar et al. 1997) to 65% by (Lilja J, 1976). Whereas 300% variations in usage of some medical and surgical procedures were found by (Chassin et al. 1986) compared to a 12 fold geographic variation in Coronary angiography rate (Leape et al. 1990)

The importance of these figures lies in the health outcomes that they cause for the patients and the financial costs the health care providers. These figures contain a number of decisions that represent a range of outcomes that extends from no consequences for all the parties concerned to sub-optimal care, added cost to the healthcare providers and even death.

As previously reported, inappropriate care in a surgical setting has been a factor attributed to 450 surgical deaths per annum in Scotland (The Royal College of Surgeons of Edinburgh, 1996). The financial costs are harder to calculate however an indication can be given with the following figures. 1% of medication errors have been found to result in adverse drug events (Bates et al. 1995) and the total cost of ADE's in the USA has been calculated at $76.7 billion (Johnson, 1995). These financial aspects of medicine are becoming increasingly important and cost containment has become a primary objective for the use of many of the methods discussed in this chapter.

The causes of these problems are attributed mainly to a lack of knowledge concerning some aspect of differential diagnosis procedure or material facts concerning the

treatment. For example (Lesar et al. 1997) found that lack of knowledge of the drug and it's application accounted for 30% of all errors whereas lack of knowledge of and use of patient factors accounted for 29.2% (Soumerai et al. 1989).

This knowledge basis for errors provides an obtainable goal for health care organisations, as changing physician's knowledge is possible in a number of ways. Indeed a number of authors have demonstrated techniques that have used changes in knowledge and in turn change behaviour. For example (Klein et al. 1981) illustrated the use of tutorial visits and (Soumerai and Avorn, 1986) showed the use of academic detailing.

These findings are important for pharmaceutical companies and health care providers wanting simple knowledge and behavioural changes. For example, it is possible for a generic manufacturer of Ranitidine or a local health authority to change physician's behaviour to prescribe generic Ranitidine rather than Zantac ™.

However, work by (Davis et al. 1992) suggests that increasing knowledge may not lead to improved health outcomes for patients. These authors report that there is a large body of evidence showing interventions changing physicians competency (i.e. demonstrating increased knowledge as tested in the studies). However, there is less evidence supporting interventions changing clinical performance and even less evidence showing that this extends to a change in health outcomes.

These authors go on to state that evidence supports the idea that it is easier to change prescribing and preventative care than it is to change clinical management of a disease. In order to change health outcomes it may be that simple changes in medication are often not sufficient and that wider issues of management need to be changed. This failure to change management strategies provides a reason why health outcomes have proven difficult to improve.

The difficulty in changing more complex behaviours, (which was also found in ***Trading Off***) can be explained by a number of factors. First, changing all the behaviours that are involved in the management of disease represents a greater level of risk than changing one component of it. Physician's conservatism may therefore be working against changes in management. Secondly, external barriers to change (administrative, economic and social) may be perceived to exist when, in conjunction with complexity issues, reduce the likelihood that changes will be attempted. Thirdly, attempts to induce change may be handicapped by poor use of learning theory in their development and application (Epstein, 1991).

The theoretical basis for modifying decision-making, including recommendations from adult learning will now be reviewed.

8.2 Principles for modifying behaviour

Work by (Bennis W G et al. 1969) and (Long, 1983) on adult learning provides decision-making with a set of principles for modifying behaviour. Techniques that are developed or implemented using these principles therefore have a higher chance of obtaining their goals.

1) Involve the targets of change in identifying and analysing problem.
2) Use techniques to develop group consensus.
3) The agent of change must be empathetic to those opposing change.
4) Feedback must be available to all targets of change.
5) An atmosphere of openness, acceptance, support, trust and confidence must be maintained.

These rules stress the importance of two-way communication between the parties which allows for a close understanding of the situation and the objectives. This, in conjunction with the "support, trust and confidence" attempts to provide an environment where the

new behaviour can be felt to be part of both parties shared experience. This in turn should allow new behaviours to be adopted more readily.

These principles develop the process of ***Shifting*** that occurs between the use of ***Surrogating*** and ***Self-Referencing***. ***Shifting*** occurs primarily as confidence develops in the use of ***Self-Referencing***, these principles add to this development. They add that before ***Shifting*** can occur, the need for change has to be recognised and feedback has to be available. This is in order for the physician's to Trade Off which source and behaviour to use.

8.3 Theoretical Perspectives

The Belief-Attitude-Intention-Behaviour (B.A.I.B.) pathway that underlies the Theory of Reasoned Action (Fishbein and Ajzen, 1975) represents the theoretical perspective on which the change models proposed, are based. In turn, the strategies and techniques that are reviewed following this section are designed to effect this pathway at some point in time and so change physician's behaviour.

For example, a physician's attitude toward risk and knowledge of certain drugs may be targeted using a mailed clinical paper (educational strategy and method). This is in order to change the physician's beliefs then attitudes, intention and therefore behaviour concerning use of particular drug.

8.3.1 Models of Change

(Armstrong et al. 1996) studied the reasons given by GP's for changing their prescribing behaviour and proposed 3 models which explained their findings:

Accumulation Model, this proposes that change occurs due to a weight of arguments from a number of sources,

Challenge model, change can occur because serious events challenge the doctor's behaviour

Continuity Model, this presents a model where change occurs because of a background of willingness to change.

These propositions all follow the Belief-Attitude-Intention-Behaviour pathway, differing primarily in how information and events change beliefs and attitudes and in turn, change intention and behaviour. For example, the accumulation model proposes that information from authoritative sources combine over a period of time to change beliefs, whereas the challenge model suggests that this belief change occurs in an immediate unexpected fashion.

These models correspond to categories of ***Shifting*** that were found. Cautious ***Shifting*** is the most common form and occurs over a period of time, this corresponds to Accumulation and Continuity whereas the rapid ***Shifting*** is aligned with the Challenge model. The continuity model also incorporates the aspect of ***Trading Off*** where the most confidently held behaviour is performed but this does not necessarily mean that the behaviour is held with high levels of confidence. This therefore creates the situation where better treatments are constantly being looked for.

Work by (Taylor R.J. and Bond, 1991) highlighted that physicians tend to work from a "personal repertoire" of treatments. This repertoire evolves over time and is

characterised by treatments that which are "Established", "Newly Adopted" or "Superseded".

One of the issues concerning poor treatment choice that is addressed is that physicians tend not to actively replace superseded treatments. This allows the use of outdated treatments to continue via repeat prescriptions after different treatments have become established. These findings suggest that a level of inappropriate care reflects superseded treatments not being actively removed from a physician's repertoire. It also questions the accuracy of audits as reflections of a physician's current practice.

The findings of (Taylor R.J. and Bond, 1991) showed that information from a variety of sources was used in changing between these categories. Human influences specifically were identified as the dominant reasons for change. This in conjunction with the "Personal Repertoire" model supports the idea of external sources of information being used in a ***Surrogated*** fashion.

These findings also support the notion of a catalogue of patient experiences providing the basis for solutions to problems. However ***Trading Off*** provides an explicit understanding of why this source is used and the psychological mechanism that leads to the choice of different pharmaceuticals.

The importance of human input into decision-making has been outlined previously and represents a major distinguishing factor in many of the strategies successfully shown to modify choice. This issue will be discussed throughout this chapter highlighting the characteristics of human input that account for its success

Having outlined the theoretical pathway used to change physician's behaviour, this chapter will now turn to a review of the specific strategies and techniques used.

8.4 Strategies for Modification

A considerable volume of work has been undertaken into strategies and techniques used to modify physician's behaviour. For example, (Davis et al. 1992) found 770 studies concerned with this issue. Importantly though, conclusions were only drawn on fifty of these due to methodological issues.

This literature review will provide details from a number of studies with the objective of highlighting the successful methods, reasons for their success and comparisons to ***Trading Off***.

8.4.1 Classification

A number of authors have suggested classifications for the large volume of work in this area. For example (Greco and Eisenberg, 1993; Horder et al. 1986; Lomas and Haynes, 1988) (Plumridge, 1984)and (Soumerai et al. 1989).

These authors suggested a number of similar divisions for example (Horder et al. 1986) proposed:

1) Financial Incentives
2) Personal contact
3) Review of performance and Unsolicited feedback
4) Literature on prescribing
5) Vocational and post-graduate education,

(Lomas and Haynes, 1988) suggest:

1) Patient centred
2) Economic incentives
3) Education
4) Administration

For the purpose of this review, a classification of Educational, Administrative and Financial strategies will be used. These categories are able to encapsulate the areas of influence that ***Trading Off*** found are used to form and change behaviour.

These strategies can be delivered by a number of different methods, for example an educational strategy can be delivered using one to one tutorials or mailed educational literature. Reviewing the effect of these methods and concluding on how to perform them constitutes a principal objective of this chapter.

The use of Feedback strategies will be incorporated into the Education section as it is an integral part of education as outlined previously in the work by (Bennis W G et al. 1969). Issues of patient education will also be mentioned briefly within this section. Educational strategies will therefore contain all information based methods for attempts to form and change the beliefs and attitudes of the physician.

Financial and Administrative strategies in this review will contain methods that provide assistance and incentives or barriers and disincentives for the use of certain treatments. As such, they can be seen to represent the perceived barriers and resources for performance that were incorporated into the TRA to formulate the TPB. (Ajzen, 1985)

(Plumridge, 1984) pointed out that most interventions combine two or more of these strategies. Combining strategies and particular methods is associated with better outcomes and for some methods e.g. impersonal mailed education and feedback it can be the only way to gain a benefit from them. Examples of this will be highlighted throughout this review.

Finally, (Plumridge, 1984) raised the important issue of intentional and unintentional use of bias and presentation to persuade and manipulate decision-makers. This examination concluded that the use of bias and manipulation can be effective in changing physician's

behaviour however the effects tend to be short lived and require constant supervision by the sponsor.

8.4.2 Education Strategies

8.4.2.1 Introduction

The educational strategies and methods reviewed in this section provide information to the physicians in order to move them along the B.A.I.B. pathway. The methods used to deliver this information combine personal and impersonal delivery of written or oral information. The particular combinations of these aspects have been shown to be crucial in successfully changing a physician's behaviour.

However, progression toward behavioural change is often more complex than providing new information for the physician. A number of external and internal factors can intervene to stop a change in knowledge developing into a change in behaviour, for example a perception of lack of availability or financial restrictions. These factors may stop the behaviour being attempted or if it is attempted, may stop it being successful. Therefore, educational methods must often be combined with other strategies to reduce these barriers.

(Davis et al. 1992) classified educational methods into three categories that can be seen to operate at different stages in the B.A.I.B pathway. They are:

1) Predisposing, i.e. Academic detailing, printed materials, affecting Beliefs and Attitudes

2) Enabling, i.e. Guidelines, clinical policies, affecting Intentions

3) Reinforcing, i.e. Feedback and reminders, affecting Beliefs, Attitudes and Intentions

The broad conclusion that was drawn from this study was that interventions using practice-enabling or reinforcing strategies in combination with Predisposing strategies consistently improved physician performance and, in some instances, health care outcomes.

A more specific conclusion of (Davis et al. 1992) was that more focussed interventions showed greater success in changing behaviour. ***Focused*** methods include Academic Detailing and one to one tutorials. This conclusion supports work demonstrating the effectiveness of social influences on prescribing (Coleman JS et al. 1966).

Trading Off stresses the use of human sources and flexibility in behavioural change. The amount of this kind of contact will therefore be used to structure this review. It will proceed through methods that involve high amounts of personal contact to ones involving little or none at all. The section will then conclude with a review of use of feedback.

8.4.2.2 Personal contact

The importance of personal contact and reasons for its success has been detailed previously in this literature review. It has been used in varying degrees in a number of educational methods including Tutorials, one to one meetings and lectures. These methods have been successful in a number of modification tasks and indeed it have been shown to lead to stronger changes in behaviour than other methods (Schaffner et al. 1983).

(Stross and Bole, 1980) evaluated a continued medical education programme (CME) that involved the use of influential physicians from the local area. They concluded that in community settings the use of these opinion leaders was successful in changing clinical management for rheumatoid arthritis patients. They followed this work up in 1983 (Stross et al. 1983) and came to similar conclusions.

(Klein et al. 1981) used a tutorial visit conducted by a graduate physician and found that this method was effective in changing prescription patterns and reducing costs associated with antibiotic prescribing.

The targeting of antibiotics is a characteristic of many modification studies and suggests that the poor use of antibiotics (from both cost and patient welfare perspectives) is seen as important. This is supported by the recent government initiatives to reduce this categories usage for certain conditions.

(Avorn and Soumerai, 1983) showed that the use of one to one tutorials was able to make a lasting difference to levels of drug use and therefore associated cost. They showed a 14% reduction in prescribing of the target compounds, one of which was an antibiotic. It was also able to avoid the issue of poor substitution, this issue is addressed in more detail in the conclusions to this chapter.

In further support for personal contact (Lomas et al. 1991) demonstrated the superiority of using opinion leaders over feedback and audit. Specifically they studied the use of these methods to improve the management of mothers who had previously had a caesarean section.

Differences in findings concerning the use of pharmacists to modify behaviour can also be explained by the use of personal versus impersonal techniques. Pharmacist used in a consultative role have been shown to have positive effects on cost containment. (Forstrom et al. 1990) and patient compliance (Lipton et al. 1992). Though the use of impersonal bulletins and prescribing review by (Stergachis et al. 1987) can explain their failure to produce a significant level of cost containment.

8.4.2.3 Academic Detailing

The use of one to one methods using peers or opinion leaders has been combined with the methods from pharmaceutical marketing. Stephen Soumerai and Jerry Avorn have used the method of one to one tutorials and developed them into what is termed "Academic detailing" (Soumerai and Avorn, 1990). This represents part of their overall work on "Demarketing" the effects of commercial change strategies.

This incorporates concepts and ideas from the main components of pharmaceutical marketing (which will be explored in detail in the next chapter), to modify physicians behaviour. Briefly, pharmaceutical companies spend enormous amount of time and money on detailing their products to physicians. For example in 1990 $3billion dollars was spent on detailing in the US with 28000 reps employed. Components that they used included a multi-faceted approach, short repeat visits and targeting specific areas.

(Avorn et al. 1982) looked at the influence on prescribing behaviour of commercial and scientific sources. They conclude that there is a need for communicating unbiased drug information in order to work against the effect of commercial sources. To achieve this they suggest using "counter-detailing" and "unadvertisements".

In their 1986 study reported in (Soumerai and Avorn, 1987) they combined visits from clinical pharmacists, printed materials, feedback and follow-up visits. They showed that this combination was able to reduce prescribing of targeted drugs and projected that this would reduce costs by over two million dollars per 10,000 physicians. An important aspect of this study is the use of clinical pharmacist as the agent of change in contrast to other studies presented where physicians were used.

They further developed this idea of academic detailing and demarketing in (Soumerai and Avorn, 1990). Here, they specifically list techniques used in pharmaceutical company detailing that they suggest should be used in CME. Specifically they recommend:

1) Conducting interviews to investigate baseline knowledge and motivations for current prescribing patterns,
2) ***Focusing*** programs on specific categories of physicians as well as on their opinion leaders.
3) Defining clear educational and behavioral objectives.
4) Establishing credibility through a respected organizational identity, referencing authoritative and unbiased sources of information, and presenting both sides of controversial issues.
5) Stimulating active physician participation in educational interactions
6) Using concise graphic education materials.
7) Highlighting and repeating the essential messages.
8) Providing positive reinforcement of improved practices in follow-up visits.

(Soumerai et al. 1993) used academic detailing to reduce the level of inappropriate use of blood transfusions. They were able to reduce this behaviour by 40%, which in turn lead to gains in cost effectiveness in the service without unfavourable side effects.

In a further development (Ross-Degnan et al. 1996) tested it's effect on community pharmacists and pharmacy owners in Kenya and Indonesia in an attempt to improve sales of antidiarrhoeal agents and communication with customers. They found that it was effective during the term in which they studied for both these objectives.

The use of pharmacists to administer academic details has been shown to be successful. For example work by (Soumerai and Avorn, 1990) and (Avorn and Soumerai, 1983). However, other authors have found that pharmacists when performing some of the tasks of academic detailing have not been successful in modifying behaviour. (Schaffner et al. 1983) found that the use of graduate level pharmacists was less effective than using physicians in the same role providing drug education visits.

These results can be explained by the differences in level of the pharmacists. It is likely that doctoral level pharmacists used by (Avorn and Soumerai, 1983; Soumerai and Avorn, 1990) were held in greater esteem and were able to provide more relevant knowledge than the graduate level studied by (Schaffner et al. 1983).

The critical difference between the techniques described above as performed by the pharmaceutical industry versus healthcare providers is the level credibility and trust that is afforded to these two sources.

Credibility is an integral part of education generally and opinion leadership more specifically. Opinion leadership (as used in academic detailing) therefore provides peer education methods with an important tool in establishing confidence and support. ***Trading Off*** and the literature (on sociological influences) both refer to these factors as crucial to the successful use of a change method.

It is an interesting situation therefore that the two industries wanting to change physicians behaviour both posses resources that the other needs in order to more effectively fulfil this goal. The healthcare providers possess credibility, access to exact prescribing data and physical access to the physicians. The pharmaceutical companies on the other hand possess the large budgets that are necessary in constructing the complex change strategies needed.

8.4.2.3.1 Summary

This section provides numerous important details concerning how to modify behaviour and consequently how to market and demarket medical treatments. Primarily the use of opinion leaders and peers (either physicians or pharmacists) in various education methods has a positive effect on changing knowledge and behaviour. The addition of other methods to enhance the learning (printed materials, feedback) as developed by

Soumerai and Avorn as De-marketing (Soumerai and Avorn, 1990) further enhances the use of personal contact.

This can be attributed to these methods demonstrating and instilling the characteristics called for by adult learning theory i.e. for involvement, motivation, relevance and credibility and feedback. ***Trading Off*** explains the success of these methods because they are able to provide flexible ***Focused*** communication that allows the "student" to surrogate specific patient and problems situation details from the other party. This ***Surrogating*** is enhanced if the other party is more experienced.

This review will now develop the use of printed educational methods.

8.4.2.4 Clinical Studies

The use of clinical studies highlights a number of issues involved in persuasion and behavioural change. As a system of presenting study results, concerning for example, performance and negative aspects of a drug, this method represents an (apparently) unbiased view of the treatment. Clinical studies can therefore provide important, unbiased information that can be used to change behaviour via the B.A.I.B pathway.

However clinical trials and studies are performed with varying degrees of quality according to recognised criteria for study design. The journals and sources in which they are published also contributes to the weight with which they hold. These issues are incorporated throughout ***Trading Off*** as preferred properties of communication that will more effectively build confidence in a behaviour.

The form in which published clinical trials present the information to the reader can reduce their effectiveness as change mechanisms. By predominately using statistics, they display information in a form that is not readily available or relevant to the kind of information used in pharmaceutical decision-making.

Trading Off contends that information sources are used to provide (***Surrogated***) experiences of actual clinical cases and that experience is used before external data. It suggest further that statistical representation of information is abnormal for physicians who base their working lives on patient orientated representations of experience.

These points are supported by a number of findings; the first showed poor use of probability data as reported in (Wennberg, 1990). The second by (Poses et al. 1995) showed that improving physicians knowledge of the likelihood of a disease did not lead to improvements in decision-making.

The work of (Bergman and Pantell, 1986) also supports this view of information usage. They concluded that physicians appear to base estimates of disease on intuition and experience rather than objective prevalence data.

This study also raises the issue that reading a clinical paper may have an effect on behaviour opposite to that desired by the educator. In the (Bergman and Pantell, 1986) study, subjects read a scientific report concerning the risk of meningitis in infants. The result of reading this was to increase dramatically the percentage of doctors who would hospitalise a particular patient type. This effect was contradictory to the data presented. However, it can be viewed as rational if the doctor is diagnosing with the advice of (Sox and Blatt., 1988) in mind i.e. considering a possibility that they cannot afford to miss.

Work by (Col et al. 1996) on the impact of large randomly controlled studies on the prescribing of cardiovascular drugs for Myocardial Infarction also questions the use of clinical papers and supports *Trading Off*'s position.

The authors wrote:

"The rigid inclusion and exclusion criteria imposed on these trials raises questions concerning the generalisabilty of the findings to patients treated in community settings". p57.

This quote goes to the heart of what ***Surrogating*** proposes concerning information usage and the specific recommendations concerning clinical papers i.e. that they do not present information in the form that it is used. Physicians use studies as representation of individual cases however this is not how they are submitted. In essence the rules of scientific inquiry produce results which are in a different form than how they are used.

8.4.2.5 Drug Bulletins

The inaccessibility and poor presentation of clinical trials can be partly overcome by summaries and recommendations based on the information held within them. This is part of what is performed by drug bulletins. (Plumridge and Berbatis, 1989) conducted a comprehensive review of this method of education and concluded that in institutional settings it can have a significant but short term effect on behaviour. In community settings however it has little effect when used alone.

These conclusions support the role of written materials as conjunctive methods to be used with personal contact. This conclusion is further supported by work by (Berbatis et al. 1982) and (Fendler et al. 1984). This work suggests that their independent use is limited, however they are a useful adjunctive methods for personalised methods such as tutorials.

(Plumridge and Berbatis, 1989) develops the research on drug bulletins further by providing a set of rules for their use. They suggest bulletins should be:

1) Precise and specific to the target audience
2) Independent of the pharmaceutical industry
3) Visually appealing
4) Distributed punctually and efficiently.
5) Use persuasion via positive messages.

The further details that are given within each of these suggestions can be seen as demonstrating good educational theory by providing credible, easy to use, practical and ***Focused*** pieces of information.

These suggestions for improvements also correspond to properties of ***Surrogated*** sources that to increase the likelihood of these sources being it is necessary to make them more accessible. One of the reasons that ***Self-Referencing*** is used before ***Surrogating*** is due to the ease of access to relevant information. If accurate ***Surrogated*** information can be provided easily then it's use is more likely.

8.4.2.6 Educational Memos

Educational memos have also been shown to have a limited and conjunctive role within physician education. These memos are shorter than drug bulletins and again demonstrate the lack of flexibility restricting the role of written communications. They have been shown be of use however in changing behaviour when used in specific situations. (Epstein, 1991) for example reports on a 7% reduction of lab costs when a one page memo was circulated on the use of a particular assay as a diagnostic test.

Similarly (Schectman et al. 1991) used this method to modify test ordering behaviour. A follow up was performed using either a simple reminder or guidelines and feedback. Both groups demonstrated a positive effect on behaviour with the original educational

memo, but surprisingly the group subsequently receiving the feedback and guidelines groups did not show a further increase.

This result is explained by the specific behaviours referred to in the feedback and guidelines differing slightly to the one referred to in the original memo. This illustrates the need when using a number of methods to ensure that they are all focused on the same specific behaviour.

An educational memo was incorporated into an antibiotic ordering form by (Avorn et al. 1988) in an attempt to reduce dosing errors. This combined educational and administrative strategy showed a net saving of $76,000. This finding is an example of the need for strategies to be contextually specific in order to be effective.

In this study the education and guidelines concerning the specific diseases and legitimate treatments were specifically incorporated into the order forms. This corresponds to the rules suggested by (Fishbein and Ajzen, 1975) and the ***Focusing*** needed in ***Trading Off*** as how to help ensure that behaviour is performed.

8.4.2.7 "Dear Doctor" letters

The final impersonal educational method that will be looked at is the "Dear Doctor" letters that are periodically produced to inform physicians about important issues concerning treatment use. This brief review provides an example of ***Trading Off*** as well as demonstrating the limited nature of the method.

The use of a dear doctor letter for the warnings concerning Zomiperac were looked at by (Ross-Degnan et al. 1993) and (Spielberg et al. 1994). They found that the letter, sent out 9 months before the product was withdrawn, was remembered for only a short time. (Ross-Degnan et al. 1993) also showed that the letter had no effects on levels of prescribing.

The subsequent withdrawal of Zomipirac did however effect the wider market with the substitute drugs used leading to problems with habituation, and dangerous side effects. A wider view of the issue and the educational methods used to deal with it are therefore called for.

The dear doctor letter in this instance was accompanied with what was described by (Spielberg et al. 1994) as marketing literature. This is likely to have reduced the credibility of the letter accompanying it and therefore the chances of changing behaviour. A number of other factors contribute to the continued use of Zomepirac. These include issues such as lack of attention and understanding of the letter, use of ***Self-Referencing***, no ill effects reported within their own population and automatic repeat prescribing.

8.4.2.8 Conclusion

Methods using opinion leaders and personal contact with peers have shown strong effects on modifying behaviour and have lead to a number of positive outcomes such as cost reduction and better use of limited resources. This is partly due to the flexibility with which these methods can adapt to the problems and issues of individual physicians. They are also able to convey information in the form that physicians use when making decisions. This is in contrast to clinical papers and the use of statistics and aggregated data.

Trading Off found that doctor's preferred other physicians as sources of information and recommendations. This is based on the other physician's knowledge of actual clinical cases and a desire to use this experience. The importance of the flexibility of personal contact is that it allows the exact pieces of information that are needed to build confidence to be elicited. This is especially important in situations as complex as medicine.

Printed materials have been shown to be of benefit as conjunctive educational methods to personal contact. The actual design of both personal and impersonal studies follow similar rules which conform to those found in ***Trading Off*** and in adult learning. They need to originate from credible sources, be brief, well presented, targeted effectively and deliver a solution to the problem that is being addressed.

Trading Off suggests further that the information provided in printed form should contain details and case studies of individuals and groups of similar patients. It needs to allow access to a wide range of patient information concerning the subjects in the trials.

These two recommendations however appear contradictory and to implement require the use of electronic storage and retrieval. For example, typical cases could be provided in simple printed material supplied to the physicians, in conjunction to this searchable databases should be available to where further experiences matching the physician's patients could be retrieved.

As previously discussed Jerry Avorn and Stephen Soumerai developed combinations of personal and written techniques along similar lines to the detailing used in pharmaceutical marketing (Soumerai and Avorn, 1990). Their studies using this "academic detailing" approach have been successful and provide details on how to use of a multifaceted approach to modifying physician's behaviour.

The use of feedback as the strategy that closes the educational circle will now be looked at.

8.4.2.9 Feedback

The Feedback of information concerning behaviour provides a guide for future performance of the same or similar behaviour. It is an integral part of skills acquisition

because without it, the true consequences of actions cannot be seen and learned from. This latter point raises the point that with feedback, it is the behaviour of the individual not the individual that is important (Ende, 1983). The section reviewing feedback also includes peer assessment because of the information this method provides for physicians.

The methods for providing feedback and assessment reported on here will include Peer Assessment, Computerised Feedback and PACT data. The information provided with these techniques includes data on how diseases are treated, (for example referral or prescription) and which classes and specific drugs are used.

Feedback impacts on ***Trading Off*** by affecting the source on which behaviour is based. The most important effect is whether the feedback on the outcome of the behaviour builds confidence further. If it does then the source of confidence in the behaviour shifts toward ***Self-Referencing***. If the feedback shows the behaviour to be unsuccessful then the use of ***Surrogated*** sources becomes more likely.

(McAuley et al. 1990) reported that peer assessment is acceptable and feasible to perform and can be effective in changing behaviour. They found that 52% of the physicians assessed by peers as having deficiencies in practice had made improvements when reassessed. (Restuccia, 1982) add to the support for assessment and feedback by using it to reduce incorrect location of patients in hospital.

However, (Parrino, 1989) found that feedback did not work when used in an attempt to reduce expenditure on antibiotics. This failure is due to the time lag between the behaviour and the feedback and also type of information presented. Information received involved with providing the physicians their rank in comparison to peers on levels of expenditure. In this instance some physicians may have interpreted that a high position is a good indicator as it shows that fewer risks are being taken.

For feedback to be effective it should be provided concurrently with the behaviour under scrutiny. It also should be ***Focused*** on the specific behaviour and desired outcome and should be compared to peers (Restuccia, 1982). These rules were not followed in the design of this studies intervention.

The feedback used in (Parrino, 1989) is very similar to that provided by PACT data by Health boards in the UK. This is seen as an important method of feedback used to provide information on every drug prescribed by individual doctors. The benefit of this information is that it provides health boards with indicators of high and low prescribing which can then form the target of educational programs on personal, practice or regional basis. As (Parrino, 1989) suggests, the information itself will have limited use as a behavioural change mechanism.

8.4.2.9.1 Conclusion

Feedback serves a vital educational function by providing information concerning the outcomes of behaviour. This information can then be used to demonstrate deviance from accepted patterns of behaviour.

In turn, it can be used to design programmes to correct the problem or to motivate decision-makers to change their actions, both occurring via the B.A.I B pathway. It is noted again however that other issues can intervene to reduce the effect of feedback on behavioural change.

For feedback to be effective it should supply information that is timely and describes specifically the behaviour under scrutiny. Details should also be supplied to individual decision-makers concerning their activities and allow comparisons with peers.

Feedback was found to be important in ***Trading Off*** by providing information which was used to ***Shift*** the location from where information was taken to develop confidence

for a particular behaviour. If the feedback demonstrated that a behaviour was successful then, independent of the source, the physician is likely to ***Shift*** toward greater degrees of ***Self-Referencing***. If it is not then the ***Trading Off*** process is started again with the physician's ***Self-Referenced*** knowledge enhanced.

Educational methods primarily provide the means by which beliefs, attitudes and intentions can be changed. Administrative and Financial strategies will now be reviewed because of their actions on different stages of this pathway.

8.4.3 Administrative Strategies

The power of administrative strategies is based on creating barriers or incentives for or against the use of certain treatments. In doing so they act on the Intentions and Behaviour components of the B.A.I.B pathway. This category also includes methods to control patient information that in turn effects treatment decisions.

In their strictest form, administrative strategies can be 100% effective in changing behaviour by ensuring that the targeted treatment is not available. The physicians are then forced into changing their behaviour. This kind of barrier can be counterproductive as suggested earlier in the work by (Ross-Degnan et al. 1993; Spielberg et al. 1994). Substitute treatments used may include treatments that are equally or more expensive, dangerous or lacking in efficacy.

Administrative strategies of this type do not address the issues of why the treatment was used initially and therefore may only be effective for as long as the strategy is in place. It is important therefore that administrative strategies are accompanied by education as to why the target behaviour is being discouraged and provide rational, alternatives that are agreed by local opinion leaders.

Administrative strategies exist in a continuum that moves from complete denial of the use of a drug to policy guidelines as to which treatments to use. They involve methods that make the drug difficult to get hold of via formularies or ordering procedures, requiring permission to use, through to various levels of policies recommendations and guidelines as to which treatments can be or should be used. It can also involve setting up special treatment teams that deal with specific situations.

Methods employed to deal with patient data involve ensuring that relevant information is available to the physicians when making treatment decisions. They can go further than this and provide reminders for check ups, tests etc.

In terms of ***Trading Off***, administrative strategies provide further properties for ***Surrogating*** and specifically Duty bound ***Surrogating***. It demonstrates the use of other tactics beyond hierarchical employment structures that can be used to ensure certain behaviours are followed.

This review will proceed as with the educational review through personal to impersonal based strategies. The first to be review will be mandatory second opinion methods.

8.4.3.1 Second Opinion

(Myers and Gleicher, 1988) studied the effect of second opinion on the levels of caesarean sections usage by individual physicians. They found that this method reduced levels by 11% in the hospital where it was administered. Importantly this did not lead to any adverse effects for mothers and infants. (Ruchlin et al. 1982) demonstrated that this method (when used for elective surgery) is also cost effective.

The strength of mandatory second opinions on the physicians making the initial decision is demonstrated by (Martin et al. 1982). They found that 85% of patients who had surgery decisions confirmed by second opinion went on to have the surgery. This

compares to only 31% of patients whose original decision to treat was not confirmed. The physician making the original decision were clearly effected by the opinions of their colleagues. This program lead to a 20% volume reduction in surgery. The results of this study are very similar to properties of ***Surrogating*** that were found that when 2nd opinions were asked for they on the whole were followed.

8.4.3.2 Further Peer Review strategies

Similar to requiring a second opinion are methods that require permission from further authorities before a treatment can be used (McGowan J E and Finland M, 1974). This authority may have to come from a senior ward colleague, pharmacist or committee (Klapp and Ramphal, 1983). This method creates a barrier against easy use of a treatment and provides the physicians with the opportunity to think why this drug is only available in this manner and whether the alternatives are acceptable.

8.4.3.3 Team Development

The development of teams to deal with certain medical situations can also be viewed as an administrative tactic for controlling treatment choice. (Drexler A et al. 1977) reported on the use of an overdose team and (Tomford and Hershey, 1985) looked at the effect of an IV therapy team. This team was set up to manage the use of venous catheters and found that it was able to improve patient care and be cost effective. An integral part of this kind of team building is the formation of policies concerning what products to use in which situations.

8.4.3.4 Order Forms

The use of order forms moves the discussion on from personal methods of administering barriers and incentives to impersonal ones. This method as with requiring permission, confronts the decision-maker with a barrier to easy use of the treatment and provokes thought into why such barriers exist.

(Echols and Kowalsky, 1984) studied the use of an antibiotic order form which also required an disease indication for the drug to be provided. This method had a significant effect on the use of certain antibiotics. By making it clear that certain decisions are not supported, this method highlights the effect social influence.

The issue of substitution is also seen with the use of order form. (Weintraub et al. 1991) looked at the effect of using triplicate prescription regulation on the use of benzodiazepines. These rules reduced the use of benzodiazepines however in some instances increased the use of less acceptable medicines.

These order forms reviewed above, rely on control to reduce usage whereas (Avorn et al. 1988) used a combined order form with specific educational messages. These combined forms were successful in reducing antibiotic usage. The important issue with the work by (Avorn et al. 1988) is that it provides a solution to the demonstrated problem which the physicians can then follow.

8.4.3.5 Drug and therapeutic committees

Drug and therapeutic committees and the use of formularies are important and widely used methods of administrative control in the UK and abroad. These committees are able to modify behaviour via their role in physician education, cost containment, drug use review and selection of therapeutic equivalents. They call on expert advice to draw up formularies for health boards and with these attempt can control local treatment usage. They also have a role in educating physicians as to their recommendations and formulary decisions.

8.4.3.6 Formularies

Formularies are used to restrict prescribing to a certain approved list of treatments. A main objective of this techniques is to improve patient outcomes by reducing sub-optimal prescribing. It is rare however for those treatments not on this list to be completely unavailable, they will just be harder for the doctor to get hold of. They allow cost containment, based on stock control and more effective negotiations with suppliers. It also allows the use of rational evidence based criteria to base inclusion or exclusion from the list.

Formularies can be approved according to (Abramowitz, 1984) in a number of ways. This includes reducing the number of similar therapies, those of marginal value and the number of combination products that are often only available in fixed doses.

In order for formularies to be used successfully they should be regularly updated, be based on consensus decisions and expert advice. The list of the available treatments should be pocket size and should allow easy cross-referencing between diseases (Plumridge, 1984).

These are similar characteristics to the other forms of intervention that have been reviewed. The importance of peers and local experts provides evidence for ***Surrogating***'s view that personal experience is what is borrowed from others. These experts are seen as holding a large number of individual cases that because they are local are likely to represent the sort of patient and context that the physicians will deal with. This therefore gives them considerable weight when recommending treatments.

8.4.3.7 Clinical Guidelines and Policies

Pharmacists, Drug and therapeutic committees and other groups within the health care provider's structure also develop clinical guidelines and policies. These can provide recommendations on a number of topics such as steps in diagnosis, use and meaning of

diagnostic tests, steps within treatment which treatments and how to use them (Bush, 1979; McDonald and Overhage, 1994).

These policies and guidelines when ***Focused*** on specific areas and following the rules set out in adult learning and ***Trading Off*** can present powerful methods in promoting or restricting behaviour. Informal policies can also form and change in behaviour (Rich et al. 1985).

8.4.3.8 Patient Information Management

The final use of administration to modify behaviour is seen with its use in managing patient information and from this the production of reminders. Many of these studies have previously been looked at during this literature review because of their use of computer technology. Computers are used extensively to hold and manage patient records, to process this information according to protocols, and to issue reminders for treatment check ups, tests etc (Dickinson et al. 1981; Garrett et al. 1986; McAlister et al. 1998; Whiting-O'Keefe et al. 1985).

The benefits are seen as improving the flow and access to relevant information which can then be used in treatment decisions. By providing physicians with all (or more relevant) data concerning their patient, this may change behaviour because of the pieces of data changing the outcome of ***Trading Off***.

The findings of these studies have been mixed with some demonstrating a positive effect on patients (Rogers et al. 1982; Whiting-O'Keefe et al. 1985) whereas (Darnell et al. 1985) was unable to find benefits. These differences can be attributed to the methods providing relevant ***Focused*** information that is in the correct form for the physicians to use when making a decision.

8.4.3.9 Conclusion

Administrative strategies provide effective means of promoting or restricting the use of certain treatments by erecting barriers or providing incentives. In doing so, administrative strategies primarily modify behaviour between the forming of intentions and performance of behaviour. There is an effect on the earlier stages of the pathway however.

Administrative strategies can be used to make it impossible to obtain certain treatments, though more commonly the barriers make obtaining them a more complicated procedure. This is often achieved by the use of order forms or need for approval from higher authorities.

The effect of reducing access to treatments has a secondary effect on the causal pathway by indicating to the physicians that their behaviour is different to that prescribed by a particular organisation. If this organisation is perceived as credible then the physician may question this behaviour and change to conform to the norm. In doing so their Beliefs, Attitudes and Intentions may also change.

The incentives provided by these strategies relate primarily to the social benefits of conformity to the groups wishes. By following the behaviours of a larger and more experienced group, an individual physician can feel more confident in taking these actions. Administrative strategies therefore provide access to recommendations that can be ***Surrogated*** if they are seen as credible and trustworthy. By following recommendations, incentives also exist for the physician by reducing the time and effort required to treat a patient.

As with other strategies, administrative strategies have shown to be successful when used in conjunction with other methods. This was specifically shown by (Avorn et al. 1988) whom combined order forms (barrier and incentive) with teachings on concerning the target behaviour.

Combinations become more important where strict administrative strategies are used to prohibit the use of behaviour. In these instances the changes in behaviour may only last as long as the prohibition, to effect longer term change, education is needed to change the beliefs and attitudes of the prescriber.

The importance of targeting specific behaviours in a flexible manner in order to change them is also seen using this category of strategy. Support from this is taken from the strong effect of personal based methods for erecting barriers. Compulsory second opinions and Peer review have shown impressive effects on the use of certain treatments including caesarean section and elective surgery (Martin et al. 1982; Myers and Gleicher, 1988).

These conclusions concerning administrative strategies provide support for ***Trading Off*** generally and ***Surrogating*** specifically. ***Focusing*** is supported by the need for targeted interventions and the social benefits of compliance provides a further factor for ***Trading Off***.

Surrogating is specifically supported by the effectiveness of peer based methods such as compulsory second opinions and peer assessment. These findings endorse the preferences for location and type of information suggested in ***Trading Off***.

Strict administrative strategies also supply examples of Duty Bound ***Surrogating***, which refers to the use of external sources through duty rather than choice. It also supports the characteristic of this category that the use of treatments from this source may not continue once the control has been reduced or changed.

This chapter will continue with a review of Financial strategies used to modify physician's behaviour.

8.4.4 Financial strategies

In a similar fashion to administrative strategies, financial methods can also promote, restrict or make treatments unavailable. However, financial strategies effect the B.A.I.B pathway by adding a further factor that is ***Traded Off*** before intentions are formed. They also modify actions by interfering between Intention and Behaviour.

A global issue in healthcare is cost containment fuelled by greater numbers of illnesses being treatable with (expensive) medical treatments. The management of budgets at all levels of health care provision and insurance cover provides important methods for attempting to contain this issue however as has been shown previously methods to contain one area can lead to problems elsewhere.

On a personal level, physicians have been shown by (Ryan et al. 1996) to believe that cost of treatments should be and is borne in mind when making treatment decisions. This research also showed however that physicians knowledge of actual cost were often inaccurate which has implications for potentially poor decisions being made because of a lack of understanding.

8.4.4.1 Budgets

Personal and practice budgets are now ubiquitous in the UK and the control of these signals an important difference between types of general practice. Fund holding practices have complete control over their budgets and are responsible for adhering to the limit set for them. Non-fund-holding practices while still possessing budgets have the benefit of the local health board covering any overspend.

These budgets have an effect on the treatments that are used (Wilson et al. 1996). The pressure from the local health authorities to control them provides a powerful financial strategy for changing and modifying expensive prescribing behaviour

Strategies for managing and controlling costs can be based on varying levels of payment and provision made by the health care provider or the patient. This is in the form of national or private health care schemes and the contribution to these schemes either in terms of insurance premiums or co-payments.

The provision of "free" health care has many benefits through the whole of society in terms of health of the nation and of individuals. A free system is however open to abuse as patients may over use it, for example demanding treatments that are of marginal benefit (Soumerai and Ross-Degnan, 1990) and is extremely expensive to maintain. In order to attempt to curb abuses and growing costs various financial tactics have been used.

8.4.4.2 Formularies

Formularies as outlined in Administrative section also have a cost containment role. This has lead to specific cost cutting methods such as generic substitution (using cheaper generic versions when brand names are written on the prescription) and promoting therapeutically equivalent cheaper medicines (Roberts et al. 1997).

8.4.4.3 Capping/Financial Restrictions

Capping represents the restriction of the number of medications that are be paid for by a health care provider. This method has shown to have a strong effect on the supply and demand for treatments by both patients and physicians. In many instances, the modification in behaviour has resulted in a detrimental effect on patient well being.

(Soumerai et al. 1987) found a 30% drop in the number of prescriptions filled when a maximum of 3 medications per patient was introduced. More worryingly large percentage drops in essential medicines were seen and the patient population which was most greatly effected were the most vulnerable (the elderly, poor and disabled).

(Soumerai et al. 1990) studied the withdrawal of payment for drugs deemed ineffective and again showed that desirable and undesirable substitutes were used. They conclude that to use this method requires the use of education to promote beneficial alternatives. This has been a common conclusion throughout this review of change strategies.

They go on to recommend that financial restrictions used should:

1) Not involve arbitrary caps on medication levels,
2) Ensure that cover is maintained for the elderly and low income families
3) Mild co-payments may act against marginally beneficial medicines
4) Be consistent with wider treatment strategies
5) Involve educational strategies

In a later study, (Soumerai et al. 1991) even question whether payment restriction save the health care provider money. In this study they found that the effect of capping reimbursement in elderly patients was to increase admissions to nursing homes and in this way increase costs to Medicaid.

8.4.4.4 Co-payments

The effect of a co-payment scheme i.e. the prescription charge that is levied on certain non-exempt groups by the NHS, can be to preserve number of prescriptions that are filled while generating revenue (Soumerai et al. 1987). The $1 contribution made in this study population is very different however from the 5.75 pounds in the UK. Work to determine at what price co-payments do have the effect of reducing number of prescriptions was not found but represents a topic for further study.

Co-payments are mentioned in this section although they primarily effect provision of healthcare via patient demand. The level of co-payment may however represent a

further factor that is ***Traded Off*** by the physician particularly with poorer patients or when medicines of marginal benefit are being considered. Capping/Financial restrictions also has an effect via patient demand.

8.4.4.5 Conclusion

The Financial strategies reviewed in this section can modify the behaviour of both physicians and patients. They do so in two ways, the first is by manipulating the financial valuation of a treatment by reducing or controlling the amount of money available to spend on treatments. In doing so, financial strategies are increasing the importance of cost as a factor that is ***Traded Off*** for making decisions. It is acting on the Beliefs, Attitudes and Intentions of the physician.

Financial strategies can also modify behaviour by interrupting the Intention-Behaviour link by capping the numbers of treatments that will be paid for.

Cost containment is becoming more important due to a number of reasons including new expensive medicines becoming available and an ageing population. It is vital therefore that the highest amount of care is purchased with the available budget and budgets and formularies have become important tools to this end.

Unfortunately, financial strategies have been shown to have negative consequences on the quality of care provided to the patients. This may be because less effective but cheaper treatments are being used or patients are failing to fill important prescriptions.

8.5 Chapter conclusions

The literature concerning the modification of physician's behaviour has been reviewed in order to frame and develop the findings of ***Trading Off***. Findings from both these sources are important because of errors in medical decision-making that have been previously reviewed. This review can therefore be used to provide rules and recommendations concerning how attempts to modify behaviour should be performed.

Many of the studies reviewed in this chapter demonstrate however how difficult it can be to modify behaviour. A good example of this is the prescribing of Propoxyphene. This treatments was subject to strong warnings from both regulatory bodies and manufacturers concerning safety yet no impact was made on the number of overdose related deaths or numbers of repeat prescriptions (Soumerai et al. 1987). This finding is supported by work by (Ray et al. 1977). This issue provides support for the use of ***Self-Referencing*** as the initial source of confidence for behaviour and the strength of this preference.

Three categories of modification strategies have been analysed using the Belief-Attitude-Intention-Behaviour pathway to explain their effect and as a theoretical model for how to use these methods to progress toward behavioural change.

This pathway has been supported by work in adult education, which provided a number of rules that should be followed in order to achieve the goals set for changing behaviour. These stress the importance of co-operation, involvement and feedback in order to develop an atmosphere where trust and confidence can be built. These rules therefore supply strong support for ***Trading Off's*** perspective on the necessary basis for behaviour to be performed.

This conclusion section will now turn to summarising how to perform modification strategies, it will then develop further conclusions concerning issues raised in this section.

8.5.1 How to perform modification Strategies.

This literature and ***Trading Off*** conclude that modification of behaviour is best achieved using personal methods such as physician visits, one to one tutorials or personal feedback. The success of these methods is due to their flexibility to deal with the individual issues and problems of the physicians and the type of information that they provide.

The information provided to change behaviour should reflect the type of information that is used by physicians in decision-making. This corresponds to experience of individual patients that have been treated previously whose details and outcomes are ***Traded Off*** to build confidence in a treatments. Other physicians are able to provide this kind of information (that is then ***Surrogated***) whereas less effective methods such as clinical papers or bulletins used on their own, are not.

Combining methods, for example one to one tutorial plus follow up with educational memos or ordering restrictions, is associated with greater levels of success in modifying behaviour. Indeed with certain educational methods such as Drug Bulletins and Educational memos their use is limited without combination to personal contact.

Interventions are more likely to be successful if they are provided by respected bodies particularly local experts and opinion leaders. This is an important characteristic in building confidence.

They should also be brief, repeated and care needs to be taken to ensure that all aspects of the strategy refer to exactly the same behaviour. The brevity and repetition properties were also discovered in ***Trading Off*** as preferred characteristics of communication.

8.5.2 Effect of the Strategies.

Methods that have followed these guidelines have demonstrated an effect on a range of outcomes, for example (Dickinson et al. 1981) showed knowledge improvements (Soumerai and Avorn, 1986) demonstrated cost benefits and (Schaffner et al. 1983) showed a reduction in prescribing. In addition to educational strategies, (Weintraub et al. 1991) reported the successful reduction of benzodiazepine prescribing using an administrative strategy.

8.5.3 Lack of Success of Interventions

Conversely interventions that have failed to show a positive effect can be explained by the poor use of educational theory. For example, (Evans et al. 1986) who used a method that was not focused and flexible to the task.

It is important to note however that the successful implementation of the above rules does not necessarily lead to the desired change in behaviour if external issues interrupt the B.A.I.B pathway. These rules therefore require therefore the additional analysis of potential external barriers and measures to overcome them.

8.5.4 Length of Effect

The issue of successful modification of behaviour needs to be developed to include the length of the effect. Many interventions have been shown to work for short periods before the effect wears off (Berbatis et al. 1982) (Plumridge and Berbatis, 1989).

This issue is particularly apparent in Administrative and Financial strategies where changes in behaviour may be due to external barriers preventing the intended courses of action taking place. The use of these strategies without modifying the precursors of behaviour is likely therefore to persist only as long as the barriers do.

This then develops Duty Bound ***Surrogating***, to include being duty bound to follow because of financial and administrative strategies in addition to the physician with clinical responsibility for the patient.

The temporary internal changes observed with the use of educational strategies call for the repeated and continued use of educational methods concluded above as a necessary component of behavioural change. Work by (Gurwitz et al. 1992) support this need but go on to conclude that the effectiveness of repetition reduces over time.

This decay of learning occurs and the return to previous modes of action may be due to the "recency" effect of new information. This well known phenomenon may lead physicians to Trade Off recent information with more weight and therefore base behaviour on it. However, the confidence developed may not be sufficient to replace their previously favoured behaviour when recency effects diminish (Hovland, 1957).

8.5.5 Unexpected implications of modification

It has been noted throughout this review that there can be a number of unwanted consequences of success in modifying behaviours. (Weintraub et al. 1991) found that benzodiazepine guidelines lead to the increased use of other undesirable agents. This was also reported by (Ross-Degnan et al. 1993) with the withdrawal of Zomepirac. This phenomenon demonstrates the importance of the wider decision context that has been a feature throughout this literature review.

8.5.6 Framing and Development of *Trading Off*

Modification of behaviour according to ***Trading Off*** occurs when the ***Trading Off*** of important factors in the ***Focused*** situation leads to greater levels of confidence in the new behaviour than the old. Critical in this process is providing experienced based information whose role was highlighted earlier in this section.

Successfully changing physician's behaviour causes a ***Shift*** in the location from where information concerning the behaviour is taken. Initially the information necessary for change comes from ***Surrogated*** sources, this is true for situations where the physician already has experience of the "new" behaviour". There is therefore a temporary ***Shift*** to the use of ***Surrogated*** sources which ends when experience and expertise develops to move the location back to ***Self-Referenced*** sources.

Shifting is also developed by adult learning research which adds that before ***Shifting*** can occur, the need for change has to be recognised and feedback has to be available. This is in order for the physician to Trade Off which source and behaviour to use.

A final aspect of ***Trading Off*** developed by this chapter has been Duty Bound ***Surrogating***. This category has been developed to include the following of behaviour imposed by health care providers as well as colleagues that are more senior.

As stated in the introduction to this chapter, many of these methods can be used by the Pharmaceutical industry in their attempts to increase usage of particular treatments. These efforts will now be reviewed.

9 Chapter Nine Modifying Physician's behaviour- The Efforts of Pharmaceutical Companies

9.1 Introduction

This chapter provides qualitative investigation of the efforts of pharmaceutical companies to modify the behaviour of physicians and other related parties to satisfy their own objectives. This investigation will be constructed around telephone discussions with marketing representatives of two highly successful pharmaceutical companies. In addition to this, literature from various sources concerning pharmaceutical marketing will be used to support or expand the issues and methods discussed.

This chapter provides an insight into how pharmaceutical companies use, (or attempt to) the strategies and methods outlined in the previous chapter to satisfy their own sales and profit objectives. A crucial factor in these attempts, is the problem with lack of credibility that the industry faces. This is an integral factor in building the confidence in pharmaceutical companies as a legitimate information source and one that will be ***Surrogated.***

The targets for the industries efforts go beyond the physician's themselves and include: Patients, Pharmacists, Prescribing Advisors, Health Board and Health Authority formulary committees[11], individual members of such committees, Practice managers and formulary management involved in Primary Care Groups[12].

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[11] Health Boards administer health on a regional basis in Scotland whereas in England the analogous body is a Health Authority. Throughout this chapter Health Board will be used to refer to both these organisations unless individual explanations are required.

[12] Primary Care Groups (PCG's) are a recent government initiative that will replace fundholding and the internal market of the NHS introduced by the last Government. This initiative involves the collaboration

This represents a development from the strict targeting of physicians due to their role as "gatekeepers" and "deciders" for patient care(Schiffman and Kanuk, 1997). This change is a result of the dramatic increase in the cost of health care caused by an ageing population, medical advances and increased patient expectations[13]. This issue is mirrored throughout the world and will be dealt with in greater depth in the next section.

The UK government reacted to this by demanding higher levels of financial accountability from the NHS in its role as the primary health care provider to the UK population. In order to achieve this management structures were imposed that were designed to ensure the cost effectiveness of the treatments used.

A main tool used to achieve this has been the formation and management of formularies on a local scale. The managers and influencers of these formularies now represent crucial target market for the pharmaceutical companies.

This chapter is primarily based on the attempts to change the behaviour of individual physicians, however the importance of formulary status means that attempts to modify the behaviour of formulary influencers will also be addressed. Pharmacists also represent an important target market for pharmaceutical companies both directly for manufacturers of off patent and OTC[14] pharmaceuticals and as influencers of physicians prescribing.

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of primary care providers in a local area, who through management of their own budgets, provide care to groups of approximately 100,000 patients. An important role of these groups is to ensure the cost effectiveness of care provided, it is expected that this will result in group buying behaviour based on cost effectiveness data.

[13] The cost of the NHS grew from 21,037 million pounds in 1987 to 44,301 in 1997(UK National Accounts, 1997).

[14] Over The Counter

The marketing efforts directed to this group will be explored under the relevant heading of the marketing mix. The core of the discussions held was however based on the efforts to modify physician's pharmaceutical prescribing behaviour as this relates directly to the topic of this thesis. Therefore, the attempts made directed to the other targets will be discussed as they contribute to this goal.

Overall, this chapter will look at the various target markets as they influence physicians and the important market conditions that influence the decisions of groups. In addition, the strategies and methods used to satisfy these targets will be reviewed and finally future developments suggested during the discussions and literature review will be outlined.

9.2 Target Markets

This section will combine details on the target markets with the important market conditions and how this has effected their decision-making and as a consequence, the industries marketing efforts.

As mentioned above, a number of target markets exist for pharmaceutical companies. (Harrar, 1994) suggest these can be categorised as:

1. Health care as a business
2. Traditional Physicians
3. Cost Sensitive physicians
4. Medical thought leaders

To this list can be added Pharmacists, Nurses, Patients and Physician Assistants (Zollocco, 1993). The findings of the discussions however suggested the following target markets are used as:

1) Physicians. Including GP's, Hospital doctors, and opinion leaders

2) Formulary influencers. Including Prescribing Advisors, Health Board and Health Authority formulary committees, Practice managers and formulary influencers involved in Primary Care Groups
3) Pharmacists
4) Patients

These groups and their influences will now be examined.

9.2.1 Physicians

The individual physicians categorised in group one were thought to remain (though arguably!) the most important group as they represent the gatekeeper who make the ultimate decisions as to treatment choice. This position is supported by (Miller, 1994).

This group is seen as being subject to two often conflicting pressures in their choice of treatments. They have (as discussed in chapter 5 a primary responsibility to provide quality care for their patients however this can be in conflict to cost pressures placed on them. Financial pressures have lead to an increasing cost sensitivity by this group.

Efficacy remains however, the most important factor in treatment choice, a contention that is supported by (Segal and Hepler, 1982). (Redwood, 1993) also add weight to this by suggesting that Research and Development into new drugs is a winning company strategy. Indeed the success of the highest selling pharmaceutical ever, Zantac ™ is seen to be based ultimately on it's efficacy.

Beyond efficacy, the side effect profile of a treatment and cost are important decision criteria. To this can be added compliance, cost to the patient of the drug (Segal and Hepler, 1982). These factors represent positive and negative consequences of action, the balance of which is important in decision-making.

The problem of patient compliance and the steps companies taken to improve it are important for two reasons. The first is related to the efficacy of the treatment that is undermined by patients not complying with the instructions of the prescriber. The second involves the cost of the treatment and means that poor compliance reduces it's cost effectiveness. Therefore, steps taken to improve this problem are important to the doctor, patient and health care providers.

In targeting physicians, the pharmaceutical companies need to provide evidence for their claims concerning their products. Whilst this has long been a feature of medical decision-making, recent market conditions mean that "Evidence based medicine" has become a crucial activity in health care.

Evidence is not only required for the individual claims made by the companies but there is a growing desire for longer term outcome data in terms of reduction in mortality, morbidity and cost effectiveness compared to other treatment options. In response to this, pharmaceutical companies have been increasing their research and output of this kind of data (News Briefs, 1994). The formulary influencers target market also requires it.

It becomes important at this stage to reiterate a number of aspects of ***Trading Off*** in order explain the relationship between this need for independent quality evidence and ***Trading Off***'s discovery of the form of information preferred by physicians.

More specifically, why is study evidence required by decision-makers when ***Trading Off*** says that experiential evidence is preferred? When new behaviours become accessible to an individual, there is not a self-referenced store of experience available so ***Surrogating*** occurs. This is most likely to be from colleagues or local eminencies. If this is not available (at some stage access to experience becomes very difficult) then in order to build confidence less preferred sources and type of data may be used. Therefore a need for study evidence develops.

As this type of information and its source (if it is being pushed by a pharmaceutical company) are less effective at building confidence then adoption is likely to be slow. This is a phenomena found in ***Trading Off*** with all products that are new to a physicians armamentarium. The rate of adoption increases as experience is developed. If this "inferior" source and type of information (in the minds of the physicians) needs to be used then clearly well constructed independent study evidence is preferred.

Secondly, it is important to note that the preference of ***Self-Referencing*** (which underlies the above explanation) is responsible for a level of inappropriate decision-making and medical errors. The movement for evidence based medicine, providing it and training physicians to use it should decrease these errors. ***Trading Off*** suggests concerning the provision of information, that by presenting the findings of well constructed studies in an experiential form that the physicians will trust and use, then modifying behaviour easier and improving performance should be made easier.

9.2.2 Summary

The physicians target market is charecterised by the conflicting pressures of providing care to the patient and need to work within a continually stretched budget. Of particular importance to this group is the efficacy of the treatment in comparison to other options and to it's negative consequences.

As a result of the pressures on these groups there is an increased desire to practice evidence based medicine in conjunction with growing cost sensitivity.

9.2.3 Formulary influencers

This group represents the individuals involved in the management of formularies (either formal or informal) for the different administrative layers of the NHS. Whereas the

physician's are regarded as having a primarily effectiveness-cost based outlook, formulary influencers are perceived as having one based on cost-effectiveness. Once again, there is a need for evidence concerning these issues.

Their role involves an increasingly strict management of prescribing budgets via formularies providing physicians with list of cost effective treatments from which they can choose. This can be interpreted as a strategy to increase Duty Bound ***Surrogating*** in physicians choice.

By proscribing certain treatments this target market is able to have an increasingly strong effect on physicians decisions. It is recognised by the pharmaceutical companies that at whatever level a formulary is set up it is crucial for it's product to be included. The importance of inclusion is also expected to increase.

In order to be included, cost and evidence of the efficacy of treatment and cost effectiveness are required. This data should be based on well constructed, independent studies. Specifically, evidence for long term cost effectiveness demonstrating a reduction in expenditure in other services and treatments is wanted. These criteria were also found in ***Trading Off***.

An example of the industries reaction to this need is seen in (Bennett et al. 1997) who produced cost effectiveness data for the use of Interferon alpha2b that would support it's inclusion on formularies. The cost effectiveness of this very expensive drug has also been studied by (Messori et al. 1997; Wong et al. 1995).

These requirements cause problems for new products and their inclusion on formularies though. As a new product it is not possible to have conducted long-term outcome studies based on a large population. Even in the medium term, these studies may be difficult to produce as a lack of formulary status may limit the numbers of patients available to study.

9.2.4 Pharmacists

Pharmacists are an important separate target market beyond their input to the formulary process. They are a source of information used by physicians and patients in their decision-making. This patient role is important for compliance to the treatment as extra direction may be needed.

The distribution channel that pharmacists control means that producers of OTC and off patent products target this group in order for their product to be recommended or sold amongst the alternatives. In the case of generic pharmaceutical companies they are their primary target market. The methods undertaken by companies to sell in these circumstances are not reviewed here as this fall outside the scope of pharmaceutical company influence on medical decision-making.

The methods that fall within this area of influencing pharmacist in order to influence prescribing can be divided into two categories. The first are those strategies and methods designed specifically for pharmacists. The second refers to campaigns where they are included along with other target markets.

9.2.5 Patients

Patients as the end users of medical care, the ultimate financiers of it and the need for physicians to take account of their wishes (see chapter 5) ensures that they are seen as a fundamental part of the medical decision-making process. This is supported by (Miller, 1994)

They are an independent target market for pharmaceutical companies because by motivating them to seek medical advice for a particular problem the size of the market can be increased. In addition to this, a number of other factors were identified as

increasing the importance of patients as a target market. These include the increase in patient consumerism resulting in demands for inclusion in the decision-making process, a shift in the patient-doctor relationship and the availability of medical information (primarily via the internet) (Solberg, 1995).

The switching of a growing number of drugs (often in the form of a reduced dose) from of Rx[15] to OTC has also created a patient target market who in addition to being the consumers are the buyers as well. For example, Ranitidine, Famotidine and Cimetidine have all been licensed for purchase OTC as indigestion therapies.

9.2.6 Summary

This section has identified the four main target markets for pharmaceutical companies. The most important driver within all of these markets currently is the increasing cost of health care which has in turn created a focus on the cost effectiveness of treatments. Efficacy, side effects and compliance issues remain important however.

This situation has increased demands from physicians and formulary influencers for good quality evidence regarding these decision factors. For the formulary influencers, outcome research is of particular importance so the benefits of the treatment can be assessed in comparison to other options and in the long-term.

Beyond the production of this data, the pharmaceutical companies need to address the issue of their poor credibility as sources of information. Without an improvement in the quality of information provided to the decision-makers, pharmaceutical companies will continue to struggle to be perceived as sources of information upon which to base decisions.

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[15] Prescription only

9.3 Methods

This section will detail the methods and tactics used by the pharmaceutical companies using the Marketing Mix as a structure. It will not provide details on specific strategies used by the companies who representatives were spoken to. This is due to conditions of confidentiality placed on the specific product details by these companies.

It will therefore provide insights into methods used to reach the target markets in the current environment as outlined in section 9.1, to which can be added the legal and regulatory constraints on the industry[16]. This section will highlight specifically the efforts made to achieve formulary status, increase patient primarily to be chosen amongst alternatives.

As cost effectiveness and the growing importance of the cost in medicine were identified in the previous section as the most important factors effecting the market, the companies use of Price will be reviewed first.

9.3.1 Price

The price of treatments is a contentious issue throughout the world. In Britain this struggle exists between the government and the Pharmaceutical industry. On one side the government and the NHS are attempting to control the enormous sums of money spent on medicines. This figure was 5608 million pounds in 1997 (UK National Accounts, 1997) and within this figure individual treatments can cost 10,000 pounds per patient per year in the case of Interferon beta-1b.

The industry argues however that they need to make high levels of profit from individual compounds. This is due to the short time they are protected by patents, very high R and

[16] The regulation of the Pharmaceutical industry is provided by the Government and by the Association of the British Pharmaceutical Industry (ABPI). This trade organisation provides a code of practice for its

D costs and the lack of guarantees that this will process will produce profitably compounds. In support of this position they claim to spend 2218 million pounds in the UK on research and development and that a drug on average takes 10-12 years to get to market at a cost of 350 million pounds (ABPI, 1998).

In order to manage these positions the prices of medicines in the UK are controlled by the Pharmaceutical Pricing Regulation Scheme (PPRS -see Appendix Twenty Three for details). This scheme dictates a range of overall profits within which the industry must set the price for individual compounds, it also sets levels for promotional budgets.

Once the price of a drug is set and it is launched it is unusual for companies to increase this price during the life of the patent. The loss of patent protection for a drug signals however a period of rapid decline in the price of the compound as generic manufacturers launch bioequivalent versions. The resulting price competition is seen as reducing the price of drug by 90% within the first year. This in turn has consequences for the original compound manufacturer. For example Zantac sales declined by 618 million pounds world wide in the first year after loss of patent protection (GlaxoWellcome, 1999).

The absolute cost of a product is seen as more of a concern to the formulary influencers when making decisions. The introduction of individual practice budgets means however that individual physicians are becoming more price sensitive in their decision. This is supported by (Ryan et al. 1996) who also found that while price was a consideration, the knowledge of the actual level was poor.

9.3.1.1 Price Strategies

The use of price as a method of changing behaviour is most clearly seen in generic pharmaceuticals. Price is used as the main tactic of many of these companies in

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members concerning their commercial activities. It represents companies responsible for 90% of medicines used by the NHS

attempts to capture scripts either within the community or hospital pharmacy. It is also used to switch the choice of physicians by changing their perception of value, this demonstrates the trade off of price and other variables. Other issues such as demonstrating bioequivalence and ensuring continuity of supply are also important.

The money saved by using generics is dependent on the physicians prescribing the treatment with its generic not branded name. This then allows the pharmacist to dispense any licensed form of the drug. As levels of generic prescribing are still less than 100% there have been calls for automatic generic substitution, the industry and some pharmacists are against this however (Pelton et al. 1994).

Cost effectiveness data mentioned throughout this chapter represents a further price tactic of the industry. In attempting to show their products represent good value for money, companies compare the cost of their product to the savings made in other areas such as:

- Reduced hospital admissions
- Surgery
- Need for other medicines
- Reduction is physicians time spent with the patient.

An interesting piece of evidence for the importance which the industry has placed on value and cost effectiveness is the ABPI's website where the "Pharmaceutical Facts and Statistics" page is dominated by statistics demonstrating these factors (ABPI, 1998).

The perception of High Price equalling High Quality is seen within the pricing tactics used by industry particularly for new classes of compounds. However the practice of entering the market at a higher price than the market leader in order to "demonstrate" it's potency, is a tactic that is declining and is tipped to disappear.

Price Discounting to hospitals is a tactic that is used to help gain access to formularies. By providing the treatment at sometime vastly reduced prices, the companies are relying on continuation of the therapies in the community setting at full price to realise profits for them.

This tactic of "buying" market share has been criticised by GP's as the cost burden is transferred to them. A variant on discounting which removes the charge of differential pricing is to provide sales promotions where free product is linked to purchased products i.e. buy one get two free.

The advent of PCG's is expected to create price discounting in community settings as groups negotiate with pharmaceutical companies in attempt to secure bulk order discounts from them. There is concern in the industry that the use of this tactic by the PCG's and Health Boards may lead to the inclusion of "me too" products who do not possess the same quality of evidence held by the market leaders. In turn fears exist concerning the denial in this way of appropriated care (Chaudhry and Walsch, 1995).

9.3.1.2 Summary

The price of pharmaceuticals is a contentious issue between providers and purchasers world-wide. It is a major tool used by pharmaceutical companies in marketing their products, despite its government-based regulation. The manufacturers prefer to highlight the value that expensive compounds represent. Data showing this is a crucial component for gaining access to formularies and in prescribing.

Discounting can be (and is) used to increase the value of the products to the formulary influencers and physicians. The use of bulk discounting is expected to increase as a tactic as PCG's are set up and cost pressures grow throughout the sector.

9.3.2 Product

The strategic development of pharmaceuticals for specific problems is, unfortunately for the companies, a risky process. Despite the huge sums of money spent on R and D it is not possible to guarantee that the process will yield effective drugs that can be marketed successfully.

Research and development remains however the fundamental business function for the majority of ethical pharmaceutical companies. It not only provides the initial compounds to replace those that have lost their patent protection, but also provides variations that are used to prolong the products life cycle.

The pharmaceutical product can be divided into two areas, the core and the peripheral attributes of the drug. The core attributes are the products mode of action (and hence efficacy) its side effect profile and interaction. These characteristics are fundamental to the drug and often cannot be changed without changing the drug. The peripheral attributes involve the length of action, presentation, packaging and range of doses. These characteristics represent variable that can often be manipulated as part of the product mix in order to provide advantages in the market place.

Peripheral attributes can be developed in order to match the needs of smaller groups of patients and therefore can be used to influence the prescribing of physicians. A wide range of options available for the product is also seen to effect formulary influencers.

9.3.2.1 Core Attributes

The efficacy and side effect profile of a drug are in general, the most important core attributes of the product and represent the central tools for gaining acceptance with physicians.

Of lesser importance are the interactions associated with compound. These become more important if they interact with commonly prescribed medicines or food and drink.

There importance is also increased in patient groups such as the elderly who are more likely to be receiving a number of medicines therefore increasing the likelihood of interaction occurring.

As has been stressed throughout this investigation, independent evidence for claims made regarding the core factors are required by both physicians and formulary manager. The production of such data can be seen as a Product function and decisions to set up and fund these trial have important bearing on the likely success of a product.

The findings of these studies and the interpretation placed on them provide pharmaceutical marketers with an opportunity to position their product in the mind of their consumers. In doing so however care must be taken to ensure that positive interpretation do not undermine the credibility of the company. It is this issue that has lead to increases in independently produced data (News Briefs, 1994).

9.3.2.2 Peripheral Attributes

Peripheral attributes provide the pharmaceutical marketer with opportunities to develop their products to match more accurately the needs of the patients. The list of characteristics in this category can be manipulated in the following ways

- Length of action, via modified release formulations
- Physical form, development of tablets, tablet coatings, capsules, injection, sprays, liquids, gels, effervescents, and "melt" formulations
- Range of doses
- Packaging, developments designed to aid compliance to the drug i.e. the contraceptive pill with clearly stated days and arrows to remind women which pill to take.

These variations are also used to extend the products life cycle in some instances beyond patent protection if the variation is unique and valued by the market. Glaxo used this tactic with Zantac ™ by introducing a number of product form variations including GELdose and an effervescent tablet. In addition to the lifecycle benefits unique formulations and modified release formulations allow higher prices to be charged, benefiting profit margins.

9.3.2.3 Summary

The information discovered concerning the product mix can be divided into two areas. The core characteristics represent the most important aspects of the product and can be developed by conducting well designed clinical studies. These studies then form the basis of the companies marketing efforts in the current market where evidence concerning claims is needed. The behaviour of both main target markets can be influenced by manipulating these factors.

The peripheral aspect which also require to be supported by clinical evidence, provide marketers with areas which can be manipulated in order to match the requirements of smaller groups of patients. In doing so they can allow niche markets to be developed or the life cycle of the product to be extended.

9.3.3 Communications

The Communications strategies of pharmaceutical companies are primarily based around the use of sales representatives. These representatives exist under a number of titles, however they can be placed into only two separate categories. The different kinds of representatives have evolved in order to target the different target markets and differing needs that exist in within healthcare.

Representatives are used in conjunction with other methods from the communications mix in order to increase their effectiveness. The effectiveness of combining techniques was discussed in chapter 5. Their use as the primary communications tool is based on the benefits of social interaction that have featured throughout this literature review and are explained in ***Trading Off***.

This section will therefore be conducted by detailing the use of the representatives and will be followed by the other components of the communications mix.

9.3.3.1 Representatives

The role of company representatives has evolved from a purely selling function into two discernible roles. The first of these mirrors the traditional role and whose job is to create "noise" in the market place. The second and more recent role is to provide Service to the customers, in order to add value to the company-customer relationship.

These approaches may be performed by the same individual though it is becoming increasingly common for different representatives undertake them. Formulary influencers, physician and pharmacists receive attention from both these groups though the physician and pharmacist remain the primary targets of the traditional selling function. Direct contact between patient and the representatives is restricted.

By providing services, the pharmaceutical companies are attempting to build their credibility in the eyes of the customers. For example physicians have been found to want information and education from pharmaceutical companies which in turn will allow them to develop the long-term relationships they desire (Andaleeb and Tallman, 1995).

9.3.3.1.1 Traditional Representative Approach

The traditional "detailers" are used to develop awareness of the medicine and deliver key messages designed to sell the product. In order to do this many pharmaceutical companies are using contract sales forces such as Innovex or RDL[17] to provide this function in the short and medium term.

This short-term approach is in contrast to the effectiveness of a long-term relationship that is seen as most effective in achieving company goals. Formulary influencers, physician and pharmacists are all targeted by this approach with the use of evidence to support their arguments crucial.

This move to evidence based selling is contrasted to the common perception of ethically dubious practices used by representatives to achieve sales. For example paying for lavish entertainment and trips abroad where the primary objective is leisure not education. Incentives still form an important tactic for representatives however controls over what is acceptable are becoming tighter. The use of incentives will examined in greater detail later in section 9.3.3.6.

9.3.3.1.2 Service Representatives

The role of the representative as a service provider has evolved more recently. The primary objective of this role is to add value to the company-customer relationship in order sell more effectively in the long-term. This is achieved by providing a number of services to all their customer groups. These services include education, training, audits and health promotion.

[17] Rapid Deployment Limited

The services that are organised are integrated to the selling function of the representatives. This is achieved in two ways; the first involves the representatives providing services as rewards for doctors who use the companies products. The second is the use of the services to build a relationship and is more dependent on integration with the selling function in order to avoid the services benefiting competitor products.

9.3.3.1.2.1 Education

The desire of physicians to be provided with information as part of their relationship with pharmaceutical companies provides an important objective for the efforts of the service representatives. This need for information (though the actual requirements differ) is also seen in pharmacists, formulary influencers and patients.

Education is used not only to provide information on the companies products but also to inform the physicians concerning developments in the wider disease area. The need for physicians to remain up to date ensures that education, if well organised, is a popular service for this group particularly.

At the lowest level, this involves providing "details" that are based on independent literature, balanced in their approach and may provide guidelines and clinical papers in support.

Education may be provided more formally by organising specific meetings to which the physicians, formulary influencers and pharmacists are invited. Educational meetings for patients are not organised, this group in educated with the use patient information literature and via health care providers.

The education may be conducted by the representative though greater benefit is gained from inviting a local or national eminence. The credibility of eminencies can be

undermined however if they are too positive toward the company's drugs or are seen as providing this service too often ("rent an expert").

The form of the meetings may be a lunchtime or evening meeting or more elaborately a weekend symposia (or longer) where a number of topic are covered. These forms of education can be organised by the representatives or sponsorship is provided to meetings organised by interested bodies.

It is expected that at such meetings entertainment is provided, the amount and expense of this is an important issue both ethically and from a credibility perspective. The entertainment component to the meetings provides the representatives with the opportunity to address a second objective of the meeting that is to develop specific relationships. These relationships can then be used to sell or to gain access in the future and to sell at that opportunity.

9.3.3.1.2.2 Training

Clearly related to education is the service provision of training for health care professionals. This category encompasses a wider range of activities including disease-related skills and business development skills. The target for these activities are formulary influencers, physicians pharmacists and other health care employee such as receptionists and administration staff.

Disease related activities include training in the use of diagnostic equipment such as lipid analysing machines, the performance of simple surgery or the running of disease clinic. The choice of these activities is clearly designed to eventually involve the company's products.

The use of business training as a service is an activity designed to enhance long-term relationships and to allow easier access to the important healthcare providers. Activities

include negotiation and presentation skills, basic marketing courses, computer training, and seminars on how to deal with disruptive patients. These activities can be viewed as general business training and also as personal development activities. They may be performed by the representatives or other specialist within the company.

9.3.3.1.2.3 Audits

The performance (or aid in performing them) of audits is an important service that can be used to help physicians, formulary influencers and patients. The two main kind of audit provided are audits of specific disease areas (benefiting physicians and patients) and prescribing audits (benefiting formulary influencers, physicians and in the longer term patients).

Disease audits are designed to identify patients within an area and ensure that they are being treated according to predetermined guidelines. The work by (Taylor R.J. and Bond, 1991) supports the use of this methods as large number of patients may be receiving superseded treatment. In doing so the company and the patients benefit if their treatment is genuinely improved.

Cost audits are similar in that they identify particular treatments and suggest alternatives to reduce cost without compromising patient care. These can be performed on a practice, PCG or health board level.

The clearest example of this is auditing patients who receive an off patent drug and ensuring that they all receive a generic equivalent to the more expensive brand. A further argument used to promote this activity is that it can be used to make saving to pay for more expensive medicines in other areas. The general patient population can benefit as do formulary influencers and physicians.

9.3.3.1.2.4 Health Promotion

The assistance in setting up, running and funding health promotion exercises is designed to aid patient, physicians and the wider healthcare community. This assistance may involve providing educational literature, equipment (such as blood pressure monitors) promotional literature advertising the event and in some instance providing nursing support.

These activities again are designed to create goodwill and a feeling of partnership within healthcare. The synergy between the company products the areas of health promotion is also likely to provide increased numbers of patient presenting and hopefully increased sales.

9.3.3.1.3 Summary

Two main roles now exist for company representatives as the most important component of pharmaceutical companies marketing efforts. These roles may be performed by the same person or as is becoming more common, a team approach to delivering these activities is used.

The traditional role of the representative is to create noise in the market place and to sell the companies products through evidence based key messages. A more recent role is to provide services such as education, training, audit and health promotion to the many markets they target. These activities are designed to improve the long-term relationship with the customer, increase the numbers of patient presenting to the physicians and ultimately to improve sales.

Their central role in pharmaceutical marketing is derived from the benefits of personal contact and communication that have been reviewed concerning social influences on choice. See chapter 7. By providing the benefits of flexibility and two-way

communication, representatives can be used as sources to be ***Surrogated*** from and hence modify behaviour. This relationship is undermined by the poor image many pharmaceutical companies have and the underlying sales objective. The development of the service role and the increased outcome research by companies can work against this credibility problem.

Representatives are used in conjunction with other communications methods to increase their effectiveness, these activities will be now be reviewed.

9.3.3.2 Advertising

Due to legislative restrictions concerning the use of television and radio advertising, pharmaceutical advertising is predominately based on print media. These regulations prohibit advertising of pharmaceuticals directly to the patient. This is not the case for OTC remedies.

The main target markets for this print media are therefore physicians, pharmacists and to a lesser extent formulary influencers, whilst radio and TV advertising is used for patients. In keeping with the medical decision-making focus of this thesis, this section will outline the advertising that effects these decision-making and not how it effects patient in their choice of medicines.

9.3.3.2.1 Print Advertising

Advertising is used to support representative's activities by creating noise in the medical environment. This noise is most commonly in the form of repeated key messages designed to enhance recall or creating awareness.

These messages can be placed in a wide range of medicine related publications, including

- General research journals e.g. NEJOM or the BMA
- Journals covering specific areas, e.g. Journal of Human Nutrition & Dietetics
- Journals covering specialties e.g. British Journal of General Practice
- Reference sources e.g. MIMs or BNF
- News based medical publications e.g. GP magazine.

The large numbers of publications who accept advertising copy and the large numbers of companies willing to take them up has created perceived problem with clutter and lack of visibility. It is felt by pharmaceutical marketers that often very little attention is paid to advertisements. This results in only small amounts of information being placed in the advertisement and the need to find novel places to place their messages. These issues effect all forms of pharmaceutical company communication.

9.3.3.2.2 Advertorials

The restrictions in the amount of information that can be provided in an advertisement has lead some companies to pay physicians to write articles for magazines on their behalf. These articles may be used to highlight specific disease related problems of developments that in turn provide opportunities for the companies. This kind of article

is known as an advertorial and can, if done subtlety, overcome credibility issues faced by overtly paid for adverts.

9.3.3.2.3 Company Magazines

A similar technique to advertorials but one which is also related to providing services to medicine is the production of company magazines. These magazines supply information and articles on a topic related closely to a companies products.

Authors are paid to contribute articles which again highlight issues in the particular area. Care is taken not to produce magazines and articles that are overtly promotional as this is seen to reduce the publications standing.

9.3.3.2.4 OTC Advertising

Radio and Television media can be used to promote medicines that have been moved to OTC status. These adverts can also effect physicians directly as it is possible they will consume the adverts as well and indirectly as patients mention or ask for the products in consultations.

9.3.3.3 Direct Mail

Direct mail techniques are used principally to create awareness and elicit responses from physicians, Formulary influencers and pharmacists. The importance of extracting a response lies with ABPI limits on the number of pieces that can be sent. Therefore, this technique tends to be used for objectives that are more elaborate than simply creating noise and repeating key messages.

The information provided in the communication is often linked with a reply paid envelope that represents the response the companies are attempting to create. The responses from direct mail can be divided into two categories. The first is requests for

representatives to call with more information on services that may have been discussed in the communications. The second is to request incentives offered by the company, for example fire extinguishers or tool kits. These incentives, delivered by the representatives then provide a sales opportunity.

The support role that other communications methods supply for representatives is clearly seen with the use of direct mail. The use of this method supports both the sales and the service role of the salesforce.

9.3.3.4 Public Relations

Public relations activities are also used to assist other marketing and communications operations in attempts to modify behaviour. Their activities are used not only to promote the companies and its perspective to health care professional but to the government and the general public. The ABPI provides an industry wide vehicle to achieve these goals.

Topics promoted in this way include new product developments and launches, scale of disease problems, charitable undertakings and information in response to criticism. This later point is illustrated by the Pfizer's response to government censor regarding the price of Viagra ™ (BBC Online Network, 1999).

9.3.3.5 Sponsorship

The use of sponsorship was mentioned briefly in the section dealing with educational services. It involves paying for a wide range of activities organised by local national and international bodies in fields as diverse as education, health promotional and business management. It therefore is used to target all groups of customers.

It is used for a number reasons including enhancing a companies reputation, developing contacts and relationships and creating associations between a company and a disease area. Sponsorship can also provide excellent opportunities to promote the company's products either at the time of the event or after.

9.3.3.6 Incentives

The practice of giving physicians, formulary influencers and pharmacists incentives is a widely criticised activity that creates ethical dilemmas for these groups. It has been suggested that incentives can be given where there are "no strings attached" (Gotthelf, 1996). This is however a naive attitude as the companies distribute them specifically to gain access to customers and build relationships. Results that are clearly linked to the goods and services provided.

The cost of the incentive clearly has a role in the ethical position of the activity. Incentives range from elaborate overseas trips to dinner, lunch, donations of equipment such as fire extinguishers and at its most simple, pens and note pads. The use of expensive incentives has seen them decline in recent years as both companies and customers become more uncomfortable with the conflict of interest and the drive to practice evidence based medicine.

A feeling remains however that incentives reward customers for their time spent listening to representatives and that they provide a useful tool in gaining access to decision-makers. The use of the method is likely to continue therefore though with stricter guidelines and greater openness.

9.3.3.7 Summary

The core information that is perceived as crucial to deliver to its target markets by the communications activities of pharmaceutical companies are: effectiveness, cost, cost effectiveness and long-term outcomes of the products.

These figures should be produced by well-constructed independent studies and may be presented differently to physicians, formulary influencers, pharmacists and in some instances patients. In doing so, the companies hope to be included on formularies at all levels, be stocked in the pharmacy, and be chosen amongst alternatives by the physician.

The delivery of this information and the other communication objectives is centred on the use of sales representatives. Recent developments have seen the sales function develop two separate roles, the first of these is to create noise in order to sell the companies products. The second is to provide a number of services in order to add value to customer relationships and to develop a long-term relationship with them. In turn however these services ultimately allow the companies further opportunities to sell their products.

The work of the representatives is supported by other methods within the communications mix most noticeably the use of print media. These other methods may be used to create sales and service opportunities or to reinforce key marketing messages.

A fundamental issue faced by pharmaceutical companies in their communications is gaining sufficient credibility so that their messages will be accepted as legitimate sources for ***Surrogating***. The use of representatives, provision of services, production of independent data, long-term relationships and a balanced approach to selling are methods that will increase the likelihood of this occurring.

This would be enhanced further if the data provided to physicians was in the form detailed in ***Trading Off***. Physicians should be given access to actual clinical cases in

order to see how real patient that match their charges react to the treatments being sold. In this way the companies would be matching the type of information used in decision-making with that provided.

9.3.4 Distribution

The final component of the marketing mix that can be employed to modify behaviour are the channels used to distribute the product. These channels are rigorous controlled by legislation in the UK which severely limits the ability of the pharmaceutical companies to use this variable. Indeed, it was an area that was only mentioned briefly during the discussions upon which this chapter is based.

In reality the crucial aspects of distribution for pharmaceutical companies is to ensure that it is available in all pharmacies where it is needed. If the product is unavailable then the physicians may change to prescription to another option.

Distribution becomes more complex in the case of generic and off patent branded pharmaceuticals. In these cases the pharmacist becomes an important decision-maker who is seen as making decisions based on cost and continuity of supply.
As regards the physician once a generic prescription has been written the choice of the actual version lies with the pharmacist.

Formularies can be viewed as form of distribution control imposed by health care providers. Currently if a physician prescribes a particular product that is not on formulary, there is a requirement for the drug to be provided. The barriers and time delay caused by this may however cause the physicians to change the drug prescribed. This is one of the fundamental reasons why formulary status is so important to a product.

9.3.4.1 Summary

The distribution function provides ethical pharmaceutical companies with a function that rather than being controllable and therefore of use in gaining competitive advantage, it is function that because of legislation is largely controlled for them. In these circumstances the company's role is to ensure supply of the product to pharmacists where it is needed.

Producers of off patent compounds can effect the sales of their product using the distribution channels. The manipulation of price and supply guarantees to pharmacist (individual or as part of an organisation) can be used in order for one companies version to be used in particular pharmacies.

Formularies are a form of distribution control and the expansion of their number and strictness increases the importance of formulary influencers to pharmaceutical companies.

9.3.5 Developments

Having completed this investigation into pharmaceutical marketing as it is practised and shaped by the health care environment, a number of future developments predicted during discussions and further reading are provided. These represent ideas on factors that will shape health care provision and the pharmaceutical industry response in the future.

- The following developments were predicted for the healthcare market.
- Cost containment pressures will continue to dominate the provision of health care.
- The pharmaceutical industry will continue to fight pressures on their profit margins
- Further pressure to practice evidence based medicine will be seen with pharmaceutical companies reacting by producing greater numbers of clinical outcome studies.

- Patient involvement in the decision-making process will increase due to higher levels of available knowledge and continued growth in healthcare consumerism.
- Greater use will be made of IT. This will be in the form on decision support systems, Higher levels of information available, increased volumes of patient information held
- Further Rx to OTC switches caused by cost containment pressures.

These developments represent an outlook that is "more of the same". These issues have changed the practice of pharmaceutical marketing to make it more scientific and less incentive based. The credibility of the companies is seen to be improving because of their reactions to these issues however this issue will remain as long as companies are driven by profit motivations.

9.4 Conclusions

This chapter has provided an insight in to the efforts of pharmaceutical companies in attempting to modify the behaviour of their target markets. Amongst these target markets the physicians and the formulary influencers are the most import groups. The pre-eminence of physicians is however now being challenged by other groups of formulary influencers.

9.4.1 Credibility and Information provision

The attempts of pharmaceutical companies to modify the behaviour of physicians and formulary influencers are undermined by this sources lack of credibility and trustworthiness. The presence of these factors is important if the source is to be ***Surrogated*** from, as a consequence pharmaceutical marketing is not viewed as strong modifying influence.

Pharmaceutical companies should be encouraged to improve the independence and quality of the study evidence they produce in order to increase the likelihood that it will

be used. Beyond the quality of the data produced, independent and balanced interpretations should be applied for further credibility building. These issues are being addressed by some pharmaceutical companies. It may take a number of years however to remove the tag of "pill pushers" from the industry.

The information provided by pharmaceutical companies also does not represent the type of information that is used by physicians. ***Trading Off*** found that pattern based problem solving is used, based on internal or external sources of experience. This contrasts to statistical data that is provided to the physicians.

A final conclusion concerning the information that pharmaceutical companies provide is that for individual physicians they should attempt to mimic the information that is used in making decisions. Therefore, the individual patient's records of those who form the sample in clinical studies should be made available. In this way, the physicians can match the ***Focused*** details of their patient with those who have been treated.

Despite this call for individual patient details, it is important to state that the correct use of quality statistical information by physicians is likely to improve the performance of medical decision-making. It is currently used however in the absence of personal experience or the experience of trustworthy others whose knowledge can be ***Surrogated***. This is partly due to the lack of understanding and poor use of statistics that has been discussed through this literature review.

9.4.2 Marketing Mix

A number of conclusions concerning the use of marketing mix variables by pharmaceutical companies can be drawn:

9.4.2.1 Price

The pricing variable is a very important tool within the current health care environment. The pharmaceutical companies are in difficult situation when setting prices. The high overheads from research and development and the limited patent protection have to be weighed against the cost effectiveness drive within the NHS. An added factor to be considered is the undercutting of market leaders or early entrants price by "me too" products in an attempt to buy market share. In this case, evidence may not exist specifically for the "me too's" but claims of a class effect are often made. This represents a Trade Off to be made by the pharmaceutical decision-makers.

The growing importance of price and the increasing strength and number of formularies makes price competition and bulk discounting more likely. Negotiations are also likely on a local basis. The market leaders or early entrants have difficult choices to make on whether to react to these pressures to drop prices or to communicate the proven benefits of their product in order to maintain profits and market share.

The practice of later entrants to a market relying on the high price-high quality perception and entering a market at a premium to leaders is expected to decline.

9.4.2.2 Communications

The use of representatives as the basis of pharmaceutical communication strategies is set to continue. The most important aspect in pharmaceutical company communication is now however the production and delivery of good quality evidence to support claims made.

The change in role away from the traditional selling function to providers likely to continue also. Ultimately however the provision of services is a more elaborate and subtle method of supplying the company with good quality opportunities to sell their products. Therefore, while representatives can increase their trustworthiness and credibility in the eyes of the customers, they will always be undermined to an extent by their profit motive.

The combination of communications techniques is an important method to support and enhance the sales messages that the companies want to convey. They also increase the likelihood that the company's messages will be heard amongst the huge volume of information and marketing that are directed at medical decision-makers. Overcoming this clutter and gaining a response from the target markets is a goal requiring a level of creativity in pharmaceutical marketing.

9.4.2.3 Product

Manipulation of product attributes is an important technique in changing medical decision-making. Core product variable can be manipulated via clinical trials that are performed. This manipulation may result in the reduction of the trustworthiness of the company and the product and needs to be conducted carefully.

The manipulation of peripheral variables allows marketers to design more specific product offerings to niches in the market that require them. In this way by producing a wide range of product options, larger areas of the market can be satisfied in a more accurate manner.

9.4.2.4 Distribution

This remains a variable that is controlled for the industry and provides the ethical manufacturers with few opportunities to gain competitive advantage. The increase in formulary usage is set to see this control increase.

This is not the case for manufacturers of off patent and OTC medicines. They are able to target the distribution system in various places in order to get their product used after the prescription has been written.

9.4.2.5 Overall

The pharmaceutical industry's efforts to modify and control medical decision-makers behaviour are hampered by a lack of credibility. A number of activities have been suggested on how to overcome this problem. These include making available information of the type used in medical decision-making.

By building credibility and trust the companies can become sources of information that the medical decision-maker are more willing to build confidence from.

This chapter concludes the literature on medical decision-making and it's influences and therefore the chapters used to frame the ***Trading Off*** process and many of its components. A final aspect of ***Trading Off*** that has not been framed in this review is the expertise development seen in ***Shifting***. This area will now be looked at.

10 Chapter Ten Expertise and Expertise Development

The area of expertise and its development is reviewed because of the findings within ***Trading Off*** concerning the development of specific areas of treatment expertise and how it is characterised by ***Shifting*** between internal and external information sources. ***Trading Off*** also addresses the development of investigative behaviour because of its role in treatment choice.

This chapter will review how expertise is defined, it's outcomes, characteristics and how it is developed. Conclusions will be drawn as to how this frames the finding of ***Trading Off*** in this area and ***Trading Off*** 's contribution to it. Links from this chapter will also be highlighted between expertise development, decision-making and modifying behaviour from the subject's perspective. This review is primarily based on work into medical expertise though findings from other areas such as expertise in chess, will be used to supplement this.

This chapter will demonstrate that expertise is a domain specific quality that is characterised by superior performance in terms of quality and speed and superior memory skills. It is based on pattern recognition and thoughtful reasoning processes when necessary. ***Trading Off*** adds to these findings by demonstrating the movement from external to internal sources of information and how this occurs.

10.1 Definition of Expertise

Expertise has been defined in a number of ways, these correspond to it's necessary inputs, internal processes and outcomes. A definition based on a necessary input is proposed by (Camerer and Johnson, 1991) who suggest that expertise relates to a volume of experience. This view is undermined however by the low correlation found between volume of experience and diagnostic accuracy (Ericsson and Lehmann, 1996). This finding highlights the importance of apprenticeships, training and learning in order to reach a superior level of performance, and will be explored in more detail in section 10.4.

This notion of expertise as consisting of a "volume" was also used by (Ericsson and Lehmann, 1996) who suggest that expertise can be seen as mastery of existing knowledge and techniques in a particular field. In this instance, it is seen as a volume of knowledge and techniques rather than experience though the two are clearly linked.

(Patel and Groen, 1991) relate expertise with a characteristic internal thought process which is data driven, includes forward processing of problems and also involves data gathering strategies. The use of the internal process as the defining characteristic is also used by (Chase and Simon, 1973). These authors argue that this process involves a pattern-based retrieval of relevant experiences. In arguing for this view, they combine an internal process with an input (volume of experience) to define expertise. A further definition is provided by (Schmidt et al. 1990) who use the outcome measure of diagnostic accuracy to define expertise within medicine.

Of the views outlined here, this chapter will be based on a description of expertise as a particular type of thought process that is built by a high volume of experience as proposed by (Chase and Simon, 1973). In doing so, it combines the ideas of pattern based retrieval and matching from which superior performance in specific activities have

been found. This also corresponds to findings within ***Trading Off*** where expertise is characterised by a high volume of experience, use of internal data sources and a pattern based retrieval of information. The characteristics of pattern based retrieval will be reviewed later in this chapter.

10.2 Outcomes of Medical Expertise

A study of outcomes associated with medical expertise is limited here to a review of findings concerning diagnostic accuracy. Work demonstrating that experts treat more effectively and that patients have superior health outcomes has not been located. This is may be due to the methodological difficulties in showing these outcomes, though may also be partly caused by brief nature of this part of the literature review.

The difficulty in demonstrating a link between improved clinical outcomes and levels of expertise is partly due to the large number of uncertainties and variables in health care management. The number of legitimate treatments that are available in most medical situations also contributes to this by ensuring that consensus is difficult to obtain. This view is supported by research by (Rutkow I et al. 1979) who found that experts disagree as to the use of surgical treatments for particular patients.

The saying that there are three important aspects to medicine "diagnosis, diagnosis and diagnosis" suggests that once a disease has been successfully identified then the treatment becomes a more straightforward task. In this way diagnosis becomes a very important skill to develop in medicine and as it is easier to measure than clinical outcomes. Therefore, diagnostic accuracy is used in this review as the important outcome measure for expertise.

10.2.1 Diagnostic accuracy

A number of studies have shown that medical experts diagnose more accurately than other levels of physician (Patel and Groen, 1991) (Ericsson and Smith, 1991) (Norman et al. 1992). These authors have demonstrated however that there are a number of characteristics of this relationship.

(Patel and Groen, 1991) report that diagnostic accuracy increases as expertise develops and this occurs because the initial diagnosis of the experts is superior. They also found that the ability to diagnose more accurately increases in a straight line as physicians move toward becoming experts.

A number of studies however have shown that the relationship between developing expertise and diagnostic accuracy is more complex than found by (Patel and Groen, 1991). (Norman et al. 1992) found that the level of diagnostic accuracy for routine cases does not improve beyond the first year of residency.

Beyond this, expertise becomes associated with superior diagnosis of difficult cases (Hassebrock and Johnson, 1993) (Norman et al. 1994) (Norman et al. 1992). For example, (Norman et al. 1992) found that for visual diagnosis, the most difficult case were diagnosed most accurately by the experts whereas for routine problems there was no difference found between experts and those in first year of residency. These results were also found to be specific only to the area of expertise of the physician.

The domain specific nature of this skill and its two-stage development has important consequences for the internal process and development involved in expertise development. The two-stage nature suggests that the internal processes changes at a certain level of expertise that is only of use in diagnosing difficult cases. The domain specific nature becomes an important methodological issue for measuring expertise and in constructing the environment where expertise can be developed. This supports the

specific nature of ***Self-Referenced*** knowledge found in ***Trading Off***. These issues will be examined in more detail later in this chapter.

The improved accuracy of experts diagnosis is not an area covered by ***Trading Off***, which is limited to expertise development, information usage and investigative behaviour. The outcome of more accurate diagnosis therefore can be used to develop ***Trading Off***.

10.3 Characteristics of Expertise

This section will outline the characteristics of expertise that are apparent in the manner in which experts manage problems. It will also address the internal characteristics that develop to account for these signs and in turn the outcomes of expertise.

10.3.1 Knowledge

(Chi et al. 1982) point out the apparently obvious aspect of expertise by saying that experts have more knowledge than others. They extend this and describe how knowledge is more effectively organised and is theoretically represented in experts memory. One specific part of knowledge that experts have more of than intermediates and novices is knowledge of more experiences.

The importance of the amount of knowledge and how it is represented is also seen in ***Trading Off***, particularly in the development of ***Self-Referencing*** as the primary source of information to solve problems. However, work reviewed from the literature adds the importance of organisation of this knowledge in allowing it to be used more effectively.

10.3.1.1 Specific to Certain Fields

As mentioned previously the knowledge of medical experts is highly specialised and leads to domain specific abilities (Ericsson and Smith, 1991) (Patel and Groen, 1991).

This is demonstrated by the higher performance of experts in memory tests being reduced to the level of novices when the structure of the test items is changed from that experienced within their domain (Patel and Groen, 1991). When kept within the expert's field, this superiority is consistently seen (Ericsson and Smith, 1991).

10.3.1.2 Source of Knowledge

Trading Off contributes to the area of expertise by its findings concerning the use of sources of information and how this changes. ***Shifting*** details the movement from external to internal sources as physicians become more expert in specific medical areas and in their management of individual cases. Information concerning this ***Shift*** was not discovered during this literature review.

These findings have implications for medical education. It suggests which sources should be used when educating physicians at different stages of development and what kinds of information to be used.

The preference to use internal sources which can be biased due to unrepresentative reactions provides a potential reasons for the volume of medical errors detailed in chapter 5.

10.3.2 Memory

Memory effects are an important characteristic of expertise and are a function that demonstrates the development of internal mental processes involved in obtaining the status of expert. There are however conflicting findings concerning these memory capabilities.

(Patel and Groen, 1991) report on a study by (Medley-Mark, 1998) which found that performance on recall of pieces of medical information by experts was better than novices but inferior to intermediate level practitioners.

This is in contrast to findings that demonstrate that experts have vast memories for domain specific information. For example, chess masters are reported to be able to recognise fifty thousand separate chess positions which is described as "an immense library of distinguishable situations" (Dreyfus and Dreyfus, 1986) p32. (Norman et al. 1989) supports this by finding that experts have good incidental memories.

Experts have also been shown to be able to access relevant information more quickly (Ericsson and Smith, 1991) and this ability persists when the time allowed for memory search is reduced (Gobet and Simon, 1995).

10.3.2.1 Explanation

These findings have been explained by greater levels of knowledge and changes in memory structure and thought processes associated with expertise development. This manifests itself with the expert having a greater familiarity with the structures of the events presented and is able to recall relevant information more quickly (Chase and Simon, 1973). These authors named this process pattern based retrieval.

A more general explanation of this superior memory performance of experts can be based around memory skills and superior perceptual abilities. (Chase and Simon, 1973) suggest that experts have superior memory skills that allow them to develop more complex chunks when attending to situations. In turn, this allows them to code more information in each chunk than novices and intermediaries. It is also thought, in line with the specificity of expertise, that advanced practitioners attend only to relevant information as it is presented and selectively code this into their memory. Intermediate level physicians are unable to filter information and attend to it all. This specific attention is seen in the expertise development of investigative behaviour found in ***Trading Off***.

Further to this, experts store information in higher order representations that allows for more linkages across experiences. This allows faster access to a larger number of patterns.

The process of pattern based retrieval and the library concept of experiences are based on the view of expert problem solving suggested by (Chase and Simon, 1973). Pattern based retrieval suggests how information held in memory is used to solve problems, this concept will be dealt with in more detail in section 10.3.3.

This view corresponds to the representations and use of knowledge found in ***Self-Referencing*** and what is being ***Surrogated*** when external sources of information are used. It also specifically supports the development of investigative questioning and testing.

10.3.2.2 Summary

The weight of opinion favours the idea of experts possessing superior memory abilities. The contradictory findings of (Medley-Mark, 1998) is explained by this study using information that lacked relevancy to the specific areas of the expert's domain.

The superior memory of experts, being able to hold a vast library of domain specific relevant structures and experiences is thought to be due to their improved memory and perceptual skills. These allow a number of separate pieces of information to be stored as one chunk in memory. This process is also aided by selective attention, filtering out of irrelevant pieces of information and use of higher order representations to store information (Patel and Groen, 1991).

The findings for experts possessing memories of experiences rather than biomedical knowledge provides strong support for ***Trading Off***'s position that experiences are

preferred when making decisions. It also supports ***Surrogating*** of experiences being taken from external sources of information.

10.3.3 Pattern Based Retrieval

The concept of pattern based retrieval as the underlying process in expert thought processes and problem solving was proposed as a simple theory by (Chase and Simon, 1973). Experience is used to draw together knowledge of a huge number of patterns that are then used as templates in memory to match with similar situations as they arise. This is performed in order to understand the situation and suggest relevant solutions. (Werner, 1995) suggests that this is the method of problem solving used by expert physicians. It also supports ***Trading Off***'s explanation of information usage and particularly the performance of habitual problem solving.

This approach was proposed as a simple theory that required elaboration and development. (Patel et al. 1989) did this with work studying the use of biomechanical knowledge and clinical reasoning. They reject the idea of simple pattern based problem solving though incorporate its main idea into their account.

They suggest that initially physicians develop a representation of the problem that is being faced. They then develop interactions between the elements of this picture and elements of experiences held in memory. These matched representations then guide behaviour. This approach therefore incorporates pattern retrieval and matching with the findings proposing that this is mediated by a cognitive role that develops with expertise. This explanation of problems solving will now be reviewed by looking at the use of reasoning as the cognitive function that develops.

This developed account corresponds closely to the retrieval of information from both ***Surrogated*** and ***Self-Referenced*** sources prior to the actual Trade Off. ***Trading Off***

develops this theory by defining the use of information sources and how this changes during expertise development.

10.3.4 Use of Reasoning.

The use of reasoning for problem solving involves the use of mental representations of the problem and the subsequent retrieval of similar experienced patterns from memory. (Patel and Groen, 1991) report that for routine problems, experts use what they call forward, data driven reasoning. This may be changed to a backward reasoning strategy in order to account for "loose ends" in the diagnosis of more difficult problems. Forward reasoning has been shown to be related to diagnostic accuracy (Patel and Groen, 1991).

This is in contrast to the backward direction used by novices who have been shown to use goal based backward searches (Patel and Groen, 1991). Forward reasoning is often attempted by sub-experts but the use of this process alone is not sufficient to produce expert levels of performance (Patel et al. 1989).

Forward reasoning is faster, somewhat superficial and error prone for individuals who don't have sufficient domain knowledge, it can be successful however when large amounts of information are presented (Patel and Groen, 1991). It involves generating diagnostic hypotheses early in the process then evaluating other information in order to confirm and refine the diagnosis. In doing so the physicians can be seen to be matching the pattern of the problem with information held in memory. The use of this error prone reasoning strategy by experts on routine diagnostic cases can explain the equal performance on these tasks between experts and intermediate level individuals.

(Hassebrock and Johnson, 1993; Norman et al. 1994) as mentioned previously showed that experts perform better when the tasks are harder. This can be attributed to the use of both forward and backward reasoning in combination with deeper use of a skilled

memory of higher order concepts. These concepts represent large amounts of experience to deal with the complexity of difficult diagnostic problems. The application of this to the problem is then moderated by cognition's including monitoring and planning the situation and its developments (Ericsson and Lehmann, 1996).

While the use of forward reasoning remains error prone, its use by experts allows them to make use of their greater levels of knowledge and superior memory abilities and therefore accounts for their higher levels of performance. Therefore, expertise develops as the use of backward reasoning makes way to forward reasoning that in turn is supported by the use of large volume of clinical experience. These factors combine to increase levels of diagnostic accuracy in difficult cases.

These different forms of reasoning used as physicians become experts was not discovered during ***Trading Off***. This may be due to fact that ***Trading Off*** is an explanation of the decision-making process used in choosing pharmaceutical treatment not differential diagnosis. As discussed in chapter 2 further theoretical sampling is necessary to determine if ***Trading Off*** represents medical decision-making in all its forms.

10.3.5 Summary

Medical expertise is a domain specific skill in applying high order representations of past experience to problems that are encountered. These experiences are held in memory as a vast library of specific patterns that are easily and accurately retrieved.

Medical expertise manifests itself in superior performance compared to other levels of physicians in the diagnosis of difficult cases though equal levels in routine cases. This is explained by the more applicable use of forward reasoning by experts compared to intermediates. The work by Patel Evans and Groen concerning clinical reasoning can be viewed as a development of the simple pattern recognition model suggested by (Chase

and Simon, 1973). This developed use of pattern based problem solving provides the process by which experts solve problems. It also supports and develops findings from ***Trading Off***.

10.4 Expertise Development

Trading Off contains the process of ***Shifting*** between ***Surrogating*** and ***Self-Referencing*** that occurs as physicians become more experienced and expert in specific areas, this section is used to frame and develop this process. ***Shifting*** describes the movement from external to internal sources of information in order to gain the necessary experience used in decision-making on an individual problem and area basis.

This section will outline literature explaining how experience is used to develop expertise and important issues concerning the practice and learning required. As such this section will provide details on how the experience used during ***Surrogating*** and ***Self-Referencing*** is gained and how it can be provided. It also therefore has consequences for educational attempts of health care providers and pharmaceutical companies.

10.4.1 Nature vs. Nurture

Expertise and it's development is underpinned by the nature-nurture discussion (Galton, 1883), (Ericsson et al. 1993). It is assumed that expertise is comprised of elements of both nature and nurture with the specific domain of the expertise determining the relative importance of these factors. For example natural muscle fibre type, which cannot be altered by training, is the essential factor for sprinting whereas training and experience are the crucial aspects in areas of cognitive expertise.

This is supported by (Baird, 1985) who found that only 2-4% of variation in ability of doctors and engineers was explained by innate capabilities. In medicine specifically, the

development of expertise is based on the addition of domain specific knowledge and skills via experience (De Groot, 1978). There remains however an innate component in medical expertise upon which the effects of training and education are based, this is supported by (Dreyfus and Dreyfus, 1986).

10.4.2 Problem Solving

In addition to the volume of experience associated with expertise development, changes occur in the use of this knowledge. This aspect of expertise and its development, has been represented by a stage structure that corresponds to the different problem solving approaches that are used. (Dreyfus and Dreyfus, 1986) provide five stages from Layperson to Expert that are characterised by the movement from the use of objective facts to solve problems to the use of a rational, holistic recognition of similarities. This is supported by the work concerning pattern recognition.

These authors propose that for routine problems expert level individual "don't solve problems…they do what normally works" p30. This is a further example of the pattern recognition approach and reflects the use of ***Self-Referenced*** sources found in ***Trading Off***. It also demonstrates how experience is used by experts.

10.4.3 Deliberate Practice

As outlined earlier in this chapter conflicting results have been found concerning diagnostic accuracy and volume of experience. These results suggest that experience needs to be managed and developed in order for the benefits of expertise to be shown.

(Ericsson and Lehmann, 1996) report that deliberate practice accounts for domain specific expertise more effectively than natural talent. (Chase and Simon, 1973) had earlier suggested that 10 years of intensive practice and experience are needed in order for the huge number of patterns and the cognitive changes to take place that characterise

expertise. (Lesgold, 1984) when looking at expertise in x-ray diagnosis, went further and added that it may take longer than 10 year because of problems remaining motivated to learn and practice over this period of time.

It is worth noting that medical training takes 7 years between medical school and hospital apprenticeships. The 10-year rule and the domain specificity of expertise, suggest therefore that it maybe as long as 17 years after starting medical school that domain specific experts physicians are produced!

Having discussed the need for deliberate practice over a number of years it becomes important to outline how training should be conducted.

10.4.4 Training

(Ericsson et al. 1993) provides a number of details on the necessary characteristics for training and optimal learning. This includes the need for the subject to be motivated to learn and having existing knowledge taken into account. Subjects should perform repeatedly a number of similar tasks and be provided with immediate feedback on their performance (Bower and Hilgard, 1981) (Towbridge and Cason, 1932).

Feedback can be problematic however because of the number of random factors that can corrupt it. (Kao, 1937) earlier had suggested that self evaluation while undertaking learning was important.

The tasks that are performed repeatedly need also to be carefully managed and prepared. (Ericsson et al. 1993) develop this and identify that tasks should involve explicit instructions and clearly set out and obtainable goals. They should be individualised and adequate resources need to be available. These authors also mention the need for effort on behalf of the subject and a period of work apprenticeship to learn the specific situational skills of the job.

These characteristics of optimal learning, the tasks used to teach it, in conjunction with work apprenticeship and motivated participation of the subject, should provide an environment where expertise can develop. These findings are important for educational attempts at changing behaviour. See chapter 8 for details.

10.4.4.1 Use of Case examples

Trading Off found that detailed case examples, not numerical representations, are sought by physicians and suggests that using actual cases will provide physicians with a wider range of experience to base their *self referral* on. This is supported by work on the stages of expertise by (Dreyfus and Dreyfus, 1986). They suggest that the poor performance by physicians on probability updating task using external data is due to this task not being performed frequently in this form in real life.

However, later in their article Dreyfus and Dreyfus report on the potential difficulties in using real examples in teaching. If an example is given using too much detail then they suggest it becomes unique and problems arise with its applicability. If too few details are used then it becomes difficult to work out the prevalence of the particular problem.

This caveat to the use of experience in teaching adds further weight to the conclusion of this research that suggests that the experience used to influence and modify physicians behaviour should be provided from well conducted clinical studies. In this case, the needs of the physicians for actual case experiences can be supported by statistically summaries.

This conclusion is also supported by this chapters demonstration that volume of experience (from either internal or external sources) in addition to changes in the use of this information, are needed to improve diagnostic accuracy. Physicians may amass the volume of experience necessary for expertise without developing the skills to use this

library to its full potential. This is because they may have failed to develop the higher order representations of this information. If the physician then attempt to replicate the experts reasoned use of this data they may as suggested by (Patel and Groen, 1991) be prone to errors.

In these instances, further support for the examples in the form of statistical summaries may reduce decision-making errors. In addition to this these finding support the continued use of organised medical education throughout a physicians career.

Further failures to use examples to their full potential may also be caused by failure to practice with the motivation to learn from their performance. This may also contribute to reduced levels of expertise medical variation and sub-optimal treatment choice.

10.4.5 Summary

Development of expertise is based on the use of training and education. As such medical expertise development represents an education based skill that is supported by a level of innate skill and intelligence.

The educational based activities practice required to develop expertise involves a period of at least 10 years meaningful, motivated practice where the performance of the individual is monitored by both the subject and facilitator. In addition to this individual based varied and repeated tasks should be used. The use of experience within these tasks will help develop the high volumes of case experience and the pattern based reasoning strategies that characterises medical expertise.

This section supports ***Trading Off's*** position that examples should be used in modifying physicians behaviour as this is the form in which physicians use information to make decisions. It also supports the conclusion that these examples should be made available from clinical studies. In doing so a support mechanism is provided for the incorrect

usage of case studies by physicians who have not developed the experts higher order schemes.

10.5 Conclusions

This review has demonstrated that expertise is domain specific and that it involves the use of pattern based retrieval of a large volume of knowledge, reasoning and matching of experiences to the problem at hand. This account corresponds closely to the retrieval of information from both ***Surrogated*** and ***Self-Referenced*** sources that is seen prior to the actual Trade Off.

Experts have been shown to be able to get more from their experiences by representing them in higher order schemes. This concept develops ***Surrogating*** from expert sources as it suggests that it is not just the volume of experiences held by senior physicians that is important in their skill but how they use it. This suggests further that by ***Surrogating*** just the case experience without possessing the internal skills then physicians will be unable to use this information fully. It can be concluded that in areas where the doctor is not expert (and therefore not ***Surrogating*** a case into developed schema) ***Surrogating*** may be a less successful tactic than ***Self-Referencing*** within their areas of expertise.

Expertise is developed over a long period of active learning and experience in a field that needs to be supported by well designed and managed practice. These factors provide information on what else needs to be provided for physicians to help ensure that they are able to get the most benefit from the data that they ***Surrogate.*** It also provides additional information on practice conditions necessary for modifying physicians behaviour. These can be added to the conclusions from chapter 8.

Trading Off describes the source, type and usage of information that physicians use as they develop expertise in a particular area. Specially, ***Shifting*** shows the movement from external to internal sources of information in order to provide the rich experiential data preferred when making decisions. This is an area where ***Trading Off*** contributes to the understanding of Expertise.

By ***Surrogating*** experience not clinical statistics, physicians are gaining the knowledge they need to become expert[18]. ***Shifting*** and ***Trading Off*** provides a description of the process of how individuals obtain this level of experience needed for expertise. ***Trading Off's*** account also provides an explanation of why experience is preferred over clinical data and statistics and supports the pattern recognition view of clinical reasoning.

This chapter concludes the review of literature needed to frame and develop the findings of ***Trading Off***. The conclusions that can be drawn from this thesis will now be presented.

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[18] It is a high level of knowledge of experiences not biomedicine that characterises expertise (Patel et al. 1989)

11 Chapter Eleven Conclusions and Recommendations

This chapter will set out the main conclusions and recommendations drawn from this thesis as an integrated work. To this end the integration of ***Trading Off*** with the literature and the literatures ability to develop ***Trading Off*** will be reported in areas where it makes a contribution to knowledge. Additional conclusions can be found in the individual chapter and the reader is referred to these for further details.

The first area concluded on shall be whether this research has been successful in producing a grounded theory. This will be performed using the criteria set out by (Glaser and Strauss, 1967a).

Following this, conclusions and recommendations will be provided for:

- Healthcare Marketing. Primarily from the view point of the pharmaceutical industry, but containing recommendations pertinent to Health Care Providers.
- Decision-making research. Specifically medical decision-making and pharmaceutical decision-making
- Expertise Development
- Methodological Conclusions
- Grounded theory as a commercial research tool

11.1 Evaluation of Grounded theory

The evaluative criteria proposed by Glaser and Strauss (Glaser and Strauss, 1967a) and developed in (Glaser, 1978) are based on the objectives of the method for producing emergent, theoretical representations of social patterns of behaviour that are important to those people who exist in the area under scrutiny.

To this end the originators propose that a grounded theory should have Fit, Workability, Relevance and Modifiability. The judges of these criteria in this study need to be medical practitioners who can determine whether the theory as presented has these characteristics. A brief note is given to assist in this.

11.1.1 Fit

It is crucial that the theory fits the data that it has been conceived from, rather than the data being forced to fit categories. In this study Appendix Eleven attempts to demonstrate the "fit" of ***Trading Off*** by demonstrating the coding process as a link between data and theory. It is believed that this theory does fit and the categories emerged from data in a systematic grounded fashion.

11.1.2 Work

The second evaluative criterion for grounded theory is whether the data is able to explain, in this instance pharmaceutical decision-making. This was established by the discussion held with a draft version of ***Trading Off*** and the comment that this is **" where we live".** Glaser goes beyond the need for explanation and says that it should have predictive and interpretative powers. The literature review has demonstrated ***Trading Off's*** interpretative powers for example, the explanation of the power of opinion leadership based physician education.

11.1.3 Relevance

The relevance of the theory should be demonstrated by the acceptance of those who perform pharmaceutical decision-making. This process has been started during the above mentioned discussion and will continue via the dissemination of this thesis's work.

11.1.4 Modifiability

The modifiability of this work has already been shown during the literature search where changes in the health care environment have meant the promotion (and predicted further promotion) of duty bound ***Surrogating***. This category initially emerged to explain a particular type of information source usage within the hierarchical structure of secondary and primary care. The importance of ***Trading Off*** remains in this modified theory but its performance may be curtailed due to continuing cost pressures. It is believed therefore that ***Trading Off*** has shown the central importance of its core category and its capability to change as the medical environment does.

This thesis has a considerable number of conclusions and recommendations concerning health care marketing, decision-making, expertise development and methodology. The first of these areas will be turned to now.

11.2 Health Care Marketing

Trading Off and the review of literature provide a number of recommendations and implications for organisational attempts to modify and maintain physicians behaviour according to their objectives. The initial (and largest) section will address these as they relate to the pharmaceutical industry. The headings used to structure this correspond to categories of ***Trading Off*** though also contain details from the literature. Further recommendations will then be provided for the Health care providers.

11.2.1 Environment

The following recommendations are products of a medical environment characterised by:

- **Individual Patient responsibility**
- **Wider public responsibility**
- **Consent**
- **Individual patient reactions to disease and treatment**
- **Uncertainty**
- **Risk**
- **Conservatism**
- **Limited financial, health care provider and patient resources**
- **Financial constraints increasing**
- **Considerable variation and high levels of inappropriate prescribing**
- **Growing number of treatment options (pharmaceuticals)**

11.2.2 Pharmaceutical Marketing

11.2.2.1 *Focusing*

It is fundamental to the performance of a ***Trading Off*** based pharmaceutical marketing approach that detailed ***Focusing*** on the situation takes place. This should occur in both marketing and sales planning and hence be performed by the product management, sales management and individual sales representatives.

The approach taken should correspond to the Wide ***Focusing*** detailed in chapter 3 where a broader view of the problem scenario is taken and factors from a wide range of aspects are taken into account. This need is based on the large number of factors that were found to influence pharmaceutical decision-making, for example patients gender (Ayanian and Epstein, 1991), Ethnic origin (Wenneker and Epstein, 1989), patients families, patient interest groups and cultural norms.

These factors are classified as:

- Physical characteristics
- Mental characteristics
- Wider Population Involvement

These variables and the combinations in which they can appear, requires that an individual approach is taken within the disease management boundaries. This ***Focusing*** should be performed to a greater degree than is currently done at a market and sales level.

The requirements for this approach mean that the current practice of global strategies being refined at a local level should be extended to local variations on a smaller geographic scale. This extension must allow individual physicians variation and via the use of case study data bases individual patients modification.

11.2.2.2 *Trading Off*

This thesis demonstrates that the cognitive process undertaken during pharmaceutical decision-making involves the combination and analysis of levels of confidence held on factors felt to be relevant to the particular situation. It is a subjective weighting and evaluation of these levels in order to determine that relevant parties gain from the behaviour. The behaviour performed will not necessarily be held in high confidence though it will be more highly regarded than the other options.

The knowledge of this process provides guidelines to practitioners on how to analyse and present the benefits and drawback associated with the behaviour they are promoting. The factors should be presented in an attempt to build greater confidence in one behaviour in comparison to other possible courses of action. These other options have to be viewed broadly as decisions as to a particular medication involve decision on:

- Treatment types (surgery vs. drug vs. rest, etc),
- The specifics options of these types (i.e. Beta Blocker Vs Calcuim Antagonist),
- The options within the subtypes (Nifedipine v.s Amlodipine)
- Various presentations of the chosen treatment (pill vs. IV).
- Dosage regimen

The ***Focusing*** performed initially will provide the specific needs of the patient and physician and demonstrate the factors that need to be stressed. This ***Trading Off*** is data driven based on the characteristics of the treatment.

11.2.2.2.1 Important Factors in Choice

The ***Trading Off*** process is highly likely to involve the following treatment factors. Within this list, belief concerning the efficacy of a treatment has been found to be the most important generic characteristic when choosing a treatment.

11.2.2.2.1.1 Benefits of Treatment

- Efficacy*[19] (Lilja J, 1976)
- Speed of Action
- Mode of Action
- Presentation
- Dosing

11.2.2.2.1.2 Costs Treatment

- Side Effects* (Lilja J, 1976)
- Interactions
- Financial Cost* (Lilja J, 1976)
- Time costs
- Opportunity costs

The factors marked* represent the most important components reported by physicians. The relative importance of these characteristics follows from efficacy to side effect to financial costs (Denig et al. 1988). The need for a wider view of ***Focusing*** is to allow the pharmaceutical marketer to understand which other of these characteristics of treatments will be important in pharmaceutical decision-making.

[19] Trading Off highlights the importance of relative efficacy as further, important dimension to this influence.

The data driven nature of ***Trading Off*** means that information on the above variables is required. The use of these information sources has important implications for pharmaceutical marketers.

11.2.2.3 Information Sources (*Self-Referencing* and *Surrogating*)

When attempting to provide physicians with the necessary information to build confidence the ***Self-Referencing-Surrogating*** continuum should be understood and used. This continuum represents the movement between these two categories as one sub-category is moved to the next. I.e. Complete ***Surrogating*** to Incomplete to Partial and the mirror ***Self-Referencing*** behaviours. Pharmaceutical companies should understand which sources physicians are likely to use and provide information accordingly.

The continuum demonstrates that physicians prefer to use internally held patient experience data when solving a problem. However as sufficient experience requires time to build they will use external data initially and ***Shift*** across to internal usage when possible.

Pharmaceutical companies should therefore supply patient case data in conjunction (or from) well constructed clinical studies. The amount of detail and the type of cases will depend on the physicians position on the continuum. Flexible databases of this information should be set up in order for the physicians to obtain what is required. The use of individual subjects from clinical trials or records from local eminencies practice are two potential sources of these cases.

This information should be augmented by clinical trial data demonstrating efficacy, incidence of side effects etc. These trials should be constructed according to the following rules:

- Double Blind
- Random assignment
- Placebo controlled
- Independently performed and analysed
- Contain large numbers of patients

Companies need to increase the number of comparative studies performed. These should provide comparisons against other treatment options. The number and quality of health outcomes, long term cost effectiveness and meta analysis studies should also be increased.

The provision of information and other factors to build physicians confidence in modes of behaviour should be controlled by certain educational principles. The methods used should:

- Be focused to the specific educational need (also: (Coleman J.S et al. 1959))
- Allow two way communication (also: (Soumerai and Avorn, 1990))
- Be adaptable to the needs of the student (also: (Ericsson and Lehmann, 1996))
- Take into account the previous knowledge of the subject (also: (Ericsson and Lehmann, 1996))
- Be able to provide information on a large number of relevant factors
- Encourage interaction (also: (Ericsson and Lehmann, 1996))
- Be integrated with other methods
- Motivate the subject (Ericsson and Lehmann, 1996)

- Use a Problem solving approach (also: (Ericsson and Lehmann, 1996))
- Be Specific (also: (Soumerai et al. 1993))
- Provide feedback on performance(also: (Bower and Hilgard, 1981))
- Be carefully managed and prepared (also: (Ericsson and Lehmann, 1996))
- Repeat tasks ((Ericsson et al. 1993))
- Use case studies carefully (also: (Dreyfus and Dreyfus, 1986))
- Involve deliberate practice (Ericsson and Lehmann, 1996)
- Use credible sources and educators (also: (Soumerai and Avorn, 1990))

11.2.2.4 Modification Techniques

These principles therefore explain and predict which methods are more likely to be successful in modifying pharmaceutical decision-making behaviour. Further details on these techniques will be provided in section 11.2.5.

The use of these principles in the methods employed by the pharmaceutical companies is complicated by the mistrust and scepticism with which their efforts are seen. Therefore the marketers and sales representatives must where possible, use and involve local and national opinion leaders. The expansion of the service representative role is therefore recommended. Relationship building activities should continue though ensuring that actions do not compromise ethical standards.

Where the company directly implements these rules they must initially build credibility and social relationships with the physicians. This should be based on the production of well-designed independent clinical trials.

Specific methods that should be used to deliver company objectives include:

- One to One Tutorials (also: (Soumerai et al. 1993))
- Small Group Tutorials
- Problem solving sessions
- Case conferences

Supported by:

- Multimedia presentation (Plumridge and Berbatis, 1989)
- ***Focused*** personalised reminders of key messages (also: (Plumridge and Berbatis, 1989))
- Feedback on performance (also: (Soumerai and Avorn, 1990))
- Reduction in administrative barriers
- Motivational techniques

11.2.2.4.1 Summary:

The efforts of pharmaceutical companies must become more ***Focused*** to the individual physician and patients. Greater detail is required to understand the problem and solve it than the general diagnosis and demographics. This widening and deepening of the understanding of the situation then allows a more ***Focused*** presentation of relevant treatment characteristics that allow the physician to trade off based on confidently held knowledge. The pharmaceutical characteristics presented should be based on comparative clinical data in the form of patient cases supported by summary statistics.

Methods used to deliver this information should be based on personal needs of the physician and performed in a flexible, ***Focused*** fashion. Where possible opinion leaders should be used to conduct this education. The service role of the representatives should be expanded to facilitate this. The construction of administrative barriers and their removal should also be a role of the pharmaceutical marketers and representative.

11.2.3 Target Markets

The following groups represent target markets for pharmaceutical companies.

- General Practitioners
- Secondary Care physicians
- Local eminencies
- National Eminencies
- International Eminencies
- Committee decision-makers (PCG, Health Boards)
- Practice managers
- Pharmacists
- Nurses (community, practice and hospital)
- Governmental policy maker and advisors
- Patient interest groups
- Medical charities

The identification of these groups and their interrelationships is a crucial aspect of designing the subsequent marketing programs. These groups represent a number of relationships that can be used as sources of ***Surrogating*** and to provide case experience. These relationships should therefore be explicitly studied on an international, national and local level in order to design the diffusion of information to each prescriber or decision-maker. Approaches ought to be made to relevant sources to provide data bases of experiences to be used in the companies marketing efforts.

The identification of these networks should then be followed by designing modification strategies for the groups individually and as a system.

11.2.4 Specific Strategies

A number of specific strategies have been indicated from the findings of this thesis.

11.2.4.1 Differentiation

This should be based on the production of comparative clinical data. Comparisons of efficacy, side effects and cost effectiveness can be used individually or in combination. These are used to define the target market and the competitors. The areas of advantage can cover a large or small (niche) areas within the total manifestations of the disease. This strategy can be used by later entrants to an established market. In addition it can be used for compounds that are the first of new classes in a market where older classes are well established.

11.2.4.2 Multiple Niche Markets

This involves the long-term commitment to production of data for a number of segments of the whole market. The amalgamation of this data can then be used to show the products suitability to a large percentage of the total disease manifestations.

11.2.4.3 Augmented Product differentiation

The differentiation in the market can be based on augmented product development (packaging, long acting preparations). These can be based on specific needs of patient groups or manifestations of the disease. This represents a less risky approach than to produce comparative data. Evidence for efficacy etc is still required.

11.2.4.4 Price leadership

This strategy combines the growing requirement for cost effective medical solutions and the confidence required to initiate behaviour. Equivalence data is required concerning efficacy and other relevant characteristics with Generalised ***Surrogating*** and ***Self-***

Referencing being encouraged. The importance of cost as a ***Trading Off*** factor is then promoted by providing equivalence at a reduced cost. Government, Purchase group committees and practice managers become more important in this strategy. Late entrants to the market and generic manufacturers may use this. It is crucial that confidence in the product is built and price alone is not used.

11.2.5 Marketing Mix

The following sections provide conclusions on marketing mix variables and their performance. They are not presented as an integrated mix for a particular strategy but as important conclusions from this thesis. The company representative provides the central conduit to implement marketing mix variables in a ***Focused*** manner that promotes the ***Trading Off*** of the company's messages.

11.2.5.1 Product

- The central and peripheral product variables must be demonstrated via clinical trial production
- Correct planning and performance of these trials represents the most important Product mix function beyond the production of quality pharmaceutical compounds.
- Production of a wide range of presentations of the compound
- Production of patient ***Focused*** packaging and methods of administration

11.2.5.2 Promotion

- Construction of Promotional activities via educational principles
- Use of ***Trading Off*** cognitive process and overall process in development.
- Clear presentation of positive and negative aspects of pharmaceutical to allow easy ***Trading Off.*** (It should be remembered that physicians act to reduce the amount of cognitive effort expended on a problem)

- Use of Academic detailing according to principles set out by (Soumerai and Avorn, 1990)
- Use of "Drug Bulletins" in support of personal efforts. Performed according to (Soumerai and Avorn, 1990)
- Use of personal methods of promotion, supported by printed materials because of their flexibility and social based influence
- Use of Opinion leaders and Eminencies to provide education and promotion (Stross et al. 1983)
- Promote case study usage
- Local and National data bases of patient experiences
- Summary statistics as support for above
- Representatives performing a Service and Promotional role
- Providing Representatives with educational and practice management based access items
- Promote long-term representatives/target market relationships
- Use of mailed materials restricted to personalised support of representatives or local campaigns (also: (Plumridge, 1984))
- Ensure shared meaning of expressions in all forms of communications (Ramsey, 1931)
- Ensure understanding of statistics used in communications
- Credibility and partnership building activities

11.2.5.3 Price

- Value is the most important function of price. This should be defined in comparison to other treatment options
- Actual price is also important and this will continue to grow
- A wide definition of other treatment options should be taken therefore producing a value representation on a number of levels
- Demonstrate wider use of price savings vs. other options

- Price leadership is advised for late entrant products or those with no differentiating evidence
- Price Quality Trade off are likely with new products therefore actual levels of those seeking price leadership should be within price bands of other options
- Allow geographic negotiation where necessary for formulary status

11.2.5.4 Distribution

- Continued close regulation of distribution of pharmaceuticals will constrain use of distribution function by pharmaceutical companies.
- Formulary status will become the critical aspect of ethical pharmaceutical distribution
- Expansion and tightening of formulary usage likely on local and national basis.
- Importance of pharmacists and pharmaceutical committee members in these decisions
- Generic compound manufacturers must ensure stocking in primary and secondary care pharmacies. However the use of price as a tactic alone places the compounds in a precarious position, they are easily ***Traded Off*** out of stock

11.2.6 Health Care Providers

Chapter 5 detailed the need for health care providers to modify physician pharmaceutical prescribing. It catalogued levels, causes and outcomes of variable and inappropriate prescribing and concluded that these artefacts of should be reduced. Health care providers represent the organisations that should and do attempt to improve these behaviours. This section develops the conclusions and recommendations from the previous section on how this can be performed. Further conclusions on decision-making process developments that will also improve prescribing are supplied in section 11.3.

Health care providers consists of governmental and local organisations who pay for and provide health care. In the UK the most important groups are the NHS, Health Authorities, Health Boards PCG's and individual practices.

11.2.6.1 Environment:

- Efforts are supported by higher credibility than that possessed by pharmaceutical companies (crucial in building of confidence).
- More trust in motives for prescribing change
- Need to be aware of "purely cost cutting" concerns of physicians about objectives of health care providers.
- Physicians anxious to protect independence
- Punitive financial and administrative strategies available
- Constrained by smaller budgets.
- Access to physicians is easier to obtain
- Access to physicians prescribing records
- Participation of Opinion leaders is more readily available

11.2.6.2 Activities

- Use Administrative and Financial strategies to modify deviant behaviour.
- Physicians resent having their clinical freedom constrained and these methods may only work for as long they are in place. Educational strategies should therefore be used to address the underlying issues.
- Academic Detailing and personal methods of education are more accessible and should be used to achieve the educational goals (Soumerai and Avorn, 1990).
- In addition to formularies, second opinion methods may prove successful administration strategies.
- Individualised feedback is important for all methods used.
- Financial and administrative strategies must take into consideration undesirable consequences (also: (Soumerai et al. 1990)).
- Explanation of the objectives of Health care providers should be given to motivate physicians to comply.

11.3 Decision-making

11.3.1 Introduction

This section will present conclusions and recommendations from this thesis regarding pharmaceutical decision-making, medical decision-making and the wider field of decision-making. These conclusions are based on ***Trading Off*** as a legitimate representation of pharmaceutical decision-making. An important contribution of this is that it can be used to reduce inappropriate and variable pharmaceutical choice.

Trading Off has been demonstrated during the literature search to conform to the fundamental principles of decision-making and in addition provide concepts as to information sources, usage and learning. These areas will be addressed in Expertise conclusions, section 11.4.

It has also been shown to be a cognitive model that can be classified further as an Expected Subjective Value Theory (ESVT). It corresponds to this class of theory in the following ways:

- Expected- Confidence concerning behavioural ability
- Subjective- Beliefs held by the prescriber
- Value- To satisfy set objectives of patient and wider audiences

The specific contributions to Pharmaceutical Decision-Making and Medical Decision-Making will now be highlighted.

11.3.2 Conclusions for Pharmaceutical Decision-making

11.3.2.1 General Conclusions

- Literature review was unable to find a holistic theory of pharmaceutical decision-making (and medical decision-making) constructed from an inductive perspective.
- Grounded theory is a suitable method of enquiry into pharmaceutical decision-making.
- Deductive methods used rely on quantified representation of theory that provides correct structural illustration but fail to capture the contextual richness of the behaviour or the variations this causes.
- ***Trading Off*** provides an accurate representation of pharmaceutical decision-making process.
- Explains decision-making outcome within the medical environment.
- Demonstrates system caused by Uncertainty, Risk, Independence, Responsibility, High number of Options, Limited Resources (also: (Edmunds and Scorer, 1967), (Grenier, 1997)). The alteration of any of these may effect the discovered behaviours and the observed outcomes.
- Chapter 6 provides a literature that can be used to teach pharmaceutical decision-making to medical students, pharmaceutical marketers (including sales representatives), pharmaceutical advisors and parties interested in this behaviour.
- The literature reviewed in the absence of ***Trading Off*** provides a structurally correct version that should be followed by pharmaceutical decision-makers. The addition of a theory of what is actually performed allows the students a greater awareness of potential errors and the contexts they can arise.

A body of literature concerned with pharmaceutical decision-making has been produced based on ESVT principles:

Drug choice model (Segal, 1980; Segal and Hepler, 1982).

This model is based on attitudes toward outcomes and beliefs concerning the drugs, a similar approach was discovered in ***Trading Off***. It was successful in predicting prescription according to the criteria set however there are problems with the methods used in these studies.

11.3.2.2 Theory of Reasoned Action (Ajzen and Fishbein, 1977)

This well known theory has been used in its entirety and its theoretical perspective. The addition of normative evaluation and rules for correspondence of behaviours and measurement, provides an approach that is superior to that used by Segal and Hepler. Correspondence supports ***Trading Off*** and ***Focusing*** specifically.

These theories provide plausible psychological precursors to choice. However ***Trading Off*** provides a credible cognitive process of how choice is performed compared to the overly ridged approaches of these other models.

Trading Off can be classified as a compensatory choice strategy (Engel et al. 1993). It however extends work on these strategies by providing a process of objective setting, information usage, learning and feedback.

11.3.2.3 Correction of Variable and Inappropriate Prescribing

As highlighted previously this thesis has a number of important conclusions concerning variable and inappropriate prescribing. Its fundamental role in this has two parts; the first is to provide a model and constituent steps from which to highlight deviations to

normative performance of pharmaceutical decision-making. The second is to provide recommendations on how to modify physician's behaviour and therefore correct these areas, these are provided in section 11.2.2.4. In addition, the review of literature into medical decision-making has supplied a number of formal techniques that could be used to performance of the individual stages of pharmaceutical decision-making.

11.3.2.4 Highlighted deviations include:

- Inappropriate prescribing goals set during ***Focusing*** such as using it as a termination strategy (Soumerai et al. 1989).
- Restricted ***Focusing*** performed.
- Reliance on mental representation and manipulation of decision task.
- ***Trading Off*** of less important factors i.e. relationship with representatives) that can be instrumental in specific choice.
- Personal relationships infringing decision-making beyond its legitimate functions.
- Marketing efforts infringing on decision-making beyond it's legitimate role (also: (Avorn et al. 1982)).
- Numerous cognitive shortcuts used (though this is a necessary aspect of the behaviour in the current medical environment).
- Promotion of one beneficiary over another where this is not appropriate.
- Preference to use internally held personal experiences to solve problem.
- Personal experience may contain:
  - Too few cases.
  - Insufficiently broad catalogue of case types.
  - Bias toward cases of a particular type.
  - Insufficiently developed diagnostic skills to discern specific problem and relevant details.
  - Overconfidence in the use of certain treatments and regimes (Einhorn and Hogarth, 1978).
  - Underconfidence in the use of certain treatments and regimes.

- Conservatism causing an over-reliance on superseded treatment.
- Performance of Overriding ***Trading Off*** represents a risky treatment strategy.
- Lack of understanding and ability to use summary statistics (Poses et al. 1985)[20].
- Generalising of study and experience data to support use of other treatments.
- When External sources are used the preferred form of information is patient experience. This allows bias from other physician's experiences to be distributed.
- ***Surrogating*** preferred from experts. Evidence exists for experts being superior diagnosticians though this is not seen in health outcomes. Education and training of experts is required in conjunction with careful selection of case studies.
- ***Shifting*** and ***Surrogating*** occurring based on poorly constructed and performed clinical studies.
- Random aspects of medicine bias learning and Feedback, therefore without the use of objective support, poor behaviours may become reinforced.
- Lack of motivation to learn due to overconfidence (Faust and Ziskin, 1988).

11.3.2.5 Correction of Prescribing Errors

The medical decision-making research reviewed has provided a number of recommendations and aids concerning the correct performance of this process.

11.3.2.5.1 Process

Deviations were not found from the process of the differential diagnosis approached outlined by (Sox and Blatt., 1988). These were only shown in ***Trading Off*** and the literature in the performance of the stages.

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[20] Lack of availability of this data is also a cause of inappropriate and variable prescribing

11.3.2.5.2 Assessment of Information

Information is gathered from internal and external sources. The use of internal sources can be improved by making the physicians aware of likely errors from the heuristics used as cognitive short cuts. The use of External sources is seen as being able to supply the necessary data to make rational decision. However there are doubts over how accurately published studies match the problems faced by practitioners.

The following four steps and methods can be grouped together because of the similarity of the conclusions that can drawn over them.

11.3.2.5.3 Understanding New Information

Use of: Bayes Theorem

11.3.2.5.4 Assessing the Accuracy of Clinical Data

Use of: ROC curves, False Positive and Negative rates

11.3.2.5.5 Decision Analysis

Use of: Decision Tree, Sensitivity Analysis

11.3.2.5.6 Decision-making

Use of: Expected Utility Theory

These methods provide accurate strategies for performing core stages in decision-making. However a number of issues exist surrounding the availability of information and their practical application. These methods will only produce accurate outcomes if they are based on accurate clinical data. The second issue is that while it is possible to complete these tasks for each patient, this would be too time consuming in their current form to be a practical way of improving decision-making.

Computer aids to these tasks are being developed and this will (eventually) address the practicality issues. These programs will remain however only as good as the data bases used as their foundation.

EUT approaches to decision-making have been used to study other forms of medical decision-making behaviour (for example patient preferences (Torrance G W et al. 1972)). The fundamental similarity to ***Trading Off*** and this approach can be used as tentative evidence supporting the use of ***Trading Off*** as representation of wider medical decision-making.

11.3.2.5.7 Decision Rules

The use of Decision Rules such as the one tested by (Stiell et al. 1996) for knee radiography have shown to be successful in accurate diagnosis of problems. These focussed and matched consolidations of expert clinical practice and data represent a useful starting point for practical methods of reducing errors due to misdiagnosis.

In summary therefore the formal methods reviewed in this section supply methods of how medical decision-making should and can be performed. Their practical introduction can be seen therefore as a legitimate way of reducing errors.

11.4 Conclusions on Expertise and its development

The conclusions provided here demonstrate the contribution ***Trading Off*** makes expertise literature and the contribution this literature makes to ***Trading Off*'s** representation of the expert-sub expert decision-making. The importance of this work is extended because of the significance of experts (in the form of opinion leaders, local consultants, prescribing advisors) as a target market for both pharmaceutical companies and health care providers.

The conclusions drawn as to the use of information, the type of information used, information sources and the development of expertise can be used to further refine programmes to modify pharmaceutical decision-making. Experts are a particularly important group to target in the reduction of medical errors and achieving marketing objectives because of their role in diffusion of information and as sources of ***Surrogating***. For example, attempts to introduce formal procedures into decision-making would be aided if the experts in the practice of medicine used these methods. The important aspects of expertise development are also emphasised.

11.4.1 Conclusions on ***Trading Off*'s** contribution to Expertise

- Experts use greater levels of ***Self-Referencing*** of internally held sources of information to solve problems in specific disease areas and use larger amounts for individual problem management. This is based on the preference to use the volume of individual cases they have represented in their internal catalogue. These contain large numbers of variations seen around the core disease and it is easier therefore to use this source to match ***Focused*** properties of the current problem with information in memory.
- ***Surrogating*** from external sources is used when gaps in knowledge are felt.

- This ***Surrogating*** may be include generalising of patient experience and clinical studies and often represents an exceptional behaviour.
- ***Self-Referencing*** allows rapid decision-making but is often flawed due to the problems of memory and information held (see section 11.3.2.4 for details).
- ***Self-Referencing*** is performed initially and then ***Surrogating*** in order to provide levels of confidence that are then ***Traded Off*** in order to make decisions.
- The use of both these sources to solve a problem is common.
- In contrast to experts other physicians use more ***Surrogating*** to solve problems.
- Physicians prefer to Surrogate from Professional sources therefore experts are very important in the diffusion of information.
- Support is often needed however from clinical studies.
- ***Shifting*** represents the movement between ***Surrogating*** and ***Self-Referencing*** that occurs as levels of confidence increase.
- Knowledge, experience and trust cause the ***Shift*** between ***Surrogating*** and ***Self-Referencing***.
- The speed of the ***Shift*** is also dependent on the complexity of the problem area.
- The ***Shift*** between one source and the other is characterised by the use of different sub-categories of ***Self-Referencing*** and ***Surrogating***. In a number of instances these sub-categories mirror each other and represent the behaviour performed in order to provide the additional information required.

11.4.2 ***Trading Off*** supports expertise literature concerning:

- Pattern based retrieval (Patel et al. 1989).
- Expert possession of large numbers of case experiences (Dreyfus and Dreyfus, 1986).
- Domain specificity of expertise and its development (Norman et al. 1992).

11.4.3 Developments of *Trading Off* by Expertise literature

- The literature reviewed concerning cognitive functions associated with levels of expertise suggest that experts use forward reasoning to solve problems. This is in contrast to the backward reasoning used by sub-experts, intermediates and novices (Patel and Groen, 1991). ***Trading Off*** does not differentiate between the form of reasoning used by different levels of expert.

- Forward reasoning is an appropriate strategy if large amounts of information are possessed and the problem faced is routine, it can be error prone if this is not the case (Patel and Groen, 1991).

- Sub-experts who do not posses sufficient memories or cognitive skills often attempt this reasoning strategy (Patel and Groen, 1991). This information can be used to reduce medical errors based on poor diagnosis.

- The reasons why forward and backward reasoning differences were not found in ***Trading Off*** may have been due to ***Trading Off's*** investigation being centred on pharmaceutical decision-making rather than differential diagnosis.

- In addition to the large catalogue of experiences held by experts they also possess superior memory skills that improve the use of these experiences (Chase and Simon, 1973). This is not seen in sub-experts, intermediaries and novices.

- These skills include chunking of information, the recognition of structural patterns (Chase and Simon, 1973) and the ability to access information more quickly (Ericsson and Smith, 1991).

- These findings suggest that the use of case studies alone is unlikely to be sufficient in developing expertise. Instruction is also required concerning how to use these

cases and assistance provided in their application. It is also vital to ensure that cases used are representative of the disease and its manifestations.

11.4.4 Training Requirements

Trading Off provides a number of factors that are required in order to ***Shift*** the physicians between ***Surrogating*** and ***Self-Referencing***. The literature review develops this by providing recommendations concerning the context within which expertise develops and how best to achieve this status. This context and recommendations are:

- Training is the key element in expertise development (Baird, 1985).
- The training should be performed according to a number of rules, these have been highlighted in section 11.2.2.3 along with other recommendations as they refer to modifying physicians behaviour. They are outlined here individually:
  - Subject needs to be motivated.
  - Existing knowledge should be taken into account during planning of training.
  - A number of similar task should be repeated.
  - Training must involve deliberate practice.
  - Immediate feedback needs to be provided.
  - Training period should be individualised.
  - Explicit instructions provided.
  - Adequate resources provided.
  - Explicit, obtainable goals discussed and set.
  - Period of work apprenticeship required in order to learn situation specific skills. (Ericsson et al. 1993)
- A minimum of 10 years of training is required in order to posses the necessary level of experiences and for the cognitive changes to occur (Chase and Simon, 1973), (Lesgold, 1984).

11.5 Methodological conclusions

A number of methodological conclusions can be drawn from this thesis.

- Glaserian grounded theory provided a useful method for building a substantive theory in the area of pharmaceutical decision-making.

- The method's flexibility ensures that further theoretical sampling could be performed in order to modify this theory for other areas of medical decision-making. This further sampling may also be used to develop a formal theory decision-making.

- The acknowledgement of pre-understanding (Appendix Two) was an important phase in this study due to the authors previous experience in pharmaceutical marketing. It is felt that this allowed the author to acknowledge a greater level of knowledge than would have occurred without this deliberate step

- The modification to the open coding stage was found to be of use as a method of tracking codes and their indicators and also in developing a deep understanding of the field data.

- Individual in-depth interviews were found to be a suitable primary method of data collection particularly in an area where observational techniques are not indicated or practical to perform.

- The use of a tape recorder during these discussions allowed the researcher to concentrate on conducting an emergent discussion rather than attempting this task as well as noting down codes as they issued from the interviews. The resultant transcript, in addition to non-verbal data provided an accurate reflection of the discussions that were as free as possible from memory failures and bias. It is

recommended therefore for the novice Grounded Theorist that this method or similar be used in conjunction with the following tactics:

- Turning off the tape recorder at the end of the discussion in order for political aspects of the behaviour to be investigated
- Being open with the respondent as to the purpose of the tape recorder and offering to turn it off at any stage and to destroy the tape once a transcript has been taken

- Returning to data collection points in order to clarify and expand on codes, their properties and relationships rather than interviewing a new subject, was a successful tactic in achieving these goals.

- Access to a large room and numerous white/black boards is thought to have been particularly useful during the sorting stage of theory development. It is essential that creativity and grounding are not compromised at this stage and these facilities are able to assist in this greatly.

- It is recommended that an individual grounded theorist join a writing group in order to assist in coding, receive criticism on current writing and provide ideas for labels, relationships and sampling. These groups also provide support and advice during the long stages of theory development.

- These groups should meet regularly and be conducted in an open friendly atmosphere where the theorist does not feel inhibited in opening their work and ideas for critical appraisal.

- Regular meetings of this sort also have the added benefit of allowing the group members to develop a level of expertise in research being carried out by the other members. If members are conscientious in reading and providing critiques then they

will develop a good understanding of the development of all the work being performed in the group.

- An additional benefit provided by a group of researchers at who are at different stages, is that the less experienced members benefit from that of the others. This may be in methodological areas or in motivation, support and the anticipation of problems.

- The teaching and learning of Glaserian grounded theory would be aided greatly if the texts were indexed and provided with meaningful tables of contents. These do not exist in current editions and therefore clarification on methodological issues requires a great deal of unnecessary reading and wasted time. This is made more important because of the "minus mentoring" form of supervision that is often used.

- Memoing and sorting also represent a useful approach to the literature search and its writing up. Memoing of ideas, sorting them and further memoing were thought to be useful in developing an integrated understanding of the literature reviewed. This was particularly useful within Expertise development as this was an area where the author had no previous knowledge.

11.6 Grounded theory as a commercial research method

The ability of grounded theory to produce understanding of the social and psychological systems of behaviour that are explanatory and predictive indicates a potentially useful tool for commercial market research. However this is restricted by a number of characteristics of the method and the setting:

- The emergent nature of the research question in grounded theory is in contrast to the need to answer specific queries in business.

- Commercial researchers are required to provide budgets and project time scale. This is made difficult with grounded theory because of the open-ended nature of theoretical sampling and the associated budget uncertainty.

- The time intensive nature of coding, memoing and sorting in conjunction with the need for the highly trained researcher to perform these tasks can make the projects extremely expensive if current charging methods are used.

- There may be difficulties in maintaining the researcher's sensitivity and lack of preconceptions if numerous studies are performed in similar areas. This may occur if the current agency/sector focus used, i.e. research agencies specialising in FMCG[21] or Pharmaceutical marketing research.

- Commissioning companies not being familiar with the method and its outputs.

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[21] Fast Moving Consumer Goods such as confectionery, household cleaning products

11.6.1 Possible Solutions to these Issues

- Grounded theory techniques may be used by integrating them into research designs. For example using coding, memoing and sorting techniques on data collected to answer a specific question. These techniques will not produce a grounded theory however they will increase the grounding and density of the final report.

- Indications as to average numbers of discussions and project times may provide sufficient guidance for commissioning companies.

- Researchers working in pairs can be used to reduce the time taken to conduct the investigation.

- Agencies providing grounded theory methodological expertise across industry sectors may reduce the likelihood of preconceptions and lack of sensitivity.

- Certain research questions lend themselves to the use of a complete grounded theory approach, for example to provide representations of new markets or for updates on existing market conditions. In these instances longer time spans may be available to conduct the research and a more emergent philosophy tolerated.

Appendixes

Appendix One

Eleven Criteria for Evaluating whether a Category is Core.

(Glaser, 1978) p95-96

- "It must be central, that is related to as many other categories and their properties as possible.
- It must re-occur frequently in the data
- It takes more time to saturate the core category than other categories
- It relates meaningfully and easily with other categories
- A core category in a substantive field has clear and grabbing implications for formal theory
- The core category has considerable carry through
- It is completely variable
- While accounting for variation in the problematic behaviour, a core category is also a dimension of a problem
- The criteria above generate such a rich core category, that in turn they tend to prevent two other sources of establishing a core which are not grounded. (Sociological Interest and Deductive Logical Elaboration)
- The above criteria also generates a false criterion yet which indicates it is core. The analyst begins to see the core category in all relations, whether grounded or not.
- The core category can be any kind of theoretical code."

Appendix Two

Pre-understanding:

"Prescribing of New drug compounds by UK GPS

The UK GP is cautious and sceptical about new compounds. Gradations of this though the average is more sceptical than other countries.

They are worried, concerned about using new compounds as many examples of mew compounds that have subsequently proved to have bad/disastrous/undesired side effects.

I am not sure about how they regard the drug reps as a source of convincing data for the persuasion to use new compounds.

The process of taking on board new products involves: Persuasion and uptakes by the local hospital specialist. Their usage and speaking in favour are important but not critical. It provides a considerable barrier if he does not recommend it.

The local Prescribing advisor and the medicine agency are important though by varying degrees to different GP's. Overall their role is not clear. Are they crucial or unnecessary? Will the quality of the medicine pre-determine this anyway? I.e. if it is a product that is a genuine advance then it will make it through this stage without problems and these the products that will succeed. How do the non-genuine or part advances make it thorough?

GP prescribing is based on comfort and security, they must be comfortable that the drug will do the job but must not cause side effects that will effect them and to a certain extent their patients. Becoming more concerned with litigation.

GP's are concerned but not too knowledgeable about price. They like comparisons of what they are using Vs new.

They are stressed and want to reduce this workload/stress load and don't want to prescribe that which will lead to problems.

It takes 3 representatives visits before a GHP will prescribe. The hospital doctors are more clinical and less patient orientated. Science not marketing works better with them.

Ward formularies are set by consultants/hospital and juniors follow this. The hospital pharmacists put an important amount of input into formulary decisions.

Local GP's formularies (wither practice or GP) are based on price, experience comfort with representatives.
Reps play an important role in some GP's prescribing. GP's who don't see (hospital also) I don't know what motivates these to change."

Appendix Three

Letter Of Request for Permission to Interview Physicians

Iain Black
Tutorial Assistant
Marketing dept
University of Strathclyde

Dr. Kenneth Harden
Medical Secretary
Glasgow L.M.C.
40 New city Rd
G4 9JT

Phone 0141 552 4400 **EXT 4472**

Dear Dr. Harden,

I am writing to you in connection to my doctoral research in the marketing department of the University of Strathclyde. I have been advised by both the Glasgow office of the B.M.A. and Dr John Macleod (of North Uist) that I should approach your office in the first instance to gain approval in order to conduct depth interviews with local general practitioners. I was told that a decision would be reached by the local medical committee and I should give you details as to what am looking to do and how.

My research involves constructing a methodology that can be used to predict individual behaviour in situations where they are acting as consumers and where the action can be described as "High Involvement" i.e. where the purchase is important and/or expensive. As a vehicle to test the methodology that I have constructed, I am investigating the "Prescription of new drug compound by UK. physicians". It is reaching and talking to local GP's for his project that I am asking for you approval.

I will also be approaching hospital physicians and hopefully running identical interviews with them. The results of the GP and hospital physicians interviews will then be combined to and will (hopefully) lead to a quantitative arm of the study in approximately 18 months time. If I was given your approval I would then contact you again to move on to the second part of the study.

The numbers that I envisage having to contact is small, approximately 15 local GP's is likely to highest number that I will need to talk to. The method that I am using does not pre-determine the numbers but past experience with it's use in sociology suggests that between 15-30 interviews is normally sufficient. I expect that half of this number will be hospital doctors and health board officials

The interviews will be similar to the type of individual depth interview used by commercial agencies. I will however be asking fewer direct questions, instead looking to have a discussion on the area with the GP talking about relevant experiences. They will last for a minimum of 20 minutes and up to one hour and there may be a necessity to conduct second interviews that would be shorter in duration. The need for these second interviews is depends on the results of further interviews and would be to cover points of interest that have been discovered.

I would like to start these interviews as soon as possible. My teaching commitments finish in 3 weeks time and I will be free to start from any time I was given approval to do so.

The benefits of this study to the pharmaceutical industry are obvious but I would like to state that this research and me personally **are not sponsored in anyway by any pharmaceutical company** and this research (as with all academic research) will remain the property of the university. No particular drugs will be discussed on my prompting, I am interested in the process that the GP goes through in deciding on which new

compounds to add to his/her armoury and the decision as to which compound is discussed will be up to the physician.

I hope I have outlined clearly what I am trying to achieve and what I will be asking of your members. If you need any more information or clarification of points that I have made please do not hesitate to get in touch.

Thank you for your help.

Yours faithfully

Iain Black

Appendix Four

Dr Harden's Reply:

Dr. K.A. Harden
Dr. R.T.W. Prentice
Dr. Jean C. Powell
Dr. Judith M. Chapman
Dr. Elizabeth A. McIntosh

85 MILNGAVIE ROAD,
BEARSDEN, G61 2DN
Tel 0141-942 2345

KAH/CF

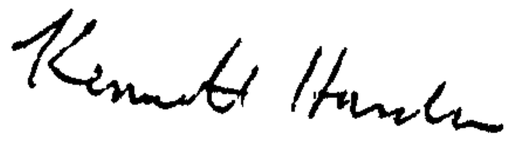
7th May, 1996

Mr. Ian Black,
Tutorial Assistant,
Marketing Department,
university of Strathclyde,
Glasgow

Dear Mr. Black,

I apologise for the delay in responding to your letter. Thank you for approaching the LMC on this matter. I appreciate the object and methodology of your research. The LMC would take no exceptions to your proposals. The only area of concern is with regard to whether a sufficient number of local GPs will be willing to spend the time you suggest. Regrettably particularly since the 1990 new contract the stresses on general practitioners time have been particularly high with large increases in work-load and no increases in manpower. There also has been a tendency for increasing numbers of researchers to target GPs with questionnaires with the tendency for GPs to express the view that their priority is to took after their patients rather than respond to questionnaires however worthwhile. The Committee thus takes the view that while it takes no exception to your proposal it cannot go as far as to express support for it. I appreciate that this may disappoint you but hope that you will understand the reasons behind this.

Yours sincerely,



K A. Harden, M B.,Ch.B.,D.Obst.,R.C O.G ,F R.C.G P

Appendix Five

Prescribing Newsletter

Medicines RESOURCE
Independent Drug Information
SMRC

A National Health Service Publication

Issue No 21
March 1995

Torasemide (Torem)

A novel potent loop diuretic?

Therapeutic Comment

Torasemide is a loop diuretic which, at low doses, shares some of the properties of a thiazide. It offers little clinically proven advantage over established diuretics.

Clinical trials have shown it to be no more effective than thiazide diuretics such as hydrochlorothiazide in essential hypertension or loop diuretics such as frusemide in congestive heart failure. However there is a lack of published data comparing it to bendrofluazide or bumetanide.

It has been well tolerated in trials to date: hearing loss has not been reported and it appears to have no greater effects on cholesterol, triglycerides, calcium and blood glucose levels than related drugs.

As with any relatively new drug, the full range of side effects will not yet be established and full reporting is encouraged.

Torasemide has little or no effect on potassium excretion at low dose but offers no advantage over low-dose thiazide diuretics in this respect. *It is not clear how higher doses compare with other loop diuretics.*

Torasemide may have marginal advantages over other diuretics, however these are not well established and, for most patients, do not justify its high cost.

It may prove useful in the treatment of patients who are either resistant to or cannot tolerate established loop and thiazide diuretics.

Mode of action

Torasemide is a loop diuretic which, like frusemide and bumetanide, acts primarily by inhibiting the reabsorption of sodium and chloride in the ascending limb of the loop of Henle.[1] However its dose response characteristics differ from those of other loop diuretics: at low dose, e.g. 2.5 mg daily, it reduces blood pressure without increasing sodium excretion and more closely resembles the thiazides.

'At such doses, torasemide's blood pressure lowering effects are difficult to ascribe solely to altered excretion of sodium and chloride.[1] At higher doses (5 mg and 10 mg daily) its action is similar to that of other loop diuretics.

Torasemide has a longer elimination half-life and a more prolonged action than other loop diuretics, though the frequency of administration is similar (once daily).

How does diuresis compare with other diuretics?

The time to onset of action of torasemide is about 1 to 4 hours, and is similar to frusemide. However, duration of diuresis is longer. The diuretic activity of frusemide 40 mg lasts on average 4-6 hours, whereas torasemide 10 mg has a diuretic activity lasting 6-12 hours. The duration is dose dependent and increases to 8-12 hours in patients treated with torasemide 20 mg.

The urinary volume following treatment with torasemide varies with dose. In a pharmacodynamic study involving 18 oedematous patients,[2] the urinary volume produced by torasemide 10 and 20 mg was compared to frusemide 40 mg. Although an overall increase in urinary volume was observed in all three groups of patients, the effect was more pronounced with torasemide than frusemide. For some patients, the marginally greater urinary volume produced over a longer period could be troublesome.

Dose and Administration

Oral: Essential Hypertension

2.5 mg once daily increasing to 5 mg once daily if necessary. Studies suggest that doses above 5 mg daily do not lead to further reduction in blood pressure. The maximum effect is exhibited after approximately 12 weeks of continuous therapy

Oral: Oedema

The usual dose is 5 mg once daily increasing if necessary to 20 mg once daily. In individual cases, as much as 40 mg per day has been administered.

An intravenous formulation is also available (10 mg/2 ml and 20 mg/4 ml).

Scottish Medicines Resource Centre, Elliott House, Hillside Crescent, Edinburgh, EH7 5EA Telephone 0131 557 3733
A part of the Scottish Pharmacy Practice Centre

Efficacy

Hypertension

Torasemide 2.5 mg daily has been shown in small comparative trials to be no more effective than thiazides in mild to moderate hypertension. It has been compared to chlorthalidone 25 mg,[3] hydrochlorothiazide 25 mg[4] and indapamide 2.5 mg.[3] A multicentre trial comparing low dose torasemide 2.5 mg with triamterene 50 mg and hydrochlorothiazide 2.5 mg found torasemide to be as effective as the combination in blood pressure reduction and in maintaining serum potassium levels.[5]

Congestive heart failure

In a study involving 114 patients with congestive heart failure, torasemide 5 mg was as effective as torasemide 10 mg and as frusemide 40 mg.[6] The improvement of clinical symptoms was slightly more evident in the torasemide groups, but the differences were not significant. In another trial,[7] high dose torasemide (20 mg) was more effective than a fixed dose of frusemide 40 mg at reducing symptoms of congestive heart failure (20 mg torasemide is approximately equivalent to 100 mg frusemide[8]).

Liver disease

There have been few studies comparing frusemide with torasemide, either alone or in combination with spironolactone, in the treatment of liver cirrhosis and hepatic oedema. Most found torasemide to be as effective as frusemide, but patient numbers have been low. As torasemide is metabolised in the liver, its elimination can be impaired in cirrhosis resulting in a more prolonged diuretic effect than frusemide.[9]

Renal failure

Torasemide 200 mg IV has been found to be of comparable efficacy to 500 mg frusemide IV in renal oedema.[10] Its kinetics differ from frusemide, which is primarily excreted unchanged. Large scale trials are required to confirm whether it has clinically relevant advantages over existing loop diuretics in renal failure.

Contra-indications and Precautions

Like all other loop diuretics torasemide should not be used in anuria, hypotension, hepatic precoma and coma. It should be avoided if there is a history of hypersensitivity to any of the ingredients or to sulphonylureas, (e.g. chlorpropamide and glibenclamide) as it is similar in structure to sulphonylureas. Torasemide appears to be safe in latent diabetes and in diabetic patients.

Pregnancy and Lactation

Malformed foetuses were observed in pregnant rabbits given high dose torasemide. As data in humans are unavailable, torasemide is contra-indicated in pregnancy and lactation.

Interactions

Torasemide exhibits similar drug interactions to other loop diuretics.

Adverse effects

▼ **As with any new drug, the CSM requests that all suspected adverse effects should be reported.**

The available evidence suggests that torasemide has adverse effects similar to those of other loop diuretics. This includes disturbances of electrolyte and water balance, raised uric acid, urea, creatinine, glucose and lipid levels. Other side effects related to electrolyte and volume depletion are headache, dizziness, weakness, loss of appetite and cramps. However, unlike commonly used loop diuretics it has not yet been associated with hearing loss or reduced calcium levels.

Does it cause potassium depletion?

Torasemide is being promoted as having no clinically significant effect on potassium, however the data sheet highlights hypokalaemia as an adverse effect. Although diuretic therapy is associated with a predictable fall in serum potassium concentration, marked hypokalaemia is rare. Low doses of thiazides (e.g. bendrofluazide 2.5 mg daily) are effective in hypertension, and at such doses changes in serum potassium are very slight.

Trials comparing low dose torasemide to thiazides have found that potassium levels were unaffected by torasemide while standard doses of thiazides led to a decrease: however levels were within the physiological range for both treatments. Studies have also shown that potassium levels resulting from treatment with low dose torasemide are not significantly different from those obtained with combination therapy (thiazide and potassium sparing agent).

There is little comparative data on the effect on potassium levels of higher dose torasemide (5-10 mg) and other loop diuretics, but the available evidence does not suggest a significant difference.

Cost

GP cost of 28 days treatment at the stated dose:

"Torem" (5 mg daily)	£6.23
"Torem" (10 mg daily)	£9.16
Bendrofluazide (2.5 mg daily)	£0.14
Frusemide (40 mg daily)	£0.11
Co-amilozide 2.5/25 (one daily)	£1.74
"Moduret 25" (one daily)	£1.94
Co-amilofruse 2.5/20 (one daily)	£3.15
"Frumil LS" (one daily)	£3.17

The uptake for torasemide has been low but is gradually increasing. From launch in May 1994 up to December 1994, there were 549 prescriptions written for torasemide in Scotland

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Newer drugs for herpes zoster (shingles)

Therapeutic Comment

Famciclovir and valaciclovir are two drugs related to aciclovir which have recently been licensed for oral treatment of herpes zoster infection (shingles).

The available evidence suggests that all three drugs have similar efficacy in reducing the time to resolution of symptoms in acute herpes zoster infection.

There is conflicting evidence for the efficacy of aciclovir in preventing or reducing the duration of post-herpetic neuralgia and no convincing evidence that the newer drugs offer an improvement.

The principal advantage of famciclovir and valaciclovir over aciclovir is that they can be given three times daily, with a possible improvement in compliance. However, for a short course of treatment in what can be a very distressing condition, patients may not need much encouragement to take their medication five times daily.

At present valaciclovir costs less than aciclovir and famciclovir, which are similarly priced However aciclovir is likely to become available as a less expensive generic after loss of patent later this year.

Treatment of herpes zoster yields better results if initiated as soon as possible after the onset of rash.

Oral aciclovir is also indicated for the treatment of varicella (chickenpox) and of herpes simplex infections of the skin and mucous membranes including genital herpes.

Oral famciclovir has also recently been licensed for the acute treatment of genital herpes infection.

Aciclovir Spelling

The spelling has recently been changed from acyclovir to aciclovir.

Herpes zoster infection

The aim of treating shingles is to reduce the discomfort caused by the acute infection, and to prevent complications. The most common complication is post-herpetic neuralgia. This is pain persisting or occurring at the site of shingles four weeks or more after the onset of the acute infection. It occurs in about 10% of patients, one third of whom will still have pain a year later. The incidence and severity of pain are increased in elderly patients, with around 50% of patients over 70 years of age experiencing pain at one year.[1,2]

Famciclovir and valaciclovir

Aciclovir has a low oral bioavailability and requires five times daily dosing. Famciclovir and valaciclovir need only be taken three times daily.

Both of the newer drugs are pro-drugs and are converted to an active form by metabolism in the body. Famciclovir is a prodrug of penciclovir which has similar activity to aciclovir. Valaciclovir is a pro-drug of aciclovir but with improved bioavailability.

Efficacy

Valaciclovir and famciclovir have been investigated for use in the treatment of shingles in a limited number of trials in immunocompetent patients presenting within 72 hours of the onset of rash. With one exception,[3] they have been published only as abstracts.

Acute herpes zoster

A multicentre double-blind study involving 545 adult patients reported similar efficacy for aciclovir and famciclovir.[3] There were no differences in time to healing of the rash or improvement in pain relief. Doses were 250 mg, 500 mg or 750 mg three times daily for famciclovir and 800 mg five times daily for aciclovir. The higher doses of famciclovir were not more efficacious.

Valaciclovir and aciclovir were found to be similarly efficacious in rash healing in a large phase III study involving 1141 patients aged 50 years or more.[4] Patients were randomised to receive treatment with valaciclovir 1 g three times daily for seven or 14 days, or aciclovir 800 mg five times daily for seven days. Extending the treatment period with valaciclovir did not improve efficacy.

Post-herpetic neuralgia

The evidence for the efficacy of aciclovir in preventing and decreasing the duration of post-herpetic pain after treating an acute attack is inconclusive,[2,5-7] and a recent study found no improvement in efficacy from extending the treatment period to 21 days or combining aciclovir with prednisolone.[6]

It is claimed that valaciclovir is more effective than aciclovir in preventing post-herpetic neuralgia. Unfortunately the evidence for this claim is limited: oral valaciclovir was shown to reduce the duration of post-herpetic neuralgia compared to oral aciclovir in one trial,[4] however the results are inconclusive since statistical significance is not known. The estimates of median time to cessation of pain were 38 days in the patients treated with valaciclovir for seven days, compared to 50 to 51 days for patients receiving aciclovir.[4,8]

In the large multicentre trial comparing famciclovir and aciclovir, the term zoster-associated pain was used to encompass all pain associated with herpes zoster, thereby avoiding the term post-herpetic neuralgia.[3] The authors concluded that, at the licensed dose of famciclovir, there was a significantly shorter time to resolution of zoster-associated pain than with aciclovir. However, this trend was only observed in a subgroup of the patients treated within 48 hours. These results are encouraging but inconclusive.

Contra-indications and Precautions

All three drugs are contra-indicated in cases of known **hypersensitivity** to the drug or its metabolites.

None is normally recommended in **pregnancy** or **lactation** because of lack of information.

Elimination is reduced in **renal failure** and dose adjustments are recommended for all three drugs.

Adverse effects

▼ **As with any new drug, the CSM requests that all suspected adverse effects with famciclovir and valaciclovir should be reported.**

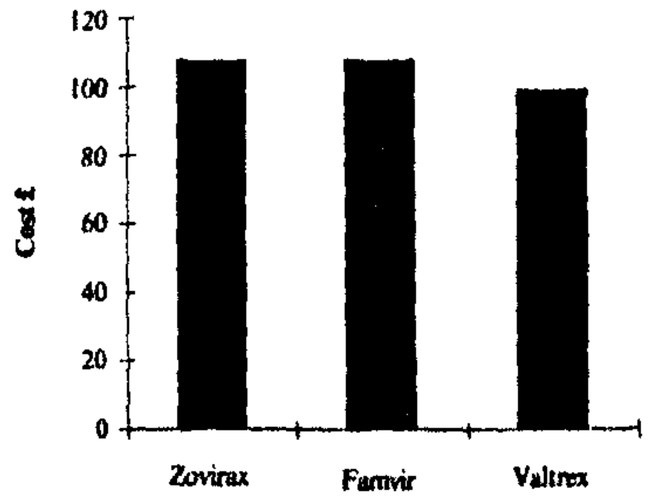
Aciclovir has been in clinical use for over 10 years. Thus, its safety is well established. The evidence to date suggests that the adverse effect profile for both of the newer drugs is similar to that for aciclovir. The most commonly reported adverse effects are mild headache and nausea, though the incidence in some trials has been similar to that with placebo.

Drug interactions

Probenecid reduces the renal clearance of aciclovir, valaciclovir and possibly famciclovir and this could result in increased plasma levels. Cimetidine may cause valaciclovir to accumulate.

Dose and Cost

Comparative costs of 7 day course of treatment



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Modified Release Correction

Licensed indications of Dilzem XL capsules

It was stated in Medicines Resource No 20 (Modified Release Preparations) that Dilzem XL capsules were licensed only for hypertension. In fact, this product is also licensed for angina.

The Scottish Medicines Resource Centre is part of the Scottish Pharmacy Practice Centre. This bulletin was prepared with the help of specialists whose contribution is acknowledged.
Enquiries, Comments and Suggestions to the Scottish Medicines Resource Centre, Scottish Pharmacy Practice Centre, Elliott House, Hillside Crescent, Edinburgh EH7 5EA (Tel 0131 537 3733).
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Appendix Six

Formal Request for Interview

Letter sent to Dr Swan, Clinical Assistant. Western Infirmary, Glasgow.

Iain Black
Tutorial Assistant
Marketing dept
University of Strathclyde

Phone 0141 552 4400 **EXT 4472**

Dr. Swan
Dept of Cardiology
Level 4
Western Infirmary
Glasgow

19 August, 1999

Dear Dr. Swan,

I am writing to you in connection to my doctoral research in the marketing department of the University of Strathclyde. I have interviewed Dr Hillis as part of my research and after the discussion he suggested I get in contact with you to see if you were also able to help. I was wondering if it would be possible to set up a time when I could come in speak to you about the prescribing of new to market pharmaceuticals.

The interviews will be similar to the type of individual depth interview used by commercial agencies. I will however be asking fewer direct questions, instead looking to have a discussion on the area talking about experiences you believe to be relevant . It is likely that the discussion will last for about 45 minutes.

The benefits of this study to the pharmaceutical industry are obvious but I would like to state that this research and me personally **are not sponsored in anyway by any pharmaceutical company** and this research (as with all academic research) will remain the property of the university. No particular drugs will be discussed on my prompting, the decision as to which compound is discussed will be purely your choice.

I shall ring the department early next week to see if it possible to set up a time

Thank you for your help

Yours faithfully

Iain Black

Appendix Seven

Discussion Guide

Dr Fleming.

Introduction

Outline what I'm doing. Interested in the training of medics. Form the centre of the discussion.

Point 1) Interested in the psychology of training are you attempting to create a certain type of individual.

Point 2) Ethics

Point 3) Values- What values and morals (if any are taught directly)

Point 4) What are they taught-is there a primary concern above all else

Ethics/Morals/Value/

Point 5) Pharmacological Training, what is provided?

ISIS RESEARCH

MONTHLY AUDIT OF PRODUCT DETAILS - JULY 1996

	Year to Jul96		MONTH Feb96		Mar96		Apr96		May96		Jun96		Jul96	
Total	5401356	100.0%	473484	100.0%	466448	100.0%	431868	100.0%	490008	100.0%	440334	100.0%	483426	100.0%
	184313	3.4%	15096	3.2%	14586	3.1%	14280	3.3%	19584	4.0%	15912	3.6%	17441	3.6%
	131471	2.4%	14484	3.1%	13672	3.0%	11934	2.8%	15606	3.2%	12444	2.8%	12947	2.7%
	121820	2.3%	11322	2.4%	12444	2.7%	10098	2.3%	15912	3.2%	10404	2.4%	9416	1.9%
	110769	2.1%	9566	2.0%	13566	2.9%	8528	1.5%	8568	1.7%	9996	2.3%	8667	1.8%
	105314	1.9%	7446	1.6%	11424	2.4%	10200	2.4%	13566	2.8%	9894	2.2%	11964	2.5%
	97755	1.8%	6732	1.4%	8262	1.8%	6222	1.4%	11322	2.3%	8670	2.0%	7383	1.5%
	93086	1.7%	8364	1.8%	6834	1.5%	6528	1.5%	6426	1.3%	7650	1.7%	10058	2.1%
	92063	1.7%	8772	1.9%	7956	1.7%	6528	1.5%	6426	1.3%	7854	1.8%	7811	1.6%
	90006	1.7%	7242	1.5%	7854	1.7%	5202	1.2%	7038	1.4%	5508	1.3%	9630	2.0%
	88607	1.6%	7038	1.5%	6732	1.4%	7446	1.7%	11016	2.2%	9690	2.2%	6741	1.4%
	83950	1.6%	7956	1.7%	9690	2.1%	7548	1.7%	6834	1.4%	6834	1.6%	6634	1.4%
	81843	1.5%	8058	1.7%	6426	1.4%	6120	1.4%	6528	1.3%	7548	1.7%	7383	1.5%
	81355	1.5%	5814	1.2%	4080	0.9%	6834	1.6%	8160	1.7%	6222	1.4%	5671	1.2%
	80673	1.5%	6426	1.4%	9996	2.1%	6936	1.6%	6426	1.3%	6120	1.4%	8453	1.7%
	80286	1.5%	5814	1.2%	6426	1.4%	5916	1.4%	5814	1.2%	4488	1.0%	8988	1.9%
	78614	1.5%	10710	2.3%	5916	1.3%	7752	1.8%	7344	1.5%	5610	1.3%	8132	1.7%
	76774	1.4%	6528	1.4%	7242	1.6%	8670	2.0%	7344	1.5%	7140	1.6%	12412	2.6%
	71782	1.3%	6120	1.3%	5814	1.2%	6120	1.4%	5202	1.1%	5406	1.2%	5992	1.2%
	70610	1.3%	8670	1.8%	4896	1.0%	4794	1.1%	6018	1.2%	2856	0.6%	4922	1.0%
	69644	1.3%	5304	1.1%	6324	1.4%	7446	1.7%	7242	1.5%	4080	0.9%	5992	1.2%
	68871	1.3%	6528	1.4%	6222	1.3%	6018	1.4%	7140	1.5%	6222	1.4%	4815	1.0%
	68055	1.3%	4590	1.0%	9588	2.1%	3774	0.9%	6732	1.4%	6426	1.5%	4815	1.0%
	66784	1.2%	8874	1.9%	5508	1.2%	6018	1.4%	6120	1.2%	5202	1.2%	5664	1.2%
	64806	1.2%	4998	1.1%	5916	1.3%	3162	0.7%	7854	1.6%	5508	1.3%	5136	1.1%
	64480	1.2%	5202	1.1%	4692	1.0%	6732	1.6%	4080	0.8%	6018	1.4%	4708	1.0%

Table-3a Total Details by Field-Force

ISIS RESEARCH

MONTHLY AUDIT OF PRODUCT DETAILS - JULY 1996

	MAT July 96						July 96				
	Total	One-to one	Surgery meeting	Meeting Elsewhere	Audio/ Video	Sample left	Total	One-to one	Surgery meeting	Meeting Elsewhere	Audio/ Video	Sample left
Total	5401356	68.6%	11.5%	5.9%	0.9%	7.2%	483426	74.1%	9.8%	4.6%	0.6%	7.5%
	17736	81.0%	9.8%	8.1%	0.6%	21.4%	1928	94.4%	-	5.6%	-	27.8%
	7563	79.8%	10.8%	8.1%	-	22.9%	749	85.7%	-	14.3%	-	14.3%
	3284	65.8%	15.5%	15.5%	3.1%	21.9%	428	100.0%	-	-	-	25.0%
	1948	84.3%	10.5%	5.2%	-	15.7%	214	100.0%	-	-	-	-
	1744	100.0%	-	-	-	35.7%	214	100.0%	-	-	-	100.0%
	61470	83.7%	11.0%	4.5%	1.0%	21.0%	5778	85.2%	13.0%	1.9%	3.7%	24.1%
	36365	80.3%	13.0%	5.6%	1.1%	28.8%	3317	80.6%	16.1%	3.2%	6.5%	35.5%
	8608	86.9%	8.4%	4.7%	1.2%	4.7%	856	87.5%	12.5%	-	-	-
	7690	84.0%	13.3%	1.3%	-	5.3%	856	87.5%	12.5%	-	-	-
	2050	100.0%	-	-	-	5.0%	214	100.0%	-	-	-	-
	1433	85.8%	14.2%	-	7.1%	14.2%	107	100.0%	-	-	-	-
	1331	100.0%	-	-	-	7.7%	107	100.0%	-	-	-	-
	1229	83.4%	8.3%	8.3%	-	50.2%	107	100.0%	-	-	-	100.0%
	52964	62.9%	17.8%	13.2%	1.7%	8.9%	4922	60.9%	26.1%	13.0%	-	2.2%
	12009	63.3%	13.7%	12.8%	2.5%	-	1605	73.3%	20.0%	6.7%	-	-
	8745	60.1%	18.9%	12.8%	2.3%	-	1605	73.3%	26.7%	-	-	-
	6125	71.6%	13.3%	10.1%	1.7%	15.0%	107	-	-	100.0%	-	-
	5722	69.5%	16.0%	10.9%	-	10.7%	214	-	-	100.0%	-	-
	5329	65.2%	21.2%	13.6%	-	19.1%	535	20.0%	40.0%	40.0%	-	-
	3692	55.5%	30.7%	11.1%	5.5%	27.8%	428	50.0%	50.0%	-	-	25.0%
	2861	64.2%	14.4%	21.4%	-	28.5%	107	-	100.0%	-	-	-
	2050	55.2%	19.9%	10.0%	5.0%	-	214	100.0%	-	-	-	-
	1328	53.8%	23.1%	7.7%	-	-	-	-	-	-	-	-

Table-7a Type of Contact - by Field-Force. (With across percentages)

N.B asterisk means less than 1%

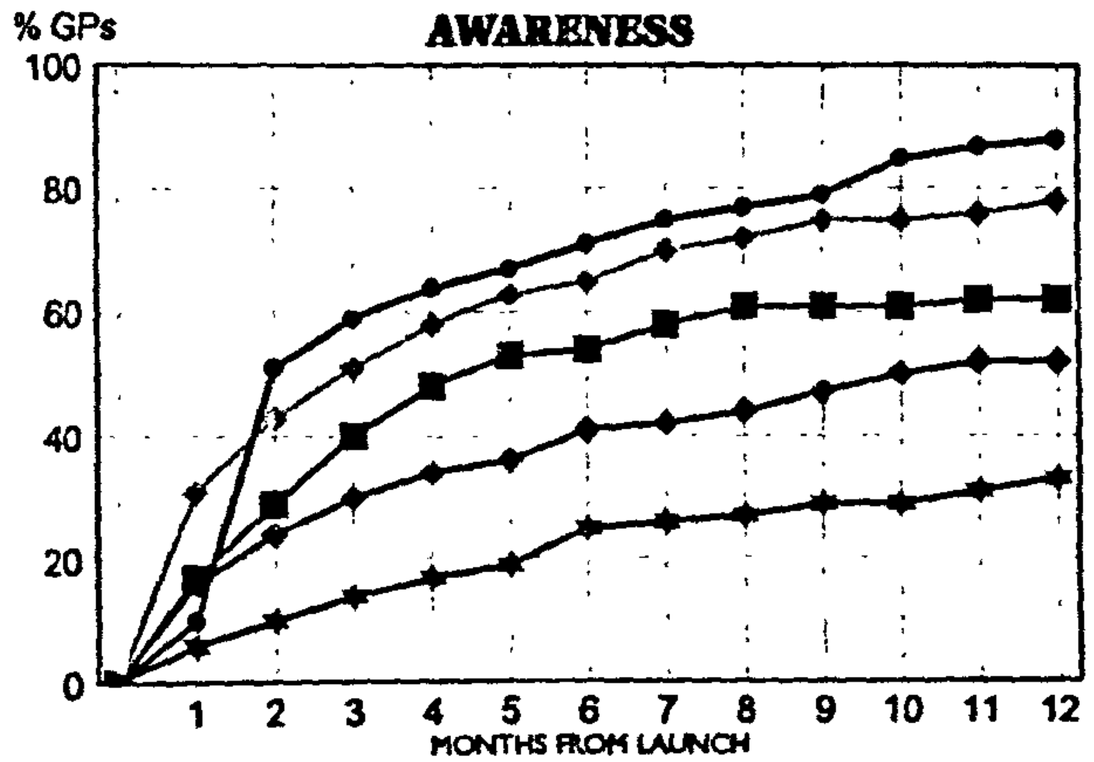
LAUNCH MONTHLY - JULY 1996

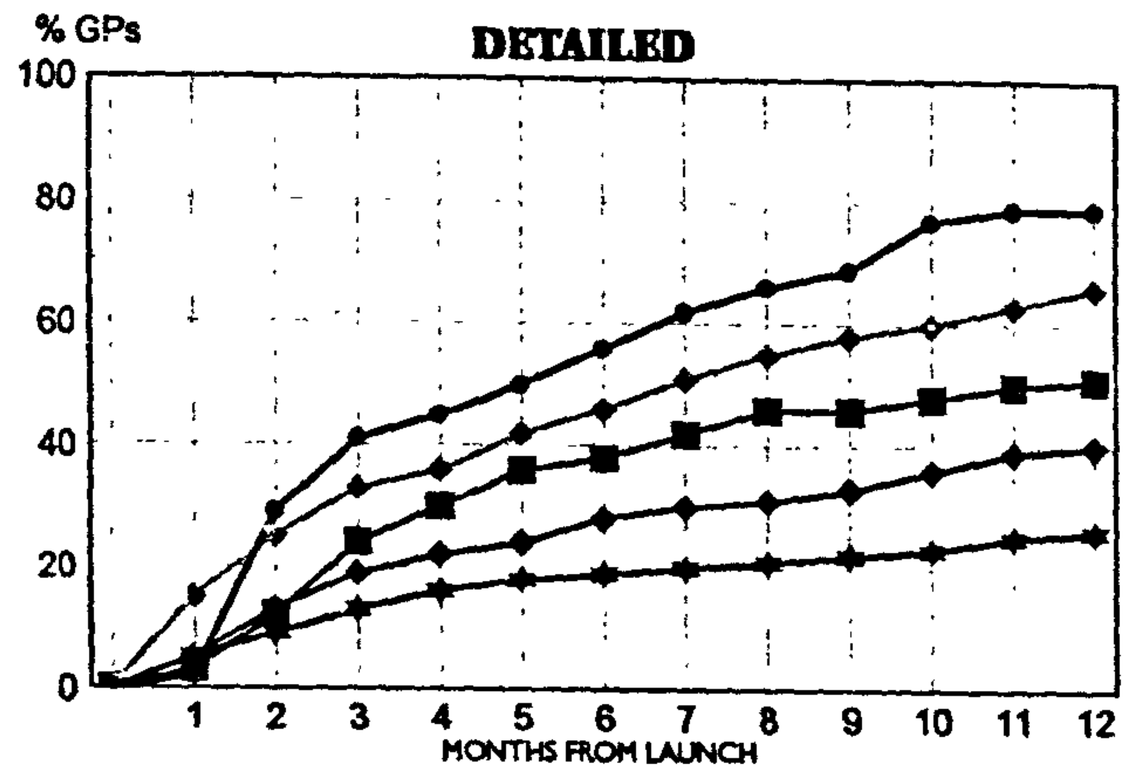
CUMULATIVE PERCENTAGE OF GPs FROM MONTH OF LAUNCH

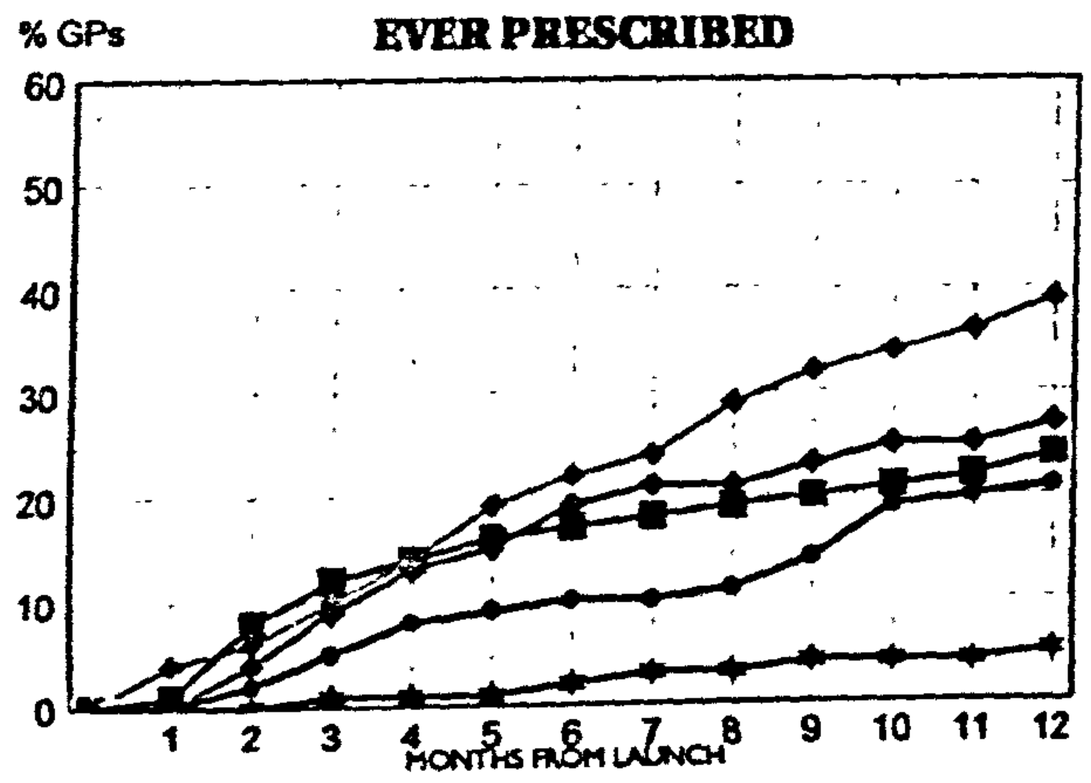
	1	2	3	4	5	6	7	8	9	10	11	12
	—	—	—	—	—	—	—	—	—	—	—	—
AWARE	26	35	41	47	53	57	61	64	65	65	67	67
DETAILED	10	17	25	32	39	43	48	51	54	56	58	59
EVER RX	*	*	1	2	2	3	4	4	5	5	5	6
AWARE	15	19	22	23	24	25	26	26	27	27	27	27
DETAILED	3	6	8	10	10	11	12	12	13	13	13	13
EVER RX	-	-	-	-	*	*	*	*	1	1	1	1
AWARE	6	9	12	16	17	19	19	20	21	22	23	25
DETAILED	4	6	9	12	13	15	15	16	17	17	17	19
EVER RX	*	*	*	1	1	1	1	1	1	2	3	3
AWARE	9	11	11	11	11	12	13	13	13	13	13	13
DETAILED	1	3	3	3	3	4	4	4	4	4	4	4
EVER RX	-	*	*	*	*	*	*	*	*	1	1	1
AWARE	1	3	3	3	3	3	3	3	3	3	3	3
DETAILED	-	-	-	-	-	-	-	-	-	-	-	-
EVER RX	-	-	-	-	-	-	-	-	-	-	-	-
AWARE	4	8	8	8	10	12	14	15	16	16	17	17
DETAILED	4	8	8	8	10	12	14	15	16	16	17	17
EVER RX	-	-	-	-	-	-	-	-	-	-	-	*
AWARE	23	34	44	49	53	58	62	65	66	69	71	75
DETAILED	13	23	33	38	43	47	52	55	58	61	64	68
EVER RX	1	6	8	11	14	15	18	18	20	22	25	25
AWARE	2	3	3	5	29	34	36	41	44	47	52	54
DETAILED	-	-	-	-	9	17	20	24	27	29	34	38
EVER RX	-	1	1	1	3	4	5	5	7	8	9	9
AWARE	3	4	8	10	11	13	14					
DETAILED	3	4	8	9	11	13	13					
EVER RX	-	*	1	1	1	1	1					
AWARE	29	38	45	48	56	59	61	63	64	65	65	66
DETAILED	7	20	29	31	39	43	45	48	49	52	52	53
EVER RX	1	1	1	3	3	4	6	7	7	8	9	9

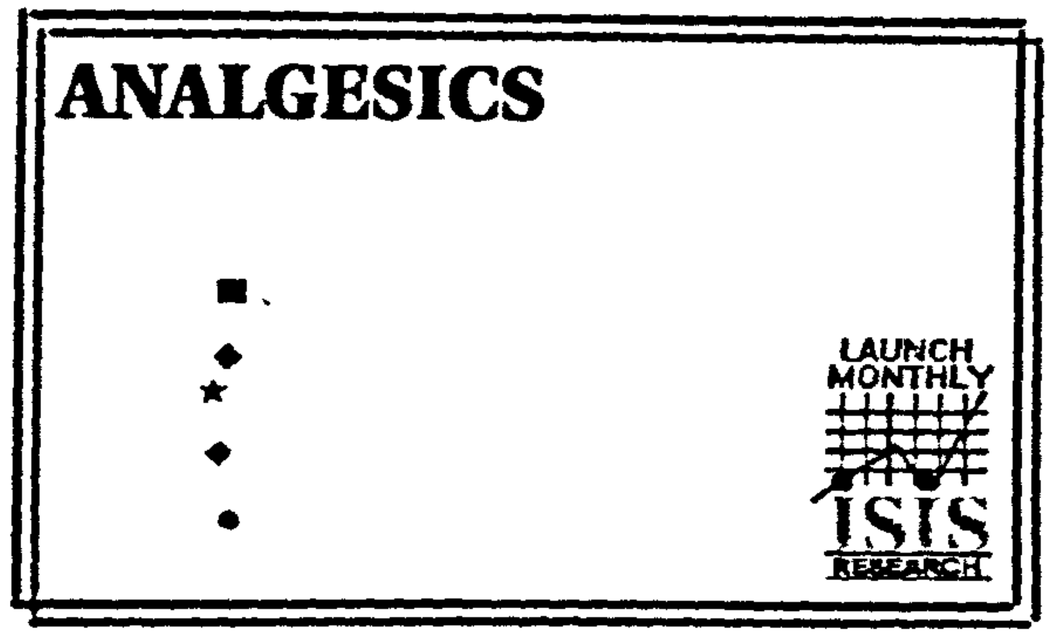
ANALGESICS

LAUNCH MONTHLY









Appendix Nine

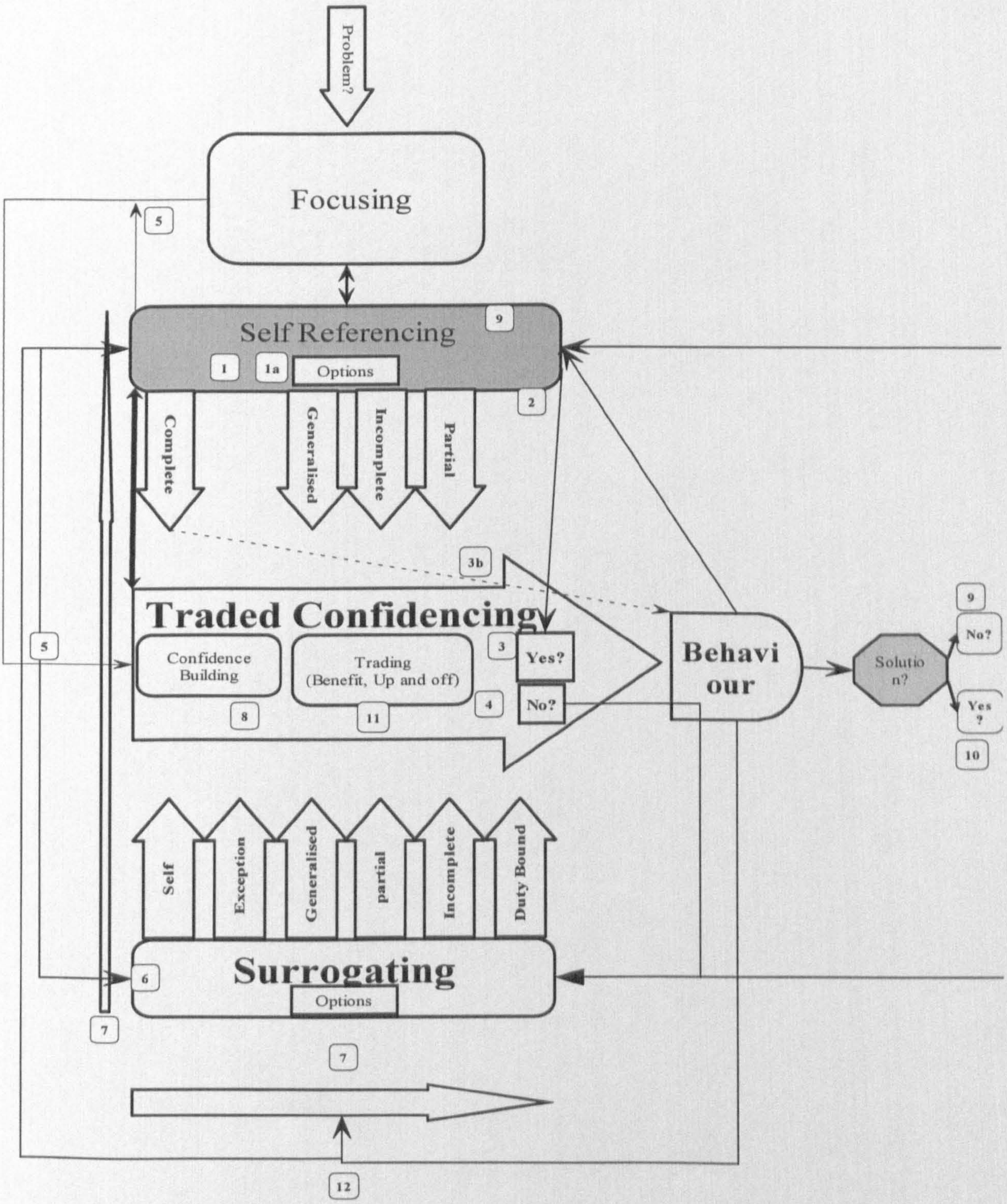
Further examples of Secondary data:

	Q1/95	Q2/95	Q3/95	Q4/95
TOTAL UK RETAIL	51,056.8	53,340 0	54,836.5	57,662.7
C8A0 CALCIUM ANTAGONIST PL	51,056 8	53,340.0	54,836.5	57,662 7
	12,486 5	13,869.7	14,598 0	16,204 5
	18,639 4	18,815.6	18,625 9	19,336 2
	4,210 6	4,235.2	4,422.5	4,267 9
	1,872 9	2,059 2	2,228.8	2,378 3
	2,764 6	2,805 0	2,843 6	2,719.9
	933 5	1,178 7	1,338.9	1,588 4
	1,573.4	2,007 7	1,836 0	2,056 5
	1,816.0	1,850.7	1,925.4	1,992 5
	1,701 5	1,722 3	1,695 6	1,756 6
	1,281.1	1,285 6	1,267 1	1,269 2
	545.2	565 5	584.6	604 2
	1,079 9	669 9	872 5	495 0
	299 3	355 8	408 1	440 4
	299.3	332 5	363 0	396 1
	245 6	245 1	254.7	270 3
	414 3	418 3	415 0	406 8
	0.0	18 0	9 9	33 7
	0 0	0 0	0.0	38 0
	0 0	0 0	0.0	0 0
	324.3	321.7	308.6	246 9
	44.6	57 3	107.4	160.8
	117 4	117 2	117.8	123 5
	89.6	80 9	82.7	94.9
	50 1	47 5	38.2	72 2
	0 0	0.0	2 6	62 2
	18 7	32.4	49 5	66 8
	66.7	83 4	38 2	70 9
	126 0	104 7	91 4	122 6
	0 0	0 0	0 0	0 0
	16 3	29 6	290 2	364 6
	10 5	17 2	11 3	10 1
	1 0	0 8	2 5	7 4
	0.0	0 0	0 0	0 0
	19.4	4.5	0 0	0 0
	0.0	0 0	0 0	0 0
	9.3	8 3	8 6	7 7
	0 0	0 0	0.0	0 0

	Q1/96	Q2/96
TOTAL UK RETAIL	58,713.3	59,695.6
C8A0 CALCIUM ANTAGONIST PL	58,713 3	59,695 6
	16,920 3	18,387 3
	18,130 3	17,571 4
	4,329.7	4,347.2
	2,436.6	2,607 2
	2,942.1	2,329.9
	1,811 3	2,162 3
	2,211 6	2,158 1
	1,953 0	2,023 8
	1,720.9	1,755.0
	1,216.0	1,183 6
	600.8	632 1
	596 6	595 9
	470 7	545 8
	404 3	439 4
	414 8	426.1
	411 6	413.5
	222 1	401 0
	404.5	379.6
	58.4	233.8
	211.0	202.6
	232 2	165.6
	119.3	119 0
	103.4	109 8
	164 6	92 7
	68 7	91.7
	78 3	83.6
	75 6	74 3
	150 8	67 9
	0.0	38.2
	230 5	37 0
	15 3	15 0
	6 4	3.6
	3 0	1 8
	0 0	0 0
	0 0	0 0
	1.5	0 0
	0 0	0 0

Appendix Ten

Diagram of Traded Confidence



Notes from meeting with Dr Mike Duffy based on above diagram.

26/08/97

Focusing:

The point is made that when the "***Focusing***" is performed then there are various methods of getting this information. Some of the information that is needed is known via notes, past experience with the patient and the wider patient society (aunt having had similar problems or wanting treatment. Asking is one method, more general interview techniques with subtle mentions and probing. The ***Focusing*** is undertaken in many ways some of which are unknown to the patient.

Focusing is not a process that just happens one it is a process where the information sources are gone back to and **Re*Focusing*** occurs.

Surrogating: He reinforces the point that it is not just other doctors who are seen as a source of extra experience and as opinion leaders.

Trading Off: As a example of his agreement with ***Trading Off*** he wanted to go through various examples which he or I would explain in terms of the diagram. He goes through Otis media (ear ache). In a child with ear ache he tends to use amoxicilin which he knows to be cheap but has the problem of being TDS. Within his practice there is another option that he looks at: Azthromocin this is less proven and more expensive but is OD for 3 days. These are ***Traded Off*** and the added efficacy with it's downsides are looked at. He likes the idea of ***Trading Off*** and thinks it works in this area.

Other examples: Where the patient won't shut up and it is in a situation where the doctor needs to explain a number of aspects of the problem and the treatment for example

where the patient has c.v disease what is traded is dealing with one problem at a time rather than all of them in order for the patient to understand.

Where it is believed that the patient has not interest in the problem being followed up the aspects of treatment are ***Traded Off***, and the most important are performed, with an eye on what can be realistically achieved.

The conversation then backed up to ***Surrogating*** and the need for extra information and experience. He talked about the need to "Get a feel for clinical papers". He admits to rarely reading them with there role instead to give them an idea of what it is all about. he says the main reason that the don't read fully is that they do not have the skills to do it. He points out that to really understand a paper you must read around it and into the literature review. So understanding the basis of the arguments etc. it is very rare that the GPs have the time, interest or knowledge to do this

Duty bound referrals: He asks where in the diagram that the situation where the Patient comes in and wants drug X is covered. This is covered within ***Trading Off*** and the ***Self-Referencing*** and ***Focusing*** as to tell him what sort of patient this is, what is likely to happen if the drug is given and whether the treatment is dangerous or not.

He also asks about the general pressure to refer that is felt in certain situations by the GP's. The example gone through is the patient presenting with Chest pain. He feels skilled enough to (if he had the machine) perform an ecg (as he has done many of these before. He therefore feels he could do these and then treat by for example putting them to bed. Overall he feels that because there is a teaching hospital next door he should not take the risk and should do what they want which is for him to refer. One eye is being kept on possible litigation.

A further example asked about is Practice policy. How is the situation of not getting all your drugs on and defer to policy that is made fit in. Again ***Trading Off*** is the key. He

says that doing what is one the practice formulary (with an example given of treatment of e coli infections) makes him feel uneasy but he goes along with it. It is pointed out the it is likely that he lost that battle to win other ones and that his favourite is still there for failures. It may be that in the long-term his practice is preferred.

Likes "***Duty bound Surrogating***" as a way of describing working in hospitals

He makes the point strongly that inaction is definitely seen as an action in itself and talked briefly about this as seen by more senior partners. We agree that Actions - inaction rather than behaviour is appropriate. He had previously queried what is meant by "behaviour".

When asked what he saw as the key to the model he talks about ***Trading Off*** and ***Confidence Building***.

His explanation goes like this. ***Focusing*** starts you off, it gives you an area to work from. From this the real thought is then done during ***Confidence Building*** and ***Trading Off***. The mental time is spent in Confidence Trading

Sees choices being made at ***Self-Referencing*** and ***Surrogating*** stage, this could be said as the directing stages but actual work goes on in Confidence Trading

We then talked about the various types of ***Surrogating*** and ***Self-Referencing***. We concentrated on Complete ***Self-Referencing***. We talk through something that might be completely habitual, though it turns out that habits are not habits in that they all appear to be thought about. The example is of a patient presenting with a Sore throat. They go ***Surrogating*** to think about what the data where to treat and where not to treat with anti-biotics. There is a worry that some patient may have a problem that needs more treatment than the standard. This is a thought whenever this problems is presented. With penicillin there is no Strep resistance and it is very cheap. One patient doesn't get a

prescription whereas the next patient because there agenda is to get a rx. The patient who wants the prescription often get it. This is contrasted with the next patient who described as "reasonable", This patient is dealt with in a different way, via advice and waiting. In his opinion even behaviours that are performed very regularly are seen to be dealt with in ***Surrogating*** and ***Confidence Building***.

He then comes up with an example where he does deal with the initial presentation of the symptoms "Tired All The Time" in exactly the same way. He says that he switches off and sends them for a series of standard blood tests. He justifies this by saying that the most likely cause is the lifestyle of the patient, there are remote chances though of serious diseases such as leukaemia. To be sure of this though he initially sends for the standard tests and then on the representation of the patient the relevant course of action is taken. He makes the point that this is an unusual situation and the difference between medicine and being a car mechanic is the fact that habits are rare or at least actions that are automatic should not exist. You cannot standardise medicine to the extent of car maintenance where x= behaviour Y.

Individuals are individuals and there are huge numbers of choices to be take into account. This situation means that there are very situations that are the same to allow habits to be formed. He says that very little medicine is not thought about even if this though is very quick.

His ideas on the importance of experience is that it allows them to review old decisions to see there applicability and success.

For example with bog standard child's Chicken pox he revisits in his mind whether this is the one case out of many that should get Acycloviror because of the severity of the spots in the throat etc. The vast majority don't get treated in this way but there are certain groups who need it.

This is to him is more evidence about the minority of medicine that is dealt with routinely.

We then start talking about the ***Shift*** with experience that occurs. He suggests that it should be expanded to include perceived expertise, and hence builds on the problem of dangerous treatment when the full facts and situations are not considered. He gives an example of a colleague whose vast experience lead him to decisions in a tiny minority of case that showed no thought at all. He stresses the point that the majority of his practice was excellent.

The conversation turned to a description of how the diagram coped with the development of drug usage. I gave he example that he gave to me in the original interview of SNRI, SSRI's and Trycyclics. The SSRI's used because of the key advantage they showed whereas the ***Trading Off*** for the SNRI's didn't show sufficient benefit for change. He agrees and mentions the saying that you used to have to "earning your prescription" with Trycyclics you really had to prove that you were ill enough to get them contrasted to SSRI's which are sometime prescribed on the first visit because of their safety and the time lag before they work giving the patient time to calm down.

He asked me what I thought the changes could be made to current marketing practice. I mentioned the idea of patient info on a CD ROM. His reaction was that it may only work for a few companies that he had sufficient trust in. His concern was have they put all the information on the CD ROM. Later he mentions that the fact that they were prepared to give a data base out that may show that their drug doesn't work in itself builds confidence and trust in the company and drug.

He talks about the type of reps he likes, those long-term and non hassling ones who can see when it is best to back off.

Specialist Can be GP etc whoever that got us

Expert

Novice

"***Trading Off*** is what GP's do" and this is seen as different to primary care where he believes that the Consultants exist more in ***Self-Referencing***, Consultant aren't seen to trade off, they don't have as much to trade off. Whereas GP's are ***Trading Off*** all the time with aspects such as cost, knowledge and patient information.

"***Trading Off*** the world GP's live in"

He then digresses a little and talks about the sort of approaches that should be made to Doctors at various level s of expertise. In a lecture to GP's they trust the speaker to know and don't need to see his working out. They want the broad brush strokes on who to use it on and how and when to refer. They can't handle the sort of information that would be critical for other specialists.

In Conclusion:

After reviewing what he has said I agree that it is ***Confidence Trading*** that is the key to the Doctors behaviour within the area of treatment decisions. This the key to making the right decision. Without it there is no need for the level of interaction that is present between ***Self-Referencing*** and ***Surrogating*** or the level of ***Focusing***. It can be seen as the culmination and directing part of the process and also the target. Traded Confidence is what is necessary to develop before treatments will be used therefore it is the key. It directs the process because of this and ***Self-Referencing*** can be seen purely as ways of achieving this.

I still think however that ***Self-Referencing*** is key in the area of expertise development and that this may require a separate sort.

Appendix Eleven

Development of the Core Category

The following appendix details the development of the core category ***Trading Off***. The developments are shown according to the coding phases they were discovered in, therefore open coding, selective coding and the final densifying of the category via sorting are represented. The developing core category is supported where necessary by developmental categories. It should be noted that these codes represent on a small collection of those used in this process.

Open Coding

Comparing

Examples of initial labels and memos (Dr. S. Hillis)

Transcript	Codes	Memo
Whereas the diuretics or the ACE INHIBITOR well the ACE INHIBITOR are a bad example but diuretics and the CALCIUM ANTAGONIST. For example have not really been shown to have a big effect	C15 Others compared to this	The effects of ace calcium and diuretics is being compared. The aces are remembered to have the same effects but the others have not.

"by having a new formulation so the new drug coming in is against an expensive formation whereas compared to conventional forms there would be a big cost difference."	C33 New formulation cost difference	The price maintenance means that the newer drugs have more of a chance because they are not competing against a high cost difference

Open Codes and Memo development.

Codes	Open Codes	Memo

C2 Benefit justification C15 Others compared to this C31 Generic formulation reasons C33 New formulation cost difference C28Reasons against	Therapy comparisons	Comparisons of therapies (classes within classes, formulations) are made on various levels and attributes. The benefits of one party vs another are made. New vs old presentation, long term usage data is used to give reasons for and against continual usage. There exists standards that are used as benchmarks to compare other (be it new, new formulation, other classes etc) against. The comparison may include a justification of the benefits of the new treatment. This suggests that there is a preference to continue use rather than moving to newness

Balancing

Example of Initial labels (Dr S. Hillis)

Transcript	Codes	Memo

or if you don't, if think that the formulary should be expanded you've got to put a stated case which may or may not be excepted	B26 Expansion needs case	The expansion of the formulary needs a **stated case** which suggests that it is a formal process that is not guaranteed success.
but if your undoubtedly a specialist in the field if you have done the basic research you think this is new innovation which is of major impact the advisory will look at and see whether that's justified or not.	B27 Justification from knowledge	Suggesting that for the formulary to be challenged special reasons have to come from the physicians by research, field specialist or new information. Inclusion needs to be justified suggesting an desire not to change unless important reasons can be given but what are these and which are more important.
So to go against a formulary is an uphill struggle to an extent	B28 Formulary struggle	Recognises that the formulary is difficult to work against though not impossible .

Now what to will do is come to you and say to you well look these are the advantages of the thing we'll put it to the advisory group you know do you think you could have if you believe that this is a significant advantage could you go to the advisory group and this occasionally happens.	B29 Advantages assessed and advisory group approached.	Explaining how company's approach and set out the advantages to the consultants who if they see advantages will then approach the committee to see if it can be accepted.
IB Again it needs to be based on strong evidence for you to ..		
SH OH yea	B30 Evidence based though	Needs to be based on good evidence again

Open Codes and Memo development.

Codes	Open Codes	Memo

B24 Consultant win B36 Limited rights to prescribe B28 Formulary struggle B29 Advantages assessed and advisory group approachedB31 Directorate appeal process.	Formulary Process	The process of formularies is seen as a process where the advantages and disadvantages are discussed. There is an appeal process to the directorate and this struggle (suggesting a hassle and conflict pattern-show again in the process of choice - conflict between old and new drugs and the need to provide a considerable amount of data to persuade change) is won by the consultant but not by the lower physicians.

Conservatism

Open Codes and Memo development

B14a Difficult cases used on first to get a handle B14 Slow growth in use B17 Conservatism challenged and changed B34 Medicinal conservatism B35 Age conservatism unsure	Medicinal conservatism	The conservatism is liimited to medicine and leads to slow growth in products. The age aspect is not thought to be one of the main reasons. It can be successfully challenged

B37 Burnt fingers B38 Thalidomide disaster spectrum B39 Early adverse reactions B39a Starting dose problems	Burnt fingers	The conservatism in drug prescription may be partly due to scares such as the thalidomide scandal though this is recognised as being one end of the spectrum. Adverse events and early dosageand side effects compound this is does the study work (done with the wrong populations (look at conservatism reasons more)

Profiting

This code was central in the development of Profiting a category that was later merged into ***Trading Off*** as a desired outcome of the process.

Open Codes and Memo development.

(Dr D. Brewster)

A17 Patient well being first, C92 Don't destroy confidence, C93 Doctor is drug, B15 Discover in other peoples patients, B1 Let other peoples patients be tested on, C48 Not stinting patients, B16 Protect patients from bad things.	**Patient caring and protecting.**	This I think is one of twin towers of doctors relationships to other parties in the healthcare sector. The doctor is concerned about his patients primarily, they are his responsibility and will treat them accordingly. They are to be protected, giveing the process a paternalistic/maternalistic feel. The patients rely on them, trust them and therefore they need to repay this trust by doing what is best for them. One of things that this seems to entail is not exposing them to harmful treatment. Therefore they are happy to let other patients be the guinea pigs and will wait until they are happy with the safety of drug. This maybe related to confidence relationship between the two parties that is essential for the optimising of treatment efficacy. I.e. the type of placebo effect created by the patients having confidence in.

Weighing Up/Balancing

At this stage a two part label was given to this developing category. This was because at that time it was felt that neither full encapsulated the central theme of this part of the data. The behaviour that this label represented was a multiple factor balancing that also involved an assessment of the importance of factors. It was expected that this label would change as the category matured.

This development of the category signalled the move into selective coding as weighing Up/Balancing had emerged as the core theme in this study.

The changing of the label to better encapsulate the ideas in the codes and developing categories occurred on a number of occasions. The use of a thesaurus was recommend by Glaser and this advice along with suggestions from the departmental grounded theory writing group proved successful in capturing the essence of the categories.

Selective codes that developed the Core Category

Balancing

Dr. J. Hanslip.

Balancing,

This is the process where the influences used in making treatmnent decisions are weighed up. The most important influence changes by the situation that it is going to be used in. The patient and the wider patient benefit are at the centre of this situation. Balancing is necessary because of the volume of influences that are important in making

decisions in this area. **Balancing** is a interactive process. The widest and fundemental forms of these interactions are the those between the **Patient** and the **Treatment.**

The concept here is the multiplicity of reasons for action and choice with the desired outcome changing dependent on numerous patient (recipient) centered variables. Therefore the balancing is centred on the patient not the disease, this allows the overriding of curing the disease for the benefit of the patient (i.e improving the quality fo life or whatever is the primary goal). This leads to there being no overriding issue for treatment though patient need is the central factor. This will override the cost and other issues such as side effects and interaction. Treatment goals can include cure, alleviation of symptoms, promotion of quality of life.

Patient. The wider **Balancing** process where the Patient is the centre and their circumstances and situations are balanced.

The decision on which treatments are based are multifunctional and they are dependent apon many patient centered factors. These factors are not only the disease that they are treating but other issues. The issues include the setting that the patient exists in (in this instance nursing home, care of elderly ward at home with various levels of nursing care), the patients need for the drug, the disease characteristics (stability, severity, multiplicity). The need for drugs in treatment is not automatic and suggests that no active treatment is treatment itself.

Treatment. This is the balancing that occurs within each treatment. There are various levels of this treament types (surgery vs drug vs rest, etc) the specifics of these types (drug class A vs class B), the options within the subtypes (drug A vs Drug B) and the various options within the chosen drug (pill vs liquid).

(continued)

Bottomlining

The thought that balancing went further to bottomlining was rejected after a brief period with this development representing the core category.

The situation where the patients well being is the bottomline when decisions are made and influences compared. Medicines will be prescribed despite cost if the patient needs it. As the experience of the physician grows their influences for prescribing changes but based on this premise. The literature is a basis for the change in prescribing. This means that influences that are important in certain circumstances will be overlooked if the patient well being depends on them having the drug. Does this place efficacy above all else in emergencies or when there are no other options? TPA is a very expensive drug that ultimately will be given to the patient if they need it. This type of prescription maybe contested by the prescribing authorities and therefore needs to be fought for. May lead to normal prescribing of expensive drugs or ones with limited proof being restricted to certian indications.

Adopting

This code was partially integrated into the core category and also provided information for the different roles played by medicines.

This is the process by which the physicians evaluate, try and adopt treatements. There is a general need for confidence in the drug to work over large numbers of patients but also with the confidence for individual usage and the individual reactions to drugs that the patients have. STANDARDISATION: is the central situation, it is the accptance of a drug to be the standard drug for a particular indication. This standardisation needs formal data and empirical usage. The actual standard drug mayy not be the only one that can do teh job but it may be the only one with the data to give the doctors condfidence in. INDIVIDUALISING: The acceptance that as individuals have personal reactions to

drugs the usage of drugs (and treatement generally has to be doctored to the individual. The consumer has a personal realtionship with the product (reactions etc) and it's use is tailored around this. This individualising proceedure includes a customising of the dosage and the actual drugs that are used (do they get the more powerful but expensive ones because of their prognosis and disease path). The individuals prognosis appears to be the most important individual factor. The individualising process is the qualitative stage. DATA CONFIDENCE: There is desire and shown preference for large studies and the size is a factor given for certain drugs being accepted for wider and deeper usage. Not only should the study be big but the impact is increased if the journal it is published in is large and reputable. The size is not the only property there is a mention of well designed. The feeling is that the size of the study contributes to the acceptance of the findings. It is the findings may eb the thing accepted not the drug that has then to prove itself via usage. At the other side of data condfidence is the CAUTIOUS INTEREST situation. Here new and newer drugs start the process of potential standardisation. There is a little of a chicken and the egg situation here as the newer drugs need experience to get used and they can't get experience because they are new. Published data helps them find a niche but it doesn't provide the big studies for inclusion as a standard drug. The lack of published data leads to LIMITING. The limiting is based on lack of confidence for moving a drug onto the next level, a limit is set for its use. The lack of evidence that is central here may mean that the physicians rely on hearsay and conversations with colleugues to asses the drugs usefulness, problems and areas to be watched. The drugs would appear to be vulnerable at this stage as a nasty reaction may colour their future usage. There is an amount of interest based around their newness and this may help them get used in a small number of patients but still the experience and data of the older drugs keeps them in the standard position. The initial use of these drugs allows them to find out how to use it (dosage, interactions) in what indications and in what position in the contiuum will it be used i.e. fourth line (similar to the ladders of the mind). The situation of licenses is interesting here. One indication (heart failure) has little to treat it and the doctors seem happy to "take the risk" in this situation with soemthing that does not have a license so that they have more options.

The license may well be the start of big usage though with the unlicensed usage part of the mini-trial and experience growth. The problem of potential litigation is not a worry because she feels that the test (peers would do the same) would be passed.

Balancing

Balancing was returned to as the core category with ***Matching*** being seen as a crucial aspect of the wider theory. The developments illustrated in the next will be demonstrated by the memoing developed by the constant comparative method and sorting.

Balancing, This is the process where the influences used in making treatment decisions are weighed up. The most important influence changes by the situation that it is going to be used in. The patient and the wider patient benefit are at the centre of this situation. Balancing is necessary because of the volume of influences that are important in making decisions in this area. **Balancing** is a interactive process. The widest and fundamental forms of these interactions are the those between the **Patient** and the **Treatment.**

The concept here is the multiplicity of reasons for action and choice with the desired outcome changing dependent on numerous patient (recipient) centred variables. Therefore the balancing is centred on the patient not the disease, this allows the overriding of curing the disease for the benefit of the patient (i.e improving the quality of life or whatever is the primary goal). This leads to there being no overriding issue for treatment though patient need is the central factor. This will override the cost and other issues such as side effects and interaction. Treatment goals can include cure, alleviation of symptoms, promotion of quality of life.

Matching

Matching. Matching is a process which links aspects together so to give a solution to the problem. This is an obvious process but it is useful to have written down to refer to it. It goes beyond matching the disease to the treatment. The outcomes of the Internal and External Centred Cataloguing are looked at and the locus of the influences for the decisions are decided when the Matching process has occured. I.e where there is a mismatch between the experience in the area and the level needed to feel confident and secure in the area then ***Surrogated*** External Influences are used.

"if somebody comes to you and say you know Joe Bloggs who you think is wonderful is running the best centre in the country is using this and is having excellent results and if you speak to Joe Bloggs and he confirms that then sure you might be influenced if you have got a particular problem area."

If the outcome of the Matching process is that the Doctors feels secure and happy in their knowledge then internal influences will dominate and the decisions is likely to be theirs rather than from external sources.

Densified via Sorting

The movement into this aspect of theory development saw the rapid advancement of Trust and then Confidence as the entities that were being balanced to make decisions. This grew from a code found in the third discussion that earned this crucial place during this phase and the final stage when the data was returned to in order to further develop ***Trading Off.***

Compensated Confidencing

Compensating

Compensating. The performance of behaviour (treatment) needs to be compensated for by certain properties that match the Centred, Situationally Catalogued details of the interaction. These properties also include personal characteristics of the Doctor such as personality level of conservatism and trust. It is necessary because of the volume of influences that are important in making decisions in this area. Compensating is a interactive process. The widest and fundamental forms of these interactions in this study are the those between the **Patient** and the **Treatment.**

The need for Compensating in all instances of treatment behaviour is that the preference of Doctors is not to treat actively where the don't have to and where treatment is needed the preference is to use their situational based habit. This is based on the risk involved in treatment.

Compensating occurs in three main situations. Primarily it is the Compensation of the properties within the drug and the Compensation of the overall option Vs the other options available. It also occurs at deeper level and looks at the basis upon which the properties are discovered and evaluated. The influences are compensated against one another in **Basis Compensating**, because of the often conflictory nature of the information that they provide. I.e. one paper showing one level of side effects but personal experience showing a different view. These two will be compensated against each other to see where the confidence lies. A further distinct category is **Exception Compensating** where <u>one</u> of the many **Compensating** factors is so strong that it outweighs the other positive or negative properties. This primary factor is often promoted to this position by the problem situation. **Primary Compensating.** This occurs when one property of the behaviour is so strong that it overrides the multiple compensations that have gone on

"the other example would be streptokinase in the treatment in the treatment of MI you know the evidence was so great that eh it is reaching the stage now that if you didn't get it you would probably be able to sue the hospital for not giving it you"

Confidencing

This is the crucial proofing exercise that is needed to create trust and confidence in a particular treatment or behaviour. The central aspect of this is the proof of the efficacy and other aspects of the treatments behaviour. Drug prescribing is a process of acceptance and Evidence (in a broad sense) is how a treatment becomes accepted.

There are certain pieces of information that the Physicians want to be told about including efficacy, side effects, interactions, overdose, cost, indications and specific uses. These should be in specific treatment situation. *"even though the side-effects only happen in a very specific situation and if you avoid that situation you shouldn't run into the side-effects but it tends completely colour your thinking that is a big influence in most drugs in that respect."* The evidence for this Confidence comes from a variety of sources often in the form of **Experience** and **Study based**.

Confidence Trading

Confidence Building

This is the crucial proofing process that is needed to create trust and confidence in a particular treatment or behaviour. The central aspect of this is the proof of the efficacy within the specific situation. Drug prescribing is a process of acceptance and evidence (in a broad sense) is the means by which a treatment becomes accepted.

The need for ***Confidence Building*** is dictated by the responsibility and consequences of prescribing. These include the saving of life, quality of life improvements, the life long nature of some medication and the need therefore for the patient to be able to live with

the drugs. The consequences of prescribing are important and therefore should be done on certainty or as close to this as possible.

The outcome of ***Confidence Building*** is that the trust and knowledge exists upon which to choose a particular behaviour. They have been shown to the doctor to have certain important evidence (formal or informal) that shows advantage over the other options available in the specific treatment situation. The use of evidence therefore is a basis for creating usage.,

The confidence that is needed for prescribing to occur is based on a knowledge of what to expect. It is not confidence that the drug will work in all cases with 100% efficacy but it is confidence that the Doctor knows how the drug/treatment will react in the particular situation being dealt with.

"Of course your affected much more by a product that really works than one that doesn't so if some body says it does what it does and, and it does it you know then you know you are going to use it again and again and again"

It is a dynamic process and shows how confidence is developed over time with more and more of the information being held personally by the doctor. The Doctors are building a picture that will allow them to have confidence in the treatments properties, it's usage and outcomes and how well it should match the benefit criteria set out by ***Self-Referencing*** and ***Focusing***.

For example, if the objectives of the situation is to relieve pain from arthritis then the doctor will need to build confidence that the drug in mind to be used will achieve this within the specific situation of the patient and the wider community. Furthermore this should happen without having a sufficiently negative effect on the patient and other parties involved.

Trading Off

Trading Off is a process of analysis where the factors are taken into account and traded against each other ensuring that the key parties benefit from the behaviour. Most frequently it is the direct patient who is the centre of the action (defined during ***Self-Referencing*** and ***Focusing***) but a number of other beneficiaries need also to be taken account of. Central to this is that one party must benefit from the action and that the cost to the other parties must be acceptable.

It involves ***Trading Off*** a number of levels of treatment options, their properties and the objectives within the problem situation of all levels of properties and objectives within the situation. ***Trading Off*** occurs within the properties of the drug, between the drugs of the same type, between different classes of drugs used for the same problem, between the different treatment options, and between the different objectives of the different parties involved. Decisions on objectives are underpinned by the need to create benefit for the patient (or who ever is at the centre of the situation).

Trading Off is a development of the outcomes of the ***Confidence Building*** process. This has produced properties and variables (both positive and negative) that the Doctors trust and are confident in. These are then ***Traded Off*** against one another to see if the patient and the wider patient group will **benefit** from the behaviour being performed.

Trading Off is the process where the positive and negative properties of the behaviour are looked at to decide whether the patients particular problem set during ***Focusing*** on the problem are likely to benefit from performance of that behaviour. **Trading** is centred on the patient situation not the disease and is an interactive process between the **Patient** and the **Treatment.**

Actions are taken on behalf of the patients only if there is an increase in the overall benefit to all the parties concerned. ***Trading Off*** is the behaviours and processes that are gone through to ensure that for the action taken the benefits outweigh the costs. The

benefits of action are centred around the patient situation and the efficacy of the treatment. i.e what is does for the patients problem though there are a large number of other benefit types.

It is the weighing up process that occurs when the characteristics of the action and the characteristics of the situation are reviewed. The characteristics can be positive or negative depending on the treatment and the drug. The importance and effect of these characteristics depend on the patient characteristics. The increased benefit to the patient may include curing, relief, increased quality of life. The increased benefit that is possible with new or different treatments must show a increased benefit over the existing treatment (whatever form that takes) and is beneficial enough to overcome the intransigence that exist in sticking to tried and tested favourite trusted treatments.

There is a need for treatments to show advantages to get used ahead of existing therapies. It is crucial that this advantage is in an area of importance to the problem and it's situation. This advantage though only has to be relative.

Factors that are compensated include drug properties (efficacy, side effects, financial cost), where the evidence for the properties comes from, and situational characteristics of the Doctor (such as personality, level of conservatism and trust) and the patient (disease, psychology. physiology, demographics).

The patient is not always interested in his or her well being they have their own agendas and this maybe to overdose or abuse the drug. This changes the doctors agendas with certain drugs to avoid this possibility. The patients illness or problem is therefore being detached from the patient himself and they can be in conflict, the overall patients well being as defined by society maybe the prime concern here then. I.e. drugs should not be abused and therefore the patient will be protected against himself.

Trading Off is necessary because of the importance of prescribing and it's effects which is complicated by the volume of characteristics and influences that are important in making decisions in medicine.

Note

Final Revision of *Confidence Trading* leads to incorporation of ***Confidence Building*** into ***Trading Off*** under the label ***Trading Off***

Trading Off

Trading Off is a decision-making process where the factors used for choice are taken into account and traded against each other ensuring that the key parties benefit from the behaviour. Most frequently it is the direct patient who is the centre of the action, this centre is defined during ***Self-Referencing*** and ***Focusing.***

A number of other beneficiaries also need to be taken account of, these include the wider society, patient supports groups and other patients. Central to ***Trading Off*** is that one party must benefit from the action and that the cost to the other parties must be acceptable.

The confidence held in experiences and knowledge from ***Self-Referencing*** and ***Surrogating*** are ***Traded Off***. These processes produced properties and variables (both positive and negative) that the Doctors trust and are confident in (to varying degrees) concerned with the ***Focused*** problem. These are then ***Traded Off*** against one another to see if the patient and the wider patient group will **benefit** from the behaviour being performed.

Trading Off is the process where the positive and negative properties of the potential behaviours are looked at and balanced off against each other. This is performed in order to decide whether the patients particular problem (discovered during ***Focusing***) are likely to benefit from performance of that behaviour.

Trading Off is the area of the treatment decision process where the most cognitive effort is made. As one GP mentioned, it is **"Where they live"**.

Trading Off is centred on the situation of the patient not the disease and is an interactive process between the **Patient** and the **Treatment.** The benefits of the actions decided on during ***Trading Off*** are centred on the efficacy of the treatment. I.e. what it does for the patient's problem though there are a large number of other types of benefits.

The increased benefit to the patient includes curing, relief, and increased quality of life. The increased benefit that is possible with new or different treatments must show an increased benefit over the existing treatment, independent of the form that takes. It must also be beneficial enough to overcome the intransigence that exist in sticking to tried and tested, trusted treatments.

It is often crucial that the advantage over existing treatments is in an area of importance to the problem and its situation. This advantage though, only needs to be relative.

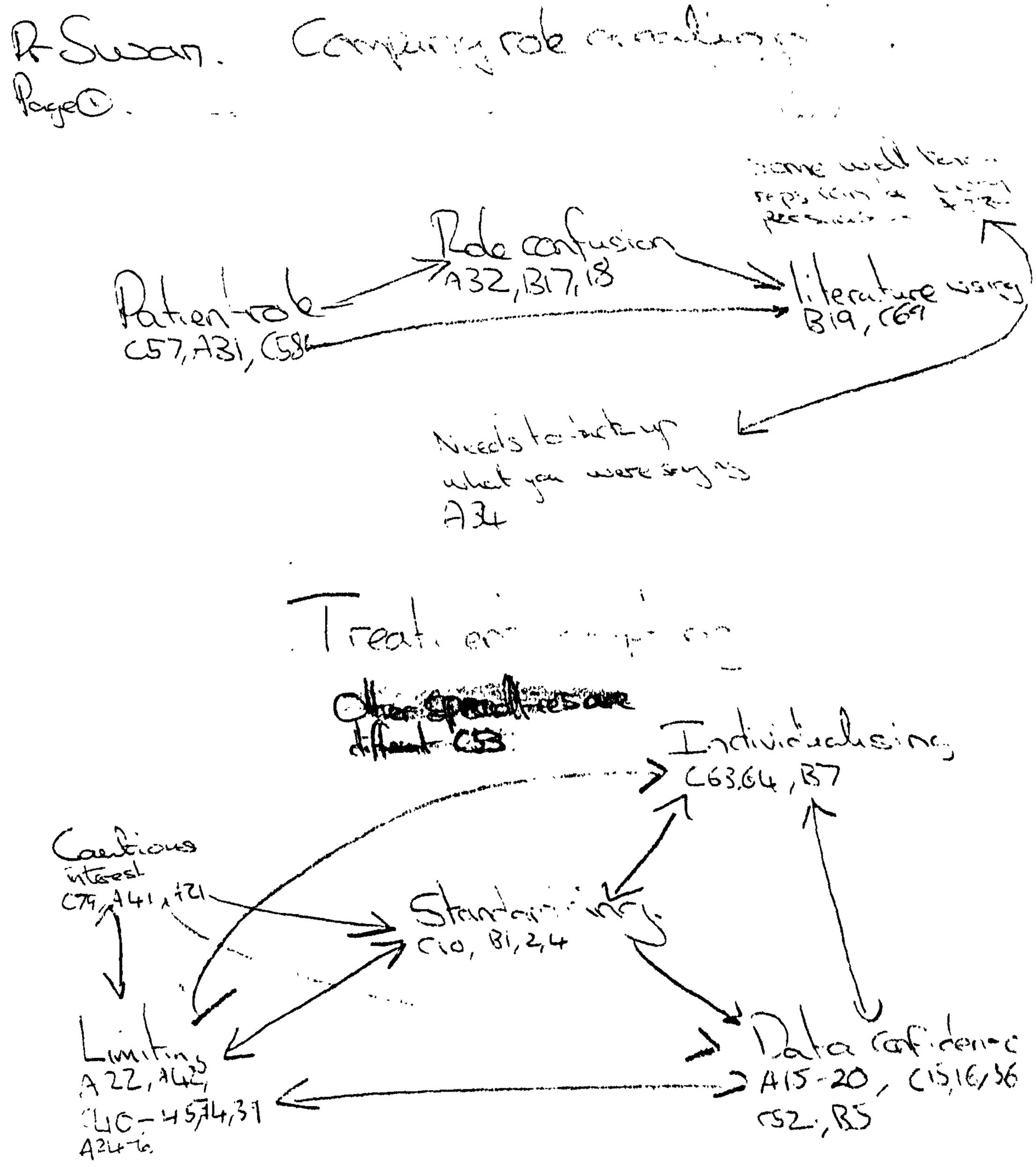
As individuals have personal reactions to pharmaceuticals and treatment generally, the treatment has to be doctored to the individual. The consumer has a personal relationship with the product (reactions etc) and its use has to be tailored around this. This individualising procedure includes a customising of the dosage and the actual drugs that are used.

Trading Off accepts the situation that treatment cannot be performed without some party losing out (however trivially). These negatives are mainly seen in the side effects that treatment causes, it's interaction with other treatments, it's effect in overdose and other characteristics (such as the nitrate tolerance effect that must be worked round). It also covers financial and opportunity cost.

The development that is looked for when new treatments are being considered is a reduction in negative effects, for example, for fewer side effects than the treatment being replaced. This again should be proven. The desired effect of treatment is a balanced benefit to the patient, therefore the specifics of the negative effects in comparison to the benefits need to be assessed.

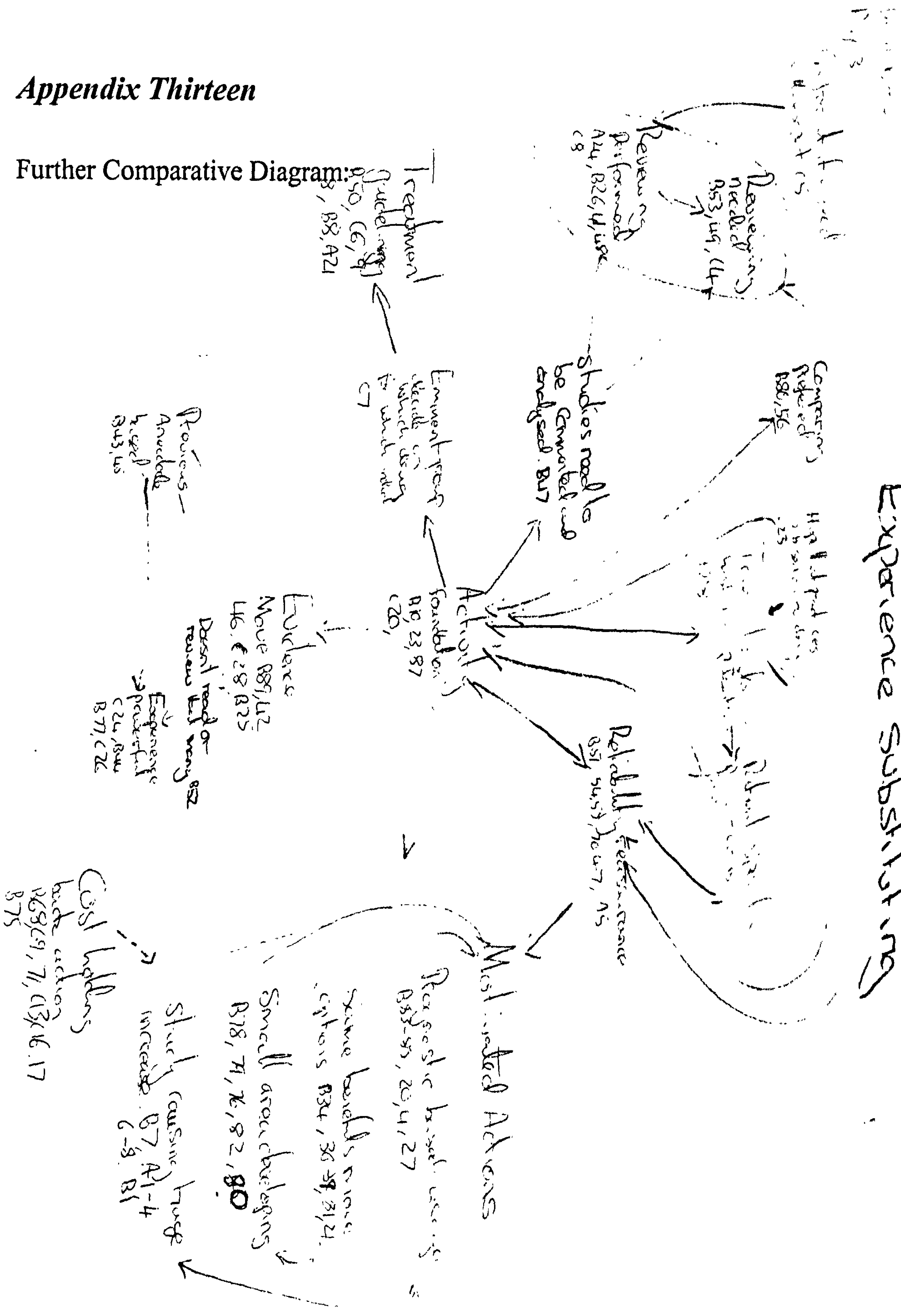
Appendix Twelve

Diagram demonstrating the output of the Constant Comparative Method



Appendix Thirteen

Further Comparative Diagram:



Appendix Fourteen

Sorted Diagrams: Diagram One

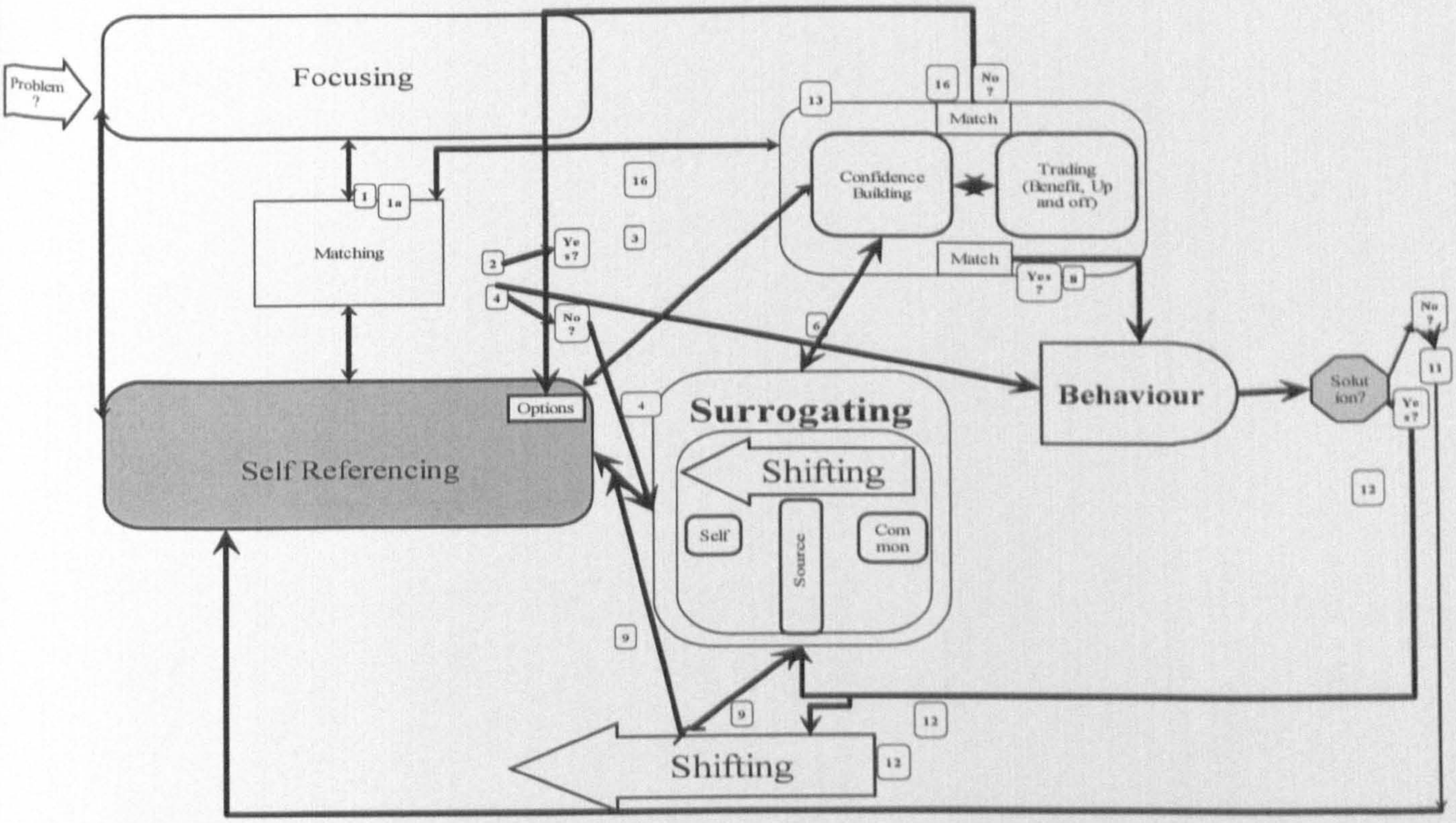
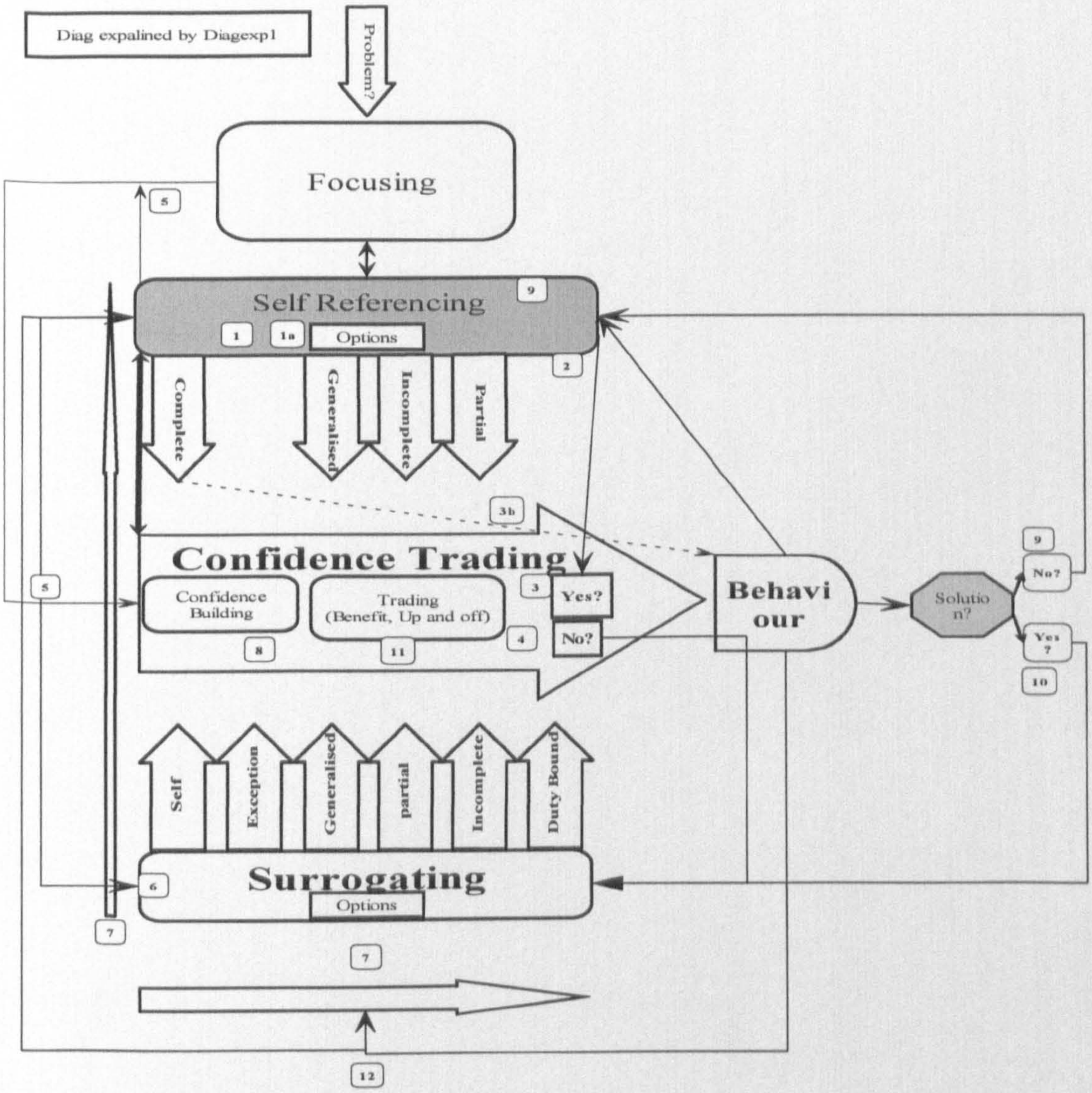


Diagram Two


Diag expalined by Diagexp1
Problem?
Focusing
5
Self Referencing
9
1
1a
Options
2
Complete
Generalised
Incomplete
Partial
3b
Confidence Trading
5
Confidence Building
8
Trading (Benefit, Up and off)
11
3
Yes?
4
No?
Behavi our
Solutio n?
9
No?
Yes ?
10
Self
Exception
Generalised
partial
Incomplete
Duty Bound
Surrogating
6
Options
7
7
12

Explanation:

Confidence Trading

Problem:

The problem that starts the overall process can be a patient presenting (first or "n" times after with the same problem), new information discovered or presented to the Doctor and new treatments being made available (information etc.). This leads the **Focusing.**

Focusing:

This is the discovery and **Focusing** on the critical properties of the problem as it is presented to the doctor. It involves a detailed look at the problem situation. The **Focusing** process highlights the areas that need to be treated and in what particular circumstances. This process leads to the performance of **Self Referencing.** During **Focusing** and **Self Referencing** the **Confidence Trading** criteria are determined.

Self Referencing:

This is the self analysis to see what they know concerning the problem as discovered during **Focusing,** and then deciding on whether the problem can be dealt with by this experience and knowledge or whether outside help is needed.

It is a two way process between **Focusing** and **Self Referencing** however as personal knowledge directs the discovery of information from the situation and decides on the centre to focus on.

The decision as to whether the problem can be dealt with internally is made based on the **Confidence Trading** criteria set out during **Focusing** and **Self Referencing.** If it is not then **Surrogating** is used. **Self Referencing** is looked at first because of the preference to use internal experience and information.

Confidence Trading

Behaviours must match both the **Confidence Building** process and **Trading Off** for behaviour to be performed, this is independent of whether they come from Surrogated or Self referred sources. If it does then the behaviour will be performed. If the Self Referred behaviour fulfils these criteria the behaviour is performed with no reference to outside source.

This is can be conscious or sub-conscious depending on the routine nature of the behaviour.

In the case of habitual behaviours, this testing for **Confidence Trading** is subconscious, it is drawn as going straight to "Behaviour" bypassing the **Confidence Trading**. It is drawn onto the **Complete Self Referencing** category because this is the type of **Self Referencing** that is most likely to be under habitual control.

If the Self Referent behaviour does not fulfil these criteria then the Doctors **Surrogate**. The failure of Surrogated behaviour in this process means that other influences/behaviours are then looked at.

Surrogating

Surrogating is process where outside sources are looked at in order to Surrogate other individuals experience in the problem area. **Surrogating** is used to develop the levels of Confidence needed to treat. The mismatch between the **Self Referencing, Focusing** and **Confidence Trading** shows the areas of experience and information that needs to be Surrogated for the behaviour to be tried. This Surrogated behaviour is then referred back to **Confidence Trading,** if it fulfils the criteria then behaviour is performed. When a Surrogated behaviour is unable to fulfil these criteria then a further search is made.

Behaviour: Behaviour can be treatment or acceptance of a new piece of information. This allows the whole variety of information being obtained (actively or passively) by the Doctor to be considered in the process.

Solution:

Is the behaviour (regardless of source) a success or failure as measured against the criteria set out during **Focusing** and **Self Referencing**. The level of success dictates the effect on Self Referencing and the shift of location of influence. Success shifts the use of evidence and location of behaviour influence toward Self Referencing. Failure however loops the Doctor back to **Self Referencing** and other Options are looked at with same process as before. The level of internal knowledge is now is developed by this failure a shift has taken place.

Performance of a Surrogated behaviour regardless of the outcome builds the level of knowledge/experience held internally. Success (partial or complete) then shifts the location of behavioural influence from **Surrogating** toward the **Self referencing**. As experience develops and because of **Self Referencing** there is a shift from the use of **Surrogating** to **Self Referencing,** it also changes the usage of evidence by the Doctor.

When the Doctor is faced with new information/options/experiences there is a temporary movement back toward external sources. These are used to Surrogate the necessary experience/knowledge to integrate the new information etc. This then builds the personal experience/knowledge and shifts evidence and influence usage back toward the **Self Referencing.**

Appendix Fifteen

Development of *Focusing*

This section will outline the development of ***Focusing*** in the same fashion that was used in appendix Eleven detailing core category development. Memos developed during sorting concerning initial codes are included under the same heading.

Situationing

Examples of initial labels. (Dr. M. Duffy)

Transcript	Codes	Memo
I think it would really depended on the patient if it was purely on a patient who was going to be very sensible who you knew would comply Is there was a huge price difference I depends on the actual patient, patient specifics	C63 Usage depending on patient C64 Depends on actual patient	The patient type is important the individual circumstance are crucial The price difference that is being talked about is dependent on the patient type to whether it is important

Extract from a Developed Memo

Situationing

The basing of treatment decisions on a range of situations and their interactions with each other.

From the decision made on the information, expert view and assessment from a wide range of specialists, the formularies and recommendations of this committee are made. The decisions are made on an assessment of efficacy, comparison, relative advantage, and eventually cost. There is an acceptance that politics comes into the decision though this can be seen to enter all levels of decision-making (where there is more than one interested party). At the heart of the decision process there is again breadth and depth of influence and appraisal. The weighting of the influences is not made clear though, again there is general move to go with the efficacy and the experts opinion though there is (as always) a get out clause when they can ignore this in favour of some other influence. One such issue and one that is clearly impinges on trust is the longterm aspect of drug safety. An example is given here of the NSAIDs where the experts were overruled because of long-term safety issues

Comparitive. A fundamental part of the **Situationing** is what is done to the situations when they have been assessed. The information is Compared based on the central needs as defined by the situation. The desire for comparison is made harder because of the type of information that is made available. The CSM do not require it for registration and it is not in the companies interest often to do it.

Targeting

Examples of initial labels (Dr. J. Hanslip)

Transcript	Codes	Memo

then adding in a diuretic or the other way round depending on you population	C17 Population dependant	The population that the patient belongs to has an effect on which drugs are used.
in the elderly you might use a diuretic and then add in a BETA BLOCKER then you had your third drug of choice which were your CALCIUM ANTAGONISTS, ACE INHIBITORS ALPHA BLOCKERS and things like that	C18 Elderly drug choice	The choices that are considered for elderly patients are outlined
Now what there saying is you should tailor the therapy to the individual	C19 Tailored therapy now	The move is said to be now towards tailoring the therapy to the individual not stepping

Selective Codes and Memo development.

Therapy targeting

Within the large number of therapies there are areas where these drugs are used depending on demographic and psychographic variables Age, sex, aggression levels are mentioned as segmentation variables used for drug choice. It is not clear whether this is a drug company driven phenomenon or a research based one, or even a combination of them both. This phenomenon is apparently a movement that has happened whether it is recent or not, I am unsure. Not only the initial treatment variable/ population dependent but the second line drug is also

<u>Extract from a Developed Memo</u>

Targeting

The large number of therapies available for many diseases means there is a process of specific **Targeting** of the areas where these drugs are used. These variables include demographic and psychographic such as age, sex, aggression levels.. It is not clear whether this is a drug company driven phenomenon or a research based one, or even a combination of them both. This phenomenon is apparently a movement that has happened whether it is recent or not, I am unsure. Not only the initial treatment variable/ population dependent but the second line drug is also.

Centring

Examples of initial labels (Dr. J. Hanslip)

Transcript	Codes	Memo
IB In the treatment what is the primary goal?		
JH Well it depends what settings you are talking about	A63 Treatment goal depends on setting	The goal of treatment is not a simple situation it depends on the patients setting
because you have got different settings, you've got the assessment settings, you've got rehabilitation, you've got continuing care.	A64 Assessment, rehabilitation and continuing care settings	The settings are a continuum from diagnosis to long term care of the patient.

Now in assessment and rehabilitation I suppose the main aim and in day hospitals as well is to promote independence in the elderly person. And help their quality of life	A65 Assessment and rehabilitation goals are independence and quality of life.	The quality of life issue generally is said to be important. Is that because of the few number of years left wanting to ensure they get the most out of these rather than giving them more uncomfortable years

Extract from a Developed Memo

Centring.

This is the process where certain aspects are taken as the focus of all other activity in the area. Here the patient's problems, situation and mental and physical function are taken to be centres in differing circumstances. These then dictate the behaviours and inter-relationships of the influences going into choice of the behaviour. There is no overriding centre but more commonly the patients problem is seen as it. The centre is determined by the assessment that takes place.

The assessment of the patients looks at the function of the patient and specifically at their mental and physical characteristics. The elderly are an extreme case but physical and mental abilities differ throughout the patient population. I.e children are less competent and need to be treated ways that allow them to benefit from the core treatment. A division is made here between the mental and the physical functions.

The assessment process determines not only the actual treatments but before that the goal of treatment. This assessment very much decides which road the patient is going to go down and this then leads to separate criteria for treatment.

Problem. The most obvious centre for consideration is the problem/s that the patient has.

Physical. The Physical Centring looks at the physical situation the patient is in. It includes the level of frailty, manual dexterity, ability to swallow, other physical problems i.e. liver and renal impairment.

Mental. The centre of prescribing behaviour can be the mental abilities, personality and agenda of the patient.

Individualising

Examples of initial labelling. (Dr. S. Fleming)

Transcript	Codes	Memo
and one of the things we try to get across to patients, eh across to students is that the ethics of every doctor student relationship is dependent partly on the doctor and partly on the individual patient	B25 Ethical situation is based on the doctor and the patient and their situation	Ethics depend on situations like the doctor and the patient situations. The interaction must therefore be important and cause different situations because each patient will bring different things to the relationship
because patients have different religious beliefs, different social beliefs different social circumstances that dictate the ethical ground rules if you like	B26 Differing Religious, social beliefs, circumstances dictate ethics	The beliefs of the individual are the dictating factor. These can be changed but are the doctors allowed to try?
so you would have to treat patients with certain religious beliefs differently from a patient with an identical clinical problem who has other religious beliefs so	B27 Beliefs can dictate the treatment of the patient.	The ethics will dictate the treatment which is based on the beliefs of the individual (and the Doctor).

Selective Codes, Doctor: Dr Fleming

Individualsing Ethics. (consumption beliefs, situational specific)

The teaching and practising of ethics in medicine are a fundamental part of practice. Ethical decisions are found in all types and levels of medical treatment (and when not to treat actively). Basically the Doctor is doing something (or not) that the patient would not normally have done to him (or put in to him etc.) therefore he has to be party to this action. All treatment has consequences and these must be thought about and brought to the patients attention i.e. the interactions and side effects that effect the patients lifestyle. This is as true for life decisions like euthanasia and abortion as it is to basic drug therapy. After all the patient has to take the drug. Tied in with this PERVASIVNESS OF ETHICS is the INDIVIDUALISING ETHICS, ethics are in every medical situation but they are also different in every situation. Ethics change as the circumstances of the patient, Doctor and situation change. There is no one overriding ethic (even life saving isn't) though patient consent seems to be. The situation changes for patient religion, social beliefs and personalities which are core values for the patient. The doctor also has rights in the debate and has the right not to treat if he or she is not happy doing so (abortion, euthanasia). He also has responsibilities for the patient which include maintaining patient confidentiality. The difficulty of the doctors position is shown by the suggestion that there are instances where the patients wishes have to override their feelings and beliefs. The patient is the central figure.

Individualising.

<u>Extract from a Developed Memo</u>

This is the development and manipulation of data, influences, treatments, behaviour and thoughts to the Doctors and the Patients own personality ethics, morals and beliefs. It is a basis apon which options in medicine are decided. Individualising has two main subjects- the Doctor and the Patient. It can also be individual in a situational sense. It appears that behaviour etc must be matched and non-conflictory between the two.

Situationing

Extract from a Developed Memo

Situationing is the area of situation, characteristics (personal and wider community), influences and solutions that are taken into consideration when a problems is looked.

It is a reaction and adaptation to the situation that the physicians find themselves (they know their patients….

The process here is that the situation that the problem exists within interacts with the resources that exist to solve it with. These interact throughout training methods, view of possible solutions, delivery of the final solution.

The situation and the resources define the solution with the width of the situation assessed and the width of the uses of the resources being defined by the availability of resources and the likelihood of success. It appears that resources are used more widely in the external patient situation (culture, attitudes, community) where specific resources are limited. And where specific resources are more available (i.e many treatments available) the resources are used defined by the internal patient situation.

There are two types of Situationing, **Restricted** and **Wide,** though the type does not change the underlying principles of treatment. …The **Personalising** that impacts the training and traditions of the medical community from whichever country, has considerable effects on the **Situationing** in which medicine is practised.

Densified by Sorting and Memoing

Centred Cataloguing

Centring.

This is the process where certain aspects of the situation (as catalogued earlier in the overall process) are seen to be the focus of all other activity in the area. These centres then dictate the behaviours and inter-relationships of the influences going into choice of the behaviour. There is no overriding centre though commonly the action must ***"boil down"*** to the patients care. The centre is determined by the assessment that takes place during **Cateloguing**.

Cataloguing

Here the patients problems, situation and mental and physical function are taken to be centres in differing circumstances. These main areas interact with each other to produce the centred characteristics that are the focal point of treatment. It is these centred characteristics that the treatment is Matched with.

The elderly are an extreme in the complexity of their medical problems and act as a good source of examples for the need to Centre. Physical and mental abilities differ throughout the patient population though and therefore centring is an important process in all treatment situations. I.e children are less competent and need to be treated in ways that allow them to benefit from the core treatment.

Treatments make demands on both mental and physical abilities both independently and dependently, therefore matching with the correct form needs to be looked at after Cataloguing has occurred.

Patients well being is often the bottomline when decisions are made and influences compared....May lead to normal prescribing of expensive drugs or ones with limited proof being restricted to certain indications.

"em I actually em in the hospital setting I would always enalapril just because I am use to using enalapril em I also use quite a bit of perindopril if I am starting patients

on it at homeand the reason for that is that there is a wee bit of data to suggests that it causes less problems with hypotension starting it than the other ones" (Dr. D. Birnie)

Focusing.

Extract from a Developed Memo

Focusing

This is the discovery and ***Focusing*** on the critical properties of the problem as it is presented to the doctor. It involves a detailed and interactive look at the problem situation. This acts as the base for ***Self-Referencing***. ***Self-Referencing*** and it are to a extent simultaneous as the ***Self-Referencing*** will direct the discovery of properties during ***Focusing*** (i.e. the questions that need to be asked, tests etc to get the full picture).

It is the process where certain aspects of the situation are seen to be the focus of all other activity in the interaction. The centre dictates the behaviours and inter-relationships of the influences going into choice of the behaviour. There is no overriding centre though commonly the action must ***"boil down"*** to the patients care.

Patients well being is often the bottomline when decisions are made and influences compared. For example medicines will be prescribed despite cost if the patient needs it. As the experience of the physician grows their influences for prescribing choice changes but is still based on the outcome of **Benefit Trading**

Extract from Final Development of Category.

Focusing.

The ***Trading Off*** process starts with the problem faced by the patient being discovered and defined. ***Focusing*** is the discovery and ***Focusing*** on the critical properties of the problem as it is presented to the doctor. It involves detailed and interactive examination of the problem situation and is performed by questioning, investigations and observations. ***Focusing*** hence directs the informational needs of the ***Trading Off***, which are satisfied via ***Self-Referencing*** and ***Surrogating***.

Focusing then acts as the base for the ***Self-Referencing*** of information to see if a solution is held with confidence internally, and hence the whole ***Trading Off*** process, if not then ***Surrogating*** is used. ***Self-Referencing*** and ***Focusing*** are to a extent simultaneous as ***Self-Referencing*** will direct the discovery of properties during ***Focusing*** (i.e. the questions that need to be asked, tests etc to get the full picture). ***Focusing*** is not a process that occurs once per problem, it is a process where the information sources returned to and **Re-*Focusing*** occurs.

This takes place when new information becoming available concerning the patient, i.e. new information about symptoms, disease development, the results of tests and relevant history.

A critical property of ***Focusing*** is that it goes beyond a diagnostic view of the core physical and mental signs and symptoms of the disease. It involves a detailed look at the patient, doctor and wider community characteristics and the personal and social situation within which the interaction takes place.

It incorporates the discovery and registering (either mentally or physically) of the highly specific nature of the assessment that is individual to the patient at that particular time.

It includes therefore patient history and the wider context that can direct treatment decisions. It is performed in order to ensure that confidence is ***Traded Off*** based on the important issues that can effect decisions beyond purely identifying the problem.

This detailed ***Focusing*** allows the matching of behaviour to the problem to occur from a base of greater knowledge and trust. This in turn allows the Doctor and the Patient to have more trust in the treatment/solution to the problem/s.

The ***Focusing*** process in addition to being performed by individual physicians is carried out by the various prescribing committees and less formal guideline and formulary bodies. Their decisions are typically made on an assessment of efficacy, comparison, relative advantage, and eventually cost.

The ***Focusing*** by committee is an example for the influence of politics in ***Focusing***. There is an acceptance that politics comes into the committee decisions though this can be seen to enter all levels of decision-making (where there is more than one interested party).

This represents a restricted approach to ***Focusing***. Further details on the continuum on which ***Focusing*** is carried out will be provided in section 3.3.2.

Focusing explains why influences that are important in certain circumstances will be overlooked in others. There is no overriding centre that is ***Focused*** on though, as is true throughout ***Trading Off***, it must commonly ***"boil down"*** to the patients care. For example, medicines will be prescribed despite cost if the patient needs it.

(cont....)

Appendix Sixteen

Development of Controlling

This appendix shows the development, rejection and integration of Controlling.

Examples of initial labels (Dr J. Hanslip)

Transcript	Codes	Memo
But , I suppose I would say still one of the main influences of our prescribing is what Ninewells and the teaching hospital have in their pharmacy because if they don't stock certain drugs then it is very difficult for us to get them.,	A59 One of the main influences is still the pharmacy because if they don't have it it is hard to get.	A mundane influence is the physical distribution of the drug to the pharmacy. Ensure that your drug is where it needs to be.

Selective Codes

Coercive External Controlling

The use of formulary and stock control is good example of excerting coercive control over an area where there is conflict between two parties. The centre of health care is the patient who because of the nature of the situation (cost picked up else where and the potential importance of the situation) is as we see it entitled to treatment regardless of cost. The other party, who have to work within a budget must therefore enforce some control over this situation or risk treatment costs outstripng their budget. Further

working agianst this is the consultants ultimate legal responsibility for the patients in his care. The control is coercive because it ultimtely works against the power of the physician

Written control.

A tactic to move the level of control on is the creeping use of formularies and protocols. The protocols are cunning, the hospitals and interested parties set up a shared care protocol which means that the patients are treated in a certain rigourous way. This includes setting out which drugs are used. Often the drugs are started in hospital and then the expense is bourne by the GP's. The hospitals have to stick to formulary and by adding the shared care to help and standardise practice across general practice they are extending this control out into general practice. It may not mean cheaper but it is control and can be used to reduce overall healthboard cost via reduction in hospital admissions etc. Protocols as well as being for shared care inititives control those very expensive drugs which realistically need to be controlled because of the huge implications to the budgets if prescrinig was even moderate. Whereas the hospital formularies are 100% the GP cannot be under his admmission because of a combination of patient centred treatment, GP independence, GP respect for colleugues and patient migration, he is looking though for increasing adherence-creeping control.

Extracts from Developed Memos.

Controlling

This is the attempt to control parts or whole of the prescribing process. Groups with vested interest such as the Prescribing Advisors attempt to rest the control the actual prescribers be they the GP's or the hospital doctors. Here we have the movement by the government to control effectively the prescribing of GP's and hospital doctors. As the GP's are currently independent and protective of this state there is movement to control

that is currently based on persuasion but may become more insistent. It can be seen however that the Patient is the ultimate location of the control.

Example of Properties of Controlling

Powerless

Because of the independence of the GP's and the doctor who is treating being responsible for the patient, there is no power to excerpt in this process. They are attempting to control actions without power to enforce them. Therefore the advisor needs to use persuasion and reasoned argument based on information to gain the respect and help of the GP....

Relationship building

is also an important tactic used and here the Prescribing Advisor is trying to be seen as a resource. He is attempting to move his visits on in the mind of many GP's from something causing anxiety to now where some are requesting visits....

Creeping

Another form of **Controlling** is the creeping use of formularies and protocols of which they have control over. The protocols are cunning, the hospitals and interested parties set up a shared care protocol which means that the patients are treated in a certain rigorous way...

Patient

A further type of Controlling is to look at it as though outside forces that should change prescribing decisions in fact are controlled and mediated by the primary treatment base of patient orientation and population benefit above that.

Coercive Controlling

The controlling of the prescribing process where coercion has to be used because the situation does not allow direct control.

The use of formulary and stock control is good example of excerpting coercive control over an area where there is conflict between two parties

Extending

Attempts are made to extend the control of one party over another. For example, The Hospital/ GP relationship. ….This control can be extended from the treatment to the budget via the formulary and the cost and effort and resource usage being passed into general practice. This can be seen as resource shepherding. The patients should benefit from this consultants and the hospitals mutuality because they are being treated by people more expert in the field than their own GP's.

This idea of **EXTENDED CONTROLLING** to shepherd resources can be seen to span all the MUTUAL RELATIONSHIPS. The company are trying to extend their control over the doctors so that the resources (prescribing opportunities, access opportunities) can be controlled and shepherded for them to exploit…

The hospital and consultants control extending is that the treatment of patients (general from the hospitals point of view and specific disease areas for the consultants) is based on practice that they want based further on their agendas (best practice, cost reduction, etc).

Further Developmental memos

Knowledge Controlling

The fundamental aspect here is the prescribing process being **Controlled** by those with superior knowledge and experience. In secondary care this is on the whole, the consultant who because of his level of knowledge is responsible for hospital patients and as such it is his choice of drugs that are on the whole will be used. The usage of drugs that are common in hospitals can take time to filter through to general practice because of their complexity and danger. This added to lack of options, time, resources and experience mean that it is safer and less risky to allow the treatment process to be controlled by the more experienced.

The individual **Controlling** the hospital treatment process changes as the consultant in charge on the day of admission changes. He or she is then in charge of the patient for the duration of the hospital treatment.

Note:

Reduction of the importance of *Controlling*- lead to emergence of many of it's properties in:

Duty Bound *Surrogating*

This refers to a further specific form of ***Surrogating*** which takes place in mainly in hospitals where the juniors are ***"Duty Bound"*** to follow individual consultants practice. It also occurs in general practice where a GP trainee is present and is duty bound to treat according to the trainer's wishes.

"Well yes it is an interesting one because when you are in the hospital you are duty bound to do what the consultant wants and in fact one of the main differences between being a junior doctor in a British hospital and being a junior doctor in a place like south Africa is that you get far more freedom elsewhere to prescribe"

Treatment of patients on behalf of the consultant means that the juniors are **Duty Bound** to treat the patients as the consultant wants. They are being forced into ***Surrogating*** the senior doctors experience for their own. This ***Surrogating*** can occur wherever the clinical responsibility for the patient does not resides with the Doctor administering the treatment.

The clinical responsibility for the patients in hospitals depends on the day and week of admission, as all patients taken in during a week tend to be the responsibility of one consultant. A consequence of the changing consultant responsibility is that the practice in the department may change week on week depending on the consultant is charge.

"if you are working for a particular consultant who has a particular preference for a particular drug you tend to follow his practice because you know he wants his patients to be on it..."

Duty Bound ***Surrogating*** also leads to drugs being used that the doctor would not use if they were free to prescribe their choices.

"Well for example we are trying to change everyone from Ranitidine onto Cimetidine at the moment...I tend to use omeprazole you sometimes see Lanzoprazole used but it tends to be Losec that we use"

The experience and evidence that is ultimately listened to is from the area that is thought to be more trustworthy and can be used more confidently.

Duty Bound Surrogating can be seen as a controlled form of teaching and as a controlled form of **Complete *Surrogating***. The difference between them is the freedom they have not to pursue the form of behaviour.

Appendix Seventeen

Standard Reference Gamble

The purpose of the standard reference gamble is to assess the level of preference for outcomes.

It consists of a choosing between a "sure thing" for an outcome that you rank as intermediate and a gamble between winning your best and worst possible outcomes. Each intermediate outcome needs a separate standard reference gamble. (Sox and Blatt., 1988)

Appendix Eighteen

EUT

The Steps involved in Expected Utility Theory:

List the outcomes that could occur

Rank the outcomes in order of preference

Assign a value of 1 to the best gamble and 0 to the worst outcome

Create standard reference gambles for each intermediate outcome

Create scenarios for each standard reference gamble

Determine the patient's indifference probability for each standard gamble

Solve for each unknown utility in terms of the known utilities. (Sox and Blatt., 1988)

Appendix Nineteen

Correspondence between Measurement and Behaviour in TRA

(Ajzen and Fishbein, 1977) This study analysed one hundred and nine studies looking into the concept of correspondence and hypothesised that if the attitude and behavioural entities correspond in the target element then attitudes will be found to predict behaviour. They reported on 3 categories: lacking, partial and high correspondence.

Lack of Correspondence

17 studies were classified into this category, they explored such diverse subjects as child-rearing practices, turning up to union meetings and attitudes to minorities. This review showed a lack of a relationship between attitudes and behaviour was explained by a lack of correspondence between behaviour and attitude measurement.

For example (Himelstein and More, 1963) studied attitudes of 100 white male undergraduates toward blacks. The experiment involved the subject entering a room to wait for an interview to find either a white or black confederate already seated. The confederate was signing a petition on extending library hours to 8.00pm. The behavioural measurement was taken as whether the subject would then sign the petition. Attitudes to blacks had previously been assessed via a self-report questionnaire.

The non-significant results that were reported can be explained by describing what was tested as whether attitudes toward blacks could predict the signing of a petition on extending library hours.

Partial Correspondence

It was suspected that in instances where only partial correspondence is found for example, where action elements correspond but target elements do not, then the results of these studies would be inconsistent. This hypothesis was supported in their results. These showed that from a total of 47 studies containing partially corresponding measurements, 17 gave non-significant results, 15 showed low to moderate significance and 15 gave inconsistent findings.

High Correspondence

This section of the review comprised 14 studies that showed a high level of correspondence between target and action elements. In line with the authors hypothesis all of these studies demonstrated clearly significant results.

Appendix Twenty

Non Compensatory Choice Strategies

Conjunctive rule: Using this rule alternatives are eliminated if they fall below predefined boundaries on certain attributes. For example if a student achieves less than 4 A's at Higher level they are not allowed into a particular University.

If a number of alternatives pass this barrier then additional rules may be needed to make a final choice. It can be useful in reducing large numbers of alternatives into a more manageable number. An example of this rule is Satisfycing (Simon, 1956).

Disjunctive: This is the strategy representing the converse approach to the conjunctive rule. Alternatives are judged as acceptable if they posses features that are rated above a predefined boundary. Once again separate rules may be needed if a number of alternatives pass the first test.

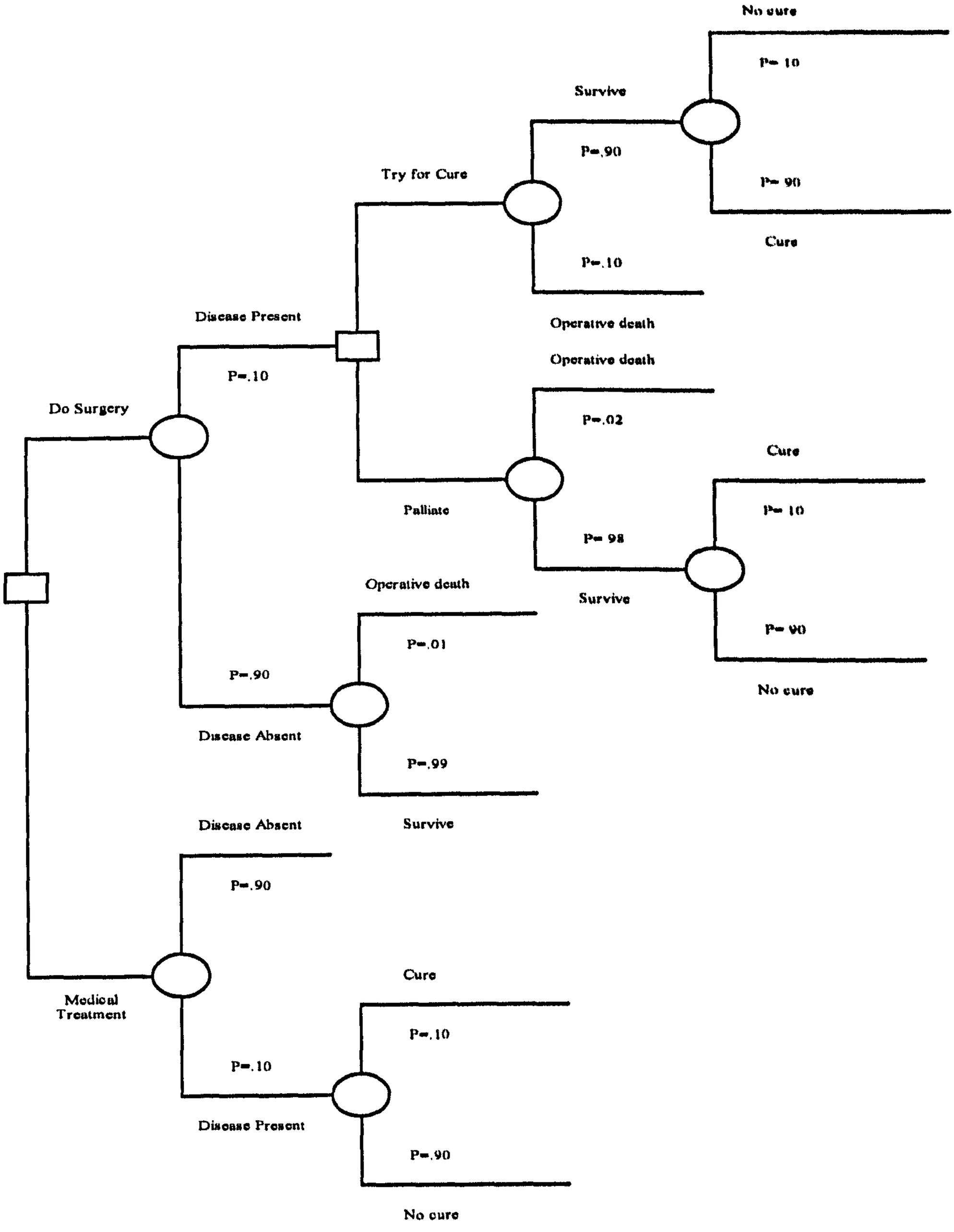
Lexicographic: The alternative is chosen that which possesses the highest rating on the most important feature. If more than one option remains then the same rule is applied to the next most important dimension.

Elimination by Aspect: Each alternative is again measured according to the most important feature and a specific cut-off point is also determined. Therefore the choice made must best on the most important attribute and have attained a certain level.

Appendix Twenty One

Decision Tree diagram

Medical vs. Surgical Treatment


No cure
P= 10
Survive
P=.90
Try for Cure
P= 90
Cure
P=.10
Operative death
Disease Present
Operative death
P=.10
P=.02
Do Surgery
Cure
Palliate
P= 10
P= 98
Operative death
Survive
P=.01
P= 90
P=.90
No cure
Disease Absent
P=.99
Survive
Disease Absent
P=.90
Cure
Medical
Treatment
P=.10
P=.10
Disease Present
P=.90
No cure

Appendix Twenty Two

QUALY:

The period of time in perfect health that a patient says is equivalent to a year in a state of ill health {Sox 1987 ID: 730} p217.

Appendix Twenty Three

PPRS

This Government/Industry negotiated scheme controls the maximum profit levels of pharmaceutical companies on their sales of branded medicines to the NHS.
It has set a target profitability level of between 17-21 per cent return on capital. However, the actual figure for each company within this range will remain a matter for negotiation by each individual company. The scheme is currently under renegotiations (ABPI, 1999).

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