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Achieving Quality Medical Equipment in Developing Countries Through Remanufacturing

by

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DECLARATION

This thesis is the result of the author's original research. It has been composed by the author and has not been previously submitted for examination which has led to the award of a degree.

Signed:

Date:

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ABSTRACT

Remanufacturing restores a used product to at least, its original equipment manufacturers (OEM) performance specification from the customer's perspective and gives the resultant product a warranty that is at least equal to that of newly manufactured equivalent product. It is a wise option as it offers high quality products at lower price since remanufactured products are substantially cheaper than new products of equivalent quality. Remanufacturing also has social, economic, and environmental benefits since it has the potential to become a source of revenue, create jobs and reduce environmental pollution. While remanufacturing is common in industries such as automobile and aviation, its application and benefits in the medical device industry have not been investigated.

Medical devices are crucial in the diagnosis and treatment of diseases and injuries but are inequitably distributed globally, such that there is acute shortage in developing countries with consequent high mortality rates over disease and adverse health conditions that could be treated if the right equipment were available. Several strategies have been considered to eliminate or mitigate this issue. However, neither has remanufacturing been considered a potential solution to this issue nor key factors in implementing medical equipment remanufacturing for developing countries been identified. This study proposes remanufacturing as a potential sustainable solution to this issue.

The research was conducted in 3 phases following a multiphase mixed methods design. Questionnaires and interviews were used to gather data while pre-figured thematic analysis, Decision-making trial and evaluation laboratory (DEMATEL) technique and confirmatory factor analysis techniques were used to analyse the data.

Main findings of this research include the following: (1) medical equipment remanufacturing can address 5 out of 11 causes of poor medical equipment availability accounting for 43.5% of the overall prominence. (2) A definition and decision support frameworks for medical equipment remanufacturing that could help to improve availability of quality medical equipment in developing countries (3) Major concerns in implementing medical equipment remanufacturing. (4) Impact of perception on the purchase intention for remaufactured medcial equipment.

This research is the first to identify the potential impact of remanufacturing in addressing medical equipment availability issues in developing countries, to characterise medical equipment remanufacturing towards this end. It is unique in its application of DEMATEL to the study of root causes of poor availability of medical equipment in developing countries and in applying behavioural science in understanding its purchase intentions.

Chapter 1:
Introduction to the study

1.1 Background to the study

Medical equipment are reusable medical devices that are durable, expensive, complex, maintainable/repairable and which often require user training, calibration and decommissioning are referred to as medical equipment (Eze, Ijomah and Wong, 2019). Medical equipment are a subset of medical devices that do not include implantable, disposable or single use devices and are usually included in the maintenance management programme of a health institution (Eze, Ijomah and Wong, 2019). Thus, healthcare administrators seek innovative means of optimising their availability (Unger and Landis, 2016), However, providing access to medical equipment can be difficult for developing countries, especially those facing extreme austerity. Developing countries are those with low or medium levels of human development (Perry and Malkin, 2011)

For many developing countries, accessing even life-saving medical equipment is difficult. This challenge is important, considering that about 85% of the world's population live in developing countries which account for 15% of global market for medical equipment (Eze, Ijomah and Wong, 2020). Consequently, the healthcare quality in developing countries is usually poor, resulting in high mortality rates over conditions that would otherwise be easy to treat and manage if the right equipment were available. For instance, over the globe, 2.6 million neonatal deaths, 2.8 million still births and over 287,000 maternal deaths were recorded in 2009. Sadly, 99% of these deaths occurred in developing countries often due to lack of complex medical equipment such as diagnosis equipment which cause delayed advising and referral (Fathima *et al.*, 2014).

Several previous studies (Rosen *et al.*, 2014; Zubizarreta *et al.*, 2015; Ademe, Tebeje and Molla, 2016; Diaconu *et al.*, 2017; Compton *et al.*, 2018; Venturini and Park, 2018) highlight the factors responsible for the problem without exploring their interrelationships. Consequently, they propose solutions from perspectives that are often either isolated or random. A more fitting solution can be obtained by taking account of the interdependencies among all the factors. This means that a potential solution should address the key availability issues and their interdependencies. Remanufacturing seems to be a solution but has not been embraced as a such.

Remanufacturing is the process of restoring a used product to at least, its original equipment manufacturer's performance specification from the customer's perspective and giving the resultant product a warranty that is at least equal to that of newly manufactured equivalent product (Paterson, Ijomah, and Windmill 2017). A variety of products including automotive products, aviation equipment, photocopiers, medical equipment, machine tools, cranes and forklifts, military equipment, furniture products, electrical and electronic products are currently being remanufactured (Matsumoto and Umeda, 2011; USITC, 2012; Zhang *et al.*, 2015). Products that are remanufactured usually fulfil specific requirements. This include the presence of a reverse flow of used products with significant residual life and fairly stable technology, a design that allows disassembly and significant customer demand for the remanufactured products (Abdulrahman et al. 2015; Gray and Charter 2007; Hatcher, Ijomah, and Windmill 2011).

Medical equipment fulfil some of these requirements and there is evidence of remanufacturing in the industry (D'Adamo and Rosa 2016; Kodhelaj et al. 2019). Till date however, there is still a paucity of research into the concept of medical equipment remanufacturing and so, only little is known of how it is implemented and what potentials it holds. For instance, the definition of remanufacturing is known to be vague in the industry (Eze, Ijomah and Wong, 2019) and this seems to affect the growth of remanufacturing in the industry. Hence a new definition and tools to help address the issues are necessary.

Remanufacturing is beneficial because it aims to preserve a product's geometrical form by reutilising its added value and energy invested in its manufacture. This usually translates to economic and environmental gains even while remanufactured products are sold at lower prices compared to equivalent new ones (Saavedra *et al.*, 2013; Abdulrahman *et al.*, 2015; D'Adamo and Rosa, 2016; Kalverkamp and Raabe, 2018).

Remanufacturing helps to reduce pollution by reusing valuable parts and components of a products. In addition, it provides an alternative supply of parts, especially for products that are no longer being manufactured by OEMs, increases market share and helps protect brand from erosion (Chaowanapong, Jongwanich, and Ijomah 2018; Shuoguo Wei et al. 2015). Hence remanufacturing seems to exhibit features that can help developing countries to improve access to medical equipment. However, the extent to which these features would address the equipment availability issues needs to be first determined to establish how much of a solution remanufacturing could be.

It would also be relevant to understand the current after-market activities in the medical device industry to ensure that solution proposed may be applicable in the industry. Such an understanding would also be necessary in characterising medical equipment remanufacturing to such a manner that best addresses the problem of medical equipment shortage. The proposed solution must also be appealing to clinical engineers and other clinicians that are potential users of medical equipment. This will indicate the potential to adopt the proposed solution. Hence, the solution should be validated by clinical engineers and clinicians. The potential acceptability of remanufactured medical equipment by healthcare practitioners in developing countries should, therefore, be evaluated.

Further, it would be important to determine the key factors that could affect the decision to conduct medical equipment remanufacturing in a developing country. This will be vital to understanding areas of focus in the quest to achieving improved access to quality medical equipment through remanufacturing. These gaps highlighted in this section will be explored in this research work.

1.2 Aims and objectives of the research.

This research aims to explore the potential for applying remanufacturing towards improving medical equipment availability in developing countries. A suitable first step in this research would be to understand the remanufacturing research domain, especially how it is done in the medical device industry including the activities that are involved in its implementation. After these, the next important stage would be to determine how much of the medical equipment availability issues that remanufacturing can address. This will be a basis for proposing remanufacturing as a solution. Hence the first set of research questions for this study would answer the following research questions:

RQ1a: What are the main causes of poor medical equipment availability in developing countries?

RQ1b: How is remanufacturing implemented in the medical device industry?

RQ1c: How can remanufacturing be characterised to solve the medical equipment issues in developing countries?

*RQ1d: By how much would remanufacturing contribute towards improving medical equipment availability in developing countries**?***

In spite of its numerous benefits, remanufacturing is still at its infancy in many developing countries (Jirapan Chaowanapong, Jongwanich and Ijomah, 2018). In

fact, “Virtually all attention and research into remanufacturing over the past decade has been concentrated in developed countries with relatively little attention to developing nations”(Abdulrahman *et al.*, 2015). If the preliminary studies in this research show that remanufacturing could be a solution, then the next pertinent question would be to determine why it has not been taken up. This will mean assessing the factors impacting on the uptake of medical equipment remanufacturing. Such a study would be important in making policies aimed at taking advantage of medical equipment remanufacturing. Thus, a second set of research questions are:

RQ2: What are the key factors in implementing medical equipment remanufacturing in developing countries?

RQ3: How would potential users perceive remanufactured medical equipment?

RQ 3a: What key factors predict the purchase intention for remanufactured medical equipment among potential users?

RQ 4. How can medical equipment be carried out cost effectively?

Inspired by the above research questions, the objectives of this research include the following:

1. To understand key elements in remanufacturing. This involves understanding the definition of remanufacturing, characteristics of remanufacturable products, benefits of remanufacturing and behavioural characteristics associated with the purchase of remanufactured products. This will help to elaborate key focus areas in the medical equipment remanufacturing research in this study.
2. To determine the contribution or potential impact of medical equipment remanufacturing towards addressing the poor medical equipment availability issues in developing countries. If remanufacturing does not have significant impact, then alternative solutions may be explored.
3. To understand developed country context of medical equipment remanufacturing and considering the developing countries’ medical equipment availability issues, propose a definition for medical equipment remanufacturing that captures the needs of developing countries while reflecting global best practice with respect to medical equipment marketing and use.
4. To identify the key factors in the implementation of medical equipment remanufacturing. If remanufacturing was a suitable solution and has existed in other industries, it would be necessary to understand why it has not been

embraced in developing countries for improving the availability of medical equipment. This can be achieved by studying the associated factors.

5. To assess the acceptance and factors affecting the purchase intention for remanufactured medical equipment among health care experts in developing countries. This ensures that medical equipment remanufactured as proposed would be acceptable to health care experts. This will highlight the key areas to focus on, in promoting remanufacturing as a potential solution.

1.3 Scope of the Research

As the research aims to propose a solution for developing country, its focus is therefore on developing countries health care system; principally to analyse the causes of poor medical equipment availability and ensure that a fitting solution is proposed. However, the solution is validated by two clinical engineers in the UK (outside the developing countries). This is to ensure that the solution agrees with global best practice. These experts also have experience in developing countries' clinical engineering and so, their inputs will be vital to the suitability of the proposition.

As the solution being proposed involves remanufacturing, a review of key elements of remanufacturing elements is conducted. To determine best practices from developed world, activities relating to remanufacturing in the United States of America (US) and the European Union (EU) were considered. These practices are part of ISO IEC PAS 63077 standard known as Good Refurbishment Practice (GRP). Other standards considered include ISO 13485, ISO 60601 group of standards and IEC PAS 62353.

A typical medical equipment: X-ray diagnostic equipment was used to study the purchase intention factors because of its value, stability of technology and versatility of applications in healthcare industry which indicate suitability for remanufacture.

1.4 Contributions to knowledge

This work will make several impactful theoretical contributions to the body of knowledge. The contributions include the following:

1. A definition of remanufacture which will help to address the critical requirements of medical equipment while increasing potential customer confidence in remanufactured medical equipment. Hopefully, this will help to address the problem of terminological inconsistency, help to standardise medical equipment remanufacturing and mitigating the involvement of unscrupulous workers.

2. Determination of the interrelationships among factors responsible for poor medical equipment availability in developing countries. From the interrelationships, the potential contribution of remanufacturing in addressing the issues is estimated and serves as a basis for proposing remanufacturing as a solution in this research.

3. Decision support framework characterising the preliminary decisions to precede medical equipment remanufacture and a model of remanufacturing process reflecting industry best practice is developed and validated in three stages. These preliminary decision support tool captures and orders the key preliminary considerations in selecting an equipment for remanufacture and/or in setting up a medical equipment remanufacturing enterprise. Similarly, the process model captures the best practice procedure for ensuring that remanufactured equipment is as good as new.

4. Identifying and prioritising the factors involved in the decision to remanufacture medical equipment in a developing country. This is to highlight the order of importance of the factors to be considered in the decision to implement cost-effective medical equipment remanufacturing in developing countries.

5. Understanding of the key factors influencing decision to purchase remanufactured medical equipment. Additionally, a Confirmatory Factor Analysis (CFA) model for the behavioural pattern of a developing country's medical practitioners towards remanufactured medical equipment was developed. The model may be used to highlight the key factors affecting the purchase intentions for remanufactured equipment and so, guide future research or action plan towards adopting medical remanufacturing as a solution.

1.5 Significance of the Study

This study makes several impacts that indicate its importance. It contibutes towards improving developing countries' healthcare outcomes by significantly addressing medical equipment availability issues through remanufacturing. The root factors affecting medical equipment availability were explored while the potential impact of remanufacturing towards addrssing the issues was estimated. The identified factors informed the proposed definitional framework for medical equipment remanufacturing, which is validated by healthcare experts from several developing countries. The validation demonstrates agreement and acceptance of the medical equipment remanufacturing as proposed showing its potential to support the implementation of

medical equipment remanufacturing in developing countries. The study also identifed the key factors that should be considered in implementing medical equipment remanufacturing. As the factors include technical factors, incentives/market and institutional factors, it therefore informs relevant individuals in authority, institutions and businessess on the key factors that need to be considered to implement medical equipment remanufacturing. In developing this framework, the technology capability framework initially proposed by Lall (1992) was used as the basis. Thus, this study also extends remanufacturing theory and opens up new perspectives for understanding the factors to be considered in implementing it. This has both academic and industry importance.

Its academic importance include providing opportunity for further studies in the area of medical equipment remanufacturing to which the findings in this study would serve as foundation. For industries and policy experts, this research has provided a guide framework and identified the factors that need to be considered in implementing medical equipment remanufacturing. This research also contributes to studies seeking approaches to improve medical equipment availability in developing countries.

1.6 Novelty of the Research

This research is novel from several considerations. This include the following:

- It is the first to estimate the potential impact of medical equipment remanufacturing in addressing the poor medical equipment availability, taking account of the interdependencies among factors responsible for the poor availability issues and the advantages of remanufacturing.
- It is the first to propose a new definition for medical equipment remanufacturing; having identified inconsistencies in the current practice of remanufacturing in the medical device industry.
- It is the first to identify and prioritise the factors affecting the decision to implement cost-effective medical equipment remanufacture in a developing country.
- It is the first to analyse the factors affecting potential users' purchase intentions for remanufactured medical equipment.

- It is the first to to propose a framework to guide the implementation of medical equipment remanufacturing.
- This study is the first to incorporate a technology development framework in remanufacturing.

1.7 Uniqueness of the Research

This study is unique from several considerations including:

- Being the first to apply DEMATEL to the analysis of the causes of poor medical equipment availability in developing countries. As already noted, previous studies such as (Rosen *et al.*, 2014; Zubizarreta *et al.*, 2015; Ademe, Tebeje and Molla, 2016; Compton *et al.*, 2018; Venturini and Park, 2018) highlight the problems without analysing their interrelationships.
- This study is the first to apply behavioural theory towards understanding purchase intentions for remanufactured medical equipment. Previous studies (Hazen et al. 2012, 2017; Jiménez-Parra, Rubio, and Vicente-Molina 2014; Wang and Hazen 2016) either applied the theory to remanufactured products in general or to automotive products and studied switching behaviour to remanufactured products in general.
- This research is also the first to link remanufacturing to a technology capability framework.

Chapter 2:
Literature review

2.1 Introduction

This chapter introduces medical devices and their classification schemes, identifies the medical equipment availability issues in developing countries and highlights the shortcomings of current approaches towards tackling the issues. Remanufacturing was then shown to be a potential sustainable solution to the problem. The chapter also explores remanufacturing to develop knowledge from other industries that can help to shape medical equipment remanufacturing practice.

2.2 Overview of medical devices and equipment

A medical device may be defined in several ways depending on the regulatory context which ensures the safety and effectiveness of medical devices by enforcing compliance to relevant quality standards (WHO, 2010). The regulatory bodies for medical devices in the United States and Europe are popular and have their own definitions. In addition, there has been a global effort to achieve a common definition for medical devices. This gave rise to the Global Harmonisation Task force (GHTF) in 1992 which also has a definition for “medical device”. These definitions are presented in Table 2-1. Each definition attempts to capture the roles of the numerous devices used in healthcare. In summary, a medical device refers to any apparatus, software, material or other items intended to be used in diagnosing, preventing, monitoring, treating or alleviating a disease or injury (Racchi et al. 2016; Santos et al. 2012). The term ‘disease’ covers all unfavourable health changes, including injuries and mental health (Santos 2013).

2.2.1 Classification of medical devices

Medical devices include about one million five hundred thousand different devices in over ten thousand generic groups available for healthcare worldwide; ranging from complex capital-intensive devices with great financial value to ordinary devices such as thermometers, software and invitro reagents. It is often challenging to clearly capture all medical device types using one classification system. In practice, several classification systems exist. Typical classifications are based on the following considerations (Santos 2013):

- Acquisition: Prescribed or over the counter

- Number of utilisations: single use and reusable devices. Reusable medical devices that are durable, maintainable/repairable and which requires user training, calibration and decommissioning are referred to as medical equipment. According to the WHO, Medical equipment does not include implantable, disposable or single use devices (WHO, 2011).
    - Stage of healthcare that they are used to deliver as preventive, diagnostic, therapeutic, and assistive/rehabilitative devices,
    - Type of use: general and disease specific
    - Risk: Classes I, IIa, IIb and III in the European Union and classes I, II, and III in the United States. In these countries, this classification is used to determine the market entrance requirement of a given medical device (Santos 2013)
    - Risk: Classes I, IIa, IIb and III in the European Union and classes I, II, and III in the United States. In these countries, device classification is used to determine the market entrance requirement of a given medical device (Santos, 2013)

There is also the Global medical devices Nomenclature (GMDN) which classifies and identifies medical devices with codes according to the application and technology (Santos *et al.*, 2012). The European Union regulators also use of the GDMN in carrying out medical device conformity assessment (Santos, 2013). The GDMN categories including specific examples are depicted in Table 2-2.

Table 2-1: Definitions of medical devices from different sources

Source	Medical device definition
United States FDA	An apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: • recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, • intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, • or intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and that is not dependent upon being metabolized for the achievement of any of its primary intended purposes.
European Union Medical Device Directive	Any instrument, appliance, apparatus, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: • diagnosis, prevention, monitoring, treatment or alleviation of disease; • diagnosis, monitoring, alleviation of or compensation for an injury or handicap; • investigation, replacement or modification of the anatomy or of physiological process; • control of conception; and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be so assisted.
GHTF	Any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent, software, material or other similar or related article: a) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of: • diagnosis, prevention, monitoring, treatment or alleviation of disease, • diagnosis, monitoring, treatment, alleviation of or compensation for an injury, • investigation, replacement, modification, or support of the anatomy or of a physiological process, • supporting or sustaining life, • control of conception, • disinfection of medical devices, • providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and

b) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its intended function.

Table 2-2: GMDN classification of medical devices.

Category	Classification	Example
01	Active implantable devices	Cardiac pacemakers, neurostimulators
02	Anaesthetic respiratory devices	Oxygen masks, gas delivery unit, anaesthesia breathing circuit
03	Dental devices	Dentistry tools, alloys, resins, floss, brushes
04	Electromechanical devices	X-ray machine, CT-scanner
05	Hospital hardware	Hospital bed, surgical lights
06	Invitro diagnostic devices	Pregnancy test kits, glucose test strips
07	Non-active implantable devices	Hip/knee joint replacement, cardiac stent
08	Ophthalmic and optical devices	Spectacles, ophthalmoscope, contact lenses
09	Re-usable instruments	Surgical instruments, rigid endoscopes, blood pressure cuffs, stethoscopes, skin electrodes
10	Single use devices	Syringes, needles, balloon catheters, latex gloves
11	Technical aid for disabled	Wheelchairs, walking aids, hearing aids
12	Diagnostic and therapeutic devices	Radiotherapy units, dialysis equipment
13	Complementary therapy devices	Acupuncture needles, bio-energy mapping devices
14	Biological derived devices	Biological heart valves
15	Healthcare facility products and adaptations	Gas delivery systems
16	Laboratory equipment.	Most invitro-diagnostic devices that are not reagents.

2.2.2 Global investments in medical equipment

According to a recent medical technology report, (MedTech Europe, 2015) the medical device technology industry is dynamic in nature and has enjoyed steady growth. In Europe, the medical device industry is estimated to worth about €100 billion, making up 31% of the global medical devices market and is the second largest after the United States' market which is valued at over $140 billion, accounting for about 45% of the global market (Commerce, 2016). The industry employs about 575000 people in in about 25,000 companies across Europe. This justifies the report that 95% of medical device technology industries are small and medium scale industries (MedTech Europe, 2015).

In Europe, 10.4% of the GDP is spent on healthcare; with 7.5% of this value spent on medical device technologies. Similarly, the weighted average per capita expenditure on medical device technology in Europe is €195 compared to that of the United States which is €380 (MedTech Europe, 2015).

For other parts of the world, utilisation of medical technology is not as impressive as presented for Europe, the United States and Japan. It is estimated that these three nations account for over 85% of the global demand for medical devices (Bamber, 2013). Thus, only three nations produce and use most medical devices. On the other hand, lack of even basic lifesaving medical device technologies is prevalent in majority of the other countries; most of which are developing and are the residence of over 80% of the world's population. This dreadful situation also shows that developing countries represent a vital growth opportunity for the medical device industry (Bamber, 2013). The present challenge is how to position them to be able to participate in the global medical device market and take advantage of available medical device technologies in healthcare. To achieve this, it would be necessary to first understand the causes of poor medical equipment availability in developing countries. These are presented in the next section.

2.3 Understanding the medical equipment availability issues in developing countries

An understanding of the medical equipment availability issues is important in this study as it would help to demonstrate the practical relevance of the solutions to be developed. Related literature was searched to identify the major themes about medical equipment availability in developing countries. The search was conducted on 10 October 2020. Specifically, Pubmed and Google Scholar searches were performed. Pubmed is the most used resource for medical literature and Google Scholar has been shown to return a high volume of articles with high precision (Shariff

et al., 2013), hence the choice of both of them in this preliminary study. A Boolean combination of keywords was used to conduct the searches for articles published between 2005 and 07/10/2020. The keywords are combined in a manner that would attract articles about medical devices or medical equipment in developing countries. The keyword combination as well as search results are shown below for the Pubmed and Google scholar searches.

Pubmed:

Keywords: "medical device" OR "medical equipment" AND "availability" AND "developing countries" OR "low -ncome countries" OR "poor countries"

Results: 3591

Google Scholar:

Keywords: "medical device" OR "medical equipment" AND "availability" AND "developing countries" OR "low -ncome countries" OR "poor countries"

Results: 16800

The paper titles were quickly reviewed and those that exhibited the following criteria were selected:

1. Paper must focus on developing country/countries.
2. Paper must be titled around investigation of medical equipment access and/or availability in developing countries/country.
3. The paper must address at least, an issue affecting the availability of medical equipment.
4. Paper must investigate impact of poor access to medical equipment in developing countries/country.
5. Paper identifies challenges to approaches such as maintenance and donation aimed at improving the availability of medical equipment in developing countries.
6. The paper introduces measures aimed at improving medical equipment availability in a developing country such as:
    a. Design of low cost/easy to use equipment
    b. Medical equipment donations
    c. Impact of shortage of medical equipment on the healthcare staff
    d. Recycling e.g reuse of used incubator

This approach led to the selection of 102 articles after merging results from Pubmed and Google Scholar and removing duplicates. Of these, full text was available for 40 articles which are finally included in this preliminary study.

Major themes from the articles include causes of poor medical equipment availability in developing countries and approaches such as medical equipment donation and design of medical equipment for developing countries. These are explored in the next sections.

2.3.1 Impact of poor access to medical equipment in developing countries

Medical devices are crucial and indispensable tools to health care delivery (WHO, 2017). Developments in medical device technology have greatly enhanced diagnosis, treatment and rehabilitation of patients. Many complex medical procedures are currently possible because of the sophistication in medical technologies. However, in many developing countries, high mortality rates are still recorded due to the unavailability of even basic medical devices. For instance, 2.6 million neonatal deaths, 2.8 million still births and over 287,000 maternal deaths were recorded in 2009. Sadly, 99% of these deaths occur in developing countries due mostly to lack of screening instruments which cause delayed advising and referral (Fathima *et al.*, 2014; Zaka *et al.*, 2018). Even small oxygen concentrators if available, could provide a solution to the associated shortage of oxygen, particularly in small hospitals. (Dobson, Peel and Khallaf, 1996)

Similarly, more than 50-90% of the cancer patients requiring radiotherapy in developing countries lack access to treatment (Zubizarreta *et al.*, 2015). For instance, about 29 countries in Africa do not provide radiation therapy for cancer patients and patients with curable malignancies remain in agony (Elmore *et al.*, 2016). A study of mortality preventability in a developing country's intensive care unit reveals that poor access to equipment is responsible for about 23% of all recorded deaths (Zeggwagh *et al.*, 2014; Zubizarreta *et al.*, 2015).

Poor access to medical equipment in developing countries also have negative effects on trauma management (Shah *et al.*, 2015), surgical practice including anaesthetics (Ologunde *et al.*, 2014; Okoye *et al.*, 2015; Oosting *et al.*, 2019), diagnostic imaging and radiology (Shah, 2014; Ngoya, Muhogora and Pitcher, 2016), laboratory capacity (Fonjungo *et al.*, 2012; Ikranbegiin *et al.*, 2019) as well as trauma and orthopaedic practice (Haonga and Zirkle, 2015; O'Hara, 2015; Shah *et al.*, 2015; Tabiri *et al.*, 2015). In all these instances, improving access to medical equipment has the potential to yield better outcomes.

Recognising the crucial role of medical devices in healthcare, the World Health Assembly (WHA) adopted resolution WHA 60.29 aiming to achieve improved access and quality service from health technologies, especially medical devices (WHO, 2011). The resolution emphasised planning medical equipment acquisition based on priority needs and compatibility with existing infrastructure. Planning ensures that equipment is used rationally and are efficiently maintained. The Global Initiative on Health Technologies (GIHT) funded by Bill and Melinda Gates was formed to advance these objectives, strengthen Resolution WHA 60.29 and contribute towards making core health technologies affordable to people in poorer settings (WHO, 2011).

2.3.2 Causes of poor medical equipment availability in developing countries.

The medical equipment availability issues in developing countries are caused by several factors. Some of the factors also impact on the success of approaches aimed at addressing the problems. These factors are identified in this section.

2.3.2.1 Corruption

According to Bouchard et al.(2012), corruption in healthcare organisation contributes significantly to medical equipment availability problems. The authors found that Corruption within the health care industry usually takes the form of inflation of equipment prices, purchase of lower quality equipment and products as well as lowering of care quality which ultimately resist the necessary response to alleviating health care challenges. Hope (2015) identified the different types of corruption in the health sector and linked corruption to government's inability to provide access to quality health. The author highlighted that corruption brings about inflated health budgets as well as poor image and trust for health institutions.

2.3.2.2 Lack of funds

Cost constraint is an important factor affecting medical equipment availability in many developing countries. Many developing countries lack funds to procure the right medical equipment. Related studies find that the high cost of medical devices make them unaffordable especially as poverty level is high in many developing countries (Malkin, 2007; Rosen *et al.*, 2014; O'Hara, 2015). For instance, a study finds a strong relationship between poverty, illness and disability (Daher and Flessa, 2010). For manufacturers of medical equipment, lack of funds makes developing countries unattractive for business. Hence, propositions for low-cost medical equipment design for developing countries abound in the literature. But reducing the price of a proposed medical equipment design may drastically decrease the available options and features for the particular equipment (Bergmann, Noble and Thompson, 2015) and so, could make less useful.

2.3.2.3 Lack of robust regulation, HTA and HTM

The World Health Organisation recognises the need for poorer countries to have stronger regulations as well as health technology assessment and management policies in place to optimise medical equipment procurement and use (WHO, 2017). However, this is often not the case (Velazquez, 2002; Perry and Malkin, 2011; Nkuma-Udah *et al.*, 2015; Coe and Banta, 2017). Health technology assessment (HTA), Health technology management (HTM) and regulatory units are expected to collaborate to achieve these objectives (WHO, 2017).

Health technology assessment supports evidence based decision-making preceding the acquisition of new technologies (WHO, 2017). This is necessary to ensure that proposed new technologies are those that will be effective, appropriate and implementable towards advancing health care quality. HTM also known as clinical engineering involves planning, needs assessment, selection, procurement, inventory, installation and maintenance of medical equipment as well as training and decommissioning (Lenel et al, 2005; WHO, 2017). The tasks associated with each element include technical advice, planning and costing, supply chain management as well as disposal and record keeping.

Poor HTA and HTM for is implicated in the absence of robust patient referral system which causes breakdown due to overuse in some hospitals (Ademe, Tebeje and Molla, 2016). As such, lack of funds to purchase medical equipment may not be the most important factor affecting availability (Okoye *et al.*, 2016). In fact, the available medical equipment in developing countries can be doubled just by implementing HTM (Perry and Malkin, 2011). The absence of effective HTM, HTA and regulation do not only bring about shortage of quality medical equipment due to lack of policies on equipment standards and planning for effective use (Fonjungo *et al.*, 2012; Ademe, Tebeje and Molla, 2016) but also exposes patients in resource-limited countries to equipment-related health hazards (Mori, Ravinetto and Jacobs, 2011).

2.3.2.4 Inappropriateness of available equipment

The implication of weak or absent HTA, HTM and regulation include lack of standards and abundance of sub-standard equipment or equipment that do not contribute to healthcare. Much of the medical equipment in developing countries are not useful in addressing prevailing disease burden. Other medical devices commonly found in developing countries are those that are not compatible with available national electricity supply (Lustick and Zaman, 2011; Gauthier *et al.*, 2013). Because medical equipment procurement is largely uncoordinated in developing countries, products from a wide variety of manufacturers are available. Under such circumstance, it

becomes difficult for the technicians to gain the proficiency necessary to maintain the available equipment varieties. This ultimately challenges the sustained use of medical equipment in developing countries (Borrás *et al.*, 2014).

2.3.2.5 Lack of skilled workers.

Lack of skilled workers also contributes to the poor availability of medical equipment in developing countries. This may be as a result of lack of in-house training on the use and maintenance of equipment (Zomboko, Tripathi and Kamuzora, 2012; Shah *et al.*, 2015; Ademe, Tebeje and Molla, 2016; Oosting *et al.*, 2019) as well as lack of emphasis on the training of biomedical equipment technicians on the national and local government levels. According to Perry and Malkin (2011), technicians were found to have inadequate skills and medical equipment users have poor understanding of how to use equipment. Consequently, equipment damage becomes frequent leading to the disrepair states of many medical equipment in developing countries (Malkin, 2007). Often there is no vendor-based service/maintenance agreement and with lack of in-house maintenance capacity, there is usually frequent equipment breakdown and protracted downtimes for the more expensive equipment like ventilators (Bhattacharjee and Cruz, 2015).

Due to lack of skilled workers, functional equipment may also be classified as damaged. For instance, a study of 1704 documented failed medical equipment finds that 25% of the equipment classified as failed were actually in good working order (Malkin and Keane, 2010).

2.3.2.6 Lack of spare parts

One reason why equipment may be unavailable in developing countries is due to the lack of spare parts (Tanyanyiwa, 2010; Ankomah *et al.*, 2015). This causes delay in carrying out procedures and an upward push in the total cost of ownership of medical equipment (Mahal, Varshney and Taman, 2018). Some of the medical equipment are obsolete and as a result, their production by their manufacturers may have been discontinued. In such cases, there would be only a minimal chance of successfully repairing the equipment due to lack of access to necessary spare parts since affected institutions would then rely on unregulated independent spare parts marketers (Mahal, Varshney and Taman, 2018) . In Malkin and Keane's study (Malkin and Keane, 2010) however, 72% of the documented failed equipment were repaired using spare parts sourced locally and so, the problem may include inability to fully explore the local market.

2.3.2.7 Lack of economic model

Some scholars argue that lack of economic model contributes to the poor availability of medical equipment in developing countries. They argue that hospitals do not often aim to minimise costs by for instance, making use of a technology only when it is absolutely necessary or minimising the duration of hospital stay (Malkin, 2007; Judd and Issakov, 2008). Malkin also notes that the poor availability of medical equipment in developing countries may not be so much about lack of fund for purchasing new ones since there are already medical equipment whose maintainability are usually not sustained (Malkin, 2007).

2.3.2.8 Poor infrastructure

Other causes of poor availability of medical equipment in developing countries include lack of infrastructure such as electricity and oxygen (Sandhu *et al.*, 2005; Enright, 2013; Rosen *et al.*, 2014; Ademe, Tebeje and Molla, 2016). The use of modern technology usually requires stable and reliable supply of electricity as well as electronic devices and the internet. These are not available in many developing countries (Marks *et al.*, 2019; Mantena, Rogo and Burke, 2020) and oppose the use of technology in health care (Gatrad, Gatrad and Gatrad, 2007, Marks *et al.*, 2019; Mantena, Rogo and Burke, 2020).

2.3.2.9 Unreliable supply chains

Unreliable or ineffective supply chains contribute to the poor availability of medical equipment in developing countries (Zomboko, Tripathi and Faustin Kamuzora, 2012; McGuire and Weigl, 2014). This is important because medical equipment are mostly manufactured abroad; necessitating well-coordinated supply chains to acquire consumables and spare parts. These are usually unavailable (Sandhu *et al.*, 2005). Unreliable supply chains affect both the quality of medical devices available, the ability to achieve sustained equipment use and ultimately, affects the quality of care in health establishments.

Hence, according to Compton,

"If the supply chain, which is inclusive of all activities and resources involved from acquisition to delivery, results in medical devices that are unusable or inappropriate to treat patients, then the health system is disadvantaged—impeding the delivery of the highest quality of care." (Compton *et al.*, 2018, p.2)

2.2.1.10 Workers' attitude

Workers' attitude and perception may also affect the availability of medical equipment in developing countries' healthcare sectors. For instance, clinical staff often refuse to

use an equipment if they consider them difficult to operate and may even declare them damaged just to avoid being asked to use them (Rosen *et al.*, 2014). Workers also complain about the mismatch in the intensity of work they do compared to the amount they are paid and so, often disable devices due to their dissatisfaction (Ademe, Tebeje and Molla, 2016). The poor condition of available medical equipment also causes frustration among health care experts in developing countries who are unable to complete tasks effectively due to the situation (Penfold *et al.*, 2013).

The causes of poor medical equipment availability in developing countries are numerous as has been shown. These are summarised in Table 2-3. Addressing these factors requires understanding the prominence of each factor in a developing country context as well as exploring the interrelationships existing among them so that efforts can be directed effectively. These objectives are pursued further in this research. The efforts that have already been made towards eliminating or mitigating these problems are presented in the following section.

Table 2-3 : Summary of the causes of poor medical equipment availability in developing countries

S/N	Factors	Details	References
F1	Corruption	Corruption often takes the form of embezzlement of funds allocated to the purchase of medical equipment or stealing of – equipment; often possible due to the peculiar nature of health care industry.	(Bouchard *et al.*, 2012)
F2	Attitude/Perception	Staff may refuse to use medical devices if they consider them difficult to use or may incorrectly declare an equipment damaged.	(Rosen *et al.*, 2014)
F3	Lack of funds to access and/or to fund the purchase of equipment	Governments in many developing countries often cannot afford the cost of state-of-the-art equipment. The people are also poor and may not be able to pay for procedures involving expensive medical equipment.	(Malkin, 2007a; Daher and Flessa, 2010; Rosen *et al.*, 2014; O'Hara, 2015).
F4	Lack of infrastructure such as electricity, water supply, oxygen.	Poor infrastructure such as reliable electricity, water supply, roads, oxygen.	(Sandhu *et al.*, 2005; Gatrad, Gatrad and Gatrad, 2007; Enright, 2013; Rosen *et al.*, 2014)

F5	Absence of HTM and HTA	The main problems faced regarding medical equipment include lack of or poor health technology management policy which results in poor planning for procurement and sustenance. Lack of regulation affects the effectiveness, durability and consequently, the effective lifetime of medical equipment.	(Coe and Banta, 1992; Velazquez, 2002; Perry and Malkin, 2011; Nkuma-Udah *et al.*, 2015; WHO, 2017)
F6	Weak or absent regulation.		
F7	Lack of skilled workers	Trained experts for use and maintenance of medical equipment are usually not available and training is poor	(Malkin, 2007; Malkin and Keane, 2010; Tanyanyiwa, 2010; Perry and Malkin, 2011; Ankomah *et al.*, 2015)
F8	Lack of spare parts and consumables	Damage to the equipment requiring spare parts cannot be rectified due to the unavailability of the spare parts in the local market.	(Malkin, 2007; Tanyanyiwa, 2010; Perry and Malkin, 2011; Ankomah *et al.*, 2015; Mahal, Varshney and Taman, 2018)
F9	Lack of clear economic model	Developing countries' hospitals do not often aim to minimise costs whereas there is need to always conduct economic evaluation of medical devices to demonstrate their cost effectiveness.	(Malkin, 2007; Judd and Issakov, 2008; Perry and Malkin, 2011)
F10	Inappropriateness of available equipment	Available equipment are often inappropriate for the needs of the developing countries. They may be for treatment of diseases that are not common in the country or are not designed to be compatible with realities on ground	(Malkin, 2007; Malkin and Keane, 2010; Gauthier *et al.*, 2013)
F11	Unreliable or ineffective supply chain communication	Medical equipment are mostly manufactured outside of developing countries necessitating supply chain frameworks which are sadly inexistent or ineffective. Biomedical technologists and engineers are also not part of the procurement process	(Sandhu *et al.*, 2005; Zomboko, Tripathi and Fausin Kamuzora, 2012; McGuire and Weigl, 2014)

2.3.3 Previous efforts at addressing the availability issues.

Due to the grave consequences of poor access to medical devices in developing countries, several efforts have been implemented to address the problem. These include the following:

- Medical equipment donation from government and non-governmental organisations abroad (WHO, 2000a, 2011; Mateosian, 2001; Gatrad, Gatrad and Gatrad, 2007; Perry and Malkin, 2011; Adjabu *et al.*, 2014; Compton *et al.*, 2018; Marks *et al.*, 2019)
- Design of low cost medical equipment for developing countries (Sandhu *et al.*, 2005; Jensen and Treichl, 2007; Nimunkar *et al.*, 2008, 2009; Zomboko, Tripathi and Faustin Kamuzora, 2012; Balsam *et al.*, 2013; Thairu, Wirth and Lunze, 2013; Eltringham and Neighbour, 2014; Myriam, 2014; O'Hara, 2015; Thallinger *et al.*, 2017; van den Heuvel *et al.*, 2018)
- Direct reuse of medical devices imported from abroad (Kirkpatrick *et al.*, 2010; Mahal, Varshney and Taman, 2018)
- Use of imported refurbished medical devices (Gatrad, Gatrad and Gatrad, 2007).
- Promotion of local production by the World Health Organisation (WHO) (Kaplan, Ritz and Vitello, 2011; World Health Organisation, 2016).

Local production of medical equipment intuitively has the capacity to make medical equipment more available and sustainable in any given setting. However, it is not an easy alternative for developing countries due to high resource costs and required technology (Hazen, Mollenkopf and Wang, 2016) which may be unavailable.

2.3.3.1 Medical equipment donations to developing countries.

Medical equipment donations usually come from governments, charity organisations, hospitals, health clinics and educational organisations (Adjabu *et al.*, 2014; WHO, 2017). Donations are usually motivated by genuine intentions. However, other donors may have some indirect financial motivation. For instance, a study of medical equipment donations from Canada found that financial incentives from manufacturers of medical equipment to hospitals that dispose of their used equipment themselves may motivate medical equipment donation programme (Adjabu *et al.*, 2014).

Major destinations of medical equipment from international donors include Malawi, India, Pakistan, Somalia, Sri-Lanka, Nigeria, Philippines, Syria, Uganda, Cuba and Cameroun (Gatrad, Gatrad and Gatrad, 2007; Adjabu *et al.*, 2014). Hospitals usually engage the services of non-profit or charity organisations to source for potential donors to avoid the legal rigours associated with medical equipment donations especially due to the restricted trans-border movement (Adjabu *et al.*, 2014).

Reports on the utility of donated equipment suggest that only few of them actually become useful to the recipients due to reasons which include mismatch in environmental characteristics, socio-economic conditions, maintenance capacity and

little or no access for training on equipment use (WHO, 2000, 2011; Perry and Malkin, 2011; Compton *et al.*, 2018; Marks *et al.*, 2019). In view of this, the WHO consistently made efforts to rationalise medical equipment donation so that recipient countries can benefit from them. The first draft guideline towards this objective became available in 2000 and was subsequently updated in 2011 (WHO, 2011). The Tropical Health Education Trust (THET) also has a publication titled: "Toolkit for medical equipment donations to low resource settings". Both efforts were geared towards improving the donation process especially for the poorest countries that rely almost entirely on donated equipment. Key measures expected of the recipients in the WHO guidelines as well as their limitations are summarised in Table 2-4.

The three government agencies in the recipient countries that are usually involved in receiving donated equipment are the Ministry of Health, Ministry of Commerce and Customs (Gatrad, Gatrad and Gatrad, 2007). However, in practice, only the Customs and Commerce get involved for tax clarifications. Thus, the use of many donated medical equipment commences before proper acceptance or quality assurance testing. Scholars observe that donated equipment are not subjected to post donation inspection and certification of quality (Zomboko, Tripathi and Fausin Kamuzora, 2012). This provides a supply of equipment which may not pass quality assurance tests. A study of Tanzanian hospital staff's perceptions of donated medical equipment shows that 78% of participants were discontented with such equipment. The most important reasons given by these discontented respondents are lack of technical support and specifications crucial to the use of the equipment (Zomboko, Tripathi and Faustin Kamuzora, 2012).

2.3.3.2 Unsustainability of medical equipment donations to developing countries.

Medical equipment donation has some inherent issues that suggest it cannot be an enduring solution for improving medical equipment access in developing countries. The WHO recommends the use of donation solicitors to improve the donation programme and requires them to refuse arranging for the donation of complex equipment if they believe that healthcare system in the destination country lack the capacity or resources for sustaining the use of such equipment. This includes situations where the medical equipment is deemed too complicated such that the expertise required to dismantle or maintain them may not be available on the recipient's side (Gatrad, Gatrad and Gatrad, 2007).

If this is the case, then donation cannot provide access to sophisticated medical equipment that are indispensable in carrying out some complex life-saving procedures. A desirable solution to medical equipment in developing countries would

provide sustained access to the equipment through promotion of commercial activities required to avail spare parts, accessories, consumables and technical support services. Clearly, medical equipment donations fall short on these requirements as its motivation is mostly compassionate rather than commercial. Consequently, donation may only be a temporary measure towards accessing simple devices. To take better advantage of used equipment from developed countries, strategies which encourage commercial activity, involve indigenous market channels while offering equipment at reduced price is required. The implementation of such strategies has the potential to promote sustained use of even the sophisticated medical equipment in developing countries since it will help to transfer necessary skill sets.

Table 2-4: Key suggestions in the WHO guidelines for medical equipment donations and their limitations

Serial Number	Content of WHO policy guidelines	Limitations
1	Determine if there is a donations policy in place. Donation solicitors can be in a much stronger position to negotiate the contents of a policy.	Medical equipment donation is interventional in nature. Countries often do not plan to rely on donated equipment, especially when they are second-hand equipment and so, do not often have policies to guide donation programme. Moreover, the Health technology management (HTM), Health technology assessment (HTA) and Regulations are weak in many developing countries (Nkuma-Udah *et al.*, 2015; WHO, 2017). Only about 40% of developing countries have regulatory framework for medical devices (WHO, 2010). This situation gives rise to weakened capacity to enforce medical device specifications reflecting contemporary healthcare realities and encourages the entry of sub-standard medical equipment.
2	List the equipment and supplies that are needed and their quantities. Prioritize the list of requested items.	It is impractical to provide all the supplies needed for a medical equipment over a substantial long duration. Donation bypasses commercial routes to the recipient country and sourcing of necessary supplies may eventually become difficult if similar equipment from the same manufacturers are not available in the recipient's local market.
3	Provide potential donors with clear and comprehensive information about the items needed and how they will be used. The requested items should comply with the specifications, standardization practices, model equipment list, etc.	Equipment are usually certified when entering developed countries' markets to demonstrate compliance with standards (Eltringham and Neighbour, 2014). While used equipment may have such certification when entering the developed country where it was first used, they will have deteriorated while in use and so, needs to be recertified again before entering the developing country. Unfortunately, many developing countries do not have their own specifications for medical equipment standards.
4	Check that the national regulations allow these goods to be imported.	Regulations are often weak or inexistent in developing countries. This makes it easy for donated equipment to bypass necessary scrutiny.
5	Before agreeing to accept a donation, check whether the equipment will come with its relevant accessories, consumables, manuals, and some	Purchase of consumables is a rolling activity with many medical equipment, hence the need to ensure a secure source. It will be extremely difficult to foresee the quantity of accessories and consumables that an equipment will need over its life to include them with the donation. Recipients of donated equipment that are different from the popular equivalents available in the local market may have difficulty accessing spares and accessories.

	spare parts, so that it can function and be used.	
6	When donations are received, check packaging for damage and make sure that equipment is fully functioning and is supplied with the relevant and agreed manuals, spare parts, consumables, and accessories. Check expiry dates and labelling of the recurrent supplies.	Acceptance testing for medical equipment demands more than just visual inspection and functionality testing. In some situations, an equipment that functions well mechanically for instance, may fall short in other quality criteria. Both the recipient and the donation solicitor may not have the right instruments to carry out the necessary testing to verify the equipment.

2.3.3.3 Designing low-cost medical equipment for developing countries

The principle of “low cost medical equipment” is often based on the use of low quality components, making improvisation in the design and manufacture of the equipment or reducing the usual complexity of the equipment just to reduce its cost (Eltringham and Neighbour, 2012, 2014). While this approach seems right given the poor socio-economic condition of many countries in the developing world, cost reduction may have disproportionate impact on the functionality of the resultant equipment (Bergmann, Noble and Thompson, 2015; van den Heuvel *et al.*, 2018). Hence, the idea may be unethical (Eltringham and Neighbour, 2012, 2014).

The concept of low-cost design may also be deceptive since the so-called low-cost equipment are in fact, subsidised as the cost of development covered by Research Grants provided to the research institutions are often ignored. This makes it difficult to determine the exact cost of the product since the manpower and other resource costs are not considered (Eltringham and Neighbour, 2012, 2014).

Moreover, whether the products designed in this manner will become available to developing countries’ healthcare systems is another question. Usually, such equipment do not get commercialised (Thairu, Wirth and Lunze, 2013).

2.3.3.4 The downside of designing low-cost medical equipment for developing countries.

Only a few of the so called low cost or subsidised product designs become successfully developed eventually and these are supplied to developing countries through non-commercial means (Eltringham and Neighbour, 2014). Since the institutions carrying out the design and manufacture of the "low cost" or subsidised devices do not usually have a commercial base or route to market, they are likely to go off business as soon as the funding ceases, leaving users of the equipment without technical support (Eltringham and Neighbour, 2014). Thus, it is vital to supply medical equipment to a low resource country through indigenous resellers, agents and suppliers as this approach would enhance commercial activities and sustained supply (Eltringham and Neighbour, 2014). This is because introducing medical equipment through commercial supply route would ensure that skills exist for maintenance and that supplies of spare parts and consumables will be easily accessible to sustain the equipment through its life cycle. A consideration of medical equipment value chain is relevant to the understanding of skills and opportunities for applying or developing indigenous capacity. This is covered in the next section.

2.3.3.5 Medical equipment value chain analysis and the unutilised opportunity.

In value chain analysis, a firm is broken down into its strategically relevant activities and examined systemically, to understand the flow of costs as well as to recognise

opportunities for improvement and profit maximisation (Kannegiesser, 2008). Value chain covers all activities through which a manufacturer creates and markets value. In the medical device industry, this includes the following (Bamber, 2013):

- Research and product development: This involves prototype development, process design and development, regulatory approval and sustaining engineering.
- Components manufacturing: The components or parts of the proposed product are manufactured using appropriate techniques such as extrusion or moulding for plastics, precision machining, weaving, and knitting. Electrical circuits are also produced.
- Assembly: Components are assembled, packaged, and sterilised.
- Distribution and marketing: The finished products are distributed. The distribution may employ wholesalers, or market directly to end clients and users. These include hospitals, doctors, nurses, and allied health professionals as well as individual patients.
- Post-sales services including training, consulting, and maintenance.

Medical equipment value chain does not usually terminate at post sales services or end of life process (the point where the products are discarded due to technological obsolescence, deterioration or change in consumer preferences). For electrical and electronic medical devices, some countries have laws such as the European Union Directive 2002/96/EC on Waste Electrical and Electronic equipment (WEEE) Directive in place, which transfers the responsibility of disposing them at their end-of-life, to the manufacturers. It is apparent that medical devices that reach their end of life due to change in user's preference (such as decision to go for a more innovative technology) would have many of their components good enough to extend the product's life or to sustain it through another lifecycle.

Instead of disposing such end-of-life products, an end-of-life strategy may be applied to extend or renew their utility. End of life strategies refer to the different ways of recovering products with differing levels of reuse. These strategies mitigate environmental impacts and add economic benefits to product disposal (Seitz and Wells, 2006; Thierry et al., 1995; Gehin et al., 2008) and include the following (Saavedra *et al.*, 2013):

- Direct reuse
- Repair

- Use of reprocessed medical devices. Reprocessed devices include the following (Parkinson and Thompson, 2003):
    - Refurbishment
    - Remanufacturing

The major characteristic features of these processes include variation in the quality as well as reduction in price of the products. In refurbishment, the used medical device is reprocessed such that its performance is returned to limits considered acceptable for reuse (Parkinson and Thompson, 2003). However, conventional remanufacturing yields a product which at least, equals an equivalent new one in terms of performance specifications and warranty. Both whole products as well as sub-assemblies can be remanufactured (Gray and Charter, 2007).

2.3.4 Remanufacturing as a superior strategy.

The interest in second-hand products or direct reuse is generally due to their perceived low price compared to new ones. However, most countries have restrictions if not outright ban on used and refurbished products due to both economic and non-economic reasons (Republic of Trinidad and Tobago Ministry of Trade, Industry, Investment and Communications:Trade, 2015). The non-economic reasons include issues with sustainability and environmental public health impacts. From economic perspective, second hand and refurbished products are nationally opposed to avoid unfair market competition and flooding of the market with outdated technologies.

As already pointed out, developing countries make up only a small fraction of the global medical devices market and tis a popular destination for used and refurbished medical equipment (Parker *et al.*, 2015). Consequently, Gatrad (2007) suggest that major equipment manufacturers and other organisations interested in trading refurbished equipment should also include full after sales support, training and liability insurance (Gatrad, Gatrad and Gatrad, 2007). In addition, D'Ademo and Rosa (2016) note that developing countries are important markets for remanufactured products since they are more interested in equipment functionality at limited costs, than just aesthetics.

Refurbishment of medical equipment is guided by minimum cost (Parkinson and Thompson, 2003), as long as the device can operate within acceptable limits and refurbished products generally have lesser warranty than equivalent new ones (Ijomah *et al.*, 2007; Saavedra *et al.*, 2013). This indicates that the resultant product's reliability may still be questionable. Remanufacturing on the other hand, involves more thorough work and replacement of damaged or weak components to guarantee

that the product can serve as good as new ones. The quality of work is indicated by the warranty which at least, equals that of equivalent new product.

Remanufacturing occurs in an industrial setting and involves sourcing of used products with sufficient residual value, known as core (Paterson *et al.*, 2018). This is followed by disassembly, cleaning, inspection, refurbishment/reconditioning of parts, optional upgrade to appropriate or required technology, reassembly, testing and warranty provision (Lund, 1984; Ijomah and Childe, 2007; Saavedra *et al.*, 2013; Paterson, Ijomah and Windmill, 2017). Thus, remanufacturing is defined as (Paterson, Ijomah and Windmill, 2017) :

> *Remanufacturing is a process of returning a used product to at least OEM original performance specification from the customers' perspective and giving the resultant product a warranty that is at least equal to that of a newly manufactured equivalent.*

Essentially, the warranty given to a remanufactured product, which is at least, equal to that given to an equivalent new product proves that they are of high quality. For most products, this provision sufficiently shows that remanufactured alternatives have comparable quality to new ones.

For medical equipment on the other hand, post sales technical service support identified in the value chain is an essential consideration and thus, may also be provided for remanufactured equipment. Post sales technical service support includes training, provision of spare parts and maintenance support. Given that lack of spare parts and technical skills are among the causes of poor availability of medical equipment in developing countries, post sales technical service support may be a key component of any measure aimed at providing sustained medical equipment supply (Gatrad et al, 2007; D'Ademo & Rosa, 2016).

Remanufacturing also provides functional products at considerably lower price than equivalent new ones (Steinhilper, 1998; Gray and Charter, 2007) and therefore, has the potential to improve access to functional medical equipment in developing countries where funding issue has been shown to exist. By increasing access to sub-assemblies which serve as spare parts, remanufacturing can help address the challenge of unavailability of spare parts which has also been identified as an issue affecting medical equipment availability in developing countries. In addition, since remanufacturing is labour intensive (Gray and Charter, 2007) and currently requires

less technological sophistication than conventional manufacturing, it can promote commercial activity in the medical device sector, contribute to medical device technology skills acquisition and so, encourage local production of medical devices as well as capacity building for efficient medical equipment maintenance.

Remanufacturing was initially proposed under the United Nations Projects GLO/80/004 and GLO/84/007, as a means of achieving economic and social benefits through sustainable resource recovery activities in developing countries. Remanufacturing was seen to be particularly applicable to developing countries because it requires less capital and fewer labour skills than that of original equipment manufacturers. In addition, developing countries show characteristics that indicate that they will benefit from remanufactured products. Such characteristics include the need to retain products longer, especially when OEM support no longer exists. People in developing countries also make relatively less use of new technologies due to price sensitivity (Pearce, 2009). While remanufacturing seems promising with regards to addressing the availability issues, it is still important to review the work already done in the field of medical equipment remanufacturing in order to determine the right approach for the current research. This is covered in the next section.

2.4 Review of medical equipment/device remanufacturing literature

Only few works relating to medical equipment remanufacturing have been published. A search of Google Scholar and Scopus was performed with the keywords "medical equipment" AND "Remanufactur" OR "Refurbi" to determine what has been published in relation to medical equipment remanufacturing or refurbishment. A total of 105 results obtained from the search. After removing irrelevant papers such as those referring to the refurbishment of non-medical hospital equipment, only 24 papers were left. Still, the majority (66.7%) of the papers only cite popular sources such as Lund's (Lund, 1984) and the USITC's (USITC, 2012) list of products considered remanufacturable; which includes medical equipment. Table 2-5 shows all such publications while D'Ademo and Rosa, 2016; Widera and Seliga, 2015; Barker and Zabinsky, 2008; Baron, 2016; Sloan, 2007; Tanyanyiwa, 2010 are explored further.

Table 2-5: Literature search results for medical equipment remanufacturing.

S/N	Document	Citation for medical equipment remanufacturability	What research is about
1	An analysis of remanufacturing practices in Japan (Matsumoto and Umeda, 2011)	Remanufacturing has spread worldwide to sectors as disparate as auto parts, electric home appliances, personal computers, cellular phones, photocopiers, single-use cameras, cathode ray tubes, automatic teller machines, vending machines, construction machineries, industrial robots, medical equipment, heavy-duty engines, aircraft parts, and military vehicles	A case study of remanufacturing in the following four products areas: single-use cameras, auto parts, and printer ink toner cartridges.
2	The Profit-Making Allure of Product Reconstruction (Pearce, 2009)	"Similarly, remanufacturing processes may be used to restore and improve other capital goods, such as airplanes, machine tools and medical equipment" page 64. "Because remanufactured products are both re- furbished and enhanced by new technologies, original equipment manufacturers have significant advantages over independent remanufacturers in industries that have high price tags or are characterized by rapid technological advancements.	The paper presents remanufacturing as the highest level of reconstruction which has the capacity to introduce performance enhancements to products. It Highlights the characteristics of each reconstruction process and considerations for their success. Most importantly it recognises the characteristics of potential users of remanufactured products.
3	Waste management of electric and electronic equipment: comparative analysis of end-of-life strategies (Sergio and Morioka, 2005)	In terms of environmental performance, end of life strategies may be categorised as follows: 1. reuse 2. servicing (repair and maintenance) 3. remanufacturing (component repair and refurbishment 4. recycling and 5 disposal. The current WEEE model covers 81 products in 10 groups, including medical equipment.	This article analyses and discusses the performance and logistic aspects of EOL strategies for electronic and electric equipment currently implemented in Japan, the United States, and the European Union. The aim is to identify logistic issues and potential improvement options for existing waste management policies
4	Analysis and taxonomy of remanufacturing	The FDA regulates the medical equipment suppliers in the United States and issues licences. According to the	To review the literature available and examine the terminology surrounding

	industry practice (Parkinson and Thompson, 2003)	regulation, remanufacturers are subject to the same quality systems requirements as manufacturers.	remanufacture and establish definitions for end-of-life strategies for clarification. Via a review of industrial practice and a set of case studies, the key business drivers faced by the remanufacturing industry are presented
5	Environmentally Benign Manufacturing: Trends in Europe, Japan, and the USA (Allen *et al.*, 2002)	the European Commission legislation on electronics take-back will most likely follow the Dutch model, except they are expected to be stricter, for example including medical equipment	The paper reports the findings of a panel that assessed the international state-of-the-art in Environmentally Benign manufacturing to identify areas of focus and opportunities for collaboration.
6	Managing New and Remanufactured Products (Ferrer and Swaminathan, (2006)	"Companies that organise their production lines to accommodate remanufacturing include manufacturers of cartridges, single use cameras, tires, hospital beds, medical equipment, military equipment and many other products" Page 5	The study analyses in a two-period, the market possibilities of an OEM that also conducts profitable remanufacturing.
7	Strategic Management of product recovery (Toffel, 2004)	Take-back regulation also affects medical equipment that are electrical and electronic equipment. Takeback laws encourage the manufacturers of these products to take them back and refurbish, remanufacture, or recycle them.	Paper uses economic theories including Dynamic Capability and Core Competency theories to explain remanufacturing strategies.
8	Strategic and Tactical Aspects of Closed-Loop Supply Chains (Mark Ferguson, 2009)	Examples of remanufactured products include automotive parts, cranes and forklifts, furniture, medical equipment, pallets, personal computers, photocopiers, telephones, televisions, tires, and toner cartridges, among others.	Attempts to answer pertinent questions about the profitability of remanufacturing, the impacts of supply chains and environmental considerations on it as well as optimal decisions with respect to core supply and recovery.
9	A multi-echelon reverse logistics network design for product recovery —a	The recovery option is widely applicable for the products like vehicle engines, computers, electrical appliances, electronic equipment, copiers, single-use	To develop a mixed integer nonlinear programming model for maximizing the profit of a multi-echelon reverse logistics

	case of truck tire remanufacturing (Sasikumar, Kannan and Haq, 2010)	cameras, cellular phones, paper, carpets, plastics, medical equipment, tires, and batteries.	network and also to present a real-life case study of truck tire remanufacturing for the secondary market segment.
10	Materials Exchanges: An exploratory US survey (Andrews and Maurer, 2001)	Many parts of the USA have durable medical equipment clearing houses, for example, that accept items such as wheelchairs and crutches from those who no longer need them and give them to needy patients.	Article classifies the US organisation that are involved in post-use products exchange. It finds that non-profit organisations and state/government-sponsored ones are predominant and are distinct from the "for profit " scrap recyclers and used products resellers.
11	Solution algorithms for dynamic lot-sizing in remanufacturing systems (Ahn, Lee and Kim, 2011)	For example, Lund (1984) classified the range of products remanufactured as four general categories: automotive, industrial equipment, commercial products, and residual products. Besides the major automotive industry, several case studies on various aspects of remanufacturing have been reported for different industries such as machine tools, aircraft engines, copier, computers, copiers, toner cartridges, mobile phones, medical equipment, office furniture, etc.	The article proposes a three-stage lot sizing integer programming model for optimising disassembly, reprocessing and reassembly by minimising the setup and inventory holding costs at the three processes.
12	A manufacturing framework for capability-based product-service systems design (Gokula Vijaykumar *et al.*, 2013)	Mentions the use of integrated service CAD and lifecycle simulator in identifying potential upgrade options in medical equipment repair.	Emphasises that PSS design should be customised solutions which are aligned to integrated stakeholders' capabilities. It then proposes a systematic framework to assist PSS solution providers to address this aim and operationalizes this through a specifically developed software.
13	The Effect of Competition on Recovery Strategies	Examples of remanufactured products include automotive parts, cranes and forklifts, furniture, medical equipment, pallets, personal computers,	To develop models to facilitate OEM's recovery activity in a competitive market for remanufactured products

	(Ferguson and Toktay, 2006)	photocopiers, telephones, televisions, tires, and toner cartridges, among others.	
14	Examination of demand forecasting by timeseries analysis for auto parts remanufacturing (Matsumoto and Ikeda, 2015)	Remanufacturing has spread worldwide to sectors as disparate as auto parts, photocopiers, single-use cameras, construction machines, mining machines, medical equipment, aerospace, military vehicles, heavy-duty engines, computers, vending machines	Presents the result of demand forecasting performed for auto parts remanufacturing using Time Series Analyses.
15	Inventory management for a remanufacture-to-order production with multi-components (parts) (Zhang *et al.*, 2015)	Remanufacturing at the first time is proposed by Lund in 1983 (Lund 1983), and since then it has been practiced in number of manufacturing industries for printer and photo copiers, toner cartridges producers, medical equipment manufacturers, automobile parts producers, computers and other electronics manufacturers, office furniture builders, aviation equipment manufacturers, tire manufacturers and Construction.	The research proposes an inventory management approach for a generic remanufacture to order (RTO) system. RTO strategy is similar to make to order and involves remanufacturing a poduct when a potential buyer has already placed an order.
16	Competitive pricing and reusability choice for remanufacturable products (Chen and Hsu, 2017).	Due to take-back legislation (e.g., the WEEE directives in the European Union) and efficient reversed logistics systems, remanufacturing is becoming more prevalent and commonly adopted. The examples include autoparts, electric home appliances, personal computers, cellular phones, photocopiers, single-use cameras, automatic teller machines, vending machines, construction machineries, industrial robots, medical equipment	The study uses the Salop spatial model in formulating the demand function, on a two-period horizon in a market involving OEM and IR as price setters. The OEM and IR however, produce different versions of the same product with different costs.

2.4.1 Inconsistent and incorrect terminology for aftermarket processes

The United States Trades and Industries Corporation (USITC) regards both reprocessing of single use devices and refurbishment as remanufacturing (USITC, 2012). Similarly, the US Food and Drug Administration (FDA) has its own definition of remanufacturing which needs to be evaluated in relation to the classical definition of remanufacturing. For this potential terminological inconsistency, both the FDA and the EU medical device directive's positions on activities relating to medical equipment remanufacturing will be examined further in this research.

Adopting remanufacturing as a means of improving medical equipment availability would require developing a definition for remanufacturing that will address the key availability issues and provide a means of promoting and encouraging acceptance. A definition for medical equipment remanufacturing would in addition, drive standardisation among remanufacturers, promote uniform image about remanufactured products to potential consumers and provide a basis for relevant organisations to monitor and access activities of the industry.

2.4.2 Need for business models and decision support tools.

Widera and Seliger (2015) developed a business model for original equipment manufacturers interested in remanufacturing their own medical devices. The model is based only on core acquisition challenges, challenges associated with marketing remanufactured medical devices, as well as variations in batches and level of automation. The wide variety of medical device types in the market was found to be an important challenge in implementing medical equipment remanufacture. This can potentially increase the number of products for which remanufacturing technology would be developed for, affect core supply and influence market potential for remanufactured medical equipment. While some classes of medical devices are considered improper for remanufacture, the authors assert that many class IIb medical devices according to the EU medical device classification, are amenable to remanufacture. According to the authors, product Sales and Services (PSS) is a key strategy for implementing medical equipment remanufacturing.

D'Adamo and Rosa (2016) examined through industrial case studies and Analytic Hierarchy Process; the strengths, weaknesses, opportunities and threats to medical device industries in Europe, United States of America (USA) and China. The medical devices considered include medical pumps, patient care apparatus, scanners, surgical, X-ray. This study shows that medical device remanufacturing has high potential for profitability but can be more expensive to undertake compared to automotive, aviation and electronic products. Furthermore, it finds that availability of

cores, health risks, and design for remanufacture issues are important considerations in medical device remanufacturing. As a result, the authors recommend the development of novel business models and instruments to support the decision-making process in remanufacturing.

2.4.3 Industrial case: Combined manufacturing and refurbishing of medical equipment.

Barker and Zabinsky (2008) proposed a conceptual reverse logistics frameworks for medical equipment remanufacturing based on the practice of a USA-based OEM that also refurbishes medical equipment. The reverse logistics framework used by the medical device manufacturer involves the collection of used products at the customer site. The used products that still have substantial value and quality are sent for refurbishment at the company. These are held in the warehouse at the company site until a customer places an order for a refurbished product. On the other hand, those devices that cannot be salvaged are sent to recyclers.

2.4.4 Potential influence of the RoHS regulation on remanufacturing

Baron, (2016) assessed the impact of the Restriction of hazardous substances (RoHS) regulation on medical device refurbishment. The author finds that the regulation has various degrees of restrictions to the supply of spare parts and used equipment that are bound for refurbishment if they are considered to contain items that can be hazardous to health. While some products were granted exemptions from the full requirements of the regulation, the conditions accompanying the exemption suggest that it is only temporal. Thus, the regulation has the potential to adversely impact or even terminate the refurbishment practice of devices that contain parts considered to be hazardous.

2.4.5 Potential risks associated with remanufacturing in medical device industry.

Sloan (2007) analysed the safety-cost trade-offs in medical device reuse using Markov process models; to resolve the perceived economic, ethical, legal and environmental perspectives of SUD reprocessing. While SUDs were initially made for “one-time use and discard”, the practice of sterilisation and subsequent reuse of these devices is on the rise (Kwakye, Pronovost and Makary, 2010; Kapoor *et al.*, 2017). Some proponents support this practice for its environmental friendliness (Kwakye, Pronovost and Makary, 2010) while the others encourage it for its cost saving potential. However, antagonists claim that this practice increases the risk of cross infection and medical device failure as these SUDs have not been designed to sustain post-use treatments and moreover, that the sterilisation processes cannot guarantee complete elimination of pathogenic organisms given the geometry and material

properties of the SUDs (Popp *et al.*, 2010; MHRA, 2013). Sloan therefore, attempts to determine the conditions under which reprocessing may be considered ethical and cost effective given the penalty for possible failure of the SUD.

2.4.6 Importance of servitisation model in developing countries' medical equipment market

The PSS model has the potential to address the poor availability of medical equipment spare parts in developing countries. Tanyanyiwa (2010) notes that poor access to spare parts create serious challenges in developing countries especially when the manufacturers seize the production of older product models. This situation according to the source, can potentially lead to the suspension of diagnostic service due to long repair periods. Tanyanyiwa (2010) recommends a sales agreement which places the responsibility of maintaining the equipment on the vendors.

2.4.7 Highlight of gaps identified.

This review shows that applying remanufacturing as a solution for improving access to quality medical equipment is novel. However, no information on what constitutes acceptable practice with regards to medical equipment remanufacturing was found. Also, while remanufacturing seems to be a solution to the medical equipment availability issues in developing countries, the extent to which it can contribute towards addressing the issues is not currently known. In addition, none of the studies examined the awareness of medical equipment remanufacturing in a developing country nor identified the factors that could impact on its successful implementation. None also analysed the potential purchase intentions for remanufactured medical equipment which will be relevant in understanding whether remanufactured equipment would be accepted. Considering the activities involved in product remanufacturing, the review finds that innovative business models would help to maximise profit by addressing issues relating to selection of products to remanufacture, access to used products, regulations, risks, design, recoverability, and marketing strategies. These are key areas to consider in implementing medical equipment remanufacturing. These observations along with the inconsistent definitions for remanufacturing which was also found underscores the need for a careful approach to this study given that its aim is to characterise remanufacturing for the purpose of improving access to medical equipment.

For this study to contribute towards the development of a business model, it must analyse all the key factors relating to medical equipment remanufacturing. To achieve this, a Technology Capability Framework from Lall (1992) is used as a theoretical framework to ensure that the study analyses all key factors.

Key components of the technology capability framework are national and firm-level technological capability, institution and incentives. In this study, firm level technological capability is represented by the remanufacturing capability. As no information was found for medical equipment remanufacturing, the search in this case is focused on automotive remanufacturing with all instances of specific products previously known to be remanufactured included in the search. Main aspects of Lall's framework were extended using information obtained from a search of Scopus database.

Scopus was searched on 18 June 2019 with the following keywords:

ALL FIELDS: "legislation" OR " law" OR " regulation" OR " litigation" OR " standards" OR "policies"

AND

ALL FIELDS: "process" OR "activity" OR "sequence" OR "flow" OR "technique"

AND

ALL FIELDS: "automotive" OR ("car" AND "engine") OR ("crank" AND "shaft") OR ("torque" AND converter ") OR (" gear AND box ") OR ("turbocharger")))

AND

TITLE-ABSTRACT- KEYWORDS: "remanufacture " OR "remanufacturing" OR "reman"

A total of 374 document results was obtained. However, the results were limited to journal articles with a minimum of 5 citations and books and this gave 263 results. After reading the abstracts to ensure that documents relate to the topic, a total of 117 documents were selected and included in this phase of the study.

2.5 Theoretical framework

2.5.1 Technology capability framework

Technology capability has been defined as the ability to select, assimilate, adapt and improve existing or imported technologies or to create new technologies; either at firm level or national level (Gonsen, 1998; Olatunji, 2002; Rennkamp and Boyd, 2015). Thus, scholars distinguish between firm level technological capability (FTC) and the broader national technological capability (NTC) in which the former is embedded (Lall, 1992; Rennkamp and Boyd, 2015). Both the NTC and FTC are motivated by the market potential which serves as incentive; within an institutional framework (Lall,

1992). Hence, technological capability involves the following (Lall, 1992; Rennkamp and Boyd, 2015):

1. The sum of firm capabilities in the development, use, investment, production, and implementation of technology.
2. The skills produced through technological learning in firms and through the national education system.
3. Current physical investment in technology and infrastructure
4. Direct support through state institutions and private technology services
5. Support from institutions for education and training
6. Existing political regimes for regulation, incentives (market), and intellectual property.

Investment in physical technology and infrastructure can be through an institution or by a firm that aims to upgrade its technology or to develop a new one. Similarly, available support for education and training may be by the firm or through appropriate government institutions. Hence, technological capability may be framed into the following interacting elements: institutions, firm level production activities and market incentives. The framework may be broken down into institutional roles, firm level production activities and incentive system as shown in Figure 2-1.

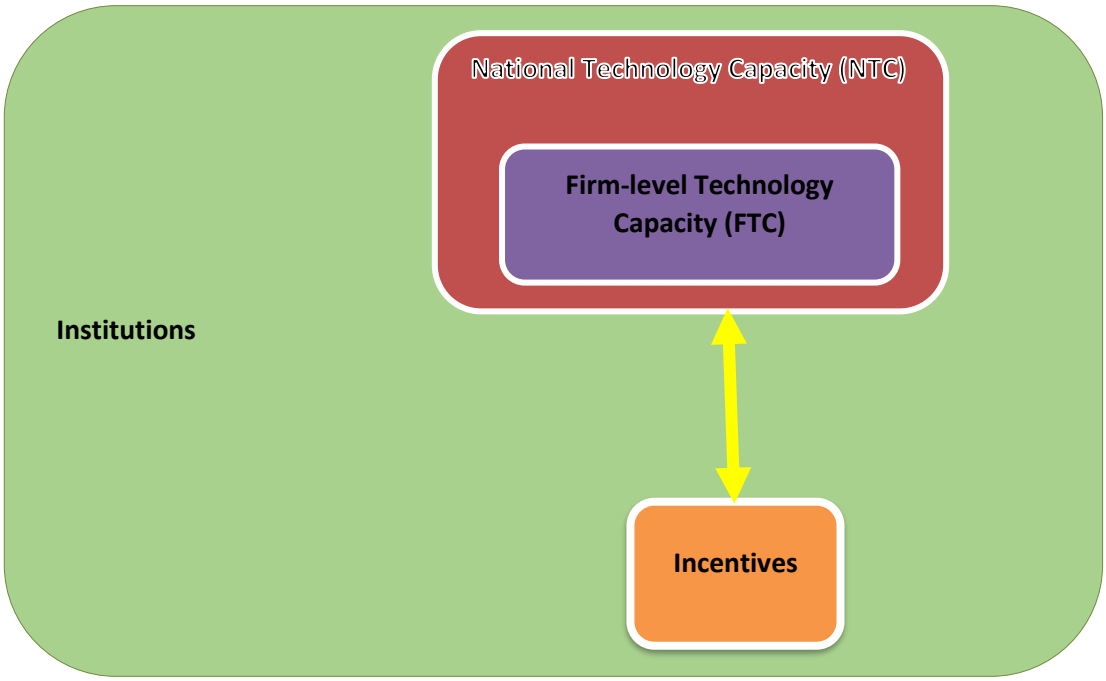

Figure 2-1: A representation of technology capability framework. capabilities interacting with incentives within an institutional framework.

As shown, FTC is embedded in the NTC which reflects a nation's effort towards industrialisation in terms of factors such as quality of education and skilled labour. Institutions include government and industry institutions such as those managing IP rights, training and education institutions and institutions that support small enterprises (Lall, 1992)

2.5.1.1 Firm level technological activities

This involves investment in assets and resources which supports the actual implementation of production processes and depends on product complexity and design characteristics as well as technical skills including those to be acquired on-the-job through learning and innovation (Gonsen, 1998; Goswami, 2018). Production requires personal skills, knowledge and experience to carry out cost effective production to satisfy dynamic market conditions; investment capability refers to the capacity to make investments covering the costs of a project and the ability to tailor the investments to the production demands. It also includes innovation capability which is the ability to develop efficient, effective and less expensive technologies by managing production and related assets (Westphal Linsu Kim and Dahlman, 1984; Grigoriev *et al.*, 2014). Table 2-6 below summarises technological requirements in remanufacturing. The considerations cover product attributes (PA), process (P) attribute, equipment (E) availability and skill set (SS).

Table 2-6: Technological factors in remanufacturing

Technological factors			
N. Mohamed, M.Z.M. Saman, S. Sharif and H.S. Hamzah (Mohamed *et al.*, 2018)	Capacity to manage potential hazards in remanufacturing (P)	An important factor in remanufacturing include access to skilled workers (SS)	Condition of the returns as well as the amenability of product's design to remanufacturing should be considered (PA)
Yan, X.-L., Dong, S.-Y., Xu, B.-S., Cao, Y. (Yan *et al.*, 2018)	It is important to develop techniques for optimising cladding which is important technology in remanufacturing (P)		
Jelena Kurilova-Palisaitiene, Erik Sundin, Bonnie Poksinska (Kurilova-Palisaitiene, Sundin and Poksinska, 2018)	Capacity to manage process times, sequences, and costs (P), (SS).		Design for disassembly noted to be a challenge to remanufacturing (P)
Chaowanapong, J., Jongwanich, J., Ijomah, W. (Chaowanapong, Jongwanich and Ijomah, 2017a)	Capacity to combine the process of remanufacturing with the manufacturing process for OEMs (P)	Availability of skilled workers (SS)	Product design maturity, representing the length of time the product has been in the market without substantial design change (PA).
Janusz, S., Marek, K., Aneta, A., Wojciech, S., Kamil, J. (S Janusz *et al.*, 2017)	The disassembly process of electronic process of modern electronic chips requires extreme caution to avoid electrostatic damage (P), (PA).	Given the sensitivity of the chips to temperature, specialised skill is required to disassemble electronic chips (PA), (SS).	The main challenge in disassembling electronic chips is that they are temperature sensitive (PA).
Kaustov Chakrabortya, Sandeep Mondala and Kampan Mukherjeeb (K Chakraborty, Mondal and Mukherjee, 2017)	Important factors in remanufacturing include availability of equipment and technologies required to carry out remanufacturing (E), (P).	Technical expertise noted to be an important consideration in remanufacturing (SS).	Product design or product design to facilitates reuse (PA).
Kannan Govindan, K. Madan Shankar , Devika Kannan (Govindan, Shankar and Kannan, 2016; Vasanthakumar,	Need for advanced technologies to facilitate disassembly and handling (P), (E).	Limited availability of skilled workforce cited as a barrier to remanufacturing (SS).	Improper product design cited as a barrier to remanufacturing (PA).

Vinodh and Ramesh, 2016)			
N.M. Yusop, D.A. Wahab, N. Saibani (Yusop, Wahab and Saibani, 2016)		Among other factors, OEMs recognise that technical know-how is a potential requirement to the success of remanufacturing (SS).	
Karina Cecilia Arredondo, Humberto Híjar RiveraJorge de la Riva RodríguezRosa María Reyes Martínez (Arredondo-Soto, Karina & Híjar Rivera, Humberto & De la Riva, Jorge & María Reyes Martínez, 2016)	Machine availability, perceived complexity of the recovery process noted as human factor considerations in remanufacturing (P), (E).	Level of expertise including organisational training linked to human factors issues in remanufacturing (SS).	corrosion, pollution, and wear from products during recovery regarded as human factor issues in remanufacturing (PA).
Qinghua Zhu, Joseph Sarkis, Kee-hung Lai (Zhu, Sarkis and Lai, 2014)			Engine manufacturers are reluctant to design for remanufacturing. There are also several brands of a product to develop remanufacturing strategies for (PA).
Xiqiang Xia, Kannan Govindan, , Qinghua Zhu (Xiqiang Xia, Govindan and Zhu, 2015a)	Noted that remanufacturing process is difficult to standardise and that technologies for damage detection are lacking (SS), (E).	Lack of skilled workers cited as a barrier to remanufacturing. There is usually a lack of information on the products to be remanufactured (SS), (PA).	
Shuoguo Wei, Dongbo Cheng, Erik Sundin, Ou Tang (Wei *et al.*, 2015)	Lack of technologies included as barrier to remanufacturing (E), (SS).	Lack of product knowledge and high labour costs cited as barriers to remanufacturing (SS), (PA)	

Lian-Yin Zhai, Wen-Feng Lu, Ying Liu , Xiang Li, and George Vachtsevanos (Zhai *et al.*, 2013)			remanufacturability which is a measure of remaining useful life and/or the reliability of recovered cores noted to be an important consideration in remanufacturing (PA).
C. Fang, H., K. Ong, S., Y.c. Nee, A. (C. Fang, K. Ong and Y.c. Nee, 2013)	Sensor data facilitates sorting and planning of remanufacturing (P).		Increased product value plays a key role in the decision to remanufacture (PA).
Margarete A Seitz, Ken Peattie (Seitz and Peattie, 2004)		Skill availability as well as labour costs affects remanufacturing.	Product proliferation and product life span since products designed to be too durable may not provide opportunity for remanufacture. Product differentiation/customisation as opposed to standardisation (PA).
G.SeligerC.FrankeM.CiupekB.Başdere (Seliger *et al.*, 2004)	Disassembly process is complicated due to unfriendly product designs (P), (PA).	High labour costs in high-income countries pointed out as an issue to remanufacturing.	Among issues to contend with in remanufacturing include rapidly changing product models as well as unfriendly product designs which complicate disassembly. Condition of returns and their prices should also be considered (PA)

NB: PA, SS, P and E refer to Product attribute, skill set, process attribute, and equipment availability. Behind each of these is cost consideration.

2.5.1.2 Roles of institutions

Institutions may be governmental or private; including education and learning systems integrated to the national system of innovation (Olatunji, 2002). Government institutions carry out market regulation, manage intellectual property rights and along with some private institutions, provide support for technology development. Similarly, education and learning institutions transfer knowledge to the people, provide a supply of workforce for industries and contribute to the development of the NTC. Effective education includes industry collaboration with national education institutions (Olatunji, 2002). Table 2-7 below presents areas of influence of institutions on the remanufacturing industry.

Table 2-7: Institutional influences on the remanufacturing industry

S/N	Institutional influence	References
1	Weak regulation decreases potential customers' confidence in remanufactured products	(Subramoniam, Huisingh and Chinnam, 2009; Wei *et al.*, 2015)
2	Lack of quality standards affects remanufactured products	(Zhu, Sarkis and Lai, 2014)
3	Legal framework supporting remanufacturing has not yet been developed. Consequently, potential remanufacturers may have problems determining the legitimacy of their activities.	(Chaowanapong, Jongwanich and Ijomah, 2017a; Bhatia and Srivastava, 2018)
4	Providing a supply of skilled workers through functional education. This has been achieved in China through establishment of several remanufacturing demonstration centres.	(Zhu, Sarkis and Lai, 2014)
5	Rules and regulations regarding opening a remanufacturing enterprise business. Some industry-specific policies discourage remanufacturing. Policies in the developed world have been formulated to support remanufacturing.	(Wei *et al.*, 2015; Chaowanapong, Jongwanich and Ijomah, 2017a; Zhang, Yang and Chen, 2017)
6	Government should regulate the remanufacturing industry to eliminate operators claiming to be remanufacturers but offer low quality products. One way is by developing technical standards for remanufacturing.	(Zhu, Sarkis and Lai, 2014; Zhang, Yang and Chen, 2017)
7	Governments have several policies that have restrictive impacts on remanufacturing. Instances include those prohibiting importations of cores or the importation of remanufactured products to protect local industries.	(Zhu, Sarkis and Lai, 2014; Wei *et al.*, 2015; Baron, 2016a; Govindan, Shankar and Kannan, 2016; Kojima, 2017)

2.5.1.3 Incentives for production

Incentives refer to the actual incentive which motivates investments and learning. According to Lall (1992), a product's market potential can be a an incentive. In Lall's (1992) terms, incentives motivate capabilities; with both interacting within an institutional framework. For example, profitability in the remanufacturing industry, a key incentive which is influenced by factors such as perceived risk is related to the technology available to the remanufacturer for improving the quality of the finished products and also, the remanufacturing awareness among potential consumers as they often do not know the exact processes involved in remanufacturing (Zhang *et al.*, 2011; Hazen *et al.*, 2012). Remanufactured products may also be perceived as risky because customers often consider them to be the same as repaired and refurbished/reconditioned products which are known to be of poorer quality and

without substantial warranty (Ijomah, 2009). Repair only focuses on addressing the failed part of the product or its sub unit (Parkinson and Thompson, 2003; Gray and Charter, 2007; Ijomah *et al.*, 2007; Paterson, Ijomah and Windmill, 2017). Similarly, refurbishment often only provides the most economical reprocessing of used equipment in order to ensure that a product's performance is within the limits considered acceptable for reuse (Parkinson and Thompson, 2003). However, refurbishment is lower than remanufacturing on the quality ladder (Parkinson and Thompson, 2003; Ijomah *et al.*, 2007; Paterson, Ijomah and Windmill, 2017). Unlike repair and refurbishment, remanufacturing takes place in an industrial setting, adhering to both relevant quality management systems and process standards. The remanufactured product is also given a warranty that is at least, equal to that of equivalent new product. In spite of these benefits, remanufacturers still compete for cores and customers with those that carry out repair and refurbishment (Lund and Hauser, 2010) and this limits profitability.

Hence, both competition for cores and market oppose the derivation of incentives from remanufacturing enterprise. Addressing this issue requires promoting awareness among customers, on the superior benefits of remanufactured products. However, as already noted, terminological inconsistency is detrimental to achieving this. Hence, it is necessary to synchronise the terminologies used to refer to alternative and often conflicting EOL processes. Such an effort will help to clarify that remanufacturing gives the best quality products of them all. The government and the private institutions contribute towards achieving this, providing definitions to various extents, for product EOL processes and formulating standards ('CFR - Code of Federal Regulations Title 21', no date; Zhang *et al.*, 2011; MHRA, 2016; Kalverkamp and Raabe, 2018). They are also to collaboratively enact enabling legislation, formulate policies and standards to promote social acceptance of remanufactured products; enhance used products availability, set minimum recovery rates for all new products and provide technological development and training (Zhang *et al.*, 2011; Das and Rao Posinasetti, 2015; Feng, Tian and Zhu, 2016). For instance, implementing policies that portray remanufactured products as acceptable options may contribute to enhancing remanufactured products' acceptance while legislation and/or policies that provide incentives such as tax rebate and preferential financing options may position remanufacturers to develop the right technologies to compete better in the market (Feng, Tian and Zhu, 2016).

2.5.2 Applying the framework to remanufacturing

In the context of this study, production activity refers to remanufacturing. Thus, remanufacturing would involve a skilled workforce, processes and products or parts. Firm level production activities in remanufacturing require technical skills to implement the restoration activities; innovation to maximise profit by resolving uncertainties that characterise remanufacturing (Guide, Jayaraman and Srivastava, 1999; Seitz and Peattie, 2004; Golinska, Golinska and Kawa, 2011; Wei and Tang, 2015; Xiqiang Xia, Govindan and Zhu, 2015b; Hartwell and Marco, 2016; Bhatia and Srivastava, 2018); investment to fund technologies and equipment needs (Zhang *et al.*, 2011; Das and Rao Posinasetti, 2015; Xiqiang Xia, Govindan and Zhu, 2015; Feng, Tian and Zhu, 2016) and consideration of product characteristics, complexity and return potentials (Xiqiang Xia, Govindan and Zhu, 2015b; Arredondo-Soto, Karina and Híjar Rivera, Humberto and De la Riva, Jorge and María Reyes Martínez, 2016; Chaowanapong, Jongwanich and Ijomah, 2017; Chakraborty, Mondal and Mukherjee, 2017; Sitek Janusz *et al.*, 2017; Kurilova-Palisaitiene, Sundin and Poksinska, 2018; Mohamed *et al.*, 2018).

Institutions may be governmental or non-governmental. There are institutions that regulate the market; usually determining the terminology for the industry (USITC, 2012; MHRA, 2016). There are also institutional framework for managing intellectual property issues related to remanufacturing (Hartwell and Marco, 2016; Zhang *et al.*, 2018); providing support for remanufacturing technology development(Zhang *et al.*, 2011; Xiqiang Xia, Govindan and Zhu, 2015b); offering standards such as ANSI and British Standards for remanufacturing; as well as a supply of skilled labour for the industry.

The incentives for Carrying out remanufacturing include profitability, brand protection, fulfilling environmental legislative requirements, providing supply of spare parts as well as to demonstrate ethical and social responsibility (Seitz, 2007; Subramoniam, Huisingh and Chinnam, 2010; Saavedra *et al.*, 2013; D'Adamo and Rosa, 2016; Chaowanapong, Jongwanich and Ijomah, 2018; Kalverkamp and Raabe, 2018). However, uncertainties associated with the remanufacturing process ultimately impact on profitability. According to Guide et al., (Guide, Jayaraman and Srivastava, 1999), these include the following:

1 The recovery rate of parts from returned products is probabilistic and introduces uncertainty in materials planning
2 The condition of recovered parts is usually unknown until they are inspected which introduces stochasticity in routings and lead times.

3 Part matching problem as some components must fit to specific products while others may be common to all products.
4 The need to disassemble a product prior to determining its condition. Disassembly becomes a wasted effort if the returned product is found not to be remanufacturable.
5 The challenge of matching demand for remanufactured products to available core
6 Uncertainty in the quantity and quality of returned products as well as in their return timing.

Some of these uncertainties emanate from the remanufacturer's relationship with stakeholders which include OEMs, suppliers, dealers, institutions especially regulatory institutions; customers, refurbishing and repairing firms (D'Adamo and Rosa, 2016; Östlin, Sundin and Björkman, 2008; Sundin and Dunbäck, 2013). Hence, the remanufacturer needs to be innovative to manage the uncertainties arising from these diverse sources. Tables 2-8 and 2-9 below summarise the potential sources of uncertainties and innovative strategies for overcoming them in the remanufacturing industry.

A remanufacturing technology capability framework developed by applying the Lall's framework to remanufacturing is shown in Figure 2-2.

Table 2-8: Uncertainties in remanufacturing. These uncertainties cut across: technological, institutional, and incentive factors.

S/N	Uncertainties in remanufacturing	References
1	To successfully implement remanufacturing, there has to be an established channel of accessing used engines in sufficient quantity and capability to manage the remanufacturing operation as well as stakeholder relationships. However, material management in remanufacturing involve addressing uncertainty in the following: timing and quantity of returns, the amount of materials to be recovered from returns and consequently, routings of materials for remanufacturing operation given the highly variable processing times. (CC, Incentive-profit)	(Guide, Jayaraman and Srivastava, 1999; Seitz and Peattie, 2004; Golinska and Kawa, 2011; Wei and Tang, 2015)
2	There is uncertainty in the price of remanufactured products due to the unbalance between demand and return as well as quality of cores used (UP, CC, incentive-profit)	(Wei and Tang, 2015)
3	There is uncertainty in the terms of limits considered as intellectual property infringement in remanufacturing. Remanufacturers may thus, have concerns about the legitimacy of their remanufacturing activities. (I- Regulation)	(Hartwell and Marco, 2016; Bhatia and Srivastava, 2018)
4	Consumers may not want to use remanufactured products due to onetime consumption habit or they may only be interested in using new products. (CC- Purchase habit, Incentive-profit)	(Kannan, Diabat and Shankar, 2014; Bhatia and Srivastava, 2018)
5	Consumers may perceive remanufactured products to be of inferior quality. This causes them to have lower willingness to pay for them and affects the overall marketability of remanufactured products and profitability of remanufacturing. (CC- Perception and willingness to pay, Incentive- profit)	(Li and V. D. R. Guide, 2006; Wei *et al.*, 2015; Govindan, Shankar and Kannan, 2016)
6	Customers may not be willing to return used products (CC-Return, Incentive- profit)	(Bhatia and Srivastava, 2018)
7	Consumer demand for remanufactured products is uncertain. Demand uncertainty may be due to rapid change in product technology coupled with the customer's desire to use the latest product technologies; whereas customer demand for remanufactured products and parts is an important reason why firms consider designing their products for remanufacture. (CC- Use habit; PC- Technological change and obsolescence, Incentive- Profit)	(Gray and Charter, 2007; Hatcher, Ijomah and Windmill, 2013; Sundin and Dunbäck, 2013; Janusz *et al.*, 2017; Bhatia and Srivastava, 2018)
8	Brand influence including brand equity, seller reputation or remanufacturer identity. Consumers purchase OEM remanufactured	(Subramanian and Subramanyam, 2012; Kurilova-

	products at higher prices. (Type of remanufacturer-OEM, IR, CR, Incentive- profit)	Palisaitiene, Sundin and Poksinska, 2018)
9	Cultivating demand for remanufactured product cited as a barrier. Market demand is thus an important issue to consider in remanufacturing. (CC, Incentive- profit)	(Seliger *et al.*, 2004; Chakraborty, Mondal and Mukherjee, 2017)
10	Poor experience from the use of lower quality refurbished or repaired products may make potential remanufactured products users to be reluctant. (CC, Refurbishment operators, Repair operators, Incentive-profit)	(Zhu, Sarkis and Lai, 2014)
11	Customers may rather get more interested in purchasing remanufactured products than new ones or otherwise, cannibalise the market for new products. Out of fear for such events, some manufacturers are reluctant to consider remanufacturing. (OEM)	(Zhang, Yang and Chen, 2017)
12	Quantity and quality of cores from suppliers are usually uncertain. A recurring problematic parameter with supplier relationships is to receive the ordered quantity of cores from the supplier (PC, Incentive-profit)	(Subramoniam, Huisingh and Chinnam, 2009; Lind, Olsson and Sundin, 2014; Wei *et al.*, 2015)
13	The remanufacturing industry is a complex industry. Remanufacturers, manufacturers, dealers, service stations, consumers, and their interactions such as competition for used products and market occur in the industry. Refurbishing firms and the government are also involved in this business, with the latter playing an important role. (OEM, I, Refurbishment, Repair, Service)	(Bulmus, Zhu and Teunter, 2014; Zhang, Yang and Chen, 2017)
14	Availability of sales channel (distributorship) for the remanufactured products found to be an important consideration in the machinery equipment remanufacturers since remanufacturers note the lack of specific market to sell remanufactured products as a barrier to remanufacturing. (D)	(Wei *et al.*, 2015; Govindan, Shankar and Kannan, 2016)
15	The quality and degree of OEM-remanufacturer communication and/or support between them affects the integration of design for remanufacture into products design. (Incentive)	(Hatcher, Ijomah and Windmill, 2013)
16	The presence of cheaper new similar products can affect the profitability of remanufacturing. A typical case exists where equivalent new products selling for lower price forced a prominent remanufacturer in the US out of business due to the entry of cheaper equivalent brands to its offering. (D)	(Subramoniam, Huisingh and Chinnam, 2009)

D: Distributors, I: Institutions, CC: Consumer characteristics, P: Profitability, CD: Channel of distribution, UP: used products availability (quality and quantity)

Table 2-9: Potential innovative solutions for managing uncertainties.

S/N	Potential innovative solutions for managing uncertainties	References
1	Core classification according to quality levels.	(Guide, Daniel, Teunter and Wassenhove, 2003; Ferguson *et al.*, 2009; Denizel, Ferguson and Souza, 2010; Teunter, Douwe and Flapper, 2011)
2	Uncertainties in demand, quantity and quality of returns and price can be managed by formulating the problem as an optimisation task.	(Guide, Jayaraman and Srivastava, 1999; Guide, 2000; Goodall *et al.*, 2015)
3	Techniques for managing quality uncertainty include prognostic health monitoring, using RFID tagging,	(Kulkarni, Ralph and McFarlane, 2007; Parlikad and McFarlane, 2007; Wang *et al.*, 2015)
4	Frameworks to clarify potential doubtful issues and promote understanding of remanufacturing.	(Ijomah and Childe, 2007; Chan, Chan and Jain, 2012)

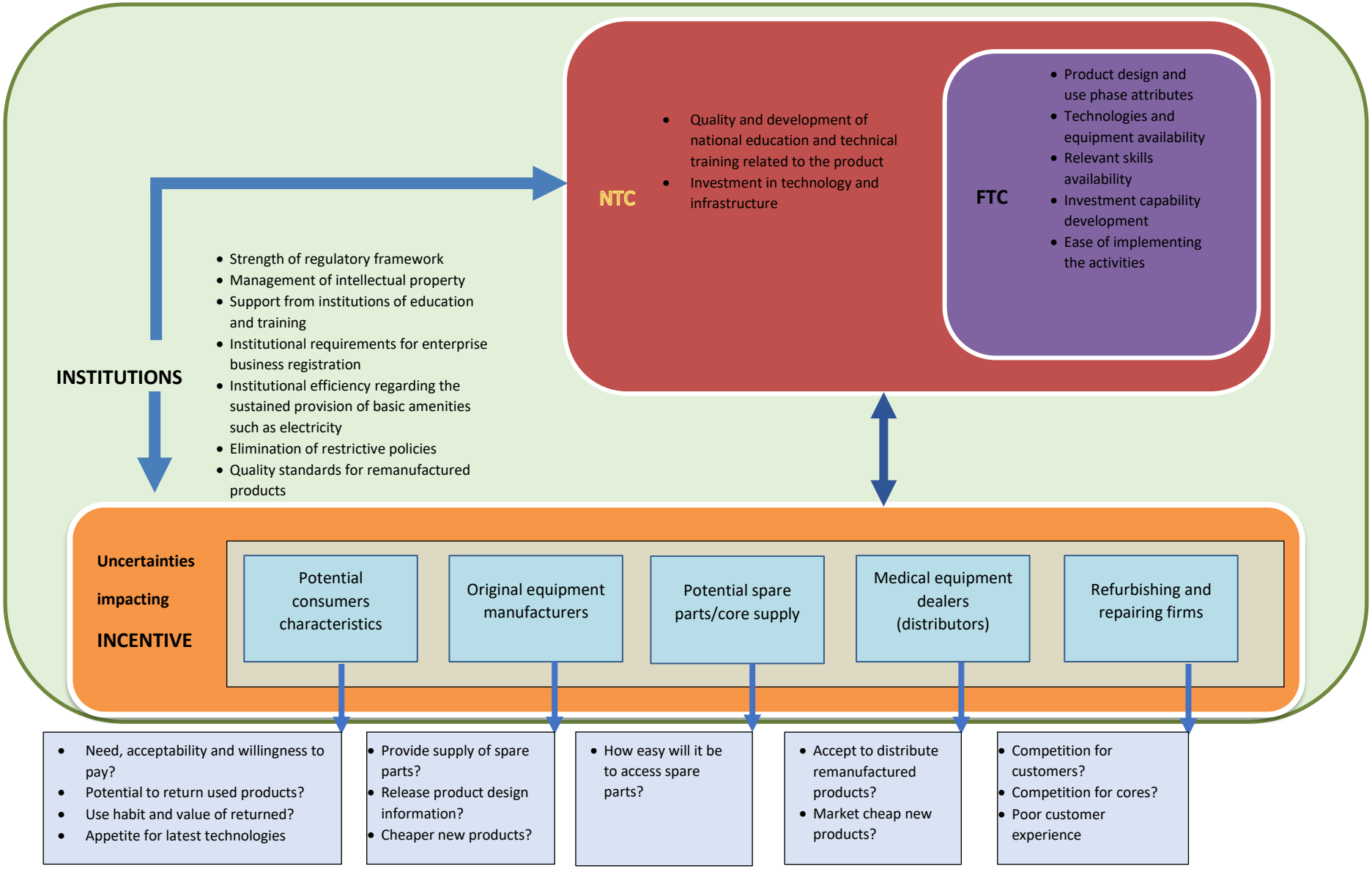

Figure 2-2: Remanufacturing framework for identifying key factors in remanufacturing

2.5.3 Positioning the current study within the framework.

The motive for conducting remanufacturing includes not just profitability but environmental and social benefits. Of the three, profitability is intuitively the most important because there is relatively low concern for environmental impacts in developing countries (Malik and Abdallah, 2019). Also, social benefits are only feasible if remanufacturing is successfully implemented profitably. In this section, factors relevant to medical equipment remanufacturing are identified using the framework.

2.5.3.1 Medical equipment as good candidates for remanufacturing

A variety of products including automotive products, aviation equipment, photocopiers, medical equipment, machine tools, cranes and forklifts, military equipment, furniture products, electrical and electronic products are currently being remanufactured (Toffel, 2004; Ferrer and Swaminathan, 2006; Matsumoto and Umeda, 2011; USITC, 2012; Zhang *et al.*, 2015). Products that are remanufactured usually fulfil specific requirements including the following (Lund, 1984; Shu and Flowers, 1999; Gray and Charter, 2007; Hatcher, Ijomah and Windmill, 2011; Abdulrahman *et al.*, 2015):

1. A reverse flow of the products exists after use.
2. The product must be disassemblable, allowing access to the internal parts and components.
3. The used products retain substantial added value because of the durability of its parts.
4. Customer demand for the product exists after remanufacturing and the product must have market value to guarantee profitability.
5. Recoverability of parts as well as the extent to which the product's parts match
6. The product's technology is stable; minimising obsolescence issues such as market destruction.
7. The used product can be upgraded during the remanufacturing process.

Medical equipment, particularly the expensive ones fulfil some of these requirements and there is strong evidence of remanufacturing in the industry (Lund, 1984; Ferrer and Swaminathan, 2006; USITC, 2012; D'Adamo and Rosa, 2016; Kodhelaj *et al.*, 2019) although it is not yet clear how it is conducted in the medical device industry.

2.5.3.2 Assessing technological requirement for the medical equipment remanufacturing process

Currently, there is no information about the technologies used in medical equipment remanufacturing. However, in the wider remanufacturing literature, technologies such as Radio Frequency Tagging has been used to monitor the transit as well as health status of cores (Kulkarni, Ralph and McFarlane, 2007; Parlikad and McFarlane, 2007). There are also technologies for carrying out component recovery on worn and/or damaged parts. Recovery involves correcting damage which requires repairing, refurbishing or reconditioning feasibility (Bras and Hammond, 1996). Some of the latest recovery technologies include laser deposition technology, laser cladding for revamping damaged surfaces and improve wear resistance (Matsumoto *et al.*, 2016; Lei *et al.*, 2017), cold spray technology which coats and/or fills surface cavities using particles accelerated to supersonic speed by compressed gas jet (Champagne and Helfritch, 2014; Yeo, Pepin and Yang, 2017) and ultrasonic non-destructive technology (Yan *et al.*, 2018). Advanced cleaning technologies including the use of supercritical carbon dioxide (Li *et al.*, 2016) have also been developed for remanufacturing. It will thus, be necessary to:

i. *consider the availability of relevant equipment ant technologies and assess how it may impact medical equipment remanufacturing*.

2.5.3.3 Other technological factors necessary for medical equipment remanufacturing.

Remanufacturing requires the availability of investment and consideration of technical skills as well as product attributes. It is necessary to assess their impacts on MER.

2.5.3.3.1 *Skill set for medical equipment remanufacturing.*

Due to the complexity of the involved activities, technical skills are important to the successful implementation of remanufacturing (Seitz and Peattie, 2004; Arredondo-Soto and Humberto, De la Riva and María 2016; Yusop, Wahab and Saibani, 2016; Chaowanapong, Jongwanich and Ijomah, 2017a; S Janusz *et al.*, 2017; Mohamed *et al.*, 2018). The availability and/or cost of hiring skilled workers have therefore been considered to be important for the implementation of remanufacturing (Seitz and Peattie, 2004; Seliger *et al.*, 2004).

While developing countries' production capability may be poor in terms of manufacturing new medical equipment, the capability to conduct remanufacturing may not be so much beyond that which is available, especially among distributors of multinational medical equipment companies. This is because the level of technological advancement needed to carry out product remanufacturing is often less than, if not different from that required to develop new products.

Remanufacturing requires assimilating the design and working principles of products and applying recovery technologies only on parts that fail beyond re-use threshold. The low wage rates in developing countries is likely to drive down the labour cost but the problem is whether the people with the required expertise can be found. It will therefore be relevant to determine the extent to which available technical expertise matches the requirements of medical equipment remanufacturing in developing countries. Hence, it will be appropriate to examine the following:

ii. Availability of workers with relevant technical skills to carry out medical equipment remanufacturing.

2.5.3.3.2 *Investment capability for medical equipment remanufacturing.*

A key barrier to the implementation of remanufacturing is the need for upfront investment which involves high initial set-up costs for new facility, recruitment and overhead (Abdulrahman *et al.*, 2015; Xiqiang Xia, Govindan and Zhu, 2015; Kaustov Chakraborty, Mondal and Mukherjee, 2017). In addition, lack of funds often threaten research and equipment procurement for remanufacturing (Zhu, Sarkis and Lai, 2014; X Xia, Govindan and Zhu, 2015).

The current study should therefore evaluate:

iii. The affordability of investment in resources to carry out medical equipment remanufacturing.

2.5.3.3.3 *Impact of product attributes on medical equipment remanufacturing.*

Products' design decisions such as materials, geometry, fits, fastener and joint types are usually determined by functionality and cost; thus, one of the main barriers to remanufacturing is the scarcity of products designed for remanufacture (Ijomah, 2009). Many decisions made at the design phase affect products' potential to be remanufactured (Hatcher, Ijomah and Windmill, 2011, 2014). According to Shu and Flowers, remanufacturable products are designed to ease transportation, cleaning, inspection, disassembly, sorting, recovery, upgrade and testing (Shu and Flowers, 1999). Several studies in remanufacturing have analysed the impact of product design. These include studies that analyse how the product's design affects remanufacturing in terms of facilitating the individual sub-processes of remanufacturing. This class of studies include design for disassembly (Soh, Ong and Nee, 2014; Wang *et al.*, 2014; Sabaghi, Mascle and Baptiste, 2016), design for cleaning which requires that components provide access for the passage of cleaning agent (Shu and Flowers, 1999) while being durable enough to withstand vigorous cleaning as may be required (Hundal, 2000; Ijomah, 2009). Similarly, design for

upgrade studies aim to promote product upgrade through improved product design (Xing *et al.*, 2007). These studies emphasise that remanufacturability is decided at the design phase of product development.

In addition to these design considerations, medical equipment remanufacturing would also require disinfection, packaging and labelling considerations. The overall impact of product design is usually incident on the ease of performing the activities involved in remanufacturing, even in instances where there are well developed technologies and skilled manpower. The ease of disassembly, cleaning, inspection and upgrade therefore reflect extents to which product design permits each of these activities.

Medical equipment vary greatly in scope from simple to very complex ones and thus, exhibit widely differing design attributes. However, since they are used on people, disinfection is therefore, an important consideration in remanufacturing them. Unlike cleaning which just aims to make the surfaces of the used product neat so as to enhance inspection and surface treatment, sterilisation/disinfection aims to eliminate (sterilisation) or reduce the bioburden on the medical device surfaces. While mild disinfection may be required for less critical medical equipment, critical medical equipment which contact the blood and sterile tissues of the body must be subjected to high level disinfection or sterilisation.

Sterilisation may cause material deterioration or even chemical invasion to patients or users if the process leaves residues. In addition, improper sterilisation can cause cross contamination (Rutala and Weber, 2004). Like cleaning, the effectiveness of sterilisation depends on geometry such as lumen length and diameter for products made of tubular parts. It can also be affected by the presence of organic materials and inorganic salts on the surface (Rutala and Weber, 2008). Thus, cleaning usually precedes disinfection.

Conventionally, remanufacturing involves upgrade to at least, as good as new quality (Lund, 1984; Guide, 2000; Gray and Charter, 2007). However, with newer product versions, the efficiency and product utility increases, making it imperative for remanufacturers to do more than “restoration to as good as new quality” in order to be competitive. Remanufacture with upgrade is therefore, an attractive way to add greater value to a product being remanufactured; while constraining it to the same physical configuration (Xing *et al.*, 2007). Upgradeability in remanufacture involves the addition or replacement of existing software, hardware parts, assemblies or subassemblies to achieve a more desirable effect from a product. Xing et al. (2007) proposes a product upgradeability and reusability evaluation model which specifies

the characteristics of products that are upgradeable during remanufacturing as follows:

1. Compatibility with generational variety: This refers to the product's ability to meet and accommodate the improvements necessary to bring its functionality to future standards. This requirement demands designers' ability to foresee the most likely functional changes during a product's lifecycle and the impact of such changes on the engineering requirements of the upgrade. Compatibility with generational variety, therefore, simply implies the difference between the product's current features' design specifications and its forecasted features' engineering requirements. The higher this value is, the less the less compatible the product would be to generational variability.
2. Fitness for extended use: Reuse of products during remanufacturing is predicated upon its fitness for extended use. This requires that the product will be both functionally and physically reusable. Functional reusability ensures that the product would still conform to the user's technological and functional expectations. These are related to technological maturity, obsolescence, functional performance, and design cycle. On the other hand, the physical reusability criterion underscores a product's ability to sustain intended functions over a prescribed time. This is time dependent and accounts for the product's potential reliability and failure.
3. Cluster independence and correspondence ratio: These are used to assess the product's modularity which facilitates disassembly, replacement, and functional integration. Cluster independence and correspondence ratio shows the strength and interrelationships of components within an assembly or subassembly.

Currently, OEM refurbished medical equipment have their software upgraded to the latest technology (Parker *et al.*, 2015). Justifications for hardware upgrade may however, also exist; especially in developing countries where upgrade may be necessary to adapt the equipment to the existing needs. Thus, it will be appropriate to assess the ease with which current designs of medical equipment permit remanufacturing by considering the following activities in the process:

iv *Types of medical equipment for which remanufacturing is possible based on design considerations: considering the following:*

a. Ease of disassembly

b. *Ease of inspection*

c. *Ease of cleaning*

d. *Ease of disinfection*

e. *Ease of recovery*

f. *Ease of upgrade*

g. *Ease of packaging*

h. *Potential hazard risk to workers*

i. *Different models of the equipment available*

2.5.3.4 Assessing potential uncertainties associated with medical equipment remanufacturing.

2.5.3.4.1 *Addressing quality, quantity uncertainty*

Due to the inherent uncertainties in core quality and quantity, processing times and costs of remanufacturing vary, complicating the process planning and scheduling. Several strategies have been developed for managing uncertainties associated with stochastic quality of cores. The approaches for managing quality issues include quality grading of returns and demand matching against production (Guide, Daniel, Teunter and Wassenhove, 2003; Teunter, Douwe and Flapper, 2011). By grading returns according to quality classes based on its known probability distribution, profitability of remanufacturing can be increased by up to 4% (Ferguson *et al.*, 2009). It is possible for either the suppliers or the remanufacturer to carry out the quality grading. However, when the grading is done by the supplier, the classification error at the collection site increases the difficulty and cost of secondary sorting at the remanufacturing floor (Wassenhove and Zikopoulos, 2010).

Pokharel and Liang (2012) Developed a model to evaluate acquisition price and quantity of used products for remanufacturing. They present a scenario where the remanufacturer acquires its cores from a third-party consolidation centre that sources used products and consolidates them with the new parts needed to make necessary replacements during remanufacturing. The analysis which assumes that returns follow a normal distribution is a potential technique to deal with cases where the consolidation centre's mean acquisition of core either equals or exceeds the remanufacturer's demand.

Some of the techniques that are available for assessing the quality of returns include Failure mode effects and criticality analysis (FMECA), prognostic and health management techniques as well as radio frequency identification technology.

The success of remanufacturing largely depends on the ability to innovatively manage the uncertainties in quality and quantity of cores as well as in demand. Thus, in implementing medical equipment remanufacturing in developing countries, it is imperative that the following be examined:

v. Availability of cores in acceptable quantity and quality

2.5.3.4.2 *Influence of uncertainties due to customer characteristics on MER*

The manufacturer's and of course, remanufacturer's overall aim is to maximise profits by satisfying the customers. Products are therefore developed to fulfil this objective. But products have different market potentials; that is, the degrees to which potential users are willing to accept and pay for them. Thus, the market potential of a remanufactured product refers to its likelihood to be sold after remanufacturing. Products with potential for mass sales and high core value also increase profitability and thus, economic potential (Lund, 1984; Widera and Seliger, 2015). Additionally, the number of competitors a product has, is an important external success factor common to remanufacturable products (Zwolinski and Brissaud, 2008)

Potential customers usually regard remanufactured products as low quality because they do not understand the quality assurance requirements of the process. This negative perception usually affects their willingness to pay for remanufactured products. Fast changing technologies may also create uncertainty in potential demand for products as technology becomes obsolete (Sundin and Dunbäck, 2013). Another important consideration is the potential users' willingness to return used products timely for remanufacture (Bhatia and Srivastava, 2018).

It is thus, necessary to assess the following with respect to developing country context:

vi. Potential demand for remanufactured medical equipment

vii. Potential users' acceptance of remanufactured medical equipment

viii. Return potential of used equipment for remanufacture.

ix. Potential impact of product obsolescence in the success of medical equipment remanufacturing.

2.5.3.4.3 *Assessing the uncertainties from OEMs, suppliers and dealers on medical equipment remanufacturing.*

Relationship with manufacturers, suppliers and dealers is important to the success of remanufacturing. Innovative strategies are therefore needed to coordinate the core acquisition strategies to improve the quality and quantity. This is usually achieved by building relationships with the supply chain players including OEMs, dealers/distributors, spare parts suppliers, and especially, customers (Östlin, Sundin and Björkman, 2008). There are cases where the main source of cores are in different geographical location from where remanufacturing is being implemented (Guide et al., 2003).

In remanufacturing, up to 30% of all parts may be have to be replaced (Guide, 2000). This underscores the importance of secure spare parts supply to remanufacturers. In addition to spare parts supply, relationship with OEMs has the potential to guarantee access to product design information or other technical support vital to the remanufacturing process and can also address potential intellectual property (IP) issues.

IP laws grant monopoly rights to individuals and organisations that initiated and registered a technological idea. This law supports and enhances commercial activity by allowing the owners of such rights the monopoly over their ideas. Intellectual property laws are broadly categorised into (Hartwell and Marco, 2016):

1. Trade secret law which aims to preserve an idea from being divulged to the public
2. Patent law which is aimed at registering an idea with the public.

In relation to remanufacturing, IP laws can be both a motivator and a challenge. It has the potential to motivate OEMs to embark on the remanufacture of their own products to avoid divulging their trade secret to third party operators who will eventually provide the service if they fail to remanufacture and service their products themselves. For the third-party operator, the law introduces issues and uncertainties that call for greater insights as to what constitutes the boundaries of IP rights (Hartwell and Marco, 2016). It is therefore appropriate to consider the following with respect to medical equipment remanufacturing in developing countries:

x. Access to product design information.

xi. Access to replacement/spare parts.

xii. Potential impact of intellectual property issues and ways of addressing them.

2.5.3.5 Institutional influence on medical equipment remanufacturing.

Institutions are responsible for making policies and legislation that guide industries and regulate them. For instance, policies on education play a key role in the availability of skilled workforce and is an essential component of national strategy for innovation (Olatunji, 2002). Legislation may also restrict remanufacturing or affect the market potential of remanufactured products. Typical examples of restrictive legislation is the regulation on hazardous substances (Baron, 2016).

Institutions in charge of medical equipment regulation in developing countries are often weak or inexistent (WHO, 2011; Coe and Banta, 2017) and this allows passage to low quality medical equipment into many developing countries. Due to poor institutional ineffectiveness and inefficiency, many developing countries also experience infrastructural decadence which makes doing business difficult and more expensive (Mamatzakis, 2008). While it seems that public infrastructure does not have significant impact on industries with lower level technological advancement (Mamatzakis, 2008), it will be interesting to determine its perceived impact on medical equipment remanufacturing as it is known that developing countries present particular difficulty to new enterprise businesses (WHO, 2016). Therefore, it is necessary to determine the following:

xiii. *Restrictive regulation and difficulty obtaining regulatory approvals to set up remanufacturing enterprise, including business registration and licensing.*

xiv. *The difficulty obtaining necessary licences to market remanufactured products.*

xv. *The condition of municipal infrastructure such as electricity, required in carrying out medical equipment remanufacturing and the potential impact it may have on the success of remanufacturing.*

xvi. *The trust in market regulatory institutions and its potential impact on the demand for remanufactured products.*

2.5.4 A theoretical framework for the current research

The theoretical framework was adapted from a technology capability framework proposed by Lall (1992). This helped to identify the key factors in remanufacturing. The factors identified will form the basis of the research that follows. One key area identified in the framework is institutional influence. In the medical device industry, this is reflected in the regulations which abound (Shah, Robinson and AlShawi, 2009). It therefore becomes necessary to study the potential impact of regulation on

remanufacturing in more detail. This is accomplished in section 2.6. Furthermore, the most likely motive for implementing medical equipment remanufacturing in a developing country would be to make profit. Other benefits such as brand protection may not be relevant as developing countries do not currently compete much in the global medical devices market. The profit from remanufacturing has been shown to be dependent on willingness to pay which is dependent on purchase intentions (Li and Guide, 2006; Bulmus, Zhu and Teunter, 2014). For medical equipment remanufacturing, this therefore deserves a further study and so, a review of work done in this area of remanufacturing is covered in section 2.6. A framework showing how the different phases of this research work address each research question is shown in Figure 2-3.

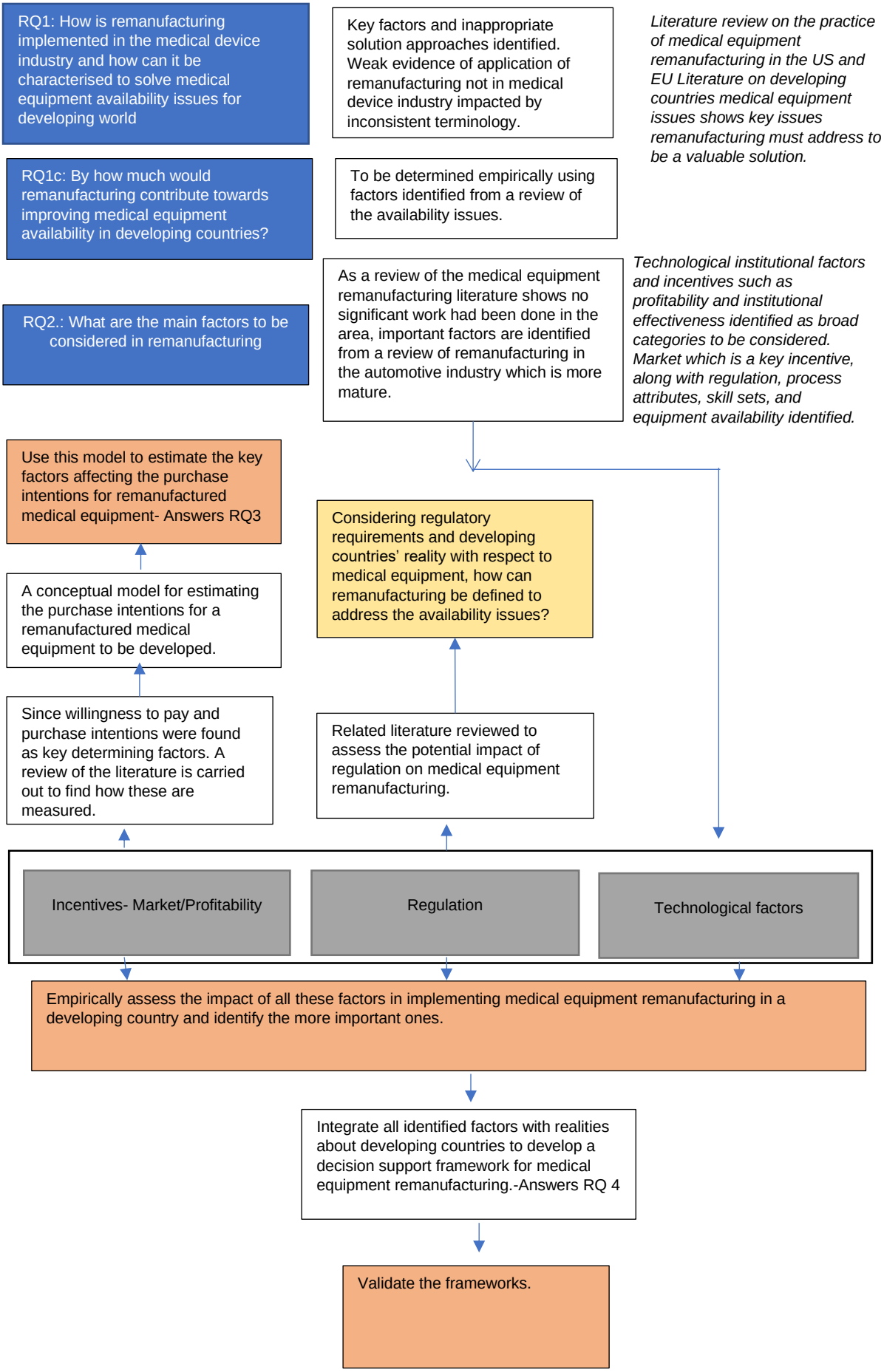

Figure 2-3: Organisation of the different phases of work in this research. The Figure also shows how the different phases address each research question.

2.6 A Potential impact of regulation on medical equipment remanufacturing.

From the literatures already completed, the developing countries' needs with respect to medical equipment remanufacturing are already obvious and include access to functional medical equipment at lower prices, building capacity for efficient maintenance of medical equipment including the more complex ones, accessing spare parts and accessories promptly and establishing effective supply chain relationships which will ultimately facilitate effective communication of medical equipment needs. To ensure the effectiveness of any solution proposed to address these requirements, it is important to consider the impact of regulation on activities like remanufacturing in the medical device industry. An understanding of potential regulatory influence on medical equipment remanufacturing will ensure that remanufactured products gain the approval to be sold in a country's market.

Initially, a literature search was performed on Scopus using the keywords "Remanufactur*" AND ("Medical equipment" OR "Medical device*") with the aim of retrieving information on publications relating to remanufacturing in the medical device sector. Grey literature search was then performed to gather information on the regulation of activities relating to remanufacturing in both the US and EU.

The positions of the European Union's (EU) MDD and United States of America (US) FDA regulations regarding remanufacturing or related activities were analysed against the conventional definition of remanufacturing in (Lund, 1984; Hammond, Amezquita and Bras, 1998; Ijomah, Childe and Mcmahon, 2004; Gray and Charter, 2007; Paterson, Ijomah and Windmill, 2017). Further, data on OEM refurbishment of medical imaging equipment were extracted from the European Remanufacturing Network's market report (Parker *et al.*, 2015). Consideration of OEM refurbishment was necessary as the practice was found to be similar in many aspects, to remanufacturing.

2.6.1 Regulation of market activities related to medical device remanufacturing in the EU.

The Centre for devices and radiological health of the Food and Drug Administration (FDA) regulates the medical device market in the US while the competent authority in each EU state performs the role according to the provisions of the Medical device directive 93/42/EEC, Directive 90/385/EEC on active implantable medical devices which are amended to Directive 2007/47/EC and Directive 98/79/EC on in-vitro diagnostic medical devices. The competent authority reports to the minister of health and ensures that the content of medical device directives are correctly integrated into

the national law and properly applied to grant qualified medical devices access to the EU states' market (Santos *et al.*, 2012). The competent authority in the UK is the Medicines and Healthcare Products Regulatory Agency (MHRA).

Across the EU states, the Directives require manufacturers to declare the conformity of their class I devices according to relevant guidelines. For other classes of medical devices, a designated independent body or notified body in the state assesses the conformity of the products before placing them on the market. Similarly, in the US, while general and special controls apply to class II and class III medical devices, only the general controls apply to class I devices.

2.6.2 Remanufacturing according to the EU Medical Device Directives

There is no mention of the term 'remanufacturing' in the EU medical device directives (MDD). The closest term to remanufacturing in the directives is 'full refurbishment' of medical equipment, which is for this reason, considered in this section. A medical equipment is fully refurbished if it is completely rebuilt or made 'as new' from existing equipment with the addition of new parts and with a new useful life assigned to the resultant product which is then, reintroduced to the market in the name of the entity that performed the full refurbishment (Coordination of notified bodies medical devices on 93/42/EEC and 98/79/EC, 2000). The act of "placing on the market" for a fee, to be paid by another user consummates medical equipment full refurbishment. The entity that performs full refurbishment according to the directive has the same obligations as a manufacturer in the appropriate EU device directives. Such operators are therefore required to satisfy the same conditions expected of manufacturers such as quality systems management as well as declaring the conformity of their products with appropriate directives by applying for and affixing a CE marking on them.

It is essential to note that fully refurbished medical equipment is based on used equipment which is adequately restored and then placed on the market for sale, hire or use by a different user. Figure 2-4 depicts the full refurbishment process in the EU MDD. As shown, the first stage is apparently the same as remanufacturing if replacement parts are identical to the replaced parts such that the intended use of the resultant product is sustained. The second stage represents the operator's intention which is to re-identify the device in its name before placing it on the market in stage 3.

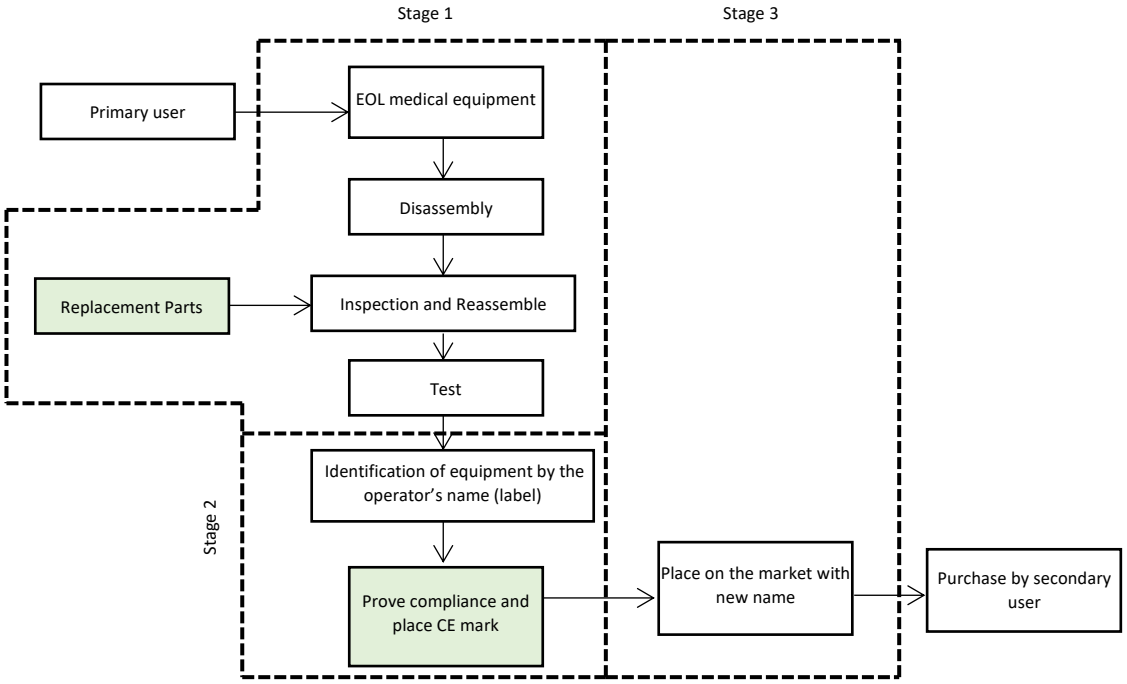

Figure 2-4: Schematic diagram showing the process of full refurbishment as portrayed in the EU MDDs 2007/42/EC and 98/79/EC.

The first stage is apparently the same as remanufacturing as long as replacement parts are identical to the replaced parts such that the intended use of the resultant product is sustained. The second stage represents the operator's intention which is to re-identify the device in its name before placing it on the market in stage 3.

2.6.3 Regulation of medical device remanufacturing in the US

The US FDA defines remanufacturing as the processing, conditioning, renovating, repackaging, restoring, or any other act that significantly changes a finished device's performance or safety specifications, or intended use (USITC, 2012).

Although relatively less strict in scope, this definition attempts to accommodate all the end-of-life processes in the medical- device sector such as reprocessing of single use and multiple use devices. FDA-defined remanufacturers are required to have their products approved by fulfilling the requirements of section 510(k) of the Federal drug and cosmetics (FD&C) Act or through the premarket approval (PMA). This is because their operation according to the regulators, would significantly change the performance and/or safety specification of the original products. In fact, the main emphasis in the FDA's definition of remanufacturing is "*significantly changes to a finished device's performance or safety specification*." The 510(k) route requires manufacturers or FDA-defined remanufacturers to demonstrate that the device is at

least, as substantially safe and effective as a marketed equivalent in the US. The PMA, on the other hand, is the most stringent approval route required by the FDA for devices that do not have an existing equivalent or predicate in the US market (Fargen Kyle *et al.*, 2013). The FDA grants it following the examination of scientific evidence such as randomised clinical trials (RCT) demonstrating the device's safety and effectiveness (van der Laan *et al.*, 1999). There is however, no regulation currently, for activities such as repair and refurbishment that are not regarded to change a finished product's performance or safety specification. Figure 2-5 summarises the FDA position on remanufacturing and related activities.

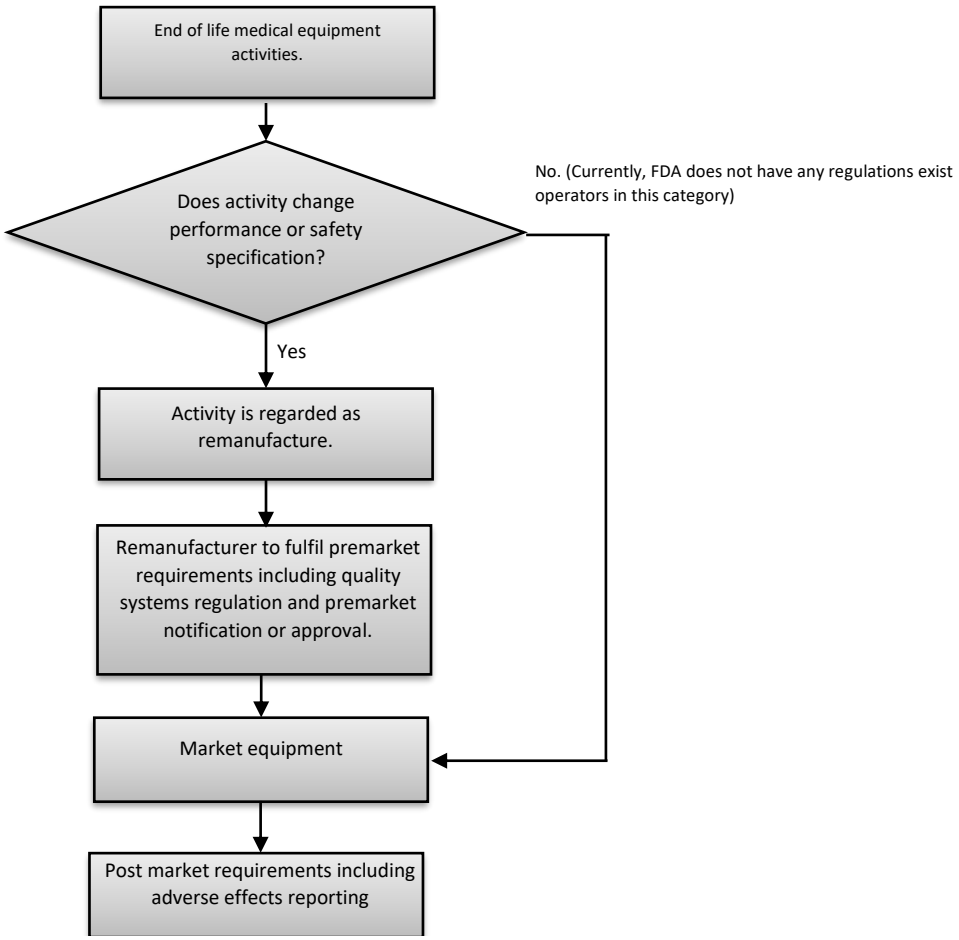

Figure 2-5: Flow chart describing FDA's end of life medical equipment activities.

2.6.4 medical device reprocessing

According to Parkinson and Thompson (Parkinson and Thompson, 2003), reprocessing includes both refurbishment and remanufacturing. In the medical device sector, reprocessing represents a broad range of activities some of which include simple cleaning, various levels of disinfection or sterilisation and/or repackaging with or without disassembly.

Sterilisation is the highest level of disinfection which aims at killing all the microorganisms present in a component using physical, chemical or physiochemical means. It is distinct from cleaning and usually introduces several quality and safety issues as the number of reprocessing cycle increases. For instance, the physicochemical Nano-scale etching of electrophysiology catheter shaft sterilised with hydrogen peroxide gas plasma increases with the number of reprocessing cycles (Tessarolo *et al.*, 2004). Also, deep cracks and deposit of contaminants begin to occur if an endoscope is reprocessed up to five times (Lee *et al.*, 2015). These effects introduced by reprocessing can be dangerous they render the device unfit for purpose and residual sterilising agent may cause toxic effects if they make contact with patients [(Smith and Agraz, 2001, 2001). Despite these observations, the reprocessing of SUDs appears to be gaining greater support both in the developed and developing countries. However, in developed countries, only expensive SUDs are reprocessed while developing countries reprocess even inexpensive SUDs to save cost (Popp *et al.*, 2010; Shuman and Chenoweth, 2012).

The main reasons why SUD reprocessing is becoming popular include:

- Economic reasons as some single-use devices are costly and several may be used in a single procedure. For instance, an ultrasound catheter costs up to 5000 US dollar (Collier, 2011)
- The belief that some devices are just labelled as SUDs by manufacturers who would profit if hospitals replace rather than reuse them (Sloan and Sloan, 2007; Collier, 2011).
- To reduce environmental pollution and cost of safe disposal of medical wastes (Collier, 2011; Unger and Landis, 2016).
- Regulators such as the FDA grant premarket approval to OEMs based on the intended use of their devices. OEMs may merely label their devices SUD because they do not wish to carry out studies to show that the devices can be reused. Moreover, OEMs of some reusable products often relabel the products SUD without changing the design significantly (Kapoor *et al.*, 2017)
- FDA finds no reasonable evidence that reprocessing and reuse of single-use devices result in increased risk of cross-infection (Smith and Agraz, 2001b; Unger and Landis, 2016).
- Some OEMs such as Stryker and Medline currently offer reprocessed SUDs as part of their overall cooperate offering (Vukelich, 2016).

2.6.5 Remanufacturability of SUDs

To correctly apply remanufacturing, it would be necessary first, to determine what constitutes remanufacturing in relation to SUDs and whether existing practice within the medical device industry can be regarded as remanufacturing or amended. It would thus, be necessary to develop a suitable means of characterising what constitutes remanufacturing for SUDs. One way of achieving this may be to develop process-dependent guidelines in line with existing definitions of remanufacturing; while specifying necessary quality system requirements. This is however, not in the scope of this research.

The EU medical device directives do not approve SUD reprocessing due to safety and quality concerns. Anyone that reprocesses a device or remanufactures it would therefore, accept the full legal responsibility of a manufacturer. Thus, the MHRA distinguishes SUD remanufacture from reprocessing and released guidelines for potential remanufacturers which explicitly regards them as manufacturers. The guideline also requires them to operate in closed loop supply arrangement with partnering healthcare institutions. According to the MHRA, the operators are to both demonstrate that their products are fit for the EU market just like manufacturers of new medical equipment and accept to be liable in case of any adverse incidents arising from using their medical device (MHRA, 2016).

More than the developed world, SUD reprocessing and remanufacturing of medical devices would be beneficial to developing countries given their poor socioeconomic reality and technological advancement. However, many developing countries do not yet have sufficient regulatory framework in place, to monitor both SUD reprocessing and remanufacture to ensure that resultant products would be safe and effective (Popp *et al.*, 2010; Kapoor *et al.*, 2017).

2.6.6 Analysis of the EU and US perspectives

The three essential components of full refurbishment include: 1) Activities involved in adequately restoring the used medical equipment, 2) Re-identification of the product to reflect the full refurbisher's identity, 3) Placing the medical equipment on the market in the name of the entity that carried out the full refurbishment. As already noted, the person responsible for full refurbishment is required to recertify the equipment.

As full refurbishment involves "placing in the market", it would be easy to observe that full refurbishment is not applicable to medical equipment that are already in the market, except the refurbisher intends to market or lease the equipment in their own name. This means that an equipment which is adequately restored without being

renamed by the refurbisher, but which is already in the market can be said to be just refurbished and there would be no need for recertification. The Medical device directives support this. The quality of the restoration activities involved in the full refurbishment process which is similar to those of the remanufacturing process can be validated through recertification when the equipment is to be placed in the market. However, when it is not full refurbishment, for example, when the equipment is already in the market and does not need to be recertified, then there would be needed to have a method of ensuring that the quality of the restoration activities are done properly. The MDD does not have such provision.

The FDA-defined remanufacturers are required to abide by the quality systems (QS) regulation which is the current good manufacturing practice (CGMP) (van der Laan *et al.*, 1999). Remanufacturers according to the FDA include those that carry out reprocessing of single-use medical devices. This class of operators are said to alter the intended use of a medical device by changing it from single-use to multiple-use (Centre for Devices and Radiological Health, 1996).

In addition to implementing QS regulations, FDA-defined remanufacturers are required to follow the designated routes of premarket notification or premarket approval to introduce their products to the market. However, the FDA's definition does not provide a basis for deciding whether a device is remanufacturable. It also regards remanufactured medical equipment to be substantially changed. This may be due to the wide variety of medical devices available in the market which may complicate characterisation of remanufacturability or misconception of the term "remanufacturing".

From the broader remanufacturing literature, a product is remanufacturable if it has a core which is disassemblable, with the possibility of thorough cleaning, inspection, replacement/repair of damaged components such that the resultant product becomes at least, as good as new with matching or better warranty (Lund, 1984; Ijomah, Childe and Mcmahon, 2004; Gray and Charter, 2007; Paterson, Ijomah and Windmill, 2017). This definition highlights that remanufacturing is about reuse and not repurposing. Hence, remanufactured products are not to have a different form from previous. Thus, remanufacturing of medical devices should follow the conventional recovery processes involved in remanufacturing and should not alter the device's intended use, safety or performance. Every process that can alter these properties in a finished medical device cannot be correctly classified as remanufacturing.

By providing warranty that is equivalent to those of new products, remanufacturing ensures high quality products. This is because warranty attests to the quality and amount of work invested in the process (Ijomah *et al.*, 2007; Ijomah, 2009). If applied to medical equipment, it can help to ensure that the restoration process of used equipment is controlled towards yielding high quality products for the local market. This is particularly necessary since refurbishment activity in the medical device industry is currently unregulated. However, remanufacturing seems to be incorrectly understood and/or absent in the industry.

Remanufacturing in the medical device industry suffers from the unspecific definition by the FDA and the absence of a definition in the EU medical device directives. The absence of a definition in the EU usually lead to associating remanufacturing with other EOL processes. This multiplicity of terminology and definitions may also be implicated in the absence of substantial evidence in the literature, of the practice of remanufacturing as defined by the FDA or full refurbishment as defined in the EU medical device directive. Lack of clear definition for remanufacturing is a major challenge to the growth of the remanufacturing industry (Ijomah, Childe and Mcmahon, 2004). In the EU, the term “remanufacturing” has not been used at all in the medical device regulatory framework and so, provides no guide for potential remanufacturers. Similarly, the FDA-defined remanufacturing which covers a broad range of processes does not emphasise the important activities such as disassembly, inspection, and re-assembly that characterise remanufacturing.

On the contrary, refurbishment according to the green paper on Good Refurbishment Practice (GRP) of medical equipment proposed by the European Coordination Committee of the Radiological, Electro-medical and Healthcare IT Industry (COCIR) abounds in the literature and is mostly carried out by OEMs. Table 2-10 compares FDA-defined remanufacturing, Full refurbishment and COCIR’s GRP with critical components in the traditional definition of remanufacturing while Table 2-11 summarises the GRP refurbishing activities of four major original medical equipment manufacturers.

The GRP was developed to standardise the refurbishment of medical imaging equipment to distinguish them from conventionally refurbished, repaired or used equivalents sold “as is” as permitted by both the EU medical device directives and by the U.S FDA (Centre for Devices and Radiological Health, 1996; Coordination of notified bodies medical devices on 93/42/EEC and 98/79/EC, 2000). The GRP aims to optimise conventional refurbishment (Parkinson and Thompson, 2003); ensuring

the resultant products are of high quality and assigning them warranty as well as sales and post-sales support equal to that of equivalent new product.

Table 2-10: comparing FDA-defined remanufacturing, Full refurbishment and GRP with key components in the traditional definition of remanufacturing. Taken from (Eze, Ijomah and Wong, 2019)

Definition by:	**Involves an EOL product?**	**Disassemble to parts level?**	**Restored at least, to an 'as good as new' quality?**	**Warranty provided?**	**Remarks**
EU Full-refurbishment	√	√	√	Not specified	Full refurbishment would qualify as remanufacturing if provision for "as good as new" warranty was specified in the definition. Provision for warranty may however, be implied since the full refurbisher places the equipment on the market in their own name; as new products. The products would therefore be expected to also come with same warranty as new ones.
FDA-Defined Remanufacturing	Not specified	Not specified	Not specified	Not specified	The FDA defines remanufacturing based on the outcome of the process namely; significantly changed finished medical device. For remanufactured equipment, either premarket assessment or 510(k) route is used just as in manufacturing, to demonstrate that the product can perform efficiently and safely without causing harm to patients.
COCIR Good refurbishment practice (GRP)	Not in all cases, equipment are inspected at the location of use to determine feasibility of being refurbished according to GRP.	√	√	√	Both EU and US MDDs allow selling of repaired and refurbished medical equipment. However, the levels of quality achievable from these operations vary greatly. The GRP thus brings standardisation to the refurbishment practice by ensuring that the facility and process comply with internationally accredited quality standards. Furthermore, the quality of GRP refurbished medical equipment can be demonstrated by their warranty and accompanying professional services that are similar to those of comparable new products. It is important to note that the GRP recommendations were formulated for medical imaging equipment.

Table 2-11: Original equipment manufacturing refurbishing. the approach and post market services are in line with the GRP. Taken from (Eze, Ijomah and Wong, 2019)

Process	**GE Gold seal refurbishment**	**Philips Diamond Select refurbishment**	**Siemens Quality Refurbishment Process**	**Toshiba Second life refurbishment)**
Selection	The GE medical imaging equipment refurbishment programme codenamed Gold seal, begins with the selection of equipment whose service history is known and which can guarantee refurbishment to GE's stringent standards.	Prime performing medical equipment are identified and selected.	Refurbishment must not change the intended use; selected equipment must have a known service history and be within manufacturer's planned lifetime. There is existing service or maintenance technology for the equipment	Selection starts at the equipment original site. A test engineer runs a test to ensure the used product is of acceptable quality.
De-installation	On selection, the equipment is de-installed and shipped to a GE facility for refurbishment using a quality system certified to ISO 13485 standard.	Selected equipment is de-installed and transported to one of Philips' global facility for refurbishment	Decontamination, De-installation, packaging and transport to refurbishment facility	The selected equipment is then de-installed and transported to Toshiba's ISO certified refurbishment facility.
Refurbishment process	At the GE facility, the equipment is inspected and refurbished and tested to ensure it meets original specifications and performance using OEM parts. Software are upgraded to latest versions	Refurbishment process involves disassembly to basic frame, cleaning and inspection to select only quality parts, non-performing parts are replaced with OEM parts. The product is then reassembled and tested to ensure it is restored to as good as new condition in terms of safety, output quality, functionality and performance. Customisable range of systems and configurations customisable to a customer's needs may be included during the process.	The received used equipment is Inspected, cleaned, disinfected and disassembled. Worn parts are repaired or replaced with original parts. The equipment is then coupled and tested after all necessary updates are completed. The GRP label is placed on the device, including the name and address of the refurbisher.	The refurbishment process begins with disinfection of the equipment, all parts and components are then subjected to certified functional and technical tests. The equipment is cleaned thoroughly and all damaged or worn parts are replaced with original Toshiba spare parts. Worn covers are repainted or replaced. Software are then upgraded to the latest available. The refurbishment can also include the customisation of configurations according to customer's specific needs. The refurbishment process concludes with electrical safety tests and quality control procedure which ensures all Toshiba specifications are met. A second life sticker is then placed on the refurbished equipment.
Delivery		Refurbished product is delivered to customer	The equipment is delivered to the customer.	The equipment is delivered to the customer
Warranty	GE provides a same as new warranty for Gold seal products	Same one-year warranty offered to new products.	Warranty equivalent to that of a new product is provided	Full one-year warranty is provided
Post sales services	1. Same service contracts as with new equipment, local service team available. 2., Accessories and supplies. 3., Flexible financing. 4. Training and optional continuing education programme	1. Accessories and supplies same as for new products, 2. Clinical education, 3. Flexible payment 4. Trade-in option.	Post market services same as new product is provided	1. Accessories are made available for up to five years, just like new products. 2. Trade-in option. 3. Factory-approved user training.

Thus, medical imaging equipment that is refurbished according to the GRP guideline would have a high degree of safety and quality like those of new products. There would be no premarket qualification costs associated with GRP since it does not claim to change the products and equipment are already in the EU market. Therefore, GRP has cost-saving advantages. COCIR sets the following criteria for determining the suitability of medical equipment for refurbishing (COCIR, 2007):

- Intended use and product specification – This implies that GRP only intends to make the equipment available to perform as originally intended when it was first introduced in the market. According to COCIR, GRP cannot be performed on a single-use device since it was originally intended for a single use.
- Satisfy same standards as at the time of first placement – A medical equipment to be refurbished according to the GRP must either be operating within the required medical equipment standards at the time of its selection for refurbishing or can be restored to that standard through refurbishing.
- Have significant residual lifetime and serviceability – A medical equipment to be refurbished in line with the GRP must have ample residual life. A significant residual life is essential to guarantee profitability and quality of the resultant product.

The GRP guideline contains a clear standard operational procedure for businesses that refurbish medical equipment; making sure the activity is performed in environments similar to those of OEMs and that the warranty as well as sales and post-sales offerings specified are the same as for new equivalent product. Thus, GRP is performed by organisations that can demonstrate required levels of i) quality management, ii) resource management iii) production and service provisions, iv) capability to control nonconforming product and conduct post sales surveillance v) validation documentation, labelling of refurbished equipment as “refurbished”, and supplier management process (COCIR, 2007). It is important to note that the labelling requirement does not require the operator to take away the OEM’s identity from the finished product.

2.6.7 Comparing FDA-defined remanufacturing, EU full refurbishment and COCIR GRP

Full refurbishment in the EU differs from remanufacturing from two principal perspectives. First, it is very specific with respect to the ownership of the resultant product which is subsequently transferred by the business that conducts the refurbishment. Hence, full refurbishment involves a claim that a new product has been

produced from used parts. The conventional remanufacturing literature is almost silent on issues relating to ownership of responsibilities arising from the resultant product. Also, by definition, full refurbishment does not specify warranty length for the resultant products although this requirement appears to be inconsequential given that the product is assumed to compete in the market exactly as new alternatives.

The FDA-defined remanufacturing appears to be conceived out of safety considerations due to operators' potential to alter the safety, performance and intended use of medical equipment while claiming to restore them. The definition apparently intends to ensure that such practices are evaluated to ensure compliance. It therefore includes such a wide range of activities in the definition of remanufacturing. Such a strong regulatory requirement apparently places extra burden on activities regarded as remanufacturing. Consequently, remanufacturing according to FDA definition rarely exists while the much less regulated refurbishment abounds (USITC, 2012). However, the GRP practiced by OEMs yields high quality products and like remanufacturing, provides the same length of warranty with new products. In addition, medical equipment remanufactured according to the GRP come with financing options and post-sales technical support similar those available to new equivalents. The selection of only high performing equipment and replacement of damaged parts with OEM parts as practiced in GRP appear to limit the green benefits of the GRP compared to remanufacturing.

2.6.8 Medical equipment remanufacturing for developing countries.

Conventionally, remanufactured products are "as good as new" equivalents. This "as good as new" quality is proven by the provided warranty which at least, equals that of equivalent new equipment. For most products, such warranty sufficiently presents a remanufactured product as being of equal or better quality with equivalent new ones and so, boosts customers' confidence. However, most manufacturers of new products also provide other professional post-sales services such as training, servicing and supply of spare parts in addition to warranty. Therefore, to argue that remanufactured product is as good as new, remanufacturers should also provide post-sales technical support. These services are necessary because medical equipment can be high capital investments that are expected to be highly reliable and safety critical. Besides, continued use of medical equipment may be impacted seriously by the unavailability of accessories as is the case in developing countries.

For medical equipment remanufacturers to show that their products are at par with new ones in terms of quality, they should therefore, also provide professional post-sales services. GRP refurbishment already has this requirement as a criterion but is

limited in scope as it is only proposed for imaging equipment. The GRP guideline therefore presents the minimum requirements for medical equipment remanufacturing especially for developing countries. Accordingly, medical equipment remanufacturing may therefore be defined as follows:

> *"The industrial process by which a used equipment is restored to at least, original equipment manufacturer's performance and safety specifications from customers' and regulatory perspectives; with the resultant product capable of performing its intended use and given a warranty as well as provision for professional post-sales technical services that are at least as good as those given to an equivalent new one."*

Table 2-12 shows that remanufacturing as proposed can contribute towards addressing 5 out of the nine causes of poor medical equipment availability in developing countries. Of these, three factors has been integrated into the definition while the balance two will be achieved naturally over time, with the implementation of medical equipment remanufacturing. The three main themes that remanufacturing should address are: making equipment to be of lower cost and/or providing optional purchase financing that reduces acquisition burden, provision of technical support, especially spare parts and skilled labour. There is also a standard requirement that remanufactured products should have warranty that at least, equals that of equivalent new products, comply with regulatory provisions and be safe. The proposed definition integrates these requirements.

Table 2-12: Mapping of availability issues against potential solutions provided by medical equipment remanufacturing as defined in this study.

Factor	References	Main theme to be included in the proposed definition
Attitude/perception	-	-
Lack of funds to access and/or to fund the purchase of equipment	Remanufacturing can provide low cost alternatives (Parkinson and Thompson, 2003; Ijomah, Childe and Mcmahon, 2004; Brent and Steinhilper, 2005; Gray and Charter, 2007; Goodall, Rosamond and Harding, 2014). GRP currently provides optional purchase financing to help customers with the acquisition cost.	Optional financing and low cost
Lack of infrastructure such as electricity, water supply, oxygen	-	-
Absence of HTM and HTA	-	-
Weak or absent medical device regulation	-	-
Lack of trained or skilled maintenance staff	Remanufacturing develops skills (Lund, 1984; Ijomah, Childe and Mcmahon, 2004; Gray and Charter, 2007; Ijomah, 2008; Goodall, Rosamond and Harding, 2014)	Greater benefits will be realised if remanufacturing is performed locally. Over the years, skilled labour in medical devices will be developed through labour mobility.
Unavailability of spare parts and consumables	One of the main motives for remanufacturing is spare parts provision which enables prolonged use of products and components even after their production has ceased (Seitz, 2007; Goodall, Rosamond and Harding, 2014)	Spare parts supply may be included in the potential remanufacturer's business model. Alternatively, by being able to provide spare parts, remanufacturers should also aim provide post sales technical support as with GRP.
Lack of clear economic model	-	-

Factor	References	Main theme to be included in the proposed definition
Equipment are inappropriate for the needs of the people	By engaging local workers where the remanufacturing is performed locally, the issue of needs communication along supply chains will be addressed (Sundin *et al.*, 2008; Sundin and Dunbäck, 2013a) and supply chain can be more effectively coordinated.	
Unreliable or ineffective supply chain communication		

2.6.9 Features of the proposed definition

It is important to emphasise that "restored to Original Equipment Manufacturer (OEM) performance and safety specification at least." implies that remanufactured medical equipment may either be upgraded or simply restored to the OEM specifications. Unlike the conventional definition where the finished product is considered new from the customers' perspective, remanufactured medical equipment should be viewed in the same light, by regulatory authority of the country in consideration or at least, be acceptable by them. This is because regulatory approval is necessary for the market entry as well as continued use of medical equipment. Consequently, there are acceptability criteria and performance level below which medical equipment use is suspended (EC, 2012).

Equipment claimed to have been upgraded or changed in the process will thus, be required to satisfy premarket evaluation to validate the claims and be functioning within acceptance limits. This is necessary as the upgrade or change in equipment specification may alter the safety or performance specification originally intended by the manufacturers. Potential remanufacturers who do not claim to upgrade their products may only be required to validate their remanufacturing process and demonstrate compliance with the appropriate quality and risk management system and ensure their products comply with all other device-specific standards.

The requirement for validating upgraded products would correspond to the FDA's current regulatory system concerning remanufacturing. In contrast to the FDA's position, the proposed approach to characterising medical equipment remanufacturing recognises that remanufacturing can be restorative as well as upgrading in nature and proposes subjecting only the equipment claimed to have been upgraded or changed during remanufacturing to premarket certification process. Figure 2-6 presents a preliminary process model of medical equipment remanufacturing based on the proposed definition.

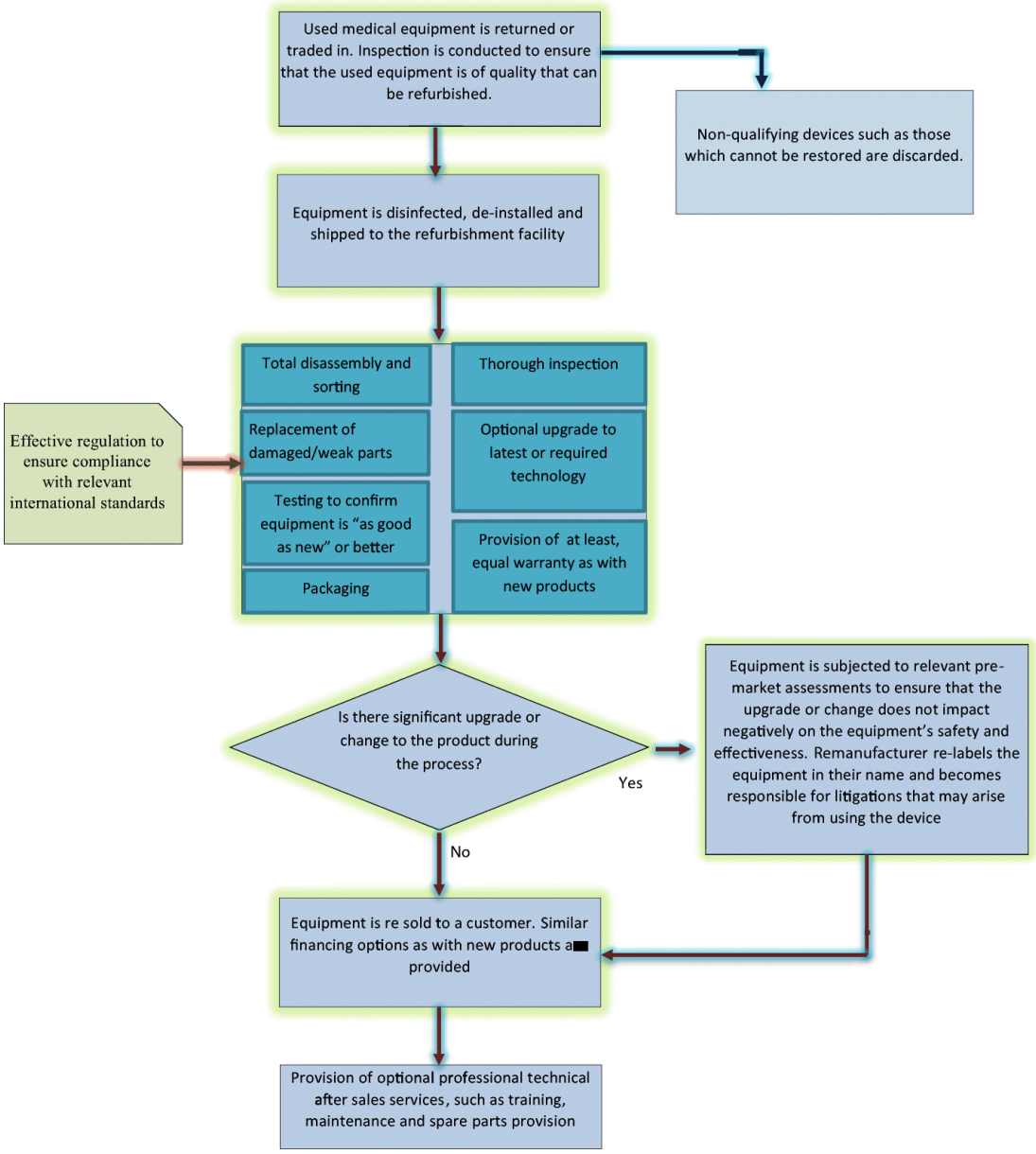

Figure 2-6: Proposed definitional model.

2.7 Factors affecting consumers' purchase intentions and willingness to pay for remanufactured products.

To identify the factors affecting consumers' purchase intentions and willingness to pay for remanufactured products, a search of Scopus was conducted on 13/06/2019. The search keywords used were as follows:

"Perceived" OR "Perce*" OR "willingness to pay

AND

"Remanufacture*"

A total of 189 document results was obtained. Upon reducing the period covered by the articles to between 2011 to date, a total of 147 document results was obtained. To ensure that information is only extracted from highly reputable articles written in the English Language with a citation count greater than or equal to10, the following restrictions were further included in the selection criteria:

1. Article written in English.
2. Article has greater than or equal to 10 citations.
3. Articles address consumer purchase intentions or willingness to pay for remanufactured products.
4. Product in question must be remanufactured not repaired, refurbished, or reconditioned.
5. An identifiable theory is used to carry out the analysis.

There were 13 articles fulfilling these criteria and these were reviewed to identify key factors used to assess purchase intention and willingness to pay for remanufactured products.

2.7.1 Consumer willingness to pay for remanufactured products.

Consumers' willingness-to-pay (WTP) for a remanufactured product is a fraction of their WTP for the corresponding new product, and this fraction, called discount factor, is assumed to be constant among consumers (Kleber *et al.*, 2018). The WTP is influenced by consumers' perceptions and is a key indicator of the product's marketability and profitability (Li and Guide, 2006; Bulmus, Zhu and Teunter, 2014). Perception according to the Cambridge English dictionary refers to a belief or opinion held by people and which is based on their impression about things. The ultimate implication of these beliefs or opinions in relation to remanufactured products is the decision to either purchase a remanufactured product or settle for alternatives. Thus, the understanding of consumer perceptions and behaviour is important to the success of remanufacturing (Hazen, Mollenkopf and Wang, 2016).

Consumer WTP affects the potential profit derivable from remanufacturing endeavour. The higher the consumer purchase intention, the higher the profit for the remanufacturers even if they are in competition and lower WTP negatively affects the industry even if government subsidies are available (Shu *et al.*, 2017). WTP is a measure of the price which the consumer is likely to pay to acquire a remanufactured product. WTP is usually expressed in terms of percentage reduction in price (Li and Guide, 2006) and has been used to analyse the possibility of cannibalisation of new product sales by remanufactured products. According to Li and Guide (2006), remanufactured consumer goods were on the average, auctioned at 15.3% lower price than new ones unlike remanufactured commercial products that were auctioned at 9.7% lower price and whose bidding history revealed significant price overlap for new and remanufactured alternatives. This finding suggests that commercial remanufactured products to which medical equipment approximately belongs to, are often marketed at lower discount compared to remanufactured consumer goods.

Another study finds that consumers display significant variability in terms of their expected discount for remanufactured products (Abbey *et al.*, 2017). The variability is due to the customers' perceived quality risk, that is, the probability in their own view, that the remanufactured product would still have unaddressed functional and cosmetic defects.

Hazen (2012) found that both perceived quality and consumers' ambiguity tolerance could predict the willingness to pay for remanufactured products. Ambiguity tolerance refers to the propensity to regard ambiguous situations as desirable while the opposite is ambiguity aversion (Hazen *et al.*, 2012). Thus, perceived risk, perceived quality and ambiguity tolerance can influence the WTP for a remanufactured product.

2.7.2 Consumer purchase perceptions for remanufactured products

Wang (2013) proposed a framework for studying how user perceptions influence their decision to purchase remanufactured products. The framework which is tested using inputs from participants drawn from China integrates the Theory of Planned behaviour, perceived risk as well as product knowledge and perceived benefits. The results show that purchase attitude has the greatest positive correlation with purchase intention, followed by perceived behavioural control and by subjective norm while product knowledge is negatively correlated. According to the results, perceived benefit and perceived risk do not have direct influence on purchase intention but indirectly, through purchase attitude such that perceived risk has a negative correlation while product knowledge is positively correlated. In addition to these two, product knowledge also influences purchase attitude.

Matsumoto (2017) sought to understand consumer perceptions relating to the purchase of remanufactured products in Japan and the United States of America. The study assessed consumer perceptions and purchase intentions based on scales adapted from Wang (Wang et al., 2013). These include scales for assessing knowledge of the remanufactured automobile parts, perceived benefits and risks associated with the use of remanufactured these product as well as price consciousness. Additionally, price consciousness was assessed by the scales developed by Lichtenstein (Lichtenstein et al., 1993). The results show that all the highlighted factors influenced consumer purchase intentions.

Hazen (2016) applied the push-pull-mooring theory of migration to the study of consumer switching intentions from new to remanufactured products. According to the source, push factors drive potential consumers away from using the current product which for instance, may be overly priced. This challenges them to seek other low-cost options, which remanufacturing can offer. Pull factors on the other hand, tend to draw potential consumers towards using remanufactured products. These include government policies, standardisation and regulations which serve to boost confidence in remanufactured products. Mooring factors are micro-level factors such as personal, social and cultural values which contribute to migration. The source regards consumer attitude towards purchasing remanufactured products as mooring factors and found that it correlates positively with switching intentions and at the same time, moderates environmental benefits, government incentives and price. This suggests that the success of remanufacturing business depends largely on the attitudes of potential consumers towards purchasing and/or using the products.

Gaur (Gaur *et al.*, 2015) found that attitudes, beliefs, individual personality, environmental consciousness, societal norms, price, quality and brand image can influence purchase intentions when the consumer has relocated to other locations.

Kumar and Sarmah (2015) studied the behavioural characteristics underpinning consumer propensity to return EOL products. Their results show that market characteristics, knowledge about returning EOL products, perceived risk and perceived benefits were the main factors that influence the decision to return products. In the study, market characteristics is a measure of the availability and maturity of reverse logistics agents; perceived risk account for consumers negative opinions about returning used products while perceived benefits refer to the possible self and social gains associated with returning products.

Clearly, certain themes recur in the research works cited above. These include knowledge of remanufactured products, value, risk, ambiguity tolerance, benefits, cost or price and attitudes towards remanufactured products. Some theories such as theory of planned behaviour, theory of perceived benefits, theory of perceived risks and push-pull theory account for some of these factors in the previous studies. Table 2-13 presents a summary of the key findings from the literature related to these themes. A combination of some of these theories and factors have been chosen to formulate a conceptual model for estimating the potential purchase intention for remanufactured medical equipment. The development of the model is discussed in the next sections.

Table 2-13: Studies on purchase behaviour for remanufactured products

Title	Author	Theoretical approach	Key findings	Key variables introduced
Consumer product knowledge and intention to purchase remanufactured products	Wang & Hazen, 2016	Prospect theory which posits that rational consumers would rather undervalue products with probable outcomes than those that have more certain beneficial outcomes.	Knowledge of perceived value and risks explain purchase intentions. Knowledge of perceived risk is explained by knowledge of cost discount and quality while perceived value knowledge relates to quality, cost and environmental friendliness	perceived value, perceived risk, quality, cost, green attribute, purchase intentions, product knowledge
Understanding the purchase intention towards remanufactured product in closed loop supply chain	Wang et al., 2013	Combined the theory of planned behaviour and perceived risk with product knowledge and perceived benefits	Purchase intention found to be directly influenced by perceived behavioural control, subjective norm, purchase attitude and negatively, by product knowledge. Purchase intention also mediates product knowledge and perceived risk to purchase intention.	purchase intention, behavioural control, subjective norm, purchase attitude, product knowledge, perceived risk.
The role of perceived quality risk in pricing remanufactured products	Abbey et al., 2017	Initial exploratory studies to determine quality risk factors	Consumers' quality risk preferences is due to their perceived probability of functional and cosmetic defects both of which affect purchase likely hood directly and indirectly influence willingness to pay through the mediation of purchase likelihood.	quality risk, perceived probabilities of cosmetic and functional defects.
Remanufacture for the circular economy: An examination of consumer switching behaviour	Hazen et al., 2016	Push-pull-moor theory of human geography which explains the antecedents of human migration is applied to explain consumer switching intention to use remanufactured products.	The authors regard consumer attitude towards purchasing remanufactured products as mooring factors and found that it correlates positively with switching intentions towards remanufactured products and at the same time, mediates among environmental benefits, government incentives and price	purchase attitude, environmental benefits, price, government incentives

Green information, green certification and consumer perceptions of remanufactured automobile products	Wang etal., 2018	A hypothesised model to examine how consumers' perceived value and trust for remanufactured products influence their purchase intention.	Authors found that Knowledge about energy and material savings as well as reduction in emission associated with remanufactured products increased consumer perceived value and trust, thus increasing their purchase intentions	value, trust, product knowledge
The role of ambiguity tolerance in consumer perception of remanufactured products	Hazen et al., 2012	Ambiguity tolerance theory which refers to the propensity to regard ambiguous situations as desirable) while the opposite is ambiguity aversion	Both perceived quality and consumers' ambiguity tolerance predicted willingness to pay for remanufactured products.	perceived quality, ambiguity tolerance
Green Consumer behaviour: An experimental analysis of willingness to pay for remanufactured products	Michaud and Llerena, 2011	Experimental economics techniques to test hypotheses.	Consumers value remanufactured products less because they regard them as not being entirely new but that informing consumers about the environmental benefits of remanufactured products increases their willingness to pay.	Knowledge about the benefits of remanufacture
Measurement of consumers' return intention index towards returning the used products	Kumar and Sarmah, 2015	Hypothesised model based on 8 factors.	Market characteristics, knowledge about returning EOL and EOU products, perceived risk and perceived benefits were the main factors that influence the decision to return products	market characteristics, perceived risks, benefits, knowledge about returning products.
Remanufactured products in closed loop supply chains for consumer goods	Abbey et al., 2014	Experiment testing of hypothesised statements	The attractiveness of remanufactured products to consumers continue to increase in a linear fashion with price discount. However, quality improvement yield far greater consumer approval of remanufactured products than price discounts.	quality improvement is superior to price discount from consumer perspective

Comparison of U.S. and Japanese Consumers' Perceptions of Remanufactured Auto Parts	Matsumoto et al., 2016	Theory based on framework developed by Wang et al., 2013 and Lichtenstein et al., 1993	Assessed the influences of knowledge of the remanufactured automobile parts, perceived benefits and risks associated with the use of remanufactured product as well as price consciousness on purchase intention. Their result shows that all these factors affect purchase intentions	knowledge of remanufactured products, perceived benefits and risks and price consciousness
Perceived quality of remanufactured products: construct and measure development	Hazen, B. T., Boone, C. A., Wang, Y. and Khor, K. S.	Hypothesised model developed and consolidated	Perceived quality found to be explained by product lifespan, features, performance and serviceability. Perceived quality is also shown to influence purchase intention.	Perceived quality, lifespan, features, performance, and serviceability.
Key drivers in the behaviour of potential consumers of remanufactured products: a study on laptops in Spain	Jiménez-Parra, B., Rubio, S. and Vicente-Molina, M. A. (2014)	Model formulated based on the theory of planned behaviour.	Shows that potential consumers' attitude, subjective norms and motivations positively influence purchase intentions for remanufactured products whereas, marketing mix variables influence it negatively	Consumers' attitude, subjective norms, motivation and marketing mix variables.
Drivers of consumer purchase intentions for remanufactured products a study of Indian consumers relocated to the USA	Gaur, J., Amini, M., Banerjee, P., Gupta, R. 2015	Used Grounded theory based on interviewing 45 consumers over a period of over 6 months	Major drivers of purchase intentions found to be the level of environmental consciousness, individual values, post-use perceptions, nature of purchase and socio-cultural norms. Sub-categories of these five drivers are personal and contextual factors. Personal factors include personal attitudes and beliefs, individual personality and environmental consciousness. Contextual factors are societal norms, price, promotion/advertisement, service quality and brand image	Attitudes, beliefs, personality, environmental consciousness, price, brand image and quality

2.7.3 Link between perceived knowledge and value and trust for remanufactured products

Both perceived value and trust for remanufactured products depend on product knowledge, that is, the consumer's awareness of specific information relating to the product (Wang *et al.*, 2018). This is because knowledge of energy and material savings as well as reduction in emission associated with remanufactured products increases consumer perceived value and trust, thus increasing their purchase intentions (Wang *et al.*, 2018). Perceived value refers to how a consumer assesses a product's attributes or performance in relation to its possibility of satisfying his goals when used and balancing the amount paid to get it. It may be expressed in terms of price reduction, utility, green attribute and quality derived from what is paid for or everything one wants in a product (Zeithaml, 1988; Wang and Hazen, 2016). Wang and Hazen (2016) concludes that perceived value is influenced the most by knowledge of a product's quality. Perceived trust is related to perceived value and refers to the consumer's conviction of the quality, safety and environmental friendliness of the remanufactured product (Wang *et al.*, 2018).

2.7.4 Perceived quality of remanufactured products

According to Abbey (Abbey *et al.*, 2017), quality concerns over remanufactured products is due to the probability of functional and/or cosmetic defects and affects WTP indirectly, through the mediating purchase likelihood. Hazen (Hazen *et al.*, 2017) attributes the concern to the several ways of defining 'quality'; ranging from transcendent to user-based views. It found that the perceived quality of remanufactured products correlates directly with purchase intention and may be explained by the following factors:

- Life span: This refers to the length of use before the product sustains significant degradation, failure or becomes obsolescent.
- Features: This serves as a measure of the secondary operating characteristics of the product that are still within initial standard.
- Performance: This is a measure of the primary operating characteristics of the product that are within initial standard.
- Serviceability: Assesses the speed or ease with which the remanufactured product may be repaired in case of damage or malfunction during use.

2.7.5 Conceptual model for estimating the Potential purchase intentions for remanufactured medical equipment.

A combination of the theories of Planned behaviour, Perceived Risk and Perceived benefit is used in this section to study the potential purchase intentions for remanufactured medical equipment. The proposed model is shown in Figure 2-7

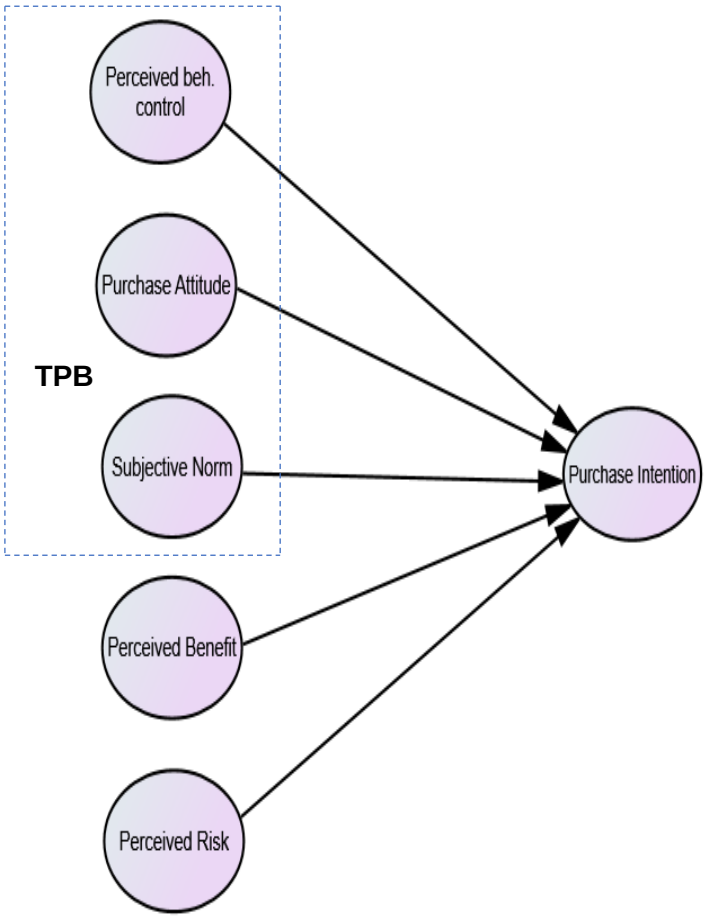

Figure 2-7: Conceptual model for estimating purchase intention for remanufactured medical equipment.

2.7.5.1 Theory of planned behaviour: Purchase attitude, perceived behavioural control and subjective norm

The theory of planned behaviour (TPB) extends the theory of reasoned action which argues that a behaviour may be predicted by behavioural intentions including attitudes, subjective norms and perceived behavioural control; which motivate the action (Wang *et al.*, 2013). Hence, this theory is particularly suitable for understanding the behavioural patterns prompting the decision to take actions. According to the Theory (Ajzen, 1991), individuals with positive attitudes, positive

subjective norms and perceived behavioural control will have strong intentions to carry out a behaviour.

Attitude refers the overall way an individual evaluates the outcome of a behaviour to be either positive or negative. This is usually preceded by a consideration of the potential outcomes of the behaviour in question. Purchase attitude is therefore, the potential consumer's evaluation of the outcome of purchasing a product. Given that the purchase of second-hand equipment is common in developing countries and remanufacturing offers higher quality products with added benefit of providing post sales technical service support, the attitude towards purchasing remanufactured medical equipment would seem to be positive where the potential buyer is convinced of the benefits and quality of the product.

Perceived behavioural control refers to the individual's belief that the behaviour in consideration is under their control (Wang *et al.*, 2013). In operationalised form, it depicts how an individual perceives the relative ease or difficulty of carrying out a given behaviour which may be dependent on the challenges presented by each behaviour (Wallston, 2001).

Subjective norm refers to individuals' perception to perform or not to perform an action due to social pressure.

Given that many medical equipment users in developing countries lack even basic equipment and have had to use poor quality equipment or even improvise to carry out some procedures; any strategy such as remanufacturing which promises quality equipment at reduced price is likely to be appreciated. This implies that potential users are likely to have positive attitude and perceived behavioural control towards purchasing remanufactured medical equipment. Positive subjective norm, attitudes and behavioural control would suggest that experts may have little or no acceptance issues for remanufactured medical equipment.

2.7.5.1.1 *Perceived risks*

People's impressions about remanufactured products usually include risks concerns. It relates to the uncertainty and gravity of resultant outcome due to the purchase of an item which inhibits purchase behaviour. According to Wang, it is multidimensional and includes performance, financial risks, time risks, safety risk and social risks. (Wang *et al.*, 2013).

Risk concerns for remanufactured products are an implication of the fact that many consumers do not trust the remanufacturing process as they do not know the

products' overall age, quality control measures in place at the industry as well as components which have been replaced or reworked. Consequently, they are not absolutely convinced that remanufactured products would serve as good as new equivalents to justify purchasing them (Hazen *et al.*, 2012). From Wang's (Wang *et al.*, 2013) perspective, perceived risks associated with purchasing remanufactured medical equipment would include the following:

- Safety risk refers to the probability that a remanufactured medical equipment results in threat to the life of the user.
- Time risk is a measure of time spent during pre-purchase planning and in actually purchasing a remanufactured medical equipment which eventually fails to serve as pre-planned. One of the important phases in medical device lifecycle is the pre-purchase phase. During this phase, important decisions concerning the suitability of the proposed equipment are made. Such decisions include determination of the proposed equipment's capacity to deliver quality and safe care, cost/benefit analysis and ease of integration to existing system. These tasks cost a lot of time and premature failure of the purchased equipment would amount to a wasting the time.
- Performance risk is an aspect of quality risks and refers to a potential consumer's uncertainty that a remanufactured medical equipment would not fail prematurely or deliver poor quality service; but instead, perform exactly as claimed, that is 'as good as new'.
- Financial risk is the uncertainty associated with deriving equivalent utility for the monetary investment in purchasing the remanufactured medical equipment. It would be a financial loss to purchase an equipment which would not serve as long as it is required to at least, break even on the funds invested in purchasing it.

Governments make effort to standardise remanufacture practice across industries to boost potential consumers' confidence in remanufactured products. A typical example is the provision of a definition for remanufacture in the British Standards. Developed countries' medical device industries are also highly regulated to ensure that only high-quality equipment capable of providing safe and effective service gain access into the market. Regulations specify acceptable terminology, requirements and practices that ensure safety and effectiveness.

Medical device regulations are however, either weak or inexistent in many developing countries. Without strong regulatory presence, it may be difficult to be convinced that medical equipment has been remanufactured according to relevant standards of quality. Such lack of conviction would increase in risk perception for remanufactured medical equipment.

Developing countries lack even the basic medical equipment. In addition, healthcare in many developing countries is usually provided by privately funded hospitals. Thus, even with the weak regulatory oversight, the impact of risk perception for remanufactured medical equipment on WTP may not be substantial.

In addition, healthcare in many developing countries is usually provided by privately funded hospitals that can be profit driven (Prowle and Harradine, 2015) and unaffordable due to poverty in poorer countries. Moreover, many health care providers have also used second hand and refurbished equipment; it is therefore likely that the perceived risk associated with remanufactured medical equipment would not directly impact its purchase intention given that it promises to be of high quality and to provide post sales technical support (Eze, Ijomah and Wong, 2019). However, the awareness of remanufacturing among developing countries' medical experts is not yet known. Also, the weak regulatory system may weaken individuals' potential trust in remanufactured medical equipment as is the case with all remanufactured products (Wang *et al.*, 2018). It will therefore be interesting to understand the impact of perceived risk on the potential purchase intentions for remanufactured medical equipment.

2.7.5.1.2 *Perceived benefit*

Product knowledge, value and trust for remanufactured products all refer to the relative understanding of the quality, price reduction and environmental benefits of remanufactured products. Benefits such as reduced prices and environmental friendliness attract some consumers to patronise remanufactured products. The literature shows that price also plays an important role in consumers' decision to purchase remanufactured products and that they are likely to switch if they find the prices of the current product providers to be high (Hazen, Mollenkopf and Wang, 2016). Moreover, consumers are becoming increasingly environment conscious. In fact, environmental concerns have encouraged the interest in green products for which some consumers are willing to pay a premium to support the initiative (Sammer and Wüstenhagen, 2006). Consumers have been shown to be more inclined to purchase remanufactured products from environmentally certified firms

(Wang *et al.*, 2018). It has also been demonstrated that a product's greenness alone cannot improve customers WTP (Michaud and Llerena, 2011). Hence, among other benefits, remanufacturing offers cost savings on high quality products as well as e**n**vironmental benefits in addition to the potential for technical service support.

2.8 Chapter summary

In this chapter, the factors responsible for the poor availability of medical equipment in developing countries were identified. Strategies that have been proposed to address the issues were also presented along with there shortcomings. Remanufacturing was shown to be a potential solution proposed for developing countries, but which has had little application, especially with regards to medical equipment. A review of the remanufacturing literature also showed that medical equipment were routinely characterised as remanufacturable products but no study had actually looked into their potential to be remanufactured in practice.

To be able to characterise remanufacturing for medical devices, there were several areas that needed to be covered, even if it is just at an exploratory level. To achieve this, a theoretical framework was adapted, and used to identify the key factors in the remanufacturing of medical equipment. Some of the factors identified included the role of institutions and incentive. The key institutional influence on medical equipment is the regulation which is strong and necessary. Hence, a further literature review was conducted to analyse how regulations may impact on the potential to remanufacture medical equipment. Similarly, a review of the literature on purchase intentions and willingness to purchase remanufactured products was completed since these affect the profitability of remanufacturing which is a key motivating incentive. A conceptual model based on the theories of planned behaviour, perceived risks and perceived benefits was formulated. This will be adapted and estimated later in this study, to understand the factors that affect the purchase intentions for remanufactured medical equipment.

Chapter 3:
Research Design

3.1 Introduction

As far back as 1982, Guba (Guba and Lincoln, 1982), highlighted that the philosophical paradigm of a research is of the highest importance in a research because it reflects the belief system and world view which guides the investigators in their inquiry and which determines how inquiry is conceived and implemented. This chapter presents different philosophical paradigms, research approaches and designs, serving as justification for the options selected for this research.

3.2 Philosophical paradigms in research

Research advances knowledge and so, is linked to theoretical developments credited to philosophers and practitioners who engage in contest concerning what constitutes knowledge and how knowledge is to be pursued. The theoretical framework under which research is performed is termed research paradigm (Crotty, 1998; Mackenzie and Knipe, 2006). Kuhn who popularised the term "paradigm" used it in the following ways (Kawulich, 2012):

1. To account for the manner of reasoning through which scientists formulate their problems, solve them, and report the solutions obtained.
2. To represent the beliefs, values, methods, and outlooks commonly shared within a discipline

Other scholars regard "paradigm" as a way of viewing the world (Mertens, 2010; Creswell, 2014); the belief about the nature of knowledge, methodology and criteria for validity (Naughton, Rolfe and Siraj-Blatchford, 2001 cited Mackenzie Knipe, 2006). Thus, a paradigm characterises the procedure and steps through which a researcher creates a relationship between the research questions and the proposed research approach and methods (Crotty, 1998; Creswell, 2014), as shown in Figure 3-1. The beliefs include those of the nature of things, regarded as ontological assumption; ways of inquiring into the nature of things and reality, known as epistemology, which inform the methodological considerations, instrumentation, and data collection strategies. However, both epistemological and ontological assumptions usually conflate in research writings since "construction of meaning" and "meaningful reality" are essentially equivalent (Crotty, 1998). Paradigms in the literature include Positivism, Postpositivism, Interpretivism, Critical realism, Pragmatism, and Critical theory (Mackenzie and Knipe, 2006)

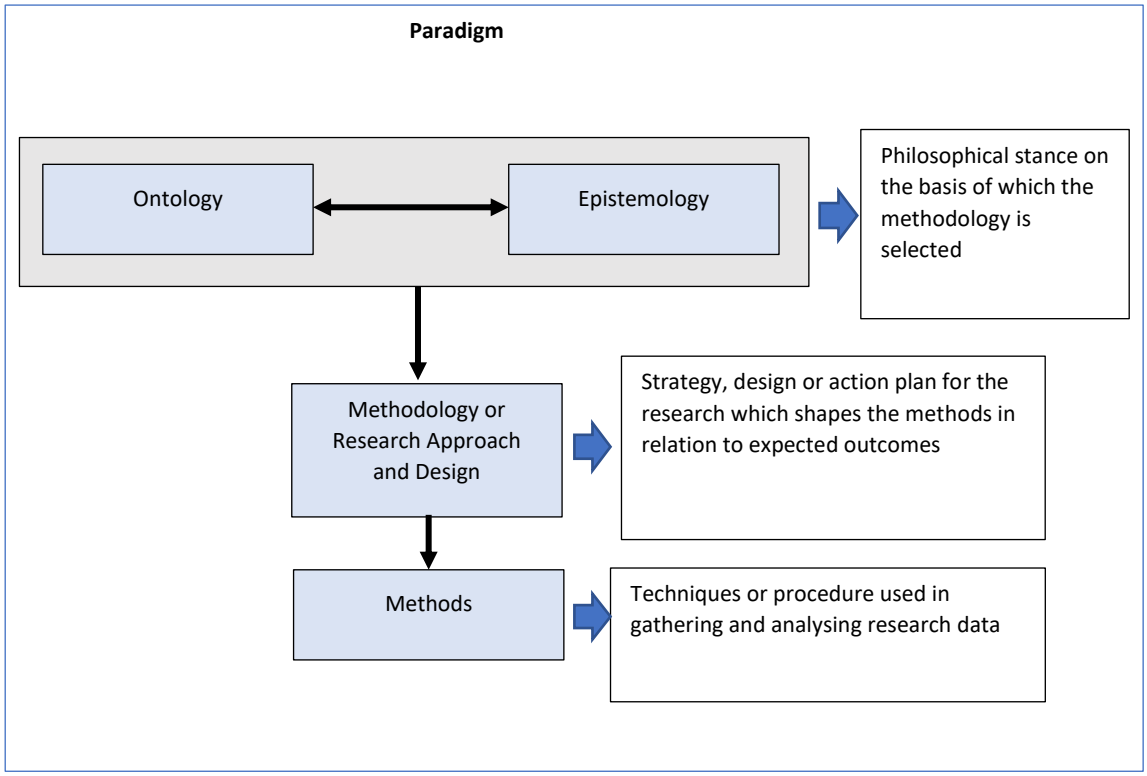

Figure 3-1: how the ontological and epistemological views determine research approach, design and methods. Adapted from (Crotty, 1998; Creswell, 2014)

According to Kuhn (1970), a paradigm is an identity of a research community embodying what is considered acceptable approach to inquiry and knowledge acquisition; and includes specifications of problems to be investigated. For several years, there has been intense debate among paradigm advocates about which paradigm is most appropriate. The following sections introduce the characteristics of paradigms with a view to justifying this study and enhancing its comprehension. First, the different ontological and epistemological positions in research are presented.

3.2.1 Ontology

Ontology is the study of "being", with a focus on understanding "what is" about existence and consequently, reality (Crotty, 2011, p.10). One notable ontological position is realism. It is an ontological position which upholds the notion that realities exist outside of the mind (Crotty, 2011). Realism differs from other ontological stances termed anti-realism, such as nominalism, idealism and relativism. Anti-realism ontologies generally oppose the belief that reality exists independently from consciousness. For instance (Crotty, 2011):

- Idealists are of the view that the mind is the only thing that exists; that the external world is an illusory creation of the mind. Idealists believe that reality is confined to what exists in the mind and is essentially ideas.
- Nominalists' position is that abstract constructs, concepts, general terms or universals do not have independent existence; but rather exist only as names.
- Relativism is key stance in social constructionism since what is said to be constructed or the way things are interpreted to be, is just the sense which can be made of them. Different people live in different worlds; with differing ways of knowing, distinct sets of meanings, beliefs and realities. Thus, description and narration would not be straightforward (Crotty, 2011, p.64). The truth in this case, is therefore, a result of human interpretation and belief.

Internal realism is somewhat like Realism but was introduced to address the conflict arising due to beliefs in Relativism and Realism by finding some common ground between them. Hence, internal realism provides a way of being realists about objects out there in the world while at the same time, acknowledging that truth may depend on one's personal beliefs as in Realism (Anderson, no date).

3.2.2 Epistemology

An epistemological assumption is an understanding of what constitutes knowledge as well as how knowledge is to be sought. Thus, epistemology deals with the nature of knowledge, its scope and general basis (Hamlyn, 1995 p.242 cited (Crotty, 1998, p.8). It provides the philosophical justification for determining which knowledge is possible as well as the basis for ascertaining its adequacy and legitimacy (Maynard, 1994 cited Crotty, 1998, p.8). The main epistemological positions in research include objectivism, constructionism, and subjectivism.

3.2.2.1 Objectivism

Objectivists' belief is that meaning and consequently, meaningful reality exists out there, independent of the mind or consciousness. For objectivists, a mountain continues to be a mountain irrespective of whether its existence is perceived. It thus carries its inherent meaning of "mountain-ness". A human being who recognises it as a mountain would only be recognising a meaning which has been out there all along. From the objectivist stance, values and understanding may be

objectified in the people being studied ethnographically for instance, to discover the objective truth.

3.2.2.2 Constructionism

Constructionism is the belief that there is no objective reality or truth waiting to be unravelled or discovered. Constructionists assert that meaning is created or constructed from engagement with realities in the universe. Constructionists believe in multiple realities in which the subjects and the objects act as partners in the creation of knowledge. Thus, constructionists believe that there is no meaning without a mind. The Constructionist's view may be appropriate in studying humanly fashioned ways of seeing things whose processes need to be explored and which can only be understood by having the subject and the object contribute towards creating meanings (Crotty, 2011; p.9).

3.2.2.3 Subjectivism

Subjectivism is often easily confused with constructionism as the two are related. However, in subjectivism, meaning is not created as result of the interaction between a subject and an object. Instead, meaning is imposed on the object by the subject. The object would not contribute to the creation of meaning. The imposed meaning is simply imported rather than emanating from the subject-object interaction. The subjectivist's view may be appropriate in studying humanly fashioned ways of seeing things whose processes need to be explored and which can only be understood by having the subject create meanings independently from the object (Crotty,1998; p.9).

3.3 Typical philosophical paradigms

In this section, several optional paradigms are presented. The paradigms presented cut across natural and social sciences since the study objectives span through policies, management and remanufacturing (production) development and assessment.

3.3.1 Positivism

Positivism was popularised by Auguste Comte through Société positivist, which he founded in 1848. He showed that positive science can be beneficial in solving sociological problems just as it is useful to natural scientists. Advocates of positivism science believe that knowledge is not achieved speculatively but rather, based on something that is posited. Thus, positive scientists do not proceed with an abstract reasoning but instead, by studying a "given" or datum (plural, data) or that which is posited (Crotty, 1998 p.19). Data may be from phenomena that occur

repeatedly which the researcher may be required to establish laws that characterise the occurrence. The data is usually quantitative but occasionally though, the positivist researcher may also quantify qualitative data as in the social research sciences (Crotty, 1998).

To adopt a positivist philosophy in social research, the researcher would view the organisation and its social elements including understandings and experiences objectively as real and external; just like physical objects and natural phenomena that are observable and measurable. Thus, a positivist researcher adopts objectivism as epistemology and realism as ontology (Crotty, 1998).

A positivist philosophy applied to research would adopt the ontological perspective of the natural scientists. It would entail studying observable physical realities to make generalizable findings. Consequently, a positivist researcher would aim to study observable and measurable facts and thereafter, explore relationships from the accumulated data to make law-like generalisations. The law-like generalisations are thereafter, used either to explain or predict physical events. In a positivist research, existing theories are often used to generate hypotheses which are then tested to arrive at further theories; this is known as hypothetico-deductive reasoning. The positivist research would have the following characteristics (Easterby-Smith, Thorpe and Jackson, 2012):

1. Independence: - the subject/researcher is independent of the object
2. Value-free and scientific: - The study is not influenced by the values, beliefs or interests of the researcher and participants/objects being studied are scientifically selected.
3. Hypothetico-deductive: - A hypothesis is initially made with data selected according to standard rules to either prove the validity or otherwise of the hypothesis.
4. Large samples: - Large samples are needed to establish the validity of findings.
5. Empirical operationalisation:- Research is often quantitative but there are currently some positivist studies that are qualitative as reported by Eisendhart (Eisenhardt and Graebner, 2007) who note that qualitative case studies may be regarded as independent experiments. From this perspective, the scholars argue that the results of case study research can be generalised to the theory.

6. Principles of probability: - Sampling, analysis and inferences are based on statistical computations.
7. Reductionism: -Problems are broken down into smallest units
8. Generalisation: - The results are generalised after hypothesis is tested over pre-calculated sample size.

Critics of the positivist philosophy argue that the observable outcome is not usually all there is about a phenomenon and that the researcher can also strive to understand more fundamental layers of what is being projected and observed on the surface. They argue that positivist research does not consider hidden patterns responsible for the laws they formulate. Thus, instead of conducting the study right away with survey-based measurements of large number of variables, an alternative approach may be to carry out small number of cases to retrieve the underlying patterns that are reflected on the surface. This is the position held by the postpositivists (Alvesson and Skoldberg, 2018).

3.3.2 Postpositivism

The aim of post positivism is to improve positivism by incorporating new ideas brought by critics. Popper's (1902-94) theory of falsification, Kuhn scientific revolution and Feyerabend's theory of methodological pluralism (Crotty, 1998) informed most of the features of the post positivism paradigm (Crotty, 1998). For Popper (1959 cited Crotty, 1998), scientific methods are not necessarily based on discoveries but involve making conjectures that cannot be refuted or falsified. In his view, scientific propositions may be tentatively valid until proven otherwise.

Kuhn showed that scientists are constrained to a background of theory comprising beliefs about science and scientific knowledge. Kuhn called the beliefs "paradigm" and found that it shaped the nature of what scientists studied and provides justification for the methodology. It is however criticised for being insufficient in explaining all scientific concepts (Kuhn, 1970 p.52-3). Thus, Kuhn's scientific research is an imperfect human endeavour.

Feyerabend is popular for his anarchist views of science and suggestion that methodological pluralism among science researchers restrains the progress of science. The perspectives presented by Popper, Kuhn and Feyerabend questions the tenets of positivism among which include belief in objective meaningful reality and neutrality of value (Crotty, 1998). Post positivistsm is the new paradigm that intends to include considerations of the issues raised by these critics.

Importantly, post positivism approves quantitative methods but, advocates for more caution in adopting it. In doing so, it does not regard quantification and the use of sophisticated techniques based on statistics and mathematical modelling techniques to be incapable of revealing scientifically relevant and useful insights. Thus, the postpositivist acknowledges the usefulness of the quantitative methods as research tools but in addition, stresses that they are neither sufficient nor suitable basis for generating valid empirical evidence and interpretation of theory. Post positivist research may, therefore, support the integration of different type of data.

In conducting a positivist/postpositivist research, the following holds (Philips and Burbules, 2000, cited Creswell, 2014, p.41):

1. Knowledge is conjectural and thus, that the evidence established through research is not infallible. Consequently, positivist/postpositivist researchers do not seek to prove a hypothesis but to determine if it failed.
2. Research involves making claims as well as refining and abandoning inferior claims while upholding superior ones. Thus, most quantitative studies often begin with a theory.
3. Data, evidence and rational considerations shape knowledge. Data is collected using instruments based on measures completed by the participants or by observations recorded by the researcher.
4. Research aim is to explore the relationship among variables based on formulated hypotheses.
5. The positivist/postpositivist researcher is objective in his inquiry; ensuring that methods and conclusions are not biased. Validity and reliability are therefore, important for the positivist study.

3.3.3 Interpretivism

In carrying out research from the interpretivist perspective, the researcher ontologically understands that humans are different from physical objects because they create meanings (Saunders, Philip and Thorhill, 2007). The researchers then go on to study these meanings in different contexts since they believe that people from different cultural backgrounds, under different times and circumstances, make different meanings and that these meanings would be lost if humans are studied like inanimate objects. Interpretivist scholars therefore, do not seek to

formulate universal laws for making predictions, rather, to offer rich insight into humanity in different contexts and times(Hudson and Ozanne, 1988). An interpretivist researcher would look at organisations as consisting of different individuals; arguing for example, that the experience of each individual or class of individuals would be different. The researcher would not lump up the individuals to explore only the summative experience as this would amount to the negligence of rich insights (Saunders, Lewis and Thornhill, 2009). The interpretivist research is thus, often detailed; showing deep understanding of a particular or categorical phenomenon. The researcher enters the field with some sort of prior insight of the research context which is assumed to be insufficient or inappropriate in developing a fixed research design due to complex, multiple and unpredictable nature of what is perceived as reality (Hudson and Ozanne, 1988). The interpretivist research is therefore, mainly qualitative in nature, using words and texts (Creswell, 2014).

3.3.4 Critical realism

Ontologically, the critical realist perceives reality as external and independent just as the positivist. However, unlike the positivist's view, the critical realist believes that what is experienced is only sensational and are only a portion of the manifestations of things in the real world. Thus, the critical realist believes that reality is not directly accessible (Saunders, Philip and Thorhill, 2007). In research, the critical realist's approach is applied in scenarios where it is believed that a given phenomenon or hypothesis needs to be studied in greater details, taking account of the potential influences from other factors. Such a position is supported by Bashkar (Bashkar, 1998) who is of the opinion that the social world can be better understood by first understanding the social structures which according to him, give rise to social phenomena. Critical realists argue that a better understanding of a phenomenon may be achieved through historical exploration; adopting ontological relativism and a mild subjectivist approach to knowledge. According to Saunders (Saunders, Philip and Thorhill, 2007), knowledge changes with time and is a subject of social constructions. By analysing the responses of a social structure over time, it would be possible to gain greater insight than when historical background is neglected. Thus, Critical realists regard both positivism and interpretivism to be too superficial and unrealistic (Alvesson and Skoldberg, 2018).

3.3.5 Postmodernism

Post modernism is a philosophical stance which attributes importance to language as a medium for building societal order and which rejects the objectivist realist ontology while emphasising that change is continuous, unstructured and unpredictable (Saunders, Lewis and Thornhill, 2009). Post modernists promote alternative ways of perceiving the universe in which language which is regarded as imperfect; plays a key role. According to advocates of this paradigm, the imperfect nature of language generates imperfect attributes of the universe. In the postmodernist view, "right" or "wrong" is only collectively decided through choices that are under the influence of power relations and contextual ideologies. Thus, postmodernist research usually aims to study power relations on the basis of which dominant realities are constructed; by deconstructing these realities essentially by using texts to facilitate detection of lacunae in the subjects of study (Kilduff and Mehra, 1997). Thus, a postmodernist researcher seeks to unravel perspectives and realities excluded by certain organisational concepts and/or to determine the interests served by them (Kilduff and Mehra, 1997).

3.3.6 Pragmatism

Pragmatists argue that the research problem should be the key determinant of the paradigm to be used (Tashakkori and Teddlie, 2003; Saunders, Philip and Thorhill, 2007) as it is outcome-oriented and focused on determining the meaning of things (Shannon-Baker, 2016 p. 322). Hence, it is taken to be more like an "approach" rather than just a paradigm (Morgan, 1998; Shannon-Baker, 2016). It provides an alternative argument compared to those held by positivism and interpretivism. For pragmatists, the earth is a moving body of interacting parts. This explains their belief that theories can be both contextual and yet, generalisable if analysed for transferability to other situations (Shannon-Baker, 2016). This means that the pragmatist research is able to maintain both epistemological subjectivity and objectivity in a single study (Feilzer, 2010, p. 8) to highlight shared meanings. As such, a continuum exists between extreme objective and subjective ontologies for pragmatists (Tashakkori and Teddlie, 1998a; Saunders, Lewis and Thornhill, 2009; Morgan, 2014). Consequently, pragmatists believe that even if there is a real world "out there", it may still be socially constructed by people who give meaning to it.

Morgan summarises the advantages of pragmatism as follows (Morgan, 2007):

1. It provides an alternative basis for conceptualising and conducting research without heeding to Metaphysical paradigms which is largely a

political and social movement that lacks the credibility to provide order to the research community. In particular, the author highlights the issue of eligibility to introduce new paradigms to the list of paradigms.

2. It addresses the issue of incommensurability among metaphysical paradigms due to the lack of a common measure as the paradigms use different concepts and methods to solve different problems. Pragmatism trivialises the concept of incommensurability as it highlights the increasing areas of overlap in the definition of paradigms.

3. It provides practical decisions about research including the choice of methodology; often determined by the nature of the research question. This is against the initial position that ontology and epistemological consideration provide the guide.

Pragmatism offers researchers an intermediate philosophical and methodological position to conduct real-world and result-oriented inquiry that is based on action and leads iteratively to further action and the elimination of doubt; and also, provides a basis for methodological mixing which is useful in answering research questions more convincingly (Creswell *et al.*, 2003; Creswell, 2014). Thus, the pragmatist research can be qualitative, quantitative, or even integrate more than one approaches and strategies within a study (Morgan, 2014).

3.4 Research approaches and designs

According to Creswell, research design is the type of inquiry within the three main research approaches: quantitative, qualitative and mixed methods (Creswell, 2014; p. 47). It is the overall strategy that the researcher choses as a guide in articulating the different aspects of the study in a coherent and logical manner, to ensure that the purpose and objective of the study are achieved. Thus, a research design acts as the blueprint for data collection and analyses. Research designs vary for both quantitative and qualitative research. Some of these variants are summarised in the following sections.

3.4.1 Research designs under the quantitative research approach

Quantitative research is traditionally attributed to the positivist/postpositivist paradigm and includes the following types of research designs:

1. Experimental and quasi-experimental design in which an individual or group of individuals are exposed to predefined treatments; the overall aim being to determine if a given treatment influences an outcome (Creswell, 2014).

2. Non-experimental quantitative research design includes causal comparative research and correlational design. In the correlational design, statistical correlation is used to investigate or describe the degree of association between two or more variables whereas the causal comparative research aims at comparing such groups based on events that have already taken place (Creswell, 2012 cited Creswell 2014, p. 47). The most notable non-experimental design is the survey research in which quantitative or numeric description of trends, attitudes or opinions of a population is obtained by studying its sample. Surveys can be cross-sectional or longitudinal in nature with data captured using questionnaires or structured interviews. The overall aim of the survey research is to make generalisation about the population based on the studied sample (Fowler, 2008 cited Creswell, 2014, p.48).

3.4.2 Research designs under the qualitative research approach

According to Creswell, qualitative research aims at exploring individuals' or groups' perspectives to a social or human problem (Creswell, 2014). The research design involves emerging questions and procedures; with data often collected in the participants' settings and analysed in such a manner that highlights individual perspectives while facilitating the inductive creation of a general theme following the researcher's interpretations. Research designs under the qualitative approach include the following (Creswell, 2014, p.49):

1. Narrative research in which the researcher studies the lives of individuals by asking them to narrate their lives' stories. The researcher then tells the story, combining the participants' stories of their lives with those of their own in a collaborative fashion (Clandin and Connelly, 2000) cited (Creswell, 2014).

2. Phenomenological research emanates from psychology and philosophy and aims to study the experience of individuals over a phenomenon. The study often involves conducting interviews after which the researcher presents the description.

3. Grounded theory in which the researcher conceptualises a general abstract theory of a process, action or interaction based on the participants' views. This usually involves multiple stages of data collection, refinement and exploration of interrelationships among the findings (Charmaz, 2006;

Corbin & Straus, 2007) cited (Creswell, 2014). This research design originated from the Social Sciences.

4. Ethnography which originates from anthropology and sociology, where the researcher explores shared patterns of behaviours, language and actions of a cultural group within a setting; over a given time period. Ethnographic research data are usually collected by observation and interviews.

3.4.3 Mixed methods research approach

Creswell defined mixed methods research as the collection or analysis of both quantitative and/or qualitative data collected either sequentially or concurrently, within a single study (Creswell *et al.*, 2003). According to the scholar, mixed methods research requires that the two types of data are integrated at least, once within the study.

Mixed methods research can answer research questions that other designs cannot answer and so, makes inferences better and stronger. The data may be collected concurrently or sequentially with priority given to one type of data but with the different types of data integrated at least, at one stage in the research. Thus, Mixed studies can present widely divergent views to a research problem(Creswell *et al.*, 2003; Tashakkori and Teddlie, 2003).

Saunders note that a research topic which does not strongly suggest that one particular method should be adopted confirms the pragmatist's stance that different methods and approaches can be combined in a study (Saunders, Lewis and Thornhill, 2009). Thus, Morgan (Morgan, 2007) concludes that with Pragmatism, the "what and how" to research is dependent on the researcher's assessment of the practicality of the chosen approach for the given context.

3.4.4 Research designs under the mixed methods approach

In mixed methods research, qualitative and quantitative approaches are usually triangulated or integrated synergistically to improve validity by neutralising the shortcomings of using only one approach in the study (Creswell, 2014). Mixed methods research designs may be differentiated based on the timing/precedence, dominance of the quantitative and qualitative components and the stage of mixing. Precedence refers to the order in which the qualitative or quantitative approach is introduced in the inquiry which could be sequential or parallel. This could be sequential or concurrent. Stage of mixing refers to the point in the inquiry during which the mixing of methods takes effect. This can be at data collection, analyses,

purposes, research questions, theoretical drive, methods, methodology, paradigm, data, analysis, and results Accordingly, the different mixed methods research designs are as follows (Creswell, 2014; Creswell and Plano Clark, 2011):

1. Explanatory sequential mixed methods design: In this mixed methods design, the researcher first carries out a quantitative study on the subject matter; analyses the results and afterwards, conducts a qualitative research on the subject again, to build upon the findings of the initial quantitative study. This design is suitable for research purposes that have strong quantitative inclination. Potential challenges include identifying the quantitative results to further explore as well as differing sample sizes for each study phase.

2. Exploratory sequential mixed methods design: The sequence in this design is the reverse of the explanatory sequential design. A qualitative inquiry is first conducted to explore participants' perspectives on the subject. The data are subsequently analysed, and the findings used to formulate a quantitative research in the next phase of the research. The aim of the initial qualitative phase may be to identify variables for further investigation or to identify suitable instruments for the subsequent inquiry.
3. Convergent Parallel mixed methods design**:** In convergent or parallel mixed methods design, the researcher collects both quantitative and qualitative data at about the same time and uses the information synergistically to interpret the findings of the research. The whole essence of this design is to use two or more different methods in a bid to achieve cross-validation or corroboration of findings within a single study with the assumption that the use of two different research approaches eliminates the inherent short comings of using one approach alone. Contradicting findings may be explained using the other data type or further investigated. Convergent designs may also be either Explanatory or Exploratory in nature.
4. Embedded design**:** This design adds a strand of another type of design in a in a traditional qualitative or quantitative design to enhance the overall design. This may be accomplished by for instance, adding a qualitative component to a study that is based on postpositivist paradigm.
5. Transformative design**:** This design follows a transformative theoretical framework such as feminism or critical race theory, which is used to shape

the interaction, priority, timing and mixing of the qualitative and quantitative component.

6. **Multiphase design:** This design involves conducting the research in more than two phases combining both sequential and concurrent strands over a time period, within a program of study addressing an overall program objective. It is also a suitable option when the research has more than two components and thus, cannot be classified within any of the sequential typologies.

3.5 Design of current research

3.5.1 Paradigm of the current study- Pragmatism

This research is not motivated by any particular scientific orientation but to answer practical questions using approaches and techniques considered appropriate and thereafter, propose a solution. It is driven by the goal of solving a practical problem of medical equipment availability using whatever approach found appropriate to demonstrate how remanufacturing can contribute towards this objective. As such, answers to some of the questions may require paradigmatic and/or methodological mixing. This implies that single philosophical perspective is insufficient, a situation popularly referred to as the incommensurability concept. As already shown, this issue is addressed by the pragmatism paradigm which provides a basis for carrying out studies of this nature, being a suitable foundation for mixed methods research (Tashakkori and Teddlie, 1998b; Creswell *et al.*, 2003; Maxwell and Loomis, 2003; Newman *et al.*, 2003; Onwuegbuzie and Collins, 2007; Creswell, 2014; Morgan, 2014). Therefore, this research is situated within the pragmatist paradigm.

3.5.2 Design of current research- multiphase mixed methods design.

The first set of questions that this study will answer include the following:

A. *What are the main causes of poor medical equipment availability in developing countries?*
B. *How is remanufacturing implemented in the medical device industry?*
C. *How can remanufacturing be described to be able to contribute towards addressing the issue?*
D. *By how much would remanufacturing contribute towards improving medical equipment availability in developing countries**?***

Given the nature of the questions, different philosophical paradigms are implied. Question A was answered through a review of related literature from where the factors were identified. To answer question B, the factors identified in A will be

deductively assessed by experts in a developing country health institution. The questions to be asked will require the experts to be able to provide or "posit" a measure of the impact of each of the factors on the problem as if they were measurable. As already explained in the preliminary sections of this chapter, this type of research where reality is seen as measurable is typical of the positivist paradigm and it is associated with an objective epistemology and ontological realism. A quantitative research technique known as Decision Making Trial and Evaluation Laboratory will be used to analyse the data. This type of analysis is suitable in this case as it appropriate for exploratory research involving the determination of critical and/or causal factors (Chen and Chi, 2015; Si *et al.*, 2018).

Addressing question C requires that the factors affecting medical equipment remanufacturing to be identified and assessed. Measures taken against these factors will help to ensure that medical equipment remanufacturing can exist in practice and that it will really contribute towards solving the availability issue. A description of medical equipment remanufacturing will in turn, answer the second set of questions which are:

E. *What factors potentially affect the implementation of medical equipment remanufacturing in developing countries?*
F. *Which of these factors are more important?*

Answers to the questions would add descriptive value to the study as it would provide insight into the potential reasons why remanufacturing may not have thrived in developing countries. This would then be important considerations in describing medical equipment remanufacturing in a manner that its practice can be sustained for the purpose of contributing towards addressing medical equipment availability issues in developing countries. A theoretical framework based on Lall's Technology Capability Approach had been used to identify key factors to address research question D. However, to determine the more important factors, it is necessary to gain some background information of a developing country context in addition to getting expert assessment of the factors which were previously identified by applying remanufacturing technology to the theoretical framework. Hence, this is a background knowledge-gathering phase which seeks to understand the subjective perceptions of how the factors affect the potential to implement medical equipment remanufacturing. The gathering of subjective views is a characteristic of qualitative research which accounts for the qualitative approach adopted in this strand. Another aspect of the answer to question E

required the experts to estimate how much each of the factors may have contributed towards influencing the implementation of medical equipment remanufacturing. This estimation assumes a reality outside, which is measurable or objective and so, consistent with quantitative research approach. Both the qualitative and quantitative data collection in this phase were done in parallel with experts in relevant developing country's health sectors as participants. The choice of experts as participants is consistent with critical case sampling technique which is a type of purposeful sampling where participants are recruited based on their rich experience and the value which they can add to the study (Benoot, Hannes and Bilsen, 2016).

The last research question assesses the factors that are important to the profitability of medical equipment remanufacturing: purchase intention. It answers the question:

G. *What key factors can potentially affect the purchase intention for remanufactured X-ray equipment?*

Answering this question required a review of the literature to identify existing means of assessing purchase intentions for remanufactured products. Based on this, a conceptual model was developed which can be estimated quantitatively. Hence this element of the study is positivist in nature.

This study, therefore, has three phases shown in Figure 3-2 involving quantitative study in phase 1, a parallel mixed design in phase 2A and a quantitative study in phase 2B. Phase 3 integrates the findings from phases 1 and 2 into tools to facilitate remanufacturing.

After a careful evaluation of the mixed methods research design options and the nature of this study, the most appropriate mixed methods design approach for this study was found to be the **multiphase design** (Creswell, 2014, Schoonenboom and Johnson, 2017) as this permit conducting the different components of the research.

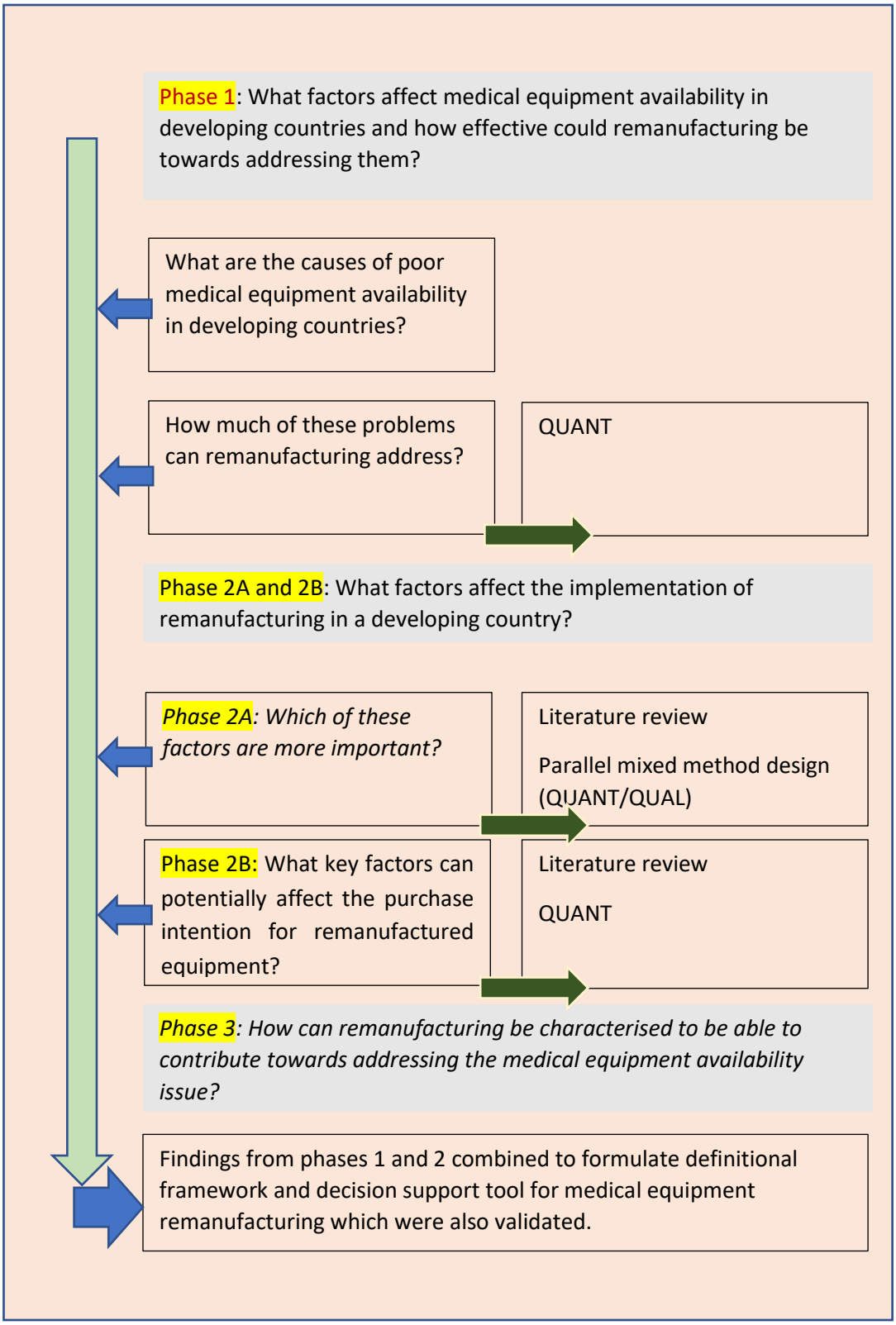

Figure 3-2: Organisation of the study into a 3-phase research

3.5.3 Setting and sampling- phases 1 and 2

Participants included experts with experience working in the Nigerian health sector. This seemed appropriate since in mixed methods research, a researcher can purposefully select settings and participants that provide rich information for the study (Onwuegbuzie & Collins, 2007 p. 287). The researcher recognises that this could affect the generalisability of the findings (Onwuegbuzie and Collins, 2007; Polit and Beck, 2010). However, the goal of this study is not to achieve generalisation to a population but rather, to understand the situation with a view to making analytic and/or logical generalisation. Analytic generalisation does not make generalisation to population but rather, to a theory of the phenomenon being studied and purposeful sampling has been shown to be suitable for studies aiming for such generalisations (Onwuegbuzie and Collins, 2007).

It is usually not possible for a researcher to study the entire population for reasons including cost and time (Fraenkel, Wallen and Hyun, 2012). It is therefore a common practice to select appropriate sample of the population within reach, using a suitable strategy (also known as sampling frame). However, samples are selected either to represent the entire population or on the basis of how they are appropriate to the purpose of the study (Bryman, 2012).

Purposeful Sampling Technique is used in each phase of this research. One variant of this sampling technique used in this study is the critical case sampling. This is a type of purposeful sampling where participants are recruited based on their experience, in order to provide important insights about the subject of the research (Onwuegbuzie and Collins, 2007). The second purposeful sampling variant used in this study is the Snow-ball technique where participants recommend other experienced persons to participate in the study (Onwuegbuzie and Collins, 2007; Benoot, Hannes and Bilsen, 2016). These sampling techniques are adopted not just because of the resource constraints in this study and the perceived difficulty getting potential participants but also because they are consistent with analytic generalisation (Benoot, Hannes and Bilsen, 2016).

3.6 Chapter summary

This chapter started with an exploration of the philosophical basis of research which plays a key role in the determination of appropriate research methods. It then explored different research approaches and designs to facilitate the selection of multiphase mixed methods design which is a proper approach and design for the current study. The pragmatist paradigm was shown to be suitable for this

research study by analysing the research questions against how they are to be answered. Finally, a high-level explanation of the sampling techniques for phases 1 and 2 was presented.

Chapter 4:
Methods for quantitative research phases

4.1 Introduction

Chapter 3 has presented the philosophical background, approach, and design for the current study. In this chapter, the quantitative data analysis techniques applied are explained. This includes the decision-making trial and evaluation laboratory (DEMATEL) technique, and structural equations modelling. The aim of this chapter is to provide some background information that will lead to understanding the analysis that will be performed.

4.2 Rationale for adopting DEMATEL.

In Chapter 2, factors that influence medical equipment availability in developing countries were identified. The nature of these factors indicates that there would be some degree of interrelationships among them. In other to determine the potential impact of remanufacturing in addressing them, it would be necessary to consider the interrelationships since the factors may not be independent of each other. To achieve this, the DEMATEL technique was selected for reasons which will be explained. The relative total prominence of the factors potentially addressed by remanufacturing is expressed as a percentage of the overall total prominence of all the factors. This approach is used to determine the potential impact of medical equipment in addressing the root causes of poor medical equipment availability in developing countries.

The DEMATEL is a multi-criteria decision-making technique that was firstly applied in the Science and Human Affairs Programme of the Batelle Memorial Institute to analyse complicated interrelationships (Wu and Tsai, 2011). It is an efficient technique for exploring the interrelationships among alternative criteria or factors (Chen and Chi, 2015). Apart from its ability to produce a model of interrelationships, DEMATEL can also measure the impact of each factor on the others and can be used to prioritise factors according to relative impacts or degrees of prominence. It also supports group decision making and can be applied to relatively large number of factors.

The DEMATEL technique was used to analyse the identified root causes of poor medical equipment availability; to evaluate the impacts and causal relationship existing among them. The DEMATEL analysis technique was chosen since it can effectively demonstrate mutual influences, both direct and indirect and is therefore suitable in analysing complex cause and effect problems such as the one

encountered in this study. Other multi-criteria decision methods such as Analytic Hierarchy Process and Technique for order performance by similarity to ideal performance (TOPSIS) fall short in these respects. Unlike these other techniques, DEMATEL also allows aggregated group decision making which can yield more valid results by including inputs from more than one decision maker in the analysis (Si *et al.*, 2018). The relative total prominence of the root causes addressed by remanufacturing may be expressed as a percentage of the overall total prominence of all the factors to determine the potential impact of medical equipment in addressing the root issue of poor medical equipment availability.

4.3 Sampling for phase 1

In the first phase where the potential contribution of remanufacturing towards addressing developing countries' medical equipment issues is studied, an instance of Critical case purposeful sampling known as Expert Review Technique was used. This involves a structured review of the factors identified through the literature review on causes of poor medical equipment availability by a small sample of experts, for validation (Beecham *et al.*, 2005). This took place between 6 June 2018 and 3 August 2018.

The respondents were selected based on their experience in their respective positions and good understanding of medical equipment-related issues in their organisations. As shown in Table 4-1, they come from private, secondary, and tertiary hospitals where medical equipment need is extensive. One of the respondents is also, actively involved in design and maintenance of medical equipment for local use. Hence, the respondents' views are valid and capable of representing the reality regarding factors affecting medical equipment availability. In this study, inputs from eight respondents were used which has the potential to provide more valid results compared to other studies adopting the same methodology such as Shao and Mier (Shao, Taisch and Ortega-Mier, 2016) which only included three participants and Ahmed which used inputs from only 5 respondents (Ahmed *et al.*, 2016).

Table 4-1: Summary of participants in study phase 2 which aims to assess the impact of remanufacturing towards addressing the medical equipment availability issues.

Respondent	Type of Organisation	Profession	Experience (Years)
1	State teaching hospital	Biomedical Engineer	9
2	Federal teaching hospital	Senior Radiographer	8
3	State university/teaching hospital	Biomedical Engineering Lecturer	10
4	Mission hospital	Medical Doctor	7
5	State Teaching Hospital	Biomedical Engineer	9
6	Federal Teaching hospital	Biomedical Engineer	22
7	Private hospital	Medical Doctor	7
8	Independent medical equipment designer and repairer	Biomedical Engineering Technologist	23

4.4 Implementing the DEMATEL Technique

DEMATEL analyses are implemented following these 3 main steps.(Ahmed *et al.*, 2016):

Stage 1. Respondents were selected as summarised in table 2, to evaluate in a pairwise manner, the direct impact of each factor Fi on Fj. Each respondent was first introduced to the identified factors as well as the pattern for conducting the pairwise comparisons. The impact is assessed using integers ranging from 0 to 4; with 0 representing no influence, 1 representing very low influence, 2 representing low influence, 3 representing high influence and 4 representing very high influence. The magnitude of each factor's influence is indicated by the notation: a_{ij} which is the degree of influence that factor i has on factor j according to the assessment of each respondent.

Given that there are n factors ($F_1, F_2, \dots F_n$) in the resultant $n \times n$ comparison matrix for each expert, then the terms $i = j = 0$ representing the diagonal terms will equal zero since a factor would have no impact on itself. Each respondent thus produces the matrix:

$$A^b = \left[a^b{}_{ij}\right], \ where\ b = 1, 2, \dots M \text{ refer to individual respondents} \qquad (1)$$

Stage 2: To aggregate the views of the respondents, the average of the direct relation matrix is evaluated as follows:

$$x_{ij} = \frac{1}{M} \sum_{b=1}^{M} a_{ij} \quad (2)$$

Stage 3: The average direct matrix $[x_{ij}]$ is normalised to give T, according to the following relation:

$$T = X \times C \quad (3)$$

Where X= $[x_{ij}]$ and C = $\min \left[\frac{1}{max \sum_{i=1}^{n} x_{ij}}, \quad \frac{1}{max \sum_{j=1}^{n} x_{ij}}\right]$

$The\ elements\ of\ the\ normalised\ matrix\ T\ are\ in\ the\ range\ 0\ to\ 1$

Stage 4: Finally, the total relation matrix U is calculated using the following equation:

$$U = T(I-T)^{-1} \quad \textit{Where I is the identity matrix} \quad (4)$$

In the matrix U, r_i is the i^{th} row sum in the matrix U and signifies the sum of direct and indirect effects emanating from F_i to other factors. Similarly, c_j is the j^{th} column sum in the same matrix and represents the sum of direct and indirect effects impacting on factor F_j from other factors. Hence,

$$\mathrm{R} = [r_i]_{nx1} = [\sum_{j=1}^{n} u_{ij}]_{nx1} \quad (5)$$

$$\mathrm{C} = [c_j]_{1xn} = [\sum_{j=1}^{n} u_{ij}]_{1xn}$$

Given that the vector$[r_i]_{n\times1}$and the vector$[c_j]_{1\times n}$ in the matrix U represent the sum of the columns and sum of the rows of the total direct relation matrix respectively, then r_i represent the direct and indirect impacts of factor F_i on other factors. Similarly, c_j represents the direct and indirect impacts of other factors on factor F_j. The sum $(R + C)$ otherwise referred to as the Prominence expresses the total effects caused and received by a factor. On the other hand, the difference $(R - C)$ called the Relation represents its net influence on the others. If the value $(\mathrm{R} + \mathrm{C}) > 0$, then the factor is a driving factor, otherwise the factor would be a driven factor if $(\mathrm{R} - \mathrm{C}) < 0$. Driving factors belong to the "Cause" group while the driven factors belong to the "effect" group. A threshold value is computed from the total relation matrix U which represents the minimum significant influence to be considered individually. The threshold may be calculated following Shao and Mier's technique by summing the mean of the total relation matrix and its standard deviation as

follows:

$$Mean(U) + \sigma(U) \quad (6)$$

Stronger causal relationships may also be highlighted by instead, adding two standard deviations of the total relation matrix; that is:

$$Mean(U) + 2\sigma(U)$$

The potential contribution of medical equipment remanufacturing in addressing the poor availability of medical equipment may be estimated as a percentage of the overall total prominence, as follows:

$$100 \times \frac{\sum_{i=1}^{m} P_i}{\sum_{j=1}^{n} P_j} = \frac{\sum_{i=1}^{k} r_i + c_i}{\sum_{j}^{l} r_i + c_i}, \quad (7)$$

$k = number\ of\ factors\ potentially\ addressed\ by\ remanufacturing$
$l = total\ number\ of\ factors$

$P_i = totalprominence\ of\ the\ factors\ potentiallyaddressed\ by\ remanufacturing$

$P_j = \ total\ prominence\ of\ all\ factors\ affecting\ medical\ equipment\ availability$

4.5 Impact relation matrix (IRM)

For each of the factors being assessed, a specific value of R and C was observed and recorded and from these, the values of R-C and R+C for each of the factors calculated as already discussed. An IRM chart is then formed using these values (R+C and R-C). The chat is a scatter plot of R+C values as X-axis and R-C values as Y-axis. Recall that R-values indicate the influence of one factor over the others and C- values indicate the influence of other factors on that particular factor. Thus, then R+C values indicate the sum of influence of a factor on other factors and influence exerted on it by the other factors. It decides the degree of importance of each factor under being assessed. R-C values on the other hand, helps to know if a factor belongs to the “cause” group or the “effect” group.

4.6 Sampling and data collection for phase 2A: Quantitative component

Critical case sampling was used in this phase (Onwuegbuzie and Collins, 2007). The participants in this study phase are medical practitioners with experience in the Nigerian health care industry. Participants are summarised in Table 4-2. They include hospital manager, medical physicist, clinical engineers, and biomedical engineers working with medical equipment suppliers.

Data collection for this phase lasted from 6 June 2018 to 30 May 2019. Some of the participants that took part in the phase1 were reused in this stage, these are marked

with the dollar sign on the table. There reuse is not considered detrimental since the objective of the study in this phase differs from that in the first phase.

Structured questionnaires were used for data collection. Descriptive statistical analysis was used to analyse the quantitative data obtained. The choice of descriptive statistical analysis was due to small sample size which would not permit inferential or relational statistical analysis as the minimum sample size required would be 30 (Kaplan, Chambers and Glasgow, 2014) which is quite greater than 12 subjects that participated.

Table 4-2: Characteristics of participants in phase 2A of the research.

Cases	Profession	Years of experience	Nature of employment
A1	*$Biomedical Engineer	> 10	Federal Hospital (Head of Biomedical Engineering unit)
A2		5-10	National supplier of medical Equipment (large scale)

A3		< 5	Medical equipment servicing and supplier (small scale)
A4	*$Biomedical Engineer		State hospital (Head Biomedical Engineering unit)
B1	*Radiographer	5-10	Federal hospital
B2	Radiographer	5-10	Federal specialist hospital
B3	*$Radiographer	>10	Federal hospital
C	**Medical Doctor	>10	Federal hospital (Chief medical Director)
D	Medical equipment marketer and servicing	>10	Large scale distribution/marketing of (Key account manager)
D1	Servicing	5-10	Small scale distribution/marketing of medical equipment
D2	Marketer	5-10	Small scale distribution/marketing of medical equipment
D3	Distributor	5-10	Large scale distribution/marketing of medical equipment
E	**Medical Physicist	> 10	Federal Teaching Hospital

*NB: * Filled the questionnaire and were also interviewed. **Only interviewed.* $ Participated in phase 1.
Sample questionnaire and Interviews are included as Appendices B1 and B2 respectively

4.7 Analysis technique for Phase 2A (Quan component): Descriptive statistical analysis

Descriptive statistical analysis was used to analyse the quantitative data included in the phase 2A of this research. Descriptive statistical analyses are used to organise and describe the basic features of a dataset in a study through summaries about the sample and measures which they provide. Descriptive statistics is frequently distinguished from inferential statistics. In descriptive statistics, analysis is limited to simply limited to finding out what is going on in the data. On the other hand, inferential statistics aims at inferring from the sample data to the population or to establish that

observed difference between groups in the study is not by chance. Descriptive analysis can be in the following forms (Tahir and Padjadjaran, 2019).

1. Use of tables and charts.
2. Distribution: This is the summary of individual values or ranges of values in the dataset
3. The central tendency: This is an estimate of the centre of the distribution by calculating either mean, median and mode.
4. The dispersion: This refers to the spread of the data around the central tendency, may be calculated as standard deviation or range

The distribution and central tendency were used to analyse the quantitative data in phase 2A. Scores were represented as grouped distribution and the median of each class was calculated and subsequently used to rank the factors. In phase 2B, descriptive statistical analysis was performed first before implementing the SEM that followed.

4.8 Sampling for 2B

For this phase of the study, the population is healthcare professionals in developing countries. As this study attempts to address an important issue in healthcare, there is strong indication that it will drive the necessary cognitive motivation to consciously provide valid inputs by respondents (Krosnick, Presser and Building, 2009). Further, the sample frame includes professionals with extensive education and understanding of the industry, that are likely to possess the cognitive ability to understand the questions and answer them coherently. This is because the respondents are experts in the field and would likely have preformulated perspectives concerning the issues relating to medical equipment availability which most likely, have also affected them. As such, participants were very likely to be motivated, understand the functions, applications as well as the potential safety issues associated with X-ray equipment.

One of the data analysis technique employed in this phase which is Structural Equations Modelling has several recommendations concerning sample size adequacy. Anderson and Gerbing (Anderson and Gerbing, 1998) recommends a sample size in the range 100 – 150 as minimum. Kline (Kline, 2011) holds a similar view, noting that sample size below 100 should be considered insufficient while between 100 and 200 samples should be considered as average and above 200 as large. Other scholars argue that the right sample size should depend on the nature of the model being estimated. There are several views on this perspective; with some scholars arguing that sample size should be 5 times the number of indicator variables

in the study if the data are normally distributed or 10 times the indicator variables otherwise (Wolf *et al.*, 2013).

In the current study, there are 18 indicator variables, a sample size of 300. There are some null fields in the 130 returned questionnaires which caused variations in the totals reported in the descriptive statistical analysis. However, empty fields cannot be used in SEM. A combination of listwise deletion and replacement with average values was used to prepare the data for the analysis and this left a total of 114 valid responses. This value exceeds the requirements of the school of thought that sample size should be above 100. Again, the value is also greater than 5 times the number of indicator variables. Thus, SEM can be performed on the sample data.

Diagnostic X-ray equipment was selected as a case study because it is a very important diagnostic imaging modality in the healthcare industry. It is also popular among many healthcare professionals because of its diverse applications and its operating principle is similar to those of other equipment such as CT scanners, Mammography equipment and Positron emission tomography equipment. Thus, participants in this study include medical doctors, radiographers and Biomedical engineers with expertise in the Nigerian healthcare industry and who have extensive experience with X-ray equipment. Having practiced their professions to various extents in Nigeria, participants would have gained an understanding of the economic and technical realities in the industry. Data collection for this study phase started on 17 July 2019 and ended on 31 January 2020. Table 4-3 summarises the participants' characteristics.

Table 4-3: Summary of participants in phase 2B study

Profession	**work in public hospital**	**Work in private hospital**	**Work in Independent diagnostic imaging centre**	**Totals**
Medical doctors	62	30		92
Radiographers	27	2	3	32
Biomedical Engineers	1	2	1	4
Manager			1	1
Radiography Lecturer (University)				1

Total	**130**		
Years of work experience			
Profession	**3-5 years**	**5-10 years**	**Over 10 years**
Medical doctors	32	53	7
Radiographers	6	20	3
Biomedical Engineers	2	2	
Manager			1
Radiography Lecturer			1

4.9 Phase 2B analysis technique: Structural equation modelling

Structural equation modelling (SEM) employs a number of models to depict and estimate relationships among variables and constructs with a view to quantitatively testing a researcher's hypothesized model (Schumacker, Lomax and Group, 2010). The model is usually developed from theory and empirical research while the SEM is used to estimate the extent to which the data supports the model. Thus, SEM advances knowledge by enhancing the understanding of complex theoretical constructs which may be made up of latent or observed variables.

Latent variables are neither observable nor directly measurable. They are indicated by the observed variables which are actually measured using techniques such as tests and surveys (Schumacker, Lomax and Group, 2010). Both observable and latent variables may either be dependent or independent. An independent variable is not influenced by any other variable in the model while a dependent variable is influenced by other variables in the model (Schumacker, Lomax and Group, 2010).

Models which can be estimated using an SEM approach include: i) Regression analysis, ii) Path analysis and iii) Confirmatory factor analysis. A regression analysis involves only observable variables with one of the variables dependent on one or more of the others that are independent. A path model is also predominantly characterized by observable variables. However, unlike the regression model, its flexibility permits analysis of more complex models than regression analysis and may include both multiple independent observable variables as well as multiple dependent observable variables (Schumacker, Lomax and Group, 2010). A confirmatory factor model is made up of several observable variables combined theoretically to represent latent variables which may be dependent or independent (Schumacker, Lomax and Group, 2010). A proposed construct will be tested consecutively using the CFA in this chapter. Hence, CFA is introduced below.

4.10 Confirmatory factor analysis (CFA)

The CFA is an SEM procedure used to assess the fitness of purpose of a single group measurement model. This is achieved by comparing the implied covariance structure of the proposed hypothesised model to the covariance model observed using the sample data for similarity (Cheung and Rensvold, 2002). It became popular in the seventy's when computer programme became available for it (Hoyle, 2004). The result of such comparison is usually stated in terms of goodness of fit, the most common of which is the chi-squared statistic; such that a non-significant value would lead to failure to reject the null hypothesis that the covariance structure of the hypothesised model is identical to that of the observed covariance model. This would imply that the model is accepted as a god fit (Marsh and Balla, 1994; Cheung and Rensvold, 2002). While LISREL which was first used in the seventy's has been updated severally, other software for conducting CFA include EQS and AMOS which is now included in SPSS (Prudon, 2015).

A hypothetical model represents the models developed from hypotheses developed from a study or theory. In general, such a model is made up of four parts (Hoyle, 2004):

ii. Indicator variables: There must be at least 2 indicator variables.
iii. Latent variable: These are the unobserved variables that are only inferred from the commonality of the indicator variables.
iv. Measurement error: This explains the variability in the indicator variables that is outside the limits characterising the latent variables.
v. Loadings: This signifies the degree to which the variability in each indicator variable contribute towards characterising the latent variable.

4.10.1 CFA measurement

In CFA, the discrepancy between the model predicted from theory and that established using the data is expressed in terms of chi square (χ^2) value and other indices used to assess the goodness of fit (GOF). The loadings and modification indices on the other hand, provide feedback about the fit at item level (Prudon, 2015). As noted above, the estimation technique used in CFA is known as structural equation modelling (SEM) which is a sophisticated statistical test for testing complex theoretical models on data (Prudon, 2015).

4.10.2 Limitations of CFA and corrective measures

The feedback from modification indices is reportedly limited while the χ^2 and GOF are problematic (Prudon, 2015). The χ^2 is functionally dependent on the sample size; such that its sensitivity is very high for large sample size in which case, trivial effects

become statistically significant. Thus, it is often possible to reject a hypothesis with smaller sample size or fail to reject a hypothesis when the sample size is large (Gatignon, 2013). Hypothesised CFA models are only approximations of reality; not exact statement of truth; consequently, any model may be rejected if the sample size is high and conversely, accepted if the sample size is much less (Marsh and Balla, 1994). Thus, hypothesis testing should not expect the proposed model to match data exactly. Consequently, researchers usually use other indices to assess model fit. (Marsh and Balla, 1994; Hoyle, 2004). Most recommended fits include the Tucker-Lewis index (TLI), Comparative fit index (CFI), Normed fit index (NNFI) and root mean square error approximation (RMSEA) (Cheung and Rensvold, 2002). As most of these new GFI do not have known sample distribution profile, researchers have come up with various thresholds for each index and suggest that the use of multiple indices for a model.

A rootmean square error approximation (RMSEA) potentially addresses the challenges to the use of chi-squared value estimate with respect to the adequacy of sample size. It ranges from 0 to 1; the values closer to 0 indicate that the discrepancy between the hypothesised model and optimally selected parameter estimates and population covariances is small.

In general, an SEM model is considered a good fit and suitable for interpreting, if it has a **Chi square** value for which **P > 0.05**, Tucker Lewis Index **(TLI) >0.95, Comparative fit index (GFI) > 0.9** or **0.8** and Root mean square error approximation **(RMSEA) <0.08 or 0.1** at most (Hooper, Coughlan and Mullen, 2008; Crockett, 2011; Kline, 2011)

4.10.3 Quality of the quantitative research: Reliability and validity

In a quantitative study, validity refers to the extent to which a concept is accurately measured. Validity is a measure of how much an instrument measures what it is designed to measure. For instance, a survey designed to explore depression, but which actually measures anxiety would not be considered to be valid (Heale and Twycross, 2015). The second measure of quality in a quantitative study is reliability, or the accuracy of an instrument. This measure assesses the degree of consistency in the results yielded by a research instrument when used in similar situation over multiple times (Heale and Twycross, 2015).

Validity demonstrates how much instruments reflect a whole domain of underlying theoretical framework as well as how the scales are effective and efficient measurement instruments. Validity considerations are exceptionally important in deciding which items to retain for further analysis during scale development. Key

types of validity to account for in instrument development include face or criterion validity, content validity and construct validity. Construct validity refers to the overall extent to which a research instrument measures the intended constructs. It may be assessed in several ways, two of which include discriminant and convergent validity (Hardesty and Bearden, 2004; Heale and Twycross, 2015). Discriminant validity assesses the extent to which the instrument can distinguish between a construct of interest and other constructs. This may be demonstrated for instance, by using the Exploratory factor analysis and having all the variables relating to a factor load strongly on it and weakly on other factors. On the other hand, convergent validity is used to demonstrate that variables measuring similar constructs are correlated.

Face or criterion validity is the extent to which a measure reflects what it is intended in relation to other instruments that measure the same variables (Heale and Twycross, 2015). Hence, it may be in the form of an assessment done by a subset of the respondents or experts in the subject area to ensure that the instrument is appropriate for the targeted construct and objectives (Hardesty and Bearden, 2004).

Content validity on the other hand, is defined as the extent to which a measure's items reflect a sample of theoretical content domain or all aspects of a construct (Hardesty and Bearden, 2004). It may therefore, be regarded as the extent to which the instrument measures all aspects of a construct (Heale and Twycross, 2015).

Reliability is a measure of how consistent an instrument would be in assessing the intended constructs. It covers three broad attributes (Heale and Twycross, 2015):

1. Homogeneity or internal consistency which is the extent to which items on a scale measure a construct. The most used measure of homogeneity assessment is the Cronbach's alpha; which ranges from 0 to 1; with values over 0.7 considered acceptable.
2. Stability which is a measure of how consistent the instrument would be if tested repeatedly.
3. Equivalence which assesses the consistency in the measurement obtained from several users of the instrument.

Measures undertaken to ensure content and face validity in this phase of the research include broad literature review covering developing country health care needs, developed country refurbishment and remanufacturing practice as well as the potential impact of medical equipment remanufacturing for developing country health care industry. Existing scales are used, which have been tested in other studies and shown to be both valid and reliable. The current study also used experts including researchers and relevant medical practitioners to pre-test the instrument.

Discriminant and convergence validity were also confirmed using Exploratory Factor Analysis while the internal consistency of each construct was assessed using Cronbach's alpha. The Cronbach's alpha for each construct were found to be greater than 0.7 as recommended.

4.11 Chapter summary

In this chapter, the methods adopted for quantitative phases of this study were presented. These include the sampling techniques as well as data collection and analyses techniques for the DEMATEL technique, Descriptive statistical analyses and Structural equations modelling (SEM). The DEMATEL technique will be used in the Phase 1 of the analyses, Descriptive statistical analyses will be used in phase 2A while the SEM in phase 2B.

Chapter 5:
Qualitative data collection and analyses methods

5.1 Introduction

This study identified the causes of poor medical equipment availability in developing countries. While the impacts of the factors identified are to be assessed quantitatively, remanufacturing was shown to be particularly applicable to the needs of developing countries especially with respect to medical equipment. As remanufacturing is new in medical equipment domain, a theoretical framework was used to identify key factors with the potential to affect the implementation of medical equipment remanufacturing. The identification of these factors was based on consideration of automotive remanufacturing which is a more advanced and stable. Factors which were identified formed the basis of the phase 2A study which employs both qualitative and quantitative research approaches. This chapter describes the qualitative component of the phase 2A study- the interview data collection method employed and the analysis approach. It also describes the validation process for the frameworks developed in this study.

5.2 Aims and objectives of the qualitative component of the study.

The Interpretivist's view which is characteristic of qualitative research is appropriate in studying humanly fashioned ways of seeing things (Crotty, 2011; p.9). This is achieved by analysing the different perspectives to the subject of the study. Research conducted in this paradigm can help to provide an understanding of the different patterns or opinions about a subject. Hence, a qualitative component was found suitable in understanding the perceptions concerning the potential to implement cost effective medical equipment remanufacturing in a developing country. The qualitative component of this research explores the factors that have been identified via preliminary literature review to understand expert perspectives regarding how they may influence the implementation of medical equipment remanufacturing. This qualitative research component will, therefore, answer the following questions:

> ***What factors potentially affect the implementation of medical equipment remanufacturing in developing countries?***

In essence, this research phase will explore how the following factors may impact on medical equipment remanufacturing:

1. Incentives- The potential to derive incentive from medical equipment remanufacturing. The factors that impact on the profitability of

remanufacturing were derived from the theoretical framework developed in chapter three.

2. Institutional factors- The potential Impact of institutions in providing suitable environment to support medical equipment remanufacturing. Institutional factors affecting remanufacturing have been presented previously in chapter three and will form the themes in this aspect of the qualitative study.

3. Technological factors- Technological factors ensure that the right equipment, processes, products and technological innovations are available for remanufacturing. The scope of technological factors considered in this work is covered in chapter three.

5.3 Interviews

As discussed in chapter three, qualitative studies follow from philosophical paradigm known as interpretivism which reflects the diverse views of reality corresponding to its varied interpretations. As discussed in chapter three also, this qualitative study employed interviews for data collection.

An interview is a qualitative research instrument that is particularly useful in understanding peoples' experience, feelings and interpretation of the social world (Mack et al., 2005). Interviews take the form of a two-way dialogue during which participants reveal their inner world experience to the researcher. According to Kvale (Kvale, 1996), qualitative interview refers to "attempts to understand the world from the subjects' point of view, to unfold the meaning of peoples' experiences, to uncover their lived world prior to scientific explanations." During interviews, participants discuss their interpretations of 'the world or phenomenon being studied, and their responses indicate their own subjective interpretations (Cohen, Manion and Morrison, 2011 p. 409). In literal sense, interview is coined from two words: "inter" and "view" which in combination refers to inter change or exchange of views between people conversing about a subject of mutual interest (Kvale, 1996 p.14). Hence, interview is a qualitative research instrument deeply seated in the interpretive or constructionism paradigm and explores how knowledge and beliefs are constructed.

In remanufacturing research, the use of interviews is popular. Usually, experts from organisations where remanufacturing is conducted are interviewed to understand their perspectives on issues or subjects of studies (Chaowanapong, Jongwanich and Ijomah, 2018).

Interviews involve a conversation between two people Talking being a very powerful tool which includes several features that mere written communication cannot convey,

can help to achieve much more in depth meaning from the participants. Hence, Robson (Robson, 2002) suggests that interviews are most appropriate method of data collection for research questions involving the determination of participants' thoughts, their contexts and feelings in relation to a subject. Interview data collection method may also be chosen because it allows asking open questions which enables unrestricted exploration of the research questions and the generation of rich data (Richardson, 2000).

For these reasons, I chose to apply the interview data collection method in the first segment of this phase 2 research so that I can get a sense of the perceptions and views of developing country experts in relation to factors that may affect the implementation of medical equipment remanufacturing. I also adopted the following recommendations by (Denzin and Lincoln, 2005), to ensure that the interviews are guided by best practice:

1. Access to the participants' setting, Understanding the Language and Culture of the respondents: This includes considering how to get access to the participants and their location as well as developing strategies to deal with language barriers. The researcher must also figure out how to read meanings from participants' responses when their cultural backgrounds differ. In the current study, the participants were from the same cultural background as this researcher, and this helped to potentially associated issues.

2. Decide how to present oneself: The researcher's general appearance to participants is also an important consideration as this gives an impression to participants about the importance of the research and how to respond. The researcher has to show an appearance, personality and stance that influence the participants to respond properly. In this study, the researcher maintained a professional outlook, and a friendly attitude towards the participants to encourage them to speak freely about the subject of the study.

3. Gaining the trust of participants: It is important for researchers to gain the trust of participants as this is essential to having them respond freely to the questions asked during the interview. It is by responding freely that participants give rich data which makes the interview an excellent data collection method in qualitative studies. In this study, the participants were assured that their responses will be anonymised.

4. Rapport: It is essential for the researcher to establish rapport with the participant. This is necessary to continue holding the conversation with the participant. Achieving

rapport requires the researcher to see the world or the issue being researched from the participant's perspective instead of forcing a perspective on them.

5. Gathering empirical data: This refers to considerations about the tools to be used in collecting data from the participants such as field notes. It is important to note everything the participants say no matter how trivial it may seem at the time of the interview. In the present study, the researcher used an electronic recorder to record participant responses to ensure that none is lost.

In this study, the researcher also implemented several other measures to ensure the quality of the research. The quality criteria considered are in accordance with those recommended by Kvale (Kvale, 1996 p. 145) and includes considerations of the nature of questions, how they are designed. Questions should not be too long. The other criteria are about the answers. The answers from the participants should be assessed against their spontaneity, specificity and how the interviewer follows up on the answers to get clarifications. Clarifying questions help interviewers to verify their interpretation of the participants' responses in the course of the interview.

Overall, the measures taken to prepare and present the interviews helped to avoid the following pitfalls (Cicourel 1964 cited Cohen et al., 2011):

1. Presence of many differing factors from one interview to another, such as mutual trust, social distance and the interviewer's control.

2. The feeling of uneasy and adoption of avoidance techniques by participants which ultimately impact on the quality and depth of the data generated.

3. Vague terms and meanings due to incorrect interpretations and lack of rapport between the interviewer and the interviewee.

I ensured that the interviewees vividly understood the purpose of the study. I also gave them the freedom to ask me to repeat or clarify confusing questions. On my own side, I asked questions that helped to clarify responses from the participants when necessary, to avoid mixing my own opinion with theirs. Throughout, I was careful not to lead or influence them any preconceived responses but allowed them to expand or elaborate their points as much as they liked.

5.4 Semi-structured interviews.

The type of the interview selected for any study depends on the research question and the purpose of the research (Cohen et al, 2011). Generally, however, interviews fall within three broad categories, namely:

1. structured interviews

2. semi structured interviews

3. Unstructured interviews

Semi structured interviews have been chosen for this research. Located between the structured and unstructured interview, the semi structured interview utilises predetermined questions but the order in which they are asked can be varied according to the researcher's discretion or consideration of appropriateness (Robson, 2002). The use of semi structured interviews still requires the researcher to have a list of issues to be addressed and questions to be answered but the interviewee has the freedom to expand their answers.

Semi-structured interviewing encourages flexibility while being accommodating in design and is particularly considers participants' personal accounts (Kvale, 1996). The flexibility aspect of the design of semi structured interviews emphasises allowing participants to make contributions in their areas of expertise (Miles and Huberman, 1994). The interviewer allows the interviewee to freely answer the questions asked in a non-leading manner. Hence to avoid potential bias, the researcher should maintain his knowledge and let the interviewee to flow naturally. It also a good practice to leave out sensitive questions till the end of the interview as this would allow the interviewee time to build the rapport and trust needed to answer such questions (Healy and Rawlinson, 1994 p.138).

During each interview, I was very mindful of the need to build a rapport with participants to enable them to develop the confidence and trust to contribute rich and valuable information. I did this so that because further questions that I was to ask would come from the richness of the initial responses from the participants. For this reason, it was important that each participant developed the trust and confidence to be able to speak at length.

The participants in this study were all very happy to be interviewed and each of them elaborated their perspectives concerning the factors influencing the implementation of medical equipment remanufacturing. The interviewees were asked to complete the survey questionnaires prior to the interview. This also provided the opportunity for them to get familiarised them with the concept of medical equipment remanufacturing ahead of the interview. A total of five participants agreed to be interviewed out of those who were initially sent the survey questionnaires.

Each interview explored the factors affecting the implementation of medical equipment remanufacturing considering the area of expertise of each of the participant. I promptly provided further explanation of remanufacturing to each of the

participant that demonstrated a lack of understanding of the term in their response. This ensured that their responses remained relevant to the study.

I chose not to ask the interviewees demographic questions related to their years of experience or training at the beginning of the interview, to avoid any possible biases or preconceptions. However, I already had some of this information from the questionnaires returned as demographic information was inclusive. During the interview, I was always aware that my background may influence the participant's responses as I have a background in Biomedical Engineering and understand most of the concepts and factors forming the basis of the research. However, I chose not to discuss my background with the participants before the interview to avoid bias or influence on the responses.

5.5 Piloting the interviews

The aim of piloting is to identify potential errors, flaws and limitations in the way the interview has been designed so that corrections and improvements may be made before the actual interviews are held with participants (Kvale, 1996). Piloting offers researchers the opportunity to gain knowledge and insight regarding how appropriate their research is supported by the interviews and helps them to gain a practical understanding of elements of the initial design that could potentially lead to detractions from the research objective (Seidman, 2013).

I piloted the interview on three PhD researchers and two master's degree students from Nigeria. During the piloting, the participants recommended improving the clarity and length of the questions. For this reason, I either rephrased or broke concerned questions down to shorter lengths. The participants also noted that they were relaxed and easily developed rapport with me as the interview progressed. Their feedback also indicated that they found the interview interesting. Reflecting on the pilot interviews helped me see how the related research questions are addressed.

5.6 Interview sampling

Purposeful sampling was used in this strand of the phase 2 study. This technique selects participants based on the experience which the researcher considers relevant to the study. Hence, in purposive sampling, the researcher purposefully or intentionally (Cohen et al., 2011) selects participants considered to be rich in the information that addresses the research question. The researcher, therefore, assesses the population and decides which cases or participants to recruit for the study to provide the richest information to answer the questions which the research aims to answer (McMIllan, 1996).

In accordance with the principle of purposive sampling is that the researcher can get the best information by concentrating on information-rich segment of the population, experts were sampled from Nigeria for the following reasons:

1. Nigeria is a typical developing country and so, the experience of its health care experts can represent those of other experts in other developing countries.
2. The researcher is from Nigeria and could build the network of experts to participate in the research.
3. The study is constrained in time and resources which deterred the researcher from recruiting participants from other countries due to potential increase in time and cost.

The participants have been shown in Table 5-1. A combination of critical case and snowball purposeful sampling was used to recruit participants. The researcher first contacted five experts who then recommended others that also agreed to participate in the study. Some of the initial participants contacted took part in the quantitative strand of this phase and were reused in this phase. There reuse was not considered detrimental to the quality of the study since the aim of the first research phase was different, with the tool used only requiring an estimation based on experience.

Data collection was stopped upon achieving saturation in content, referring to a convergence in the themes contained in the responses from participants (Vasileiou *et al.*, 2018). In qualitative studies, data gathering may only be stopped upon achieving data saturation (Onwuegbuzie and Collins, 2007). Data were collected using unstructured interviews in the first strand and semi structured questionnaires in the second. Only a subset of the participants was interviewed. The interview transcripts are attached at Appendix B along with the questionnaire sample and related data.

The analysis technique used in the first strand of phase 2A is the Deductive thematic Analysis (Bennett, Barrett and Helmich, 2019). It involves the use of predetermined categories as the basis of a new study to enhance the relevance of its findings. For instance, in the study students' perspectives on professional roles (Bennett *et al.*, 2013), students' learning is reported relative to an established framework on professionalism. In the current study, data is analysed to demonstrate the occurrence of themes which have been predetermined from the literature review on factors affecting the implementation of remanufacturing.

Table 5-1: Characteristics of participants in phase 2A of the research

Cases	Profession	Years of experience	Nature of employment
A1	*$Biomedical Engineer	> 10	Federal Hospital (Head of Biomedical Engineering unit)
A2		5-10	National supplier of medical Equipment (large scale)
A3		< 5	Medical equipment servicing and supplier (small scale)
A4	*$Biomedical Engineer		State hospital (Head Biomedical Engineering unit)
B1	*Radiographer	5-10	Federal hospital
B2	Radiographer	5-10	Federal specialist hospital
B3	*$Radiographer	>10	Federal hospital
C	**Medical Doctor	>10	Federal hospital (Chief medical Director)
D	Medical equipment marketer and servicing	>10	Large scale distribution/marketing of (Key account manager)
D1	Servicing	5-10	Small scale distribution/marketing of medical equipment
D2	Marketer	5-10	Small scale distribution/marketing of medical equipment
D3	Distributor	5-10	Large scale distribution/marketing of medical equipment
E	**Medical Physicist	> 10	Federal Teaching Hospital

*NB: * Filled the questionnaire and were also interviewed. **Only interviewed.* $ Participated in phase 1. *Sample questionnaire and Interviews are included as Appendices B1 and B2 respectively.*

5.7 Ethical issues

The researcher adopted measures to guarantee the reliability and validity of this phase of the study. The issues considered and measures implemented are discussed below.

5.8 Confidentiality

It is a good practice to maintain the privacy of participants of a research. This is because assuring participants of their privacy helps to get the most honest responses from them. Hence, considerations for participants' privacy should run from the start to the end of the research, with safety nets put in place to guarantee confidentiality. Measures which help to realise this include ensuring that only the minimal personal information needed to ensure proper sampling is collected. Also, information that are personal and traceable to a participant should not be collected and participants should be promised that their personal information would not be transmitted (Cohen et al., 2011 p.92).

In line with these recommendations, participants' names and personal data were not taken during the interviews. Each participant was also assured of the confidentiality of their inputs; that only their responses will be collected while any other personal data will be destroyed. I therefore ensured that the published study would not contain any participant information that could be used to trace their responses to them.

5.9 Reliability and validity

Reliability and validity are key indicators of the quality of a research. As such, parameters used to assess reliability and validity essentially distinguish between good and bad research. Implementing these parameters rigorously in a study assures the reader that the findings from the study are credible and can be taken seriously. In this qualitative segment of the study, the use of the term "validity" is appropriate however, for the entire study, which is multiphase in nature, the term legitimation replaces validity as the measures for become more complicated.

In the context of qualitative studies, identification and implementation of validity and reliability parameters are not as straight-forward as in quantitative studies because of the subjective nature of interviews. However, key considerations to ensure the validity of a research include situating the research within the right philosophical paradigm and applying triangulation. Choosing the right philosophical paradigm helps the researcher to understand the needs of the research including the process guidelines to ensure that they are in place. Before delving into this study, the researcher took a course in research philosophy and gained extensive understanding of research philosophy. The researcher also understands how research philosophy translates into

methodological options possible for any research context. Hence, the researcher adopted a mixed methods approach to the entire research. This justifies the inclusion of a qualitative component, which is this phase 2A of the broad study. Being a qualitative research, collecting data via interviews is allowed and is supported by the interpretivist philosophical background adopted in this segment of the study.

While triangulation has been shown to improve research validity, the extent of triangulation in this phase of the study was highly limited. The researcher was limited in time and resources to broaden the sources of data to achieve triangulation. While the impact on this research is unknown, the similarity of developing countries and the recruitment of highly experienced participants would mitigate this effect.

The easiest to improve reliability in qualitative research is to use a highly structured instrument- such as interviews (Silverman,1993, cited Cohen et al., 2011). Even though the interview in this study was semi structured, due effort was put in place during the pilot, to ensure that bias, inconsistencies, and misleading questions were minimised.

5.10 Data collection

Data collection took place between 7 June 2018 and 30 May 2019. I located the first 6 potential participants via Linked In and contacted them with a description of the overall objectives of my research and asking them to participate in the study. The participants are senior members of their respective health institutions and in the position to take decision in with due regards to the required level of ethical approval. Some of the participants were from institutions collaborating with the University of Strathclyde in a larger scale research in medical equipment remanufacturing and ethical approval had been obtained from the top management and so, was no longer necessary in this occasion. All participants voluntarily consented to contribute to the study and were guaranteed confidentiality and anonymity as well as their right to withdraw from the study at any point.

Some of the interviews was taken face to face while others were over the phone. This is because some participants became ready for the interviews after I came back from Nigeria. The online interviews were taken via Skype. The interviews were recorded on an electronic recording device and transcribed into text (transcript) afterwards. Each interview lasted approximately 30 minutes. Prior to the interview the participants were asked to the survey questionnaires whose analysis will be described in the second strand of Phase 2A study. Some of the initial participants also recommended other participants and altogether, there were 12 participants that returned completed survey questionnaires. Not all participants finally took the interview after returning

completed questionnaires. All details about participants are in Chapter 3. Extracts from the interviews are documented in Appendix B2.

5.11 Data analysis

In qualitative research, the researcher has a key role in interpreting the data, thus preserving 'the subjectivity of each participant's inputs was considered to be of paramount importance throughout the research process' (Miles and Huberman, 1994 p.6). Consequently, it was important to consider how my background, experiences, views, and values impacted on the way I interacted with the participants and the way I interpreted the data. I aimed to maintain a professional disposition throughout the interviews, without attempting to suggest or provide clues on answers to the questions. This way, I minimized the chances of including my own assumptions into the data. During transcription and coding, I also ensured I am objective in highlighting phrases, themes and words that demonstrate the themes already identified from the literature. The interpretivist paradigm guided the approach to the analysis in this strand of phase 2A and as such, I believed there was no objective reality or truth 'out there' waiting to be discovered. I entered each participants' world, used my background to understand them and focused on listening and interpreting their perspectives in relation to the subject of the study.

5.11.1 Thematic analysis process

Thematic Analysis was the chosen analysis technique. Thematic Analysis is a method for identifying, analysing and reporting patterns or themes within data. Themes consist of words or sets of words denoting an important idea that occurs several times in the data (Johnson and Christensen, 2014). This technique was chosen because it illustrates data in detail and deals with diverse subjects via interpretations. Thematic analysis also allows the researcher to dive deep into the data and generate interpretations.

In this study, the thematic analysis has been performed in accordance with the framework recommended by Braun and Clark (Braun and Clarke, 2006) which is quite intuitive but overall, it is the researcher who decides how to interpret the data. While this approach provided some form of freedom to the researcher, it also added some responsibility for ensuring that the participants' views are maintained. Themes were already prefigured from the literature. The analysis only involved identifying themes from the interview transcripts that match each prefigured theme. Hence, there were three main steps followed in achieving the qualitative data analysis. These are discussed in turn.

5.11.2 Immersion

According to Braun and Clark (2006), it is necessary for the researcher to be immersed in the data. The aim of this immersion is for the researcher to gain a high degree of familiarity with the data. The authors recommend repeated active reading of the data with the purpose of identifying patterns and meanings. Hence, the first step taken during the analysis in the current study strand was repeated reading of the transcripts. While reading the transcripts, I was aiming to identify the patterns in the transcripts, particularly those that were most recurring. I was also aiming to get an understanding of the perspectives in relation to some of the questions asked during the interview.

5.11.3 Coding

Coding involves identifying and grouping similar statements or responses into a heading. After reading the transcripts a couple of times, I used a spreadsheet containing the pre-identified factors which the interview is structured to further explore. Themes in the transcripts addressing each of the factors were identified and matched to corresponding factors in the spreadsheet. To achieve this, I read through the transcripts a couple of times, identifying, and extracting parts of the responses for each theme. Figure 5-1 shows how the responses are coded into pre-identified themes.

Factor	Category	Participant B1
i. *Availability of relevant equipment and technologies and the complexity of carrying out medical equipment remanufacturing.*	Technological The technology to carry out complex hospitals may not be present in the hopspital but can be located within the country.	B1: *In our hospital we have biomedical equipment department. In my opinion, I do not thinl they have experience enough to handle such repairs. But when there is a breakdown, they have to be the ones to escalate to the need to invite experts. They first assess the damage t see if it is within their capacity, otherwise escalate. So, they would continue trying to repair, wasting time. So, the amount of time lost before the equipment is finally repaired becomes unduly prolonged. Upon escalation, experts from Lagos who are proper engineers often have the capacity to carry out the repairs. So considering local to be the hospital, I would answer no but if referring to the country as a whole, I would answer yes.*
ii. *Availability of workers with relevant technical skills to carry out medical equipment remanufacturing*	Technological/Educational institution Peple with skills may exist and the problem may be that existing organisational structure does not locate or encourage them. This may be due to existing policies. If the hospital is unable to locate talents within its premises, then how can it locate resources outside?	On whether local skills can carry out medical equipment remanufacturing: I think there are people who can do it. Those engineers in Lagos are quite knowledgeable and will definitely be able to remanufacture medical equipment. But they are not many.

Sheet1

Figure 5-1: The coding of participants' responses into prefigured themes.

5.11.4 Report writing

The qualitative report was collated logically based on how the themes addressed the related research questions. The themes are stitched together by the researcher, with some words infused to clarify how each participant's perspective contributes to this component of the research. Verbatim quotes were used throughout the report to demonstrate how participants words support each argument introduced by the researcher. The qualitative report is integrated to the quantitative results, since the qualitative research was conducted in parallel to a quantitative research as already described. This writeup procedure is in line with known practice in qualitative research (Braun and Clarke, 2006).

5.12 Validation techniques for the developed medical equipment remanufacturing frameworks.

Validation is necessary to demonstrate their industrial relevance of research outputs. According to Platts (1993), research output without validation may be of little industrial relevance. To avoid this pitfall, tools developed in this work are validated by experts in the field. The validation was conducted in two phases. Key questions relating to the suitability of the process as represented basic model proposed in section 2-6 was used to develop questionnaires that were used to gather data for phase 1 validation. The questionnaires were of the semi-structured type (Sample shown in Appendix A) and were developed and distributed using Qualtrics Online Survey tool. The questionnaires requested participants to explain the rationale for their assessment. Each participant's assessment was considered in the light of the rationale given and participants with inconsistent inputs were contacted for further clarification.

The first validation raised important insights that were incorporated into the basic model. This, along with a decision support framework developed by integrating findings from this work, necessitated a second phase validation. The validation was by Expert Review Technique involving 7 participants. Review by a small sample of expert is a well-known technique for validating findings of a research (Beecham *et al.*, 2005). Validation by expert review has been used in several studies, examples including risk assessment, clinical supervision, patient behaviour and software process improvement studies (Priyono, 2015; Paterson, Ijomah and Windmill, 2017). Details of the entire validation process are shown in the next section.

5.12.1 Sampling, data collection and analysis techniques for the validation of developed frameworks

In the first phase, critical case and snowball purposeful sampling (Onwuegbuzie and Collins, 2007) were used to ensure participants are those that are knowledgeable in the field and can provide rich information needed by answering posed questions

coherently. Participants were also sourced through LinkedIn profile search. A total of 30 experts sourced both from Linkedin and from the researcher's existing network were contacted to participate in this phase. The participants included experts with developing country experience and in career positions covering key responsibilities with respect to medical equipment. They were made up of Medical doctors, Biomedical Engineers, Medical Physicist, Medical equipment regulatory expert and medical device experts in the academia. The participants were from Nigeria, Ghana, Malawi and Nigeria. The first validation process took place between 23 January 2018 and 30 April 2018. A total of 30 experts were invited to fill the questionnaire out of which 12 responded. The participants that responded are already shown in Table 5-2.

Since the questionnaires request participants to explain the rationale for their assessment both numerical data in the range 1 to 10 text data used to explain rationale were collected. The texts are included as a measure to motivate participants to rationalise their entries and avoid including unsubstantiated values. This measure helps to eliminate bias and promote validity of the results (Ijomah, 2002). Each participant's assessment was considered in the light of the rationale given.

While the data are numerical in nature, a qualitative analysis technique was used to analyse them. This is because of the small number of participants which though are highly experienced, still does not justify the use of quantitative analysis technique.

Table 5-2: Summary of participants in study Phase 3 stage 1 validation

Respondents	***Organisation***	***Country***	***Profession***	***Years of Experience***
A	Ministry of Health	Nigeria	Medical doctor	7
B	Food and Drug Agency	Ghana	Biomedical Engineer	14
C	Clinics service provider	Nigeria	Biomedical Technician	5
D	Industry and Tertiary education institution	Nigeria	Biomedical Engineer	25
E	Tertiary education institution	Nigeria	Medical Devices	6

F	Tertiary education	Iraq	Medical Instrumentation technology	2
G	Tertiary education institution	Malawi	Biomedical Engineer	4
H	Medical centre	Nigeria and United Kingdom	Medical Doctor (General practitioner)	8
I	Medical equipment sales and servicing	Cameroun	Biomedical Engineer	4
J	Tertiary education institution	Nigeria	Medical Physicist	22
K	Tertiary education institution	Nigeria	Biomedical Engineer	16
L	Federal Institute of Industrial Research	Nigeria	Independent equipment developer	15

In the second and final validation process, 7 participants were involved. This took place from 18 March to 30 May 2020. The participants included 3 academics working on medical equipment remanufacturing and 4 clinical engineers with experience in both developed and developing country best practices in relation to the medical device industry. Two of the clinical engineers were from the Scottish NHS and brought developed country experience. One of the UK clinical Engineers have both developed and developing country experience. One of them is the coordinator of the Scottish Government's Global Citizenship programme. The other UK clinical engineer has been to several developing countries for capacity building projects. The Global Citizenship programme is a Scottish Government initiative through which equipment is supplied to developing countries with the greatest needs. Having been on the programme since its inception, the coordinator who participated in this study understands the peculiarities of developing countries. Other participants from developing country include experts with managerial positions and scholars whose research area is related to medical equipment. Details of participants in the final validation are shown in Table 5-3.

Table 5-3: Participants in the independent review (final validation) of the developed frameworks

S/N	Area of expertise	Years of experience
***A**	Clinical engineering, Scottish Global Citizenship Programme	Over 20 years
B	Clinical engineering and Research, Scottish NHS	Over 20 years
C	Researcher/Academic in Public health and Environmental Engineering - Nigerian Tertiary institution	5 years
D	Clinical Engineer- Nigerian Tertiary hospital	10 years
E	Clinical Engineer- Nigerian Tertiary hospital	10 years
F	Researcher- Medical Equipment refurbishment- UK university	3 years
G	Business Lead Service NHS Scotland	Over 20 years.

*Participant provided feedback without filling out the questionnaire.

5.13 Criteria and instrument used in the final validation of developed frameworks.

According to Thomas and Tymon (1982), research relevance may be assessed against 5 main criteria that represent the key requirements of new operations tools. These include descriptive relevance, goal relevance, operational validity, non-obviousness, and timeliness. These criteria are still relevant and have been used in several studies on remanufacturing (Ijomah, 2002; Ridley, 2012; Priyono, 2015) . In developing the tools, 3 statements were formulated based on each criterion. The statements were adapted from (Priyono, 2015) and include some which are negatively worded to check the consistency participants' responses. Table 5-2 shows the statements and the criteria that each of them assess. However, the actual instruments distributed to participants, these statements were randomised to improve the chances of obtaining objective inputs.

Table 5-4: Criteria for assessing the validity of proposed frameworks. For the purpose of this exercise, the decision support framework and process model are collectively referred to as "tools".

Criteria	Description (Thomas and Tymon, 1982)	Statements requiring participants' opinion
Descriptive relevance	*The accuracy of research findings in capturing phenomena encountered by practitioner in their organisational setting*	• The process represented tools is feasible for medical equipment remanufacturing. • The tools are acceptable description of high-level activities necessary in medical equipment remanufacture. • Medical equipment remanufactured based on the tools will be poor.
Goal relevance	*The degree of correspondence of the study outcome or dependent variable(s) to the things, behaviour or relationships proposed.*	• The activities represented in the tools are important to medical equipment remanufacturing. • Failure to implement medical equipment remanufacturing as represented in the tools may introduce unwanted results. • Preliminary decisions and process model in the tools are useful in some way
Operational validity	*This assesses practitioners' ability to implement action implications of a theory by implementing proposed relationships.*	• I find the tools difficult to follow. • The tools can be used to help medical equipment remanufacturers to make improvements. • The activities represented in tools can be implemented in real practice.
Non-obviousness	*The degree to which a theory meets or exceeds the complexity of common sense already used by practitioners*	• The tools will help to understand the various strategies for carrying out medical equipment remanufacture. • There are many major issues missing from the tools. • The tools have the potential to help medical equipment remanufacturers to make better decisions.

Timeliness	*Assesses the whether the theory addresses a current needs or problems*	• The tools are not useful for remanufacturing companies in organising their operations. • The medical equipment remanufacturing process described in tools is an important area to address. • The tools will be useful for medical equipment remanufacturers in the present time.

5.14 Chapter summary

This chapter explained the qualitative component of phase 2A study. It presented the sampling and rationalized the philosophical background, the data collection method- interview, as well as the data analysis method- deductive/prefigured thematic analysis. In addition, measures taken to ensure the reliability and validity of the study in this research phase were also highlighted and shown to be compliant with best practice. The chapter also presented the sampling techniques and criteria adopted in validating the frameworks developed in this study.

Chapter 6:
Results

6.1 Introduction

Identification of the research problems, methods and other important considerations have been addressed in the previous chapters. In this chapter, the results of the different phases of this study are presented.

6.2 Impact of remanufacturing in addressing the poor medical equipment availability issues.

This section answers follows from chapter two which answered the research question: what are the causes of poor medical equipment availability issues in developing countries? These factors are tabulated in Table 2-3. The nature of these factors indicates that there would be some degree of interrelationships among them. No withstanding, this section aims to answer the question: *How much of these problems can remanufacturing address?*

In other to determine the potential impact of remanufacturing in addressing the causes of poor medical equipment availability, it would be necessary to consider the interrelationships. To achieve this, the DEMATEL technique was selected for reasons which have been discussed. The relative total prominence of the factors potentially addressed by remanufacturing is expressed as a percentage of the overall total prominence of all the factors. This approach is used to determine the potential impact of medical equipment in addressing the root causes of poor medical equipment availability in developing countries.

6.2.1 Participants' pairwise comparisons and average direct relation matrix

Each participant produced the matrix: $A^b = [a^b{}_{ij}],\ where\ b = 1, 2, \dots M$ refer to individual respondents. Each individual participant's output is shown in the matrices below.

$$\mathbf{A^1} = \begin{bmatrix} 0 & 4 & 4 & 3 & 4 & 2 & 3 & 3 & 3 & 3 & 3 \\ 4 & 0 & 1 & 3 & 1 & 2 & 2 & 1 & 1 & 0 & 1 \\ 4 & 4 & 0 & 3 & 3 & 1 & 2 & 3 & 0 & 3 & 2 \\ 4 & 4 & 4 & 0 & 2 & 1 & 1 & 3 & 2 & 1 & 0 \\ 4 & 4 & 4 & 3 & 0 & 3 & 3 & 1 & 1 & 4 & 3 \\ 4 & 4 & 2 & 4 & 3 & 0 & 1 & 3 & 1 & 4 & 2 \\ 3 & 4 & 4 & 4 & 1 & 2 & 0 & 4 & 1 & 2 & 1 \\ 3 & 4 & 4 & 4 & 1 & 1 & 3 & 0 & 3 & 1 & 1 \\ 2 & 2 & 3 & 3 & 1 & 1 & 2 & 3 & 0 & 3 & 2 \\ 2 & 1 & 2 & 4 & 1 & 4 & 1 & 3 & 3 & 0 & 1 \\ 2 & 1 & 4 & 3 & 1 & 4 & 3 & 4 & 3 & 4 & 0 \end{bmatrix}$$

$$A^2 = \begin{bmatrix} 0 & 4 & 4 & 4 & 3 & 4 & 4 & 4 & 3 & 4 & 3 \\ 0 & 0 & 1 & 1 & 0 & 3 & 3 & 0 & 1 & 0 & 2 \\ 0 & 0 & 0 & 4 & 2 & 2 & 2 & 4 & 1 & 2 & 0 \\ 0 & 3 & 0 & 0 & 0 & 3 & 0 & 0 & 1 & 0 & 1 \\ 4 & 3 & 2 & 2 & 0 & 4 & 2 & 0 & 4 & 0 & 1 \\ 4 & 4 & 2 & 2 & 4 & 0 & 3 & 4 & 3 & 0 & 1 \\ 0 & 3 & 0 & 2 & 0 & 0 & 0 & 0 & 3 & 0 & 1 \\ 0 & 3 & 0 & 0 & 0 & 0 & 0 & 0 & 3 & 0 & 2 \\ 0 & 4 & 3 & 2 & 3 & 4 & 4 & 3 & 0 & 0 & 2 \\ 1 & 3 & 0 & 0 & 0 & 0 & 0 & 0 & 0 & 0 & 1 \\ 0 & 1 & 0 & 0 & 0 & 0 & 0 & 0 & 1 & 0 & 0 \end{bmatrix}$$

$$A^3 = \begin{bmatrix} 0 & 3 & 3 & 3 & 2 & 3 & 2 & 3 & 3 & 2 & 3 \\ 3 & 0 & 2 & 2 & 2 & 3 & 3 & 2 & 3 & 3 & 2 \\ 3 & 4 & 0 & 2 & 2 & 2 & 2 & 3 & 3 & 2 & 2 \\ 3 & 3 & 0 & 0 & 2 & 3 & 2 & 2 & 3 & 2 & 2 \\ 0 & 3 & 0 & 1 & 0 & 3 & 2 & 3 & 2 & 3 & 2 \\ 3 & 2 & 2 & 0 & 0 & 0 & 3 & 2 & 3 & 3 & 3 \\ 3 & 2 & 0 & 0 & 0 & 0 & 0 & 3 & 3 & 2 & 2 \\ 0 & 3 & 1 & 0 & 0 & 0 & 0 & 0 & 3 & 3 & 2 \\ 0 & 3 & 3 & 3 & 3 & 0 & 3 & 3 & 0 & 4 & 3 \\ 0 & 3 & 0 & 0 & 0 & 0 & 0 & 0 & 0 & 0 & 3 \\ 0 & 2 & 0 & 0 & 0 & 0 & 0 & 3 & 3 & 0 & 0 \end{bmatrix}$$

$$A^4 = \begin{bmatrix} 0 & 3 & 2 & 2 & 4 & 4 & 3 & 0 & 3 & 1 & 1 \\ 3 & 0 & 2 & 3 & 2 & 4 & 1 & 0 & 1 & 1 & 1 \\ 3 & 3 & 0 & 1 & 3 & 3 & 1 & 3 & 3 & 1 & 1 \\ 1 & 2 & 2 & 0 & 1 & 3 & 0 & 1 & 3 & 3 & 0 \\ 2 & 3 & 3 & 3 & 0 & 2 & 3 & 3 & 3 & 2 & 0 \\ 4 & 2 & 2 & 1 & 4 & 0 & 1 & 1 & 3 & 3 & 3 \\ 3 & 3 & 3 & 1 & 1 & 3 & 0 & 2 & 3 & 3 & 0 \\ 1 & 2 & 2 & 2 & 3 & 1 & 2 & 0 & 2 & 2 & 3 \\ 3 & 3 & 1 & 0 & 1 & 2 & 3 & 3 & 0 & 0 & 1 \\ 1 & 1 & 0 & 1 & 0 & 1 & 0 & 0 & 3 & 0 & 0 \\ 2 & 1 & 0 & 0 & 3 & 2 & 0 & 3 & 2 & 3 & 0 \end{bmatrix}$$

$$A^5 = \begin{bmatrix} 0 & 4 & 3 & 0 & 3 & 3 & 0 & 2 & 2 & 3 & 0 \\ 1 & 0 & 3 & 3 & 4 & 3 & 2 & 2 & 1 & 0 & 0 \\ 3 & 1 & 0 & 4 & 3 & 3 & 3 & 4 & 0 & 3 & 1 \\ 4 & 3 & 0 & 0 & 3 & 3 & 3 & 3 & 0 & 3 & 3 \\ 3 & 1 & 3 & 3 & 0 & 0 & 3 & 3 & 4 & 3 & 0 \\ 3 & 1 & 3 & 3 & 4 & 0 & 3 & 3 & 3 & 2 & 2 \\ 4 & 3 & 2 & 1 & 0 & 0 & 0 & 3 & 0 & 2 & 0 \\ 3 & 2 & 3 & 0 & 0 & 0 & 3 & 0 & 0 & 4 & 0 \\ 2 & 2 & 3 & 1 & 3 & 3 & 2 & 3 & 0 & 3 & 1 \\ 3 & 4 & 3 & 4 & 0 & 1 & 2 & 4 & 3 & 0 & 0 \\ 1 & 1 & 0 & 4 & 0 & 3 & 0 & 4 & 1 & 4 & 0 \end{bmatrix}$$

$$A^6 = \begin{bmatrix} 0 & 3 & 4 & 4 & 3 & 3 & 3 & 2 & 2 & 4 & 3 \\ 3 & 0 & 3 & 3 & 4 & 4 & 3 & 3 & 2 & 3 & 2 \\ 4 & 3 & 0 & 3 & 2 & 3 & 4 & 4 & 2 & 3 & 1 \\ 4 & 4 & 4 & 0 & 1 & 3 & 4 & 3 & 1 & 3 & 2 \\ 3 & 1 & 2 & 2 & 0 & 2 & 3 & 2 & 1 & 1 & 2 \\ 3 & 2 & 4 & 4 & 2 & 0 & 2 & 3 & 1 & 2 & 2 \\ 3 & 4 & 2 & 2 & 3 & 3 & 0 & 3 & 2 & 2 & 1 \\ 3 & 2 & 3 & 3 & 1 & 2 & 3 & 0 & 2 & 2 & 2 \\ 2 & 1 & 3 & 3 & 2 & 3 & 1 & 1 & 0 & 2 & 1 \\ 3 & 1 & 1 & 1 & 1 & 1 & 1 & 1 & 1 & 0 & 2 \\ 2 & 3 & 4 & 4 & 4 & 3 & 2 & 3 & 3 & 3 & 0 \end{bmatrix}$$

$$A^7 = \begin{bmatrix} 0 & 2 & 2 & 3 & 2 & 2 & 2 & 3 & 2 & 1 & 1 \\ 1 & 0 & 1 & 2 & 3 & 4 & 3 & 3 & 1 & 1 & 1 \\ 1 & 4 & 0 & 3 & 1 & 2 & 3 & 1 & 2 & 2 & 3 \\ 4 & 3 & 4 & 0 & 2 & 2 & 3 & 1 & 2 & 1 & 1 \\ 1 & 2 & 1 & 3 & 0 & 4 & 4 & 4 & 1 & 4 & 3 \\ 3 & 1 & 1 & 1 & 1 & 0 & 1 & 1 & 1 & 3 & 1 \\ 1 & 2 & 1 & 1 & 1 & 1 & 0 & 1 & 2 & 1 & 1 \\ 1 & 3 & 1 & 1 & 1 & 2 & 1 & 0 & 2 & 2 & 1 \\ 1 & 1 & 3 & 2 & 3 & 3 & 3 & 1 & 0 & 3 & 2 \\ 1 & 2 & 1 & 1 & 1 & 1 & 2 & 2 & 2 & 0 & 2 \\ 1 & 1 & 1 & 1 & 1 & 1 & 4 & 2 & 2 & 4 & 0 \end{bmatrix}$$

$$A^8 = \begin{bmatrix} 0 & 3 & 4 & 2 & 2 & 2 & 3 & 3 & 2 & 3 & 1 \\ 1 & 0 & 1 & 1 & 1 & 0 & 1 & 2 & 2 & 1 & 1 \\ 1 & 4 & 0 & 3 & 1 & 1 & 3 & 4 & 1 & 3 & 3 \\ 0 & 3 & 1 & 0 & 0 & 0 & 0 & 1 & 3 & 1 & 1 \\ 3 & 2 & 1 & 3 & 0 & 1 & 3 & 4 & 4 & 3 & 2 \\ 2 & 1 & 1 & 1 & 2 & 0 & 1 & 1 & 1 & 3 & 1 \\ 1 & 2 & 2 & 1 & 3 & 1 & 0 & 3 & 2 & 1 & 1 \\ 1 & 4 & 1 & 1 & 1 & 1 & 2 & 0 & 2 & 1 & 1 \\ 3 & 3 & 3 & 1 & 1 & 1 & 3 & 3 & 0 & 2 & 1 \\ 1 & 3 & 3 & 1 & 1 & 1 & 2 & 2 & 3 & 0 & 1 \\ 2 & 2 & 1 & 1 & 1 & 1 & 3 & 3 & 2 & 4 & 0 \end{bmatrix}$$

And Average Direct Relation Matrix $x_{ij} = \frac{1}{M}\sum_{b=1}^{M} a_{ij} =$

$$\begin{bmatrix} 0 & 3 & 3.25 & 2.5 & 2.875 & 2.75 & 2.375 & 2.625 & 2.5 & 2.125 & 1.375 \\ 0.875 & 0 & 1.5 & 1.625 & 1.75 & 2 & 2 & 1.75 & 1.5 & 0.875 & 0.875 \\ 2.75 & 2.875 & 0 & 3 & 2.25 & 2.375 & 2.75 & 3.375 & 1.875 & 2.375 & 1.625 \\ 2.125 & 3.125 & 1.875 & 0 & 1.375 & 2.5 & 2 & 1.875 & 2 & 2 & 1.5 \\ 2.75 & 2.375 & 2 & 2.625 & 0 & 2.125 & 3 & 2.875 & 2.875 & 2.5 & 1.75 \\ 3 & 2.125 & 2.125 & 2 & 2.625 & 0 & 2.25 & 2.375 & 2.25 & 2.5 & 2.125 \\ 2.375 & 2.875 & 2 & 1.5 & 3.5 & 1.5 & 0 & 2.375 & 2.25 & 1.75 & 1.125 \\ 1.625 & 2.875 & 2 & 1.375 & 1.25 & 1.25 & 1.875 & 0 & 2.125 & 2.25 & 1.875 \\ 1.875 & 2.625 & 2.625 & 2 & 2.5 & 2.5 & 2.875 & 2.625 & 0 & 2.125 & 1.75 \\ 1.75 & 2.625 & 1.25 & 1.25 & 0.875 & 1 & 1.375 & 1.625 & 2 & 0 & 1625 \\ 1.5 & 1.75 & 1 & 1.75 & 1.625 & 1.625 & 1.625 & 2.75 & 2.125 & 2.75 & 0 \end{bmatrix}$$

6.2.2 Degrees of prominence of factors

The degrees of prominence and characteristics of each factor are as summarised in Table 7-2. It is based on the $(\mathrm{R} + \mathrm{C})$ values and is as follows:

$$F1 > F9 > F3 > F5 > F6 > F8 > F7 > F2 > F4 > F10 > F11.$$

Thus, corruption (F1) is the most prominent reason for shortage of medical equipment while unreliable supply chain communication (F11) is the least. In addition, corruption (F1), lack of clear economic model (F9), lack of funds (F3), absence of HTA and HTM policies (F5), Weak or absent regulation (F6), lack of infrastructure (F4) and unreliable or ineffective supply chain and communication involving recipients (F11) are net drivers. On the other hand, the driven factors include unavailability of spare parts and consumables (F8), lack of trained or skilled maintenance staff (F7), workers' attitudes and perception (F2) and equipment inappropriate for the needs (F10) are net influenced factors responsible for the poor availability of medical equipment.

Table 6-1 also shows that corruption is driven by lack of funds (F3), absence of HTA and HTM (F5) and weak or absent medical device regulation (F6). Similarly, workers' perception and attitude (F2) are driven by corruption (F1), lack of funds (F3), lack of infrastructure (F4), absence of HTA and HTM (F5), weak or absent medical device regulation (F6), lack of trained or skilled maintenance staff (F7) and lack of clear economic model (F9). Corruption (F1) is the main cause of lack of funds (F3) which is at the same time, responsible for lack of infrastructure (F4).

Corruption (F1) is also the most important factor responsible for the weak or absent medical device regulation (F6). Lack of trained maintenance staff (F7) and unavailability of spares and consumables (F8) are both driven by corruption (F1), lack of funds (F3), absence of HTA and HTM (F5), weak or absent medical device regulation (F6) as well as lack of clear economic models (F9). However, lack of clear economic models (F9) is caused by corruption (F1) and absence of HTA and HTM (F5). Finally, equipment is inappropriate for healthcare needs (F10) because of corruption (F1), lack of funds (F3) and absence of HTA and HTM (F5).

Table 6-1: Strengths of influences exerted by each factor on the others. Values displayed exceed thresholds obtained by adding the mean of the total relation matrix to (1) one standard deviation and (2) two times the standard deviation. Cells whose values are marked asterisk are those exceeding the threshold obtained by adding two times the standard deviations of the total relation matrix to its mean. the figure also shows the prominence ranking of each factor.

Factor	(R-C)	(R+C)	Prominence rank	Remarks	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11
Corruption (F1)	0.8702	8.1743	**1**	Net driver		0.518*	0.4285			0.4097	0.4358	0.4704*	0.4266	0.4064	
Attitude/perception (F2)	-1.9297	7.3741	**8**	Net driven											
Lack of funds to access and/or to fund the purchase of equipment (F3)	0.8872	7.9821	**3**	Net driver	0.4134	0.5067*		0.4079			0.4388	0.4854*		0.4075	
Lack of infrastructure such as electricity, water supply, oxygen (F4)	0.1253	7.12	**9**	Net driver		0.4391									
Absence of HTM and HTA (F5)	1.0464	7.7461	**4**	Net driver	0.4109	0.4869*					0.4447	0.4666	0.4297	0.4093	
Weak or absent medical device regulation (F6)	0.6601	7.6975	**5**	Net driver	0.4041	0.4579					0.4037	0.4333			
Lack of trained or skilled maintenance staff (F7)	-0.4902	7.3959	**7**	Net driven		0.4165									
Unavailability of spare parts and consumables (F8)	-0.9836	7.5289	**6**	Net driven											
Lack of clear economic model (F9)	0.3558	7.9898	**2**	Net driver		0.4735*					0.4238	0.4408			
Equipment are inappropriate for the needs of the people (F10)	-0.9822	6.4873	**10**	Net driven											
Unreliable or ineffective supply chain communication (F11)	0.4408	6.0966	**11**	Net driver											

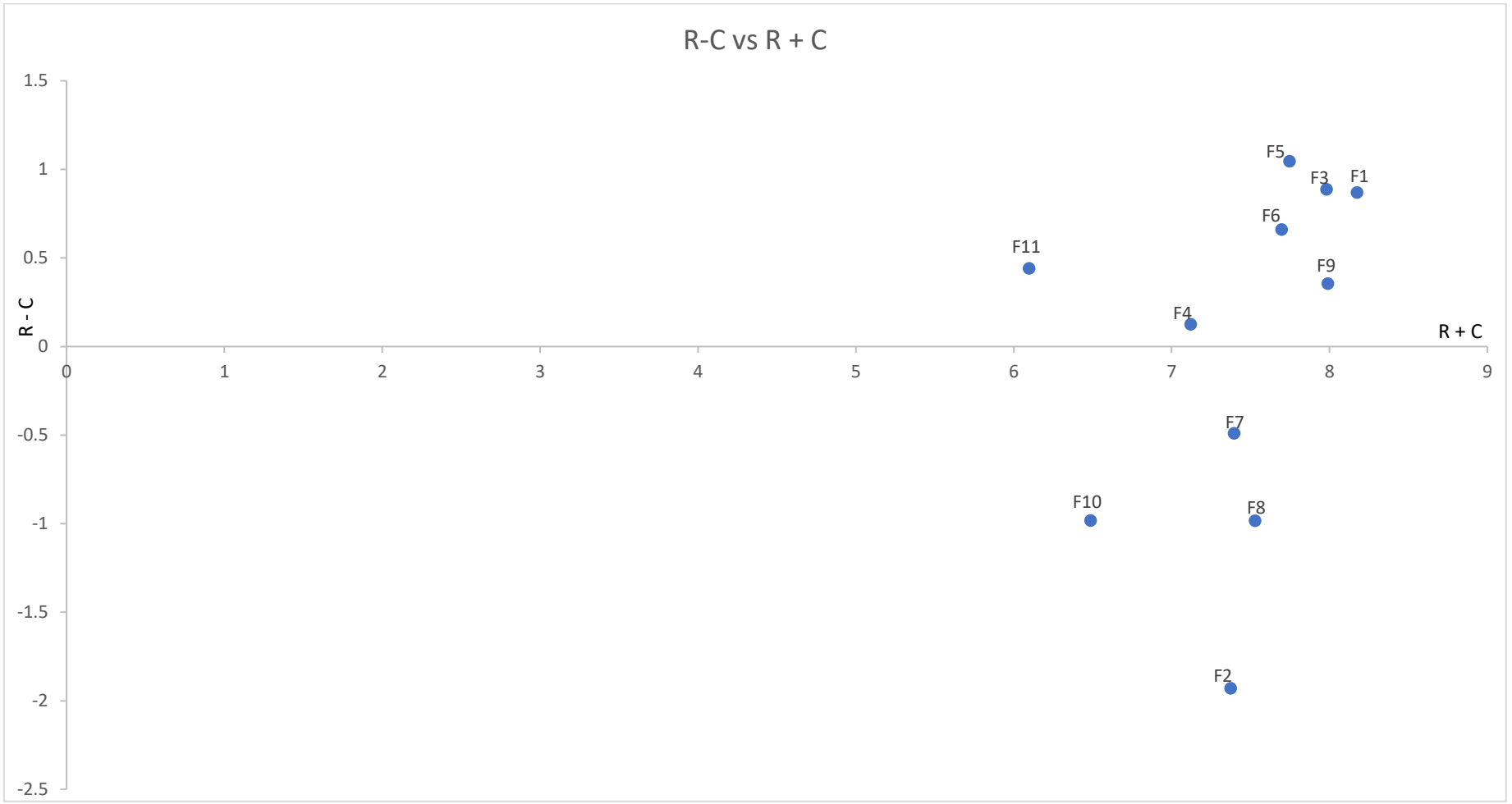

Figure 6-1: Impact relation matrix of the identified factors. The figure shows the cause-and-effect groups of factors in the positive and negative sides of the R -C axis.

6.2.3 Cause and effect factors

As explained in section 4.4, the factors identified in this study can be grouped as influencing or influenced factors. The influencing factors were called the “cause” group of factors while the influenced/receiving factors were called the “effect” group of factors. Both the cause-and-effect group of factors become more visible when plotted on a chart as shown on figure 6-1.

Clearly, the cause group of factors are decreasing order of impact: F5: Absence of HTM and HTA, F3: Lack of funds to access and/or purchase medical equipment, F1: Corruption, F6: Weak or absent medical device regulation, F9: Lack of clear economic model and F4: Lack of infrastructure such as electricity, water supply, oxygen.

6.2.4 Impact of remanufacturing in addressing the availability issues

Remanufacturing can contribute towards addressing some of the factors responsible for the poor availability of medical equipment. Specifically, remanufacturing can provide affordable quality medical equipment since in general, remanufactured products are sold at much lower price than equivalent new ones (Steinhilper, 1998; Ijomah, Childe and Mcmahon, 2004; Gray and Charter, 2007). The price of remanufactured products average at 60 percent of those of equivalent new products (Giutini and Gaudette, 2003; Parkinson and Thompson, 2003). This lower price achievable since only about 15 percent of the energy required to manufacture equivalent new products is utilised in remanufacturing (Brent and Steinhilper, 2005; Gray and Charter, 2007). Moreover, remanufacturing has the potential to create an industrial base for developing countries (Lund, 1984) through associated workforce training, new equipment procurement and technology transfer. This is because remanufacturing is labour intensive (Lund, 1984; Gray and Charter, 2007) and currently requires less technological sophistication than conventional manufacturing. Thus, it can potentially promote commercial activity in the medical device sector and contribute to skills development in medical equipment technology. Thus, medical equipment remanufacturing can help to develop skilled manpower needed for the maintenance of medical equipment.

Another key feature of remanufacturing is its incorporation with product sales service (PSS) which involves a greater focus on the product’s functionality rather than mere products (Widera and Seliger, 2015; Eze, Ijomah and Wong, 2019). Through this strategy, remanufacturing can provide increased access to spare parts (Seitz, 2007). This is achievable since both whole products and sub-assembles can be remanufactured (Gray and Charter, 2007). Medical equipment remanufacturing therefore, also has the potential to increase access to functional medical equipment spare parts and can help address the challenge of unavailability of spare parts.

The success of remanufacturing depends largely on communication among supply chain players including users (Östlin, Sundin and Björkman, 2008; Sundin and Dunbäck, 2013a). Medical equipment remanufacturing can help bridge such communication gap among users through its emphasis on PSS which is aimed at optimising the utility that products offer their users. Further, by implementing remanufacturing, imported medical equipment can be adapted to developing country needs and specifications in a manner that will ensure that the product would serve appropriately.

Table 6-2 summarises the aspects of developing countries issues with medical equipment provision that remanufacturing can address.

The potential contribution of medical equipment remanufacturing in addressing the poor availability of medical equipment may be estimated as a percentage of the overall total prominence, as follows:

$$100 \times \frac{\sum_{i=1}^{m} P_i}{\sum_{j=1}^{n} P_j} = \frac{\sum_{i=1}^{k} r_i + c_i}{\sum_{j}^{l} r_i + c_i}, \quad (8)$$

$k = 5 = number\ of\ factors\ potentially\ addressed\ by\ remanufacturing$ as shown in Table 4

$l = 11 = total\ number\ of\ factors$

$P_i = total prominence of the 5 factors potentially addressed by remanufacturing (Table\ 4)$

$P_j = total\ prominence\ of\ all\ 11\ factors\ affecting\ medical\ equipment\ availability$

Thus, the potential contribution of medical equipment remanufacturing in addressing medical equipment availability is approximately 43.5%.

6.2.5 How medical equipment remanufacturing addresses some of the availability issues

According to Pearce (Pearce, 2009), the following types of customers are likely to be interested in remanufactured products:

• Those that need to retain a specific product for their processes.

• Users that want to avoid the rigour of the recertification or re-approval process preceding product purchasing.

• Those that make relatively less use of new equipment and are price sensitive.

• Those that would like to continue the use of products whose OEMs no longer produce

• Customers that may only want to extend the service life of their used equipment.

• Customers that are environmentally conscious.

Table 6-2:Potential contribution of remanufacturing in increasing availability of medical equipment remanufacturing.

Factor	$\boldsymbol{Total\ prominence}$ $(R + C)$	Potential to be addressed by remanufacturing	References
Corruption	8.1743		
Attitude/perception	7.3741		
Lack of funds to access and/or to fund the purchase of equipment	7.9821	√	Remanufacturing can provide low cost alternatives (Parkinson and Thompson, 2003; Ijomah, Childe and Mcmahon, 2004; Brent and Steinhilper, 2005; Gray and Charter, 2007; Goodall, Rosamond and Harding, 2014)
Lack of infrastructure such as electricity, water supply, oxygen	7.12		
Absence of HTM and HTA	7.7461		
Weak or absent medical device regulation	7.6975		
Lack of trained or skilled maintenance staff	7.3959	√	Remanufacturing develops skills (Lund, 1984; Gray and Charter, 2007; Goodall, Rosamond and Harding, 2014)
Unavailability of spare parts and consumables	7.5289	√	Spare parts provision which enables prolonged use of products and components even after their production has ceased (Seitz, 2007;

Factor	$\boldsymbol{Total\ prominence}$ $(R + C)$	Potential to be addressed by remanufacturing	References
			Goodall, Rosamond and Harding, 2014)
Lack of clear economic model	7.9898		
Equipment are inappropriate for the needs of the people	6.4873	√	By engaging local workers, the issue of needs communication along supply chains will be addressed (Sundin *et al.*, 2008; Sundin and Dunbäck, 2013a)
Unreliable or ineffective supply chain communication	6.0966	√	

The shortage of basic life-saving medical equipment in developing countries suggests that health care institutions would wish to retain their medical equipment for long time, even after OEMs have discontinued their production. Moreover, developing countries are not accustomed to using new and state of the equipment (Nkuma-Udah *et al.*, 2015) and are price sensitive due to lack of funds. It therefore appears highly likely that health care systems in developing countries will benefit from medical equipment remanufacturing as demonstrated in this study.

6.3 Key factors in the decision to implement medical equipment remanufacturing.

This section presents the analysis of the themes from the transcripts and the questionnaire survey on factors to consider in achieving cost effective implementation of medical equipment remanufacturing in a developing country. The main aim of the section is to answer the research question:

a. *What factors affect the implementation of remanufacturing in a developing country?*
b. *Which of the factors are more important?*

The interview analysis involved identifying and matching portions of the transcripts to themes identified from the literature. The themes/factors identified from the literature are broadly grouped into institutional, incentives and technological factors. This is the level where the interview aimed to explore. However, there are instances where

portions of the transcript matched some of the categories under these broad groupings. The survey questionnaire was used complementarily, to assess all the factors including those categories which the interview did not assess. This is deliberately done to avoid making the interview tiring. Moreover, the impact of those other factors was indirectly reflected in the responses to each broad factor groupings.

6.3.1 Potential market incentives for medical equipment remanufacturer

In the survey results, participants strongly demonstrated that remanufactured medical equipment will be in high demand. In the interview, one of the participants even noted that some outdated technologies could satisfy their demands. According to the participant (D):

"Developing countries have many medical equipment that are not functioning. I was sure that we can benefit from the concept. We know that there is usually not much difference between older equipment and newer ones other than updated software. External cosmetic appearance does not matter".

Similarly, participant A1 noted that some outdated equipment seems to be more durable than newer ones, demonstrating that functionality is more important to them than cosmetic or recentness of technology. Talking about how relatively easier it is to recover the older equipment compared to newer ones, the participant notes:

"I can tell you about very old Ultrasound equipment that we recovered like that; it is still operational till date. There are, however, many that were bought new recently that have damaged BER"

Another participant (A4) noted that a condition for accepting remanufactured medical equipment and thereby increasing incentives to remanufacture is if remanufactured equipment is priced considerably lower than newer ones and those from China. According to him, Chinese manufacturers can supply equipment at reduced prices by altering the quality accordingly and people often choose their products for the reduced prices even if they know that quality has been sacrificed to some extent.

When asked whether the stockpiled equipment would still have value, participant A1 noted:

"We have successfully repaired and brought back to life; some equipment that would have been thrown away. In most cases, the repair simply involved identification and replacement of damaged and/or faulty parts. This means that the hospital has been discarding equipment with significant residual life until we intervened".

This response indicates that there is still substantial value in some of the medical equipment that are discarded in the hospital. The participants generally believe that equipment could be used for 10 to 15 years. However, one of the participants (C) highlighted that some government officials prefer to push for the purchase of new products rather than focusing on remanufacturing or refurbishing used out of service products. According to him, the reason for doing so is because they usually get a kickback of up to 10% of the price of the new product once the purchase is completed. Hence, while there is a weak indication that older equipment that have been remanufactured may be rejected for being obsolete, emphasis may be placed on ensuring an objective selection of equipment based on HTA instead of for personal advantage.

An important consideration in relation to the potential to derive incentive from conducting medical equipment remanufacturing is the potential acceptability and demand for remanufactured equipment. In the interview, some participants indicated that lack of trust in the quality of the finished products can affect their decision to accept remanufactured medical equipment. Participant B3 felt it is not possible to restore used products to an “as good as new” condition as remanufacturing promises. The participant however, indicated that he may have confidence inn remanufactured products if the remanufacturing had been carried out by the OEM. His justification was that only the OEM would clearly understand what being new means for the equipment- how it should perform when new. In his view, only the OEM may also have the right facility to accurately identify and remove worn parts, a critical step in the renewal or remanufacturing process.

Still in relation to the potential acceptance of remanufactured medical equipment, participant B1 notes that a remanufacturer would have to first of all prove themselves by demonstrating their ability to remanufacture medical equipment to a high degree of quality. According to the participant, the warranty and provision of post sales services are key aspects of remanufacturing that makes it appealing. However, the participant prefers that the remanufacturer is local so as to fully understand how equipment fails and ensure that their services are improved accordingly.

The participants’ assessment of the key factors of incentive derivation from MER is depicted in Table 8-2 below.

Table 6-3: Participants' ratings for factors grouped under incentives for medical equipment remanufacturing.

Rating groups	I1	I2	I3	I4	I5	I6	I7
1 - 2	1	2	1	0	1	3	0
3 - 4	2	3	2	2	3	3	4
5 - 6	3	2	4	4	4	3	4
7 - 8	4	2	1	3	3	0	1
9 - 10	1	2	3	2	0	2	2

I1: Willingness to pay for remanufactured medical equipment, I2: Demand for remanufactured medical equipment, I3: Availability of marketing/distribution channel, I4: Availability of used products in acceptable quantity, I5: Access to design information, I6: Access to replacement/spare parts, I7: Availability of lower cost new or used products

From the table, I1: The willingness to pay for remanufactured medical equipment has a median rating of 5-6 while the mode of the ratings is the group 7-8. Hence, I1 as a factor seems to be supported by the participants. However, I3: Availability of marketing or distribution channel, I4: Availability of used products in acceptable quantity and quality and I5: Access to design information of products all have the same median and mode classes as I1. While I2: Demand for remanufactured medical equipment has the same median as I1, its mode is however, the group 3-4. For this factor, the frequencies of each rating classes are equal, except for the class 3-4. The total frequency of classes 5-6 to 9-10 is 6. This suggests that more than half of the participants are of the opinion that I2 is an important factor in medical equipment remanufacturing. Unlike factors I1 to I5, I6: Access to replacement parts has a median class of 3-4 with 3 participants giving a rating class of 5-6 while 2 participants gave a rating of 9-10. Hence, the evidence also suggests that I6 is recognised as an important factor. I7: Availability of lower cost new or second-hand medical equipment also has 5-6 as its median rating class. There is no rating in the class 1-2 for this factor while there are ratings in the classes 7-8 and 9-10. I7 may thus, be regarded as an important factor in medical equipment remanufacturing.

6.3.2 Technological capability assessment

To assess the technical capability for medical equipment remanufacturing, an assessment of the country's biomedical engineering training, capacity to maintain hospital equipment and the current technical activities in the medical equipment market were studied.

The biomedical engineering education in the country is still developing but some progresses have been made recently and some of the biomedical engineers are beginning to make impacts. According to participant D,

"I would say that biomedical engineering is a growing profession in the country. Currently, one of the main biomedical engineering training institutions is the Lagos University Teaching Hospital funded by GE Health. The programme was founded by a professor of Cardio-Thoracic surgery ho went ahead to study biomedical engineering and is now a professor in the field. Our hospital usually gets slot for staff training in there and some of them that did very well were retained to teach. Recently, we got ventilation and laboratory equipment experts trained there. In fact, I can comfortably say that I have a viable biomedical engineering unit and so, would say that biomedical engineering in Nigeria is improving. The biomedical engineers here at our hospital has the capacity to read circuit boards to detect faults and provide first line of maintenance for even complex equipment. In other cases, they would trouble shoot faults and tell us what the problems are and then, we can invite the company that can take over subsequent maintenance or repair when necessary

The university affiliated to our hospital has also started a Biomedical engineering programme. Students have undertaken projects such as blood sugar monitor, infant warmer, needle crusher and separator"

One potential complication to the development of remanufacturing technology capability includes having many different models of the same equipment. Participant D again, was asked to comment on the issue. He noted that:

"Our equipment come from up to 40 different makers. However, many of them have the same basic principle, only slight design changes and difference in aesthetic quality. Recognising the challenges this may cause, the Federal Government has developed a gazette listing the companies from where medical equipment can be purchased. Under each equipment category, there is usually not more than four options of manufacturers to choose from. For instance, for radiological equipment, the options are GE Health, Siemens, and Philips. This helps address maintenance issues as these manufacturers have maintenance units in Nigeria."

The capacity to provide prompt equipment maintenance may be an indication of the availability of skills and technology to carry out medical equipment remanufacturing. The responses indicate that the major problem affecting the indigenous biomedical experts' capacity is due to poor management which is often experienced in the form hospital inappropriate organisational structure and delayed release of funds to facilitate

maintenance. Participant A1's assessment of the indigenous biomedical capacity to provide prompt maintenance service for the hospital is:

"*My answer is a "yes". But it's been a struggle all along with the hospital management. First, the time of response to getting spare parts is an issue because funds for conducting maintenance and repairs are usually not made available easily until it gets too late. The biomedical engineering unit has been integrated into the larger works department till recently, and the separation has allowed us to focus on our tasks effectively. As soon as we were set up as a department, the entire hospital started seeing the immense value we can deliver. I can tell you that my team has saved the hospital huge sums of money. We have been able to easily bring equipment marked beyond economic repair back to life. I have been to the more developed African countries than Nigeria and can tell you that they do not discard equipment like we do in Nigeria".*

On the ability to provide prompt maintenance in the hospital, participant A4 answers:

We do most of our maintenance in-house. The only delay we experience is often due to delay in processing funds for maintenance by the hospital management. The delay may take a lot of time in some cases."

The data also show that there are some equipment breakdowns that are well beyond the capacity of the on-house biomedical engineers/technicians. In such cases, experts are called upon from outside the hospital. These experts are located within the country, usually working for the OEMs and have extensive knowledge about medical equipment. In participant B1 terms:

"In our hospital we have biomedical equipment department. In my opinion, I do not think they have experience enough to handle such repairs. But when there is a breakdown, they have to be the ones to escalate to the need to invite experts. They first assess the damage to see if it is within their capacity, otherwise escalate. So, they would continue trying to repair, wasting time. The amount of time lost before the equipment is finally repaired becomes unduly prolonged. Upon escalation, experts from Lagos who are proper engineers often have the capacity to carry out the repairs. So considering local to be the hospital, I would answer no but if referring to the country as a whole, I would answer yes."

Participant B3's opinion regarding the ability of local capacity to provide prompt maintenance and repair of medical equipment such as CT scanner is as follows:

"Local capacities are employed in repairing minor damages. I do not think they can carry out major repairs. More complicated problems are usually beyond their expertise and the manufacturers or suppliers are contacted by the hospital management. By manufacturers and suppliers. I mean Nigerians employed and trained by the foreign companies on handling such repairs".

Participant B3 also highlighted a broken-down CT Scanner on which a massive amount of repair work was done. The participant noted that the repair was done by suppliers who are based in Nigeria and that the actual repair was done by employed Nigerians. Based on this experience, the participant was convinced that the trained experts could carry out medical equipment remanufacturing:

"Those engineers in Lagos are quite knowledgeable and will definitely be able to remanufacture medical equipment. But they are not many."

Participant A4 believed that remanufacturing is similar to refurbishment and noted that such practices are already in existence within Nigeria which according to him, is an indication that the capacity currently exists. He is of the opinion that those actors only need to be recognised and supported to give a more refined and quality products. According to the participant:

"There are people already doing refurbishment in the country. A lot of work in medical equipment refurbishment is going on in Aba, Onitsha, and Lagos. If the people doing the job are respected and patronised, they would be able to do better".

From this discussion, biomedical engineering education has taken off in Nigeria, as is the case with many developing countries. This provides a supply of people knowledgeable in medical equipment. There is also evidence of refurbishing activities going on in the industry which could be a source of labour. This workers or others may also receive further training by a potential remanufacturer to understand the equipment technology.

Sourcing of spare parts for repairs is also an important technical factor. To this, participants A1 and A4 noted that they start by first conducting online search of medical equipment manufacturers to contact for the supply of the parts. He noted that they provide potential suppliers with the specifications of the equipment for which they need the part replacement and that in most cases, they have been able to get the parts this way. Recognising the difficulty that it would pose when the equipment manufacturer has ceased producing that model of the equipment, participant A1 noted:

"We first try to identify the manufacturers of the parts, that is, the people that supply the parts to those that manufacture the medical equipment. Such suppliers have helped us out a number of times, but the parts usually come very expensive. This is because the benefit of mass supply which drives price down is no longer considered in this situation. In some cases, it may cost up to USD 1500 to produce only a printed circuit board"

Participant A4 also contacts parts OEMs for parts:

"We deal with manufacturers directly, to obtain spare parts. Some OEMs, however, do not agree to send their parts to Nigeria for intellectual property violation issues but we always find a way out in such situations. It is easy for us to have such an international network with manufacturers, but others may find it difficult to do so. Some hospitals contact us to help them source their parts".

Participants' ratings of the technological factors are represented on Table 8-3

Table 6-4: Technological factors in medical equipment remanufacturing.

Rating groups	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	P11	P12	P13	P14
1 - 2	0	2	2	0	1	1	1	1	1	2	0	0	0	1
3 - 4	2	2	3	3	2	3	4	5	4	1	1	1	2	2
5 - 6	3	4	1	7	2	3	4	2	3	2	4	3	1	3
7 - 8	3	1	5	1	5	3	1	1	2	4	1	3	3	3
9 - 10	2	2	0	0	1	1	1	2	1	2	5	4	5	2
n	10	11	11	11	11	11	11	11	11	11	11	11	11	11

P1: Availability of equipment and technologies for remanufacturing, P2: Availability of skilled workforce, P3: Potential hazard risks to workers, P4: Labour costs, P5: Design will not permit remanufacturing, P6: Ease of disassembly and reassembly, P7: Ease of inspection and testing, P8: Ease of cleaning, P9: Ease of disinfection/sterilisation, P10: Ease of upgrade to appropriate technology, P11: Wide variety of medical equipment to develop capability for, P12: Residual value of recovered products, P13: Recovered used medical equipment may be obsolete, P14: Affordability of requisite investment.

From the table, the median rating class is taken to be an indication of how important each factor is in the implementation of medical equipment remanufacturing. For P1: Availability of equipment and technologies, n=10 as a participant omitted a slot. The median rating class in this case is split between 5-6 and 7-8 which also represent the modes of the ratings distribution. Thus, the factor is an important one. Apart from P1, there are seven other technological factors that have median rating class of 5-6. These are P2: Availability of skilled workforce, P3: Potential hazards to workers, P4: Labour costs, P6: Ease of disassembly, P7: Ease of inspection and testing, P9: Ease of disinfection/sterilisation, and P14: Affordability of requisite investments. Like I1, only P14 is bimodal in the rating classes 5-6 and 7-8. P7 is bimodal in the classes 3-4 and

5-6 while P6 is trimodal in the classes 3-4, 5-6 and 7-8. The modes are in the class 7-8 for P3, for P2 it is in the class 5-6, and in the class 3-4 for P9. Since the median and mode classes are above the half mark of the scale (except for P9 where mode is in the class 3-4) in each of these factors, they may therefore be considered important in medical equipment remanufacturing.

There are five factors with median rating class of 7-8. These are P5: Design will not permit remanufacture, P10: Ease of upgrade to appropriate technology, P11: Wide variety of medical equipment models to develop capability for, P12: Residual value of recovered used medical equipment, and P13: Recovered used products may be obsolete. For P5 and P10, the modal rating class is also 7-8; the modal class for P11 is 5-6 while that of P13 is 9-10. However, P12 is bimodal in the classes 5-6 and 7-8. Since the medians and modes of the rating these classes are above the half mark of the scale, they may be considered important in medical equipment remanufacturing.

The factor P8: Ease of cleaning seems to have the lowest ratings of all the others. The median and modal classes are both 3-4. However, since 5 participants scored it 5-6 and above, it would be improper not to recognise it as a factor to be considered in the implementation of medical equipment remanufacturing.

6.3.3 Assessing institutional factors

Institutions provide a framework within which businesses operate and interact. It may be governmental or non-governmental. Example of governmental regulatory framework includes medical device regulatory bodies, frameworks, and policies for capacity development in the industry.

An important issue in the medical device industry is the regulation of radiological equipment in order to ensure that patients and staff are only exposed to the right dosages of radiation. Acceptable practice in this regard, in the EU exists (EC, 2012). To determine the effectiveness of this regulation in Nigeria, a medical physicist, participant E, was interviewed. The participant recognises the importance of regulations but is of the opinion that greater emphasis should be on enforcement:

“NNRA (Nigerian Nuclear Regulatory Authority) which was instituted in 2001 is responsible for radiation equipment in Nigeria, including X-ray equipment, CT scan. They regulate whatever comes into the country that has to do with radiation especially in manufacturing and medical sectors but also in oil and gas. The Act establishing the agency came up in 1995 and so, NNRA replaced the federal radiation protection service.

The NNRA gives licence to importers of radiation equipment. When installed, part of their work is to ensure that performance of the equipment is optimal. They insist that each organisation with installed equipment appoints a radiation officer. I have been one. However, they have not been able to cover the whole country. They should have a task force going around the country, taking inventory of radiation emitting equipment in order to achieve their objectives. But sadly, this is not the case. They don't even know the number of CT equipment in the country. They have ambitious objectives but seems not to have the will and machinery to implement them. Cobalt 60 radiotherapy equipment mostly used for nuclear medicine in the country is also being regulated by the agency. There are only 9 radiotherapy equipment in Nigeria including just about 3 Linacs. Cobalt 60 equipment usually come as donations. The one in our hospital usually gets damaged but there are biomedical technicians that fix them. There has also been issues with improper disposition of damaged cobalt 60 equipment (radioactive materials are often disposed together with the equipment) among operators that collect them for recycling."

The participant thinks that the leadership of the NNRA influences its effectiveness and noted that existing regulations and laws on ground could be very effective if properly implemented. According to the participant:

"It depends on leadership. The institution once had a vibrant leader that mobilised task force for intensive monitoring of compliance with the regulation. Some hospitals were even sealed off in Lagos at that time, where patients stay up to 10 times more than they should, under X-ray exposure. There are also several independent X-ray diagnostic centres where the buildings are not designed appropriately to protect the staff and nearby people from radiation exposure. Since the leader left, there has not been any meaningful supervision from the organisation. The current Director General seems to be quiet on radiation safety. Whereas in the dispensation I just told you about, every establishment with X-ray equipment usually keep searching for radiation safety advisers whose responsibility it would be to ensure that the equipment in their possession comply with standard.

The regulations and laws on ground would be very effective if properly implemented. So, I think that mostly implementation efforts should be improved. This will involve elimination of corruption in the system so that no one bypasses it."

Weak regulatory control was also reported by participant A4 who noted that the Standards organisation of Nigeria does not provide any standards because they do not have people appropriately trained in checking standards. Similarly, participant A1

attributes the weak regulatory control on medical equipment to the infancy of the biomedical engineering profession and emphasised that developing and implementing robust medical equipment regulatory framework would require the collaboration of the Federal ministry of health.

Concerning the implementation of Quality Control and Assurance practices in the hospital, participant B1 noted:

"Those ones are done monthly or immediately after repair. We have our internal radiation physicists and biomedical engineers that carry out those procedure"

And participant A4 noted:

"*We have different analysers used for calibration and quality assurance. For X-ray and CT-scanner, we perform the procedure to determine the amount of radiation exposure that patients and staff are at risk of. Our team is highly trained so we know and implement what is required but I cannot say the same about other hospitals"*

From the participants' perspectives, it appears to be entirely up to practitioners to exhibit best practices as regulation seems not to be strong enough to make the push. It was also inferred that the infancy of the biomedical engineering profession contributes to the low skill set for regulatory tasks. This links technical skills to the effectiveness of regulation.

Regulation can help boost confidence in remanufactured products. In advanced countries, risk is a critical consideration in the medical device industry for obvious reasons including the possibility of adverse effects. Hence, to ensure that remanufacturing produces safe equipment, operators should be subjected to the requirement to demonstrate compliance with necessary standards.

The participants' assessment of relevant institutional influences is depicted in Table 8-4 below.

Table 6-5: Assessment of institutional factors.

Rating groups	II1	II2	II3	II4	II5
1 - 2	0	0	1	2	2
3 - 4	5	0	0	2	1
5 - 6	0	1	3	1	1
7 - 8	2	1	1	2	1
9 - 10	1	6	3	1	3

II1: Difficulty obtaining licences to market remanufactured medical equipment, II2: Municipal infrastructure such as electricity, II3: Intellectual property management issues, II4: Obtaining regulatory approval to set up medical equipment remanufacturing enterprise, II5: Weak regulation. Total number of participants in this part n = 8.

Only 8 participants had the knowledge to complete this part of the questionnaire. As shown on the table, the median rating class for II1: Difficulty obtaining licences to market remanufactured medical equipment is 3-4 and that is also the modal class. Slightly similar, II4: Obtaining regulatory approval to set up medical equipment remanufacturing enterprise has its median between classes 3-4 and 5-6. For II3: Intellectual property management issues and II5: Weak regulation, the median rating is between 5-6 and 7-8. However, II3 has two modes in the classes 5-6 and 9-10 while for II5, the mode is the rating class 9-10. The factor II2: Municipal infrastructure such as electricity stood out conspicuously, with median and modal class of 9-10. Apart from II1, all the factors highlighted in this section can be considered important based on the same reasonings used in the previous two sections. However, II1 may be regarded as being of little importance based on this assessment rather than discarding it.

6.3.4 Priority of factors

All the factors assessed in this research phase have been shown to be relevant considerations in implementing medical equipment remanufacturing in a developing country. However, as there are many factors considered, a ranking framework may be handy, to support practice. It will also help to identify the more important factors. Given the analysis so far, the only pertinent means of achieving such structuring is by using the median rating classes of each factor. To achieve this, the following heuristic is adopted:

If Median class is above the range [7 – 8] Factor is extremely important

If Median class is up to the range [7 – 8] Factor is very important

If Median class is in the range [3 – 4] to [5 – 6] Factor is important

If median class is in the range [1 – 2] Factor is almost unimportant

Based on this heuristic, all the factors studied in this chapter are at least, somewhat important. The most important factor identified is II2: municipal infrastructure which is an institutional factor. This is particularly important because the institutions responsible for providing this facility have so failed that many businesses have to individually generate their own power. This would drive the production cost very high and except the potential remanufacturer is able to enjoy high volume sales (assuming other costs are constant), then this will severely affect the profitability of the business. Figure 6-2 shows the order of priority of the factors.

A key well known technique for determining whether a product would sell is by studying the potential customers' purchase intentions which is a measure of their willingness to pay. This is explored in the next section for remanufactured medical equipment.

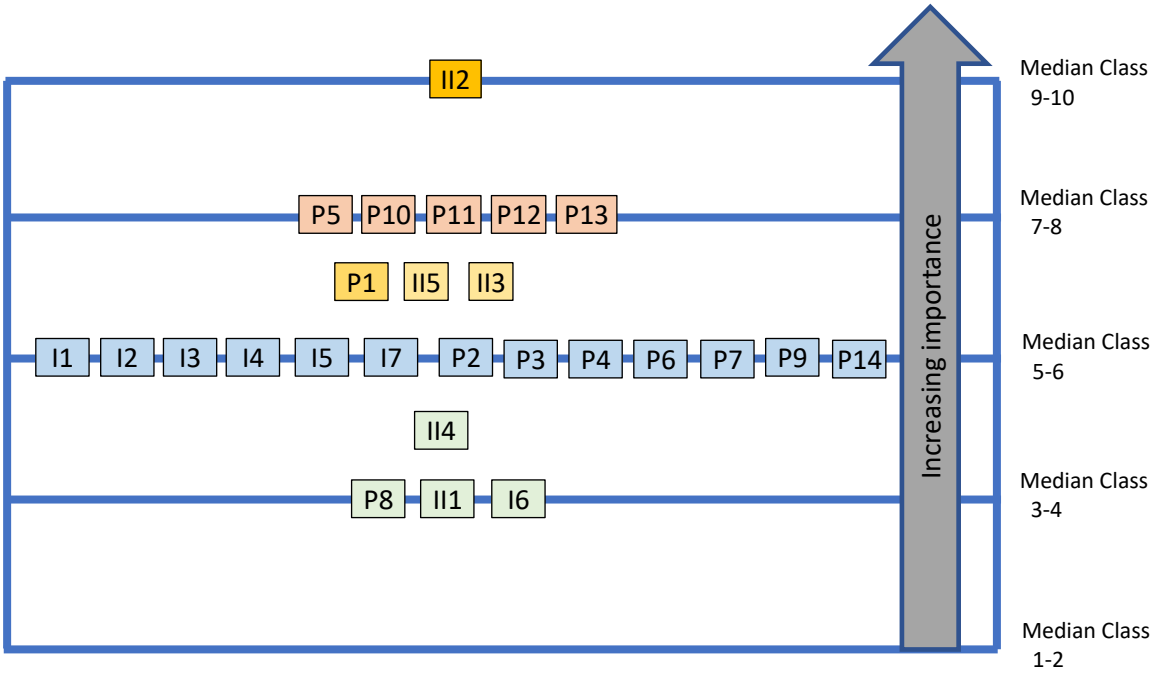

Figure 6-2:Priority framework for the factors in medical equipment remanufacturing

6.4 Factors affecting the acceptability and purchase intention for remanufactured medical equipment.

The market potential for remanufactured medical equipment would depend on how much they are accepted by clinicians. Therefore, understanding the acceptability of remanufactured medical equipment is necessary in determining the suitability of the concept of remanufacturing being proposed as a solution in this research. This chapter reports the results of the investigation into the acceptability and behavioural factors

informing the purchase intentions for remanufactured medical equipment and so, answers the following research questions:

How would potential users perceive remanufactured medical equipment?

What key factors predict the purchase intention for remanufactured medical equipment among potential users?

In the first part, potential acceptability of remanufactured medical equipment was assessed by analysing responses to questions directly assessing participants' preference for key features of remanufactured medical equipment. In the second part, previously developed instrument based on Perceived Benefit, Perceived Risk and Theory of Planned Behaviour was used to analyse the purchase intentions for remanufactured equipment. Factors considered have been explored in chapter 3, where behavioural factors influencing the purchase intention for remanufactured products were reviewed and theories used in previous studies summarised. The instrument used is shown in Figure 6-6 below.

Table 6-6: Instrument used in the study of potential purchase intentions. The instrument is developed from previous studies as shown.

	Perceived benefits		
1	Purchasing remanufactured X-ray equipment will give access to reliable and durable products.	Lifespan	(Wang *et al.*, 2013)
2	Purchasing remanufactured X-ray equipment will reduce purchasing cost compared to new X-ray equipment.	cost reduction	(Wang *et al.*, 2013)
3	I will be satisfied with the appearance of remanufactured X-ray equipment.	Features	(Hazen *et al.*, 2012)
4	The performance of remanufactured X-ray equipment can satisfy my expectations	performance	(Hazen *et al.*, 2012)
5	Purchasing remanufactured X-ray equipment can help reduce patient safety issues in our hospitals.	safety	(Wang *et al.*, 2013)
	Purchase attitude		
6	I like the idea of purchasing remanufactured X-ray equipment		(Wang *et al.*, 2013)
7	Purchasing remanufactured X-ray equipment is a wise decision		(Wang *et al.*, 2013)
	Perceived behavioural control		
8	It is possible for me to purchase remanufactured X-ray equipment		(Pouta and Rekola, 2001)
9	I cannot purchase remanufactured X-ray equipment		(Pouta and Rekola, 2001)
	Purchase intention		
10	If I have the option, I will choose to purchase remanufactured X-ray equipment		(Wang *et al.*, 2013)

11	Given the opportunity, I would encourage my colleagues to purchase remanufactured X-ray equipment		(Wang and Hazen, 2016)
	Subjective norms		
12	Those that have important influence on me would approve my purchase and use of remanufactured X-ray equipment		(Pouta and Rekola, 2001; Wang *et al.*, 2013)
13	My colleagues and friends would also purchase remanufactured X-ray equipment if given the option		(Pouta and Rekola, 2001; Wang *et al.*, 2013)
	Perceived risks		
14	Remanufactured X-ray equipment will not be as safe as new ones.	safety risk	(Wang *et al.*, 2013)
15	Remanufactured X-ray equipment will not perform as good as new ones	performance risk	(Wang *et al.*, 2013)
16	Remanufactured X-ray equipment will not perform as good as new ones such that I may spend more time on repairs.	Time risk	(Wang *et al.*, 2013)
17	It will not be possible to derive commensurate utility for monetary investment in purchasing remanufactured X-ray equipment.	financial risk	(Wang *et al.*, 2013; Matsumoto, Chinen and Endo, 2017)
18	I am afraid that after sales services for remanufactured product will not be possible	serviceability	(Wang and Hazen, 2016)

6.4.1 Respondents' remanufacturing awareness assessment

To understand the general awareness of remanufacturing among participants, questions were included to determine if they had heard about remanufacturing, used, or know anyone who has used remanufactured medical equipment. 27 participants had heard about remanufacturing while 97 had not. Similarly, only 22 participants noted that they have used remanufactured medical equipment in the past while 102 said the contrary. Furthermore, only 23 participants agreed to know anyone who has used remanufactured medical equipment while 100 said otherwise. Figure 6-3 below summarises the medical equipment remanufacturing awareness among the survey participants.

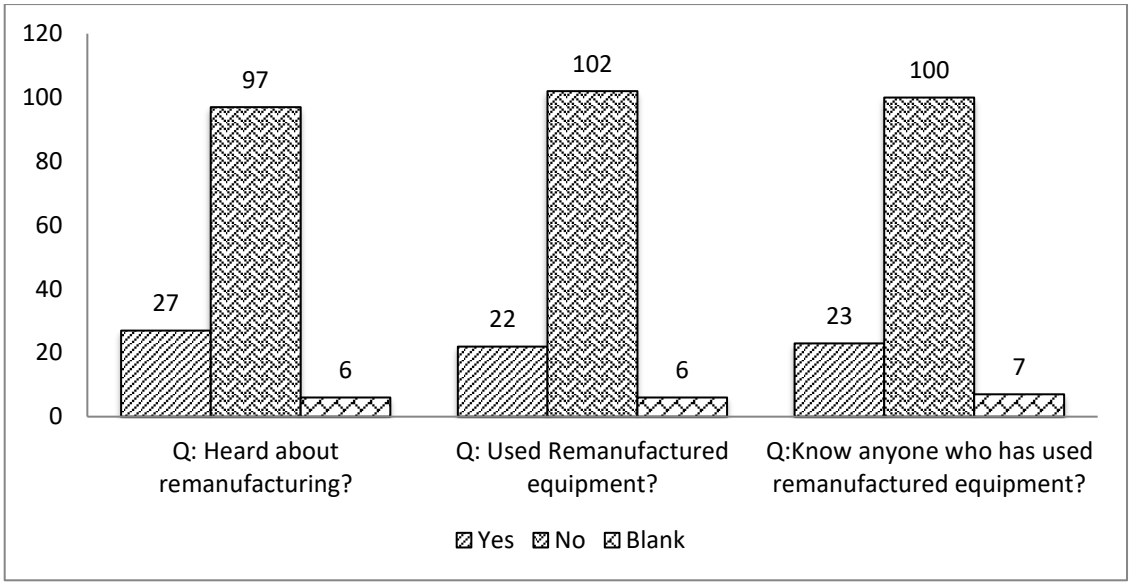

Figure 6-3: Awareness of remanufacturing among study participants

The Figure shows that medical equipment remanufacturing awareness is poor among the participants. The introductory explanation of the concept presented in the questionnaire was therefore highly relevant.

6.4.2 Importance of price reduction on remanufactured medical equipment

As the main highlights in the proposed definition were price reduction and provision of post sales technical support with the remanufactured equipment, participants assessment of the importance of these provisions were tested. As shown in Figure 6-4 below, 36 of the participants would consider remanufactured medical equipment if the price reduction is up to 50% while 26, 39, 13 and 3 participants would consider remanufactured medical equipment if price reductions were 40%, 30%, 20% and 10% respectively. On the other hand, 9 participants did not provide answer to the question while 2 participants consider remanufactured medical equipment as unsafe and would not consider purchasing them for any price reduction.

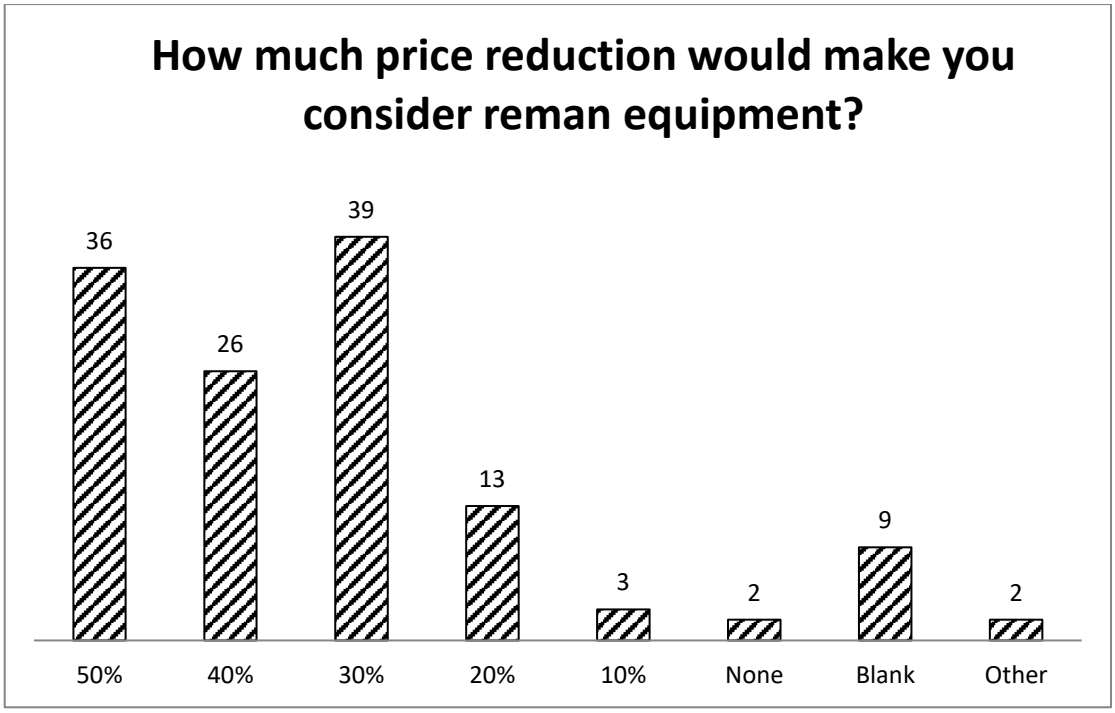

Figure 6-4: Impact of price reduction on the decision to use remanufactured medical equipment.

6.4.3 Importance of post sales technical support

To assess the importance of providing post sales technical support with remanufactured medical equipment, the participants were asked to rank the extent they feel such provision is important. The ranking is based on 5-point Likert scale including Strongly agree, agree, neither agree nor disagree, disagree, and strongly disagree. As shown on Table 6-7 below, 57% of the participants strongly agree that post sales technical support is necessary while 31% agree. Altogether, 88% agree or strongly agree.

Table 6-7: Importance of providing post sales technical support with remanufactured medical equipment.

Do you think that post sales technical service support should be sold together with remanufactured medical equipment?		Relative freq.	Percentage relative frequency
Strongly agree	71	71	57
Agree	38	109	88
Neither agree nor disagree	10	119	96
Disagree	3	122	98
Strongly disagree	2	124	100
Blank	6		
Total	**130**		

88% of the participants agree that post sales-technical support should be sold together with remanufactured medical equipment.

6.4.4 Influence of post-sales support on the choice of remanufactured X-ray equipment

When asked to state the extent to which the provision of post sales technical support would encourage them to switch to purchasing remanufactured X-ray equipment on a scale of 10, Figure 6-5 summarises the findings. As shown, 15, 12, 22, 22 and 11 participants accounting for 68% of total respondents ranked the influence of post sales technical support provision on their switching behaviour as 10, 9, 8, 7 and 6 respectively. Hence, providing post sales technical support will have more than average switching effect on 82 participants.

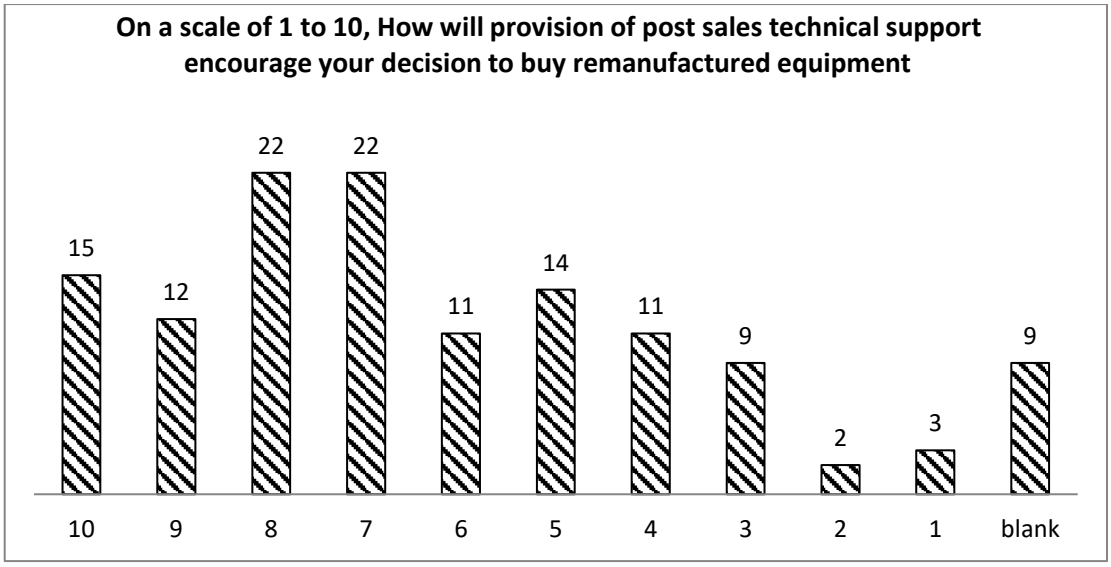

Figure 6-5: Impact of post sales technical support provision on the decision to purchase remanufactured medical equipment.

6.4.5 Purchase intentions analysis: Data summary

This section presents a summary of the data gathered in this phase of the study.

6.4.5.1 Perceived benefits

The descriptive statistics for the perceived benefit indicator variables are summarised in Table 6-8. As shown, all indicator variables have at least, a mean value of 5.0, except for Q5 "I like the idea of using remanufactured X-ray equipment" whose mean value is 4.4. This suggests that the variables have relatively similar relevance. In descending order of magnitudes, Q2 "Purchasing remanufactured X-ray equipment will reduce purchasing cost compared to new X-ray equipment" has a mean of 5.6; Q4 " the performance of remanufactured X-ray equipment can satisfy my expectations" has a mean of 5.08; Q1 "Purchasing remanufactured medical equipment will give access to reliable and durable products" has a mean of 5.026 and Q3 "I will be satisfied with the appearance of remanufactured X-ray equipment" has a mean of 5.00. The results show that on the average, the participants find the reliability and durability, cost savings, aesthetic quality, performance as well as reduction in patient safety issues associated with remanufactured X-ray equipment to be satisfactory.

6.4.5.2 Perceived risk

The risk perception for remanufactured X-ray equipment was assessed using variables Q14 to Q18. Table 6-9 summarises the descriptive statistics. As shown, Q14 "Remanufactured X-ray equipment will not be as safe as new ones" has the highest mean response of 4.71 while the least response of 4.03 comes from Q17 "it will not be possible derive commensurate utility for monetary investment in purchasing

remanufactured X-ray equipment". The mean values of the other indicator variables are as follows: Q15 "Remanufactured X-ray equipment will not perform as new ones"; 4.51; Q16 "Remanufactured X-ray equipment will not perform as new ones such that I may spend more time on repairs", 4.36 and Q18 "I am afraid that after sales services for remanufactured X-ray equipment may not be possible, 4.32. Overall, the mean values of the risk perception indicator variables suggest that participants have fairly negative perception about using remanufactured X-ray equipment.

6.4.5.3 Purchase attitude

The descriptive statistics for indicator variables measuring the purchase attitude are presented in Table 6-10. The table shows that the variable Q6 "I like the idea of purchasing remanufactured X-ray equipment" has a mean value of 4.86 while the variable Q7 "purchasing remanufactured X-ray equipment is a wise option" has a mean value of 4.87. These values suggest that the indicators have almost equal relevance in specifying the construct.

6.4.5.4 Perceived behavioural control.

The indicator variables used to assess the perceived behavioural control are Q8 "It is possible for me to purchase remanufactured X-ray equipment" and Q9 "I cannot purchase remanufactured X-ray equipment". Clearly, Q9 is framed negatively and inputs from participants need to be recoded reversely. The descriptive statistic for the construct is summarised in Table 6-11. The Table shows the mean values of Q8 and recoded Q9 as 5.04 and 5.7, respectively. This shows that participants demonstrate fairly high behavioural control towards purchasing remanufactured X-ray equipment.

6.4.5.5 Purchase intention

The purchase intention is the dependent latent variable in the current phase. It is measured using variables Q10 and Q11 which respectively stand for "If I have the option, I will choose to purchase remanufactured X-ray equipment" and "Given the opportunity, I encourage my colleagues to purchase remanufactured X-ray equipment". Table 6-12 summarises the descriptive statistics for this variable. It shows that Q10 has an average value of 4.59 while Q11 has an average value of 4.77.

6.4.5.6 Subjective norms

The subjective norm construct was measured by indicator variables Q12 "those that have important influence on me would approve my purchase and use of remanufactured X-ray equipment" and Q13 "My colleagues and friends would also purchase remanufactured X-ray equipment. The mean values of the inputs collected for these variables are 4.57 and 4.73 respectively. Descriptive statistics for this latent variable are summarised in Table 6-13.

Table 6-8: Descriptive statistics for perceived benefits measures

Q1		*Q2*		*Q3*		*Q4*		*Q5*	
Mean	5.02631579	Mean	5.640351	Mean	5	Mean	5.078947	Mean	4.412281
Standard Error	0.13272286	Standard Error	0.139935	Standard Error	0.1398649	Standard Error	0.128976	Standard Error	0.136955
Median	5	Median	6	Median	5.5	Median	5	Median	4
Mode	6	Mode	6	Mode	6	Mode	6	Mode	4
Standard Deviation	1.41709241	Standard Deviation	1.494102	Standard Deviation	1.4933481	Standard Deviation	1.377086	Standard Deviation	1.462277
Sample Variance	2.00815091	Sample Variance	2.23234	Sample Variance	2.2300885	Sample Variance	1.896367	Sample Variance	2.138255
Kurtosis	0.57026652	Kurtosis	2.690137	Kurtosis	0.2963036	Kurtosis	1.266203	Kurtosis	-0.58344
Skewness	-0.95882062	Skewness	-1.71093	Skewness	-0.9250205	Skewness	-1.0962	Skewness	-0.42014
Range	6	Range	6	Range	6	Range	6	Range	6
Minimum	1	Minimum	1	Minimum	1	Minimum	1	Minimum	1
Maximum	7	Maximum	7	Maximum	7	Maximum	7	Maximum	7
Sum	573	Sum	643	Sum	570	Sum	579	Sum	503
Count	114	Count	114	Count	114	Count	114	Count	114
Conf level (95.0%)	0.26294793	Conf level (95.0%)	0.277237	Conf level (95.0%)	0.2770975	Conf level (95.0%)	0.255525	Conf level (95.0%)	0.271332

Table 6-9: Descriptive statistics for perceived risk measures

Q14		***Q15***		***Q16***		***Q17***		***Q18***	
Mean	4.710526316	Mean	4.50877193	Mean	4.359649123	Mean	4.035087719	Mean	4.324561
Standard Error	0.138595705	Standard Error	0.143289375	Standard Error	0.15062216	Standard Error	0.148965185	Standard Error	0.155874
Median	5	Median	5	Median	5	Median	4	Median	5
Mode	5	Mode	5	Mode	5	Mode	5	Mode	5
Standard Deviation	1.479797189	Standard Deviation	1.529911872	Standard Deviation	1.608204589	Standard Deviation	1.590512939	Standard Deviation	1.664282
Sample Variance	2.189799721	Sample Variance	2.340630337	Sample Variance	2.586322	Sample Variance	2.529731408	Sample Variance	2.769834
Kurtosis	-0.260195416	Kurtosis	-0.454536849	Kurtosis	-0.848324528	Kurtosis	-0.949543587	Kurtosis	-0.94731
Skewness	-0.754267911	Skewness	-0.650763194	Skewness	-0.358694244	Skewness	-0.031555466	Skewness	-0.31978
Range	6	Range	6	Range	6	Range	6	Range	6
Minimum	1	Minimum	1	Minimum	1	Minimum	1	Minimum	1
Maximum	7	Maximum	7	Maximum	7	Maximum	7	Maximum	7
Sum	537	Sum	514	Sum	497	Sum	460	Sum	493
Count	114	Count	114	Count	114	Count	114	Count	114
Conf level (95.0%)	0.274583089	Conf level (95.0%)	0.283882096	Conf level (95.0%)	0.298409665	Conf level (95.0%)	0.295126899	Conf level (95.0%)	0.308815

Table 6-10: Descriptive statistics summary for purchase attitude

Q6		***Q7***	
Mean	4.859649123	Mean	4.877192982
Standard Error	0.142000475	Standard Error	0.137706022
Median	5	Median	5
Mode	6	Mode	6
Standard Deviation	1.516150184	Standard Deviation	1.47029797
Sample Variance	2.29871138	Sample Variance	2.161776122
Kurtosis	0.462132376	Kurtosis	0.431248445
Skewness	-0.998441884	Skewness	-0.974285956
Range	6	Range	6
Minimum	1	Minimum	1
Maximum	7	Maximum	7
Sum	554	Sum	556
Count	114	Count	114
Confidence Level (95.0%)	0.281328552	Confidence Level (95.0%)	0.272820466

Table 6-11: Descriptive statistics summary for perceived behavioural control

Q8		***Q9***	
Mean	5.035087719	Mean	5.271929825
Standard Error	0.13588413	Standard Error	0.132033578
Median	6	Median	6
Mode	6	Mode	6
Standard Deviation	1.450845494	Standard Deviation	1.409732842
Sample Variance	2.104952647	Sample Variance	1.987346685
Kurtosis	1.108534394	Kurtosis	0.399148219
Skewness	-1.283148313	Skewness	-1.017568921
Range	6	Range	6
Minimum	1	Minimum	1
Maximum	7	Maximum	7
Sum	574	Sum	601
Count	114	Count	114
Confidence Level (95.0%)	0.26921097	Confidence Level (95.0%)	0.261582331

Table 6-12: Descriptive statistics summary for purchase intention

Q10		***Q11***	
Mean	4.587719298	Mean	4.771929825
Standard Error	0.145741924	Standard Error	0.140438181
Median	5	Median	5
Mode	6	Mode	6
Standard Deviation	1.556097931	Standard Deviation	1.49946945
Sample Variance	2.42144077	Sample Variance	2.248408632
Kurtosis	-0.33570894	Kurtosis	-0.171872929
Skewness	-0.732901493	Skewness	-0.867810775
Range	6	Range	6
Minimum	1	Minimum	1
Maximum	7	Maximum	7
Sum	523	Sum	544
Count	114	Count	114
Confidence Level (95.0%)	0.288741038	Confidence Level (95.0%)	0.278233366

Table 6-13: Descriptive statistics summary for subjective norm

Q12		***Q13***	
Mean	4.570175439	Mean	4.728070175
Standard Error	0.127050362	Standard Error	0.115069414
Median	5	Median	5
Mode	4	Mode	4
Standard Deviation	1.356526657	Standard Deviation	1.228605136
Sample Variance	1.840164571	Sample Variance	1.509470579
Kurtosis	-0.135133937	Kurtosis	0.618166117
Skewness	-0.540606697	Skewness	-0.658411795
Range	6	Range	6
Minimum	1	Minimum	1
Maximum	7	Maximum	7
Sum	521	Sum	539
Count	114	Count	114
Confidence Level (95.0%)	0.251709682	Confidence Level (95.0%)	0.227973263

6.4.6 Factor analysis results

Factor analysis was performed to determine the structure of relationship among the constructs for perceived benefit, perceived risk, purchase attitude, subjective norm, and perceived behavioural control. The Kaiser Meyer Olkin measure of sampling adequacy, which is greater than 0.5, and diagonal the elements of the anti-image matrix which are also, greater than 0.5 indicate that the sample is adequate for factor analysis. Items which have low variance extraction, and which loaded on multiple factors were also removed. The two items Q6 and Q7 measuring perceived behavioural control were removed because they loaded on multiple constructs. On the other hand, items Q5 and Q18 were removed because they have very low variance extractions (<0.5). The remaining items loaded on four factors after the analysis using the Principal Component Analysis and varimax rotation; with the factors accounting for 73.048% of the average variance explained (AVE). The communalities, loadings and variance extractions from the remaining items and the factor loadings are shown in Tables 6-14, 6-15 and 6-16. Accordingly, perceived risk ranks highest (AVE = 4.71), followed by perceived benefit (AVE = 1.740).

Table 6-14: Communalities and factor loadings

Communalities

	Initial	Extraction
Q1	1.000	.705
Q2	1.000	.697
Q3	1.000	.765
Q4	1.000	.751
Q8	1.000	.769
Q9	1.000	.830
Q12	1.000	.835
Q13	1.000	.823
Q14	1.000	.650
Q15	1.000	.853
Q16	1.000	.784
Q17	1.000	.600

Extraction Method: Principal Component Analysis.

Table 6-15: Factor loadings

Rotated Component Matrix[a]

	Component			
	1	2	3	4
Q15	.895			
Q16	.871			
Q14	.776			
Q17	.703			
Q2		.828		
Q3		.794		
Q4		.762		
Q1		.678		
Q13			.867	
Q12			.855	
Q9				.899
Q8				.800

Extraction Method: Principal Component Analysis.

Rotation Method: Varimax with Kaiser Normalization.

a. Rotation converged in 5 iterations.

Table 6-16 : Variance extractions from factor loadings

Total Variance Explained

	Initial Eigenvalues			Extraction Sums of Squared Loadings			Rotation Sums of Squared Loadings		
Component	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
1	4.741	39.511	39.511	4.741	39.511	39.511	2.913	24.271	24.271
2	1.740	14.496	54.007	1.740	14.496	54.007	2.452	20.434	44.705
3	1.228	10.236	64.243	1.228	10.236	64.243	1.778	14.817	59.523
4	1.057	8.805	73.048	1.057	8.805	73.048	1.623	13.526	73.048
5	.763	6.359	79.407						
6	.583	4.855	84.262						
7	.480	3.997	88.259						
8	.442	3.681	91.940						
9	.338	2.814	94.755						
10	.276	2.296	97.050						
11	.187	1.559	98.609						
12	.167	1.391	100.000						

Extraction Method: Principal Component Analysis.

6.4.7 CFA model output

The CFA model estimated following the modifications determined from the factor analysis is shown in Figure 6-6, below.

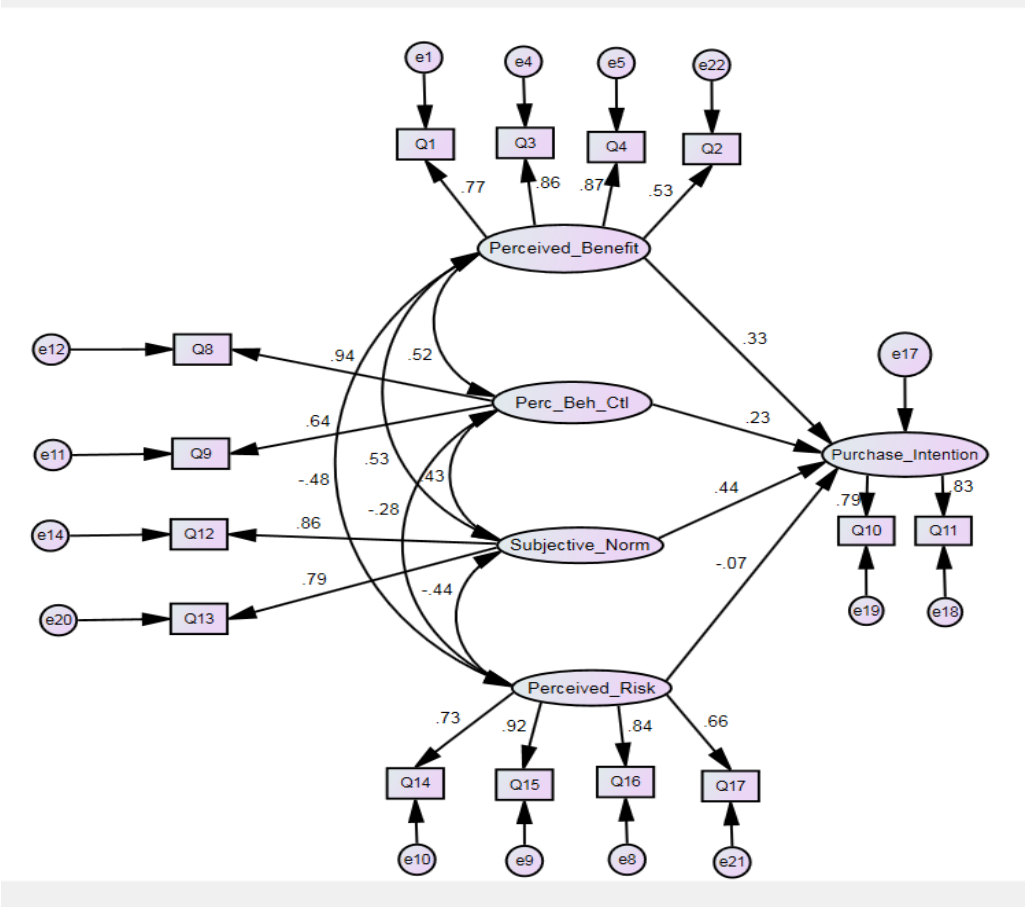

Figure 6-6: Estimated Model before modification

For the model, TLI, CFI and RMSEA values of 0.943, 0.958 and 0.058 suggest an acceptable model fit. With a Chi square value that is significant (P= 0.005) however, the model is rejected. The fit indices for the model are summarised in Tables 6-17 to 6-19 below.

Table 6-17: Chi square statistics for proposed model

Model	NPAR	CMIN	DF	P	CMIN/DF
Default model	38	100.915	67	.005	1.506
Saturated model	105	.000	0		
Independence model	14	895.043	91	.000	9.836

Table 6-18: Baseline comparisons of the proposed model

Model	NFI Delta1	RFI rho1	IFI Delta2	TLI rho2	CFI
Default model	.887	.847	.959	.943	.958
Saturated model	1.000		1.000		1.000
Independence model	.000	.000	.000	.000	.000

Table 6-19: Root mean square error approximation of the proposed model

Model	NPAR	CMIN	DF	P	CMIN/DF
Default model	38	92.097	67	.023	1.375
Saturated model	105	.000	0		
Independence model	14	840.652	91	.000	9.238

An examination of the model output shows that the variable Q2 loads poorly (loading = 0.53) on the perceived benefit construct. For this reason, it is removed. The removal of Q2 results in a model with acceptable fit indices as summarised in Tables 6-20 to 6-21 and depicted in Figure 6-7. The root mean square error approximation was 0.044 which is still within acceptable limits.

Table 6-20: Chi squared statistics of the modified model.

Model	NPAR	CMIN	DF	P	CMIN/DF
Default model	36	69.522	55	.095	1.264
Saturated model	91	.000	0		
Independence model	13	781.799	78	.000	10.023

Table 6-21: Baseline comparisons of the modified model

Model	NFI Delta1	RFI rho1	IFI Delta2	TLI rho2	CFI
Default model	.911	.874	.980	.971	.981
Saturated model	1.000		1.000		1.000
Independence model	.000	.000	.000	.000	.000

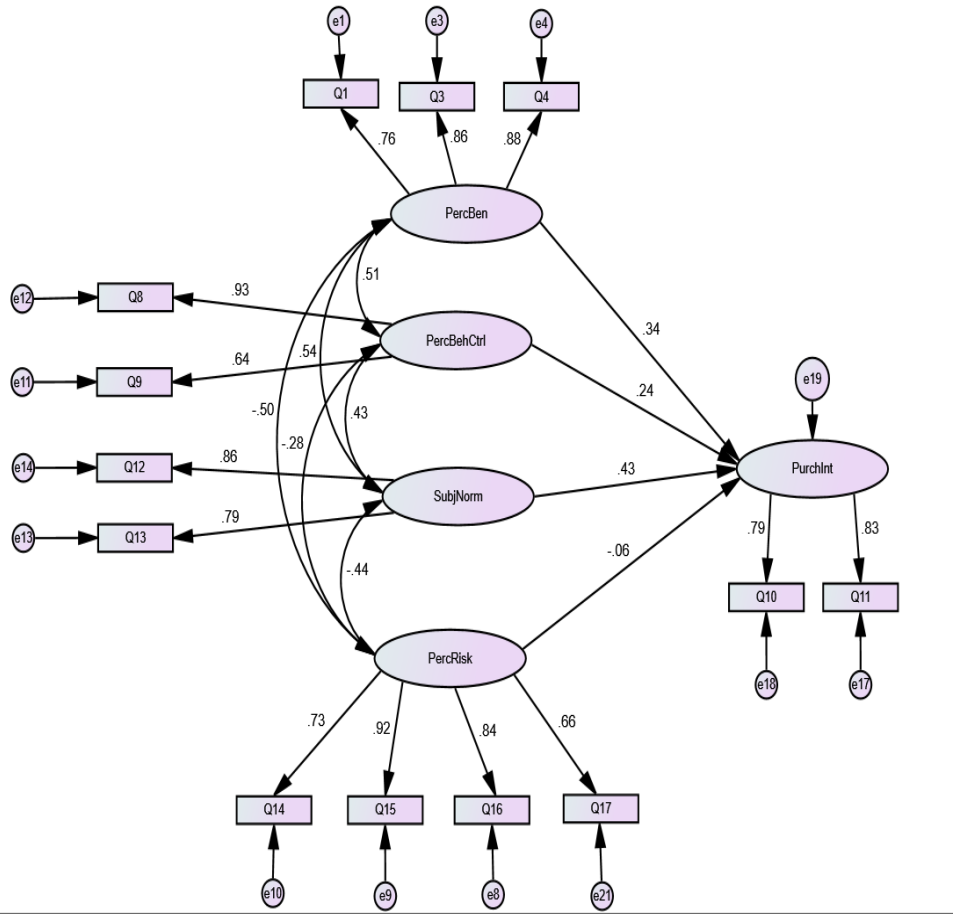

Figure 6-7: Estimations of the modified model

The current model is thus, considered a good fit, with Chi square value of 69.165, **P = 0.095**, **TLI** of **0.968**, **CFI** of **0.981**, and **RMSEA** of **0.044**.

As shown on Figure 6-7, perceived risk has an insignificant influence (**β = 0.062 P=0.24)** on purchase intention. It also has statistically significant negative correlations with perceived benefit **(r = -0.495, P = 0.000)**, perceived behavioural control **(r = -0.280, P = 0.023)** and subjective norm **(r = -0.444, P= 0.000)** respectively.

On the other hand, perceived benefit has a significant positive effect on purchase intention (**β=0.341, P = 0.004**. Perceived behavioural control also has a significant positive effect on the purchase intention (**β =0.236, P = 0.019**) while the subjective norm has a significant positive effect (**β = 0.429, P = 0.000)** on the purchase intention.

Perceived benefit has a significant positive correlation with perceived behavioural control (**r = 0.512, P = 0.001)** and subjective norm (**r = 0.540, P = 0.000)**; while there is a significant positive relationship between perceived behavioural control and subjective norm **(r = 0.428, P = 0.004).** Table 6-22 summarises the outcomes from the modified model estimated.

Table 6-22: Summary of outcomes from model estimation

Influences and correlations	Influence direction	Nature of influence	Path coefficient/correlation rank and significance	Outcome
1	PR--->>PI	Negative insignificant effect	**β** = -0.062	Supported
2	PR<<--->> PB	Negative relationship	**r =** -0.495***	Supported
3	PR<<--->> SN	Negative relationship	-0.444***	Supported
4	PB---->>PI	Positive effect	**β =** 0.341**	Supported
5	PBC---->>PI	Positive effect	**β =** 0.236*	Supported
6	SN ----->> PI	Positive effect	**β =** 0.429***	Supported
7	PB<<--->> PBC	Positive relationship	**r =** 0.512**	Supported
8	PB<<--->> SN	Positive relationship	**r =** 0.540***	Supported
9	PR<<--->> PBC	Negative relationship	**r =** -0.280*	Supported
10	PBC<<--->> SN	Positive relationship	**r =** 0.428**	Supported

Note: superscript * *significantly different from zero at 0.05 level*
** *significantly different from zero at 0.01 level*
*** *significantly different from zero at 0.001 level*
Where β = regression path coefficient while r = correlation coefficient

6.4.8 Interpretation of the model

The analysis results show that perceived benefit, perceived behavioural control, and subjective norm have direct positive influences on the purchase intention for remanufactured medical equipment while perceived risk was shown to have an insignificant negative effect. However, perceived risk has significant negative correlations with subjective norm (r = -0.444), perceived behavioural control (r = -0.280) and perceived benefit (r = -0.495). Thus, perceived risk acts to diminish the

benefit perception, positive subjective norm, and behavioural control towards remanufactured X-ray equipment. This finding is similar to that of Wang (Wang *et al.*, 2013) with respect to perceived risk.

Risk consideration is so essential in the medical device industry that it determines medical device classifications in the US and EU. The classifications in turn, determine the regulatory requirements that manufacturers must fulfil.

Given the importance of risk consideration in the industry, an insignificant negative risk perception would suggest that the participants in this study would not reject remanufactured X-ray equipment outrightly for fears that:

Q14 “Remanufactured X-ray equipment will not be as safe as new ones”.

Q15 “Remanufactured X-ray equipment will not perform as new ones”.

Q16 “Remanufactured X-ray equipment will not perform as new ones such that I may spend more time on repairs”.

Q17 “it will not be possible derive commensurate utility for monetary investment in purchasing remanufactured X-ray equipment”.

The strong positive influence of subjective norm on the purchase intention shows that health care experts that participated in this study would recommend purchasing remanufactured X-ray equipment to their colleagues. They would not disparage remanufactured equipment or criticise colleagues that use them. Moreover, since the benefit perception has strong positive correlation with ($r = 0.5440$) with perceived benefit, it could be concluded that the health care experts recognise the benefits which remanufactured X-ray equipment could introduce to the industry. Subjective norms also have positive correlation with perceived behavioural control ($r = 0.428$).

6.5 Development of frameworks to support medical equipment remanufacturing.

This section discusses the development of frameworks to support the implementation of medical equipment remanufacturing. It does this by integrating the results found earlier in this work. Its aim is to answer the research question:

How can remanufacturing be characterised to be able to contribute towards addressing the medical equipment availability issue?

In addressing this question, the researcher inductively identifies patterns and findings from the findings in preceding chapters, to develop a new theory in the form of tools- process model and preliminary decision model. Following Eisenhart’s and

Graebner's (2007) recommendation, the researcher aimed to be as objective as possible in doing this, to ensure that the emerging concepts produce the same interpretation to different readers.

6.5.1 Development of the process model for medical equipment remanufacturing.

In phase 1 of this research, remanufacturing was shown to be able to address 5 of the issues affecting developing countries' medical equipment availability with up to 43.5% degree of prominence. Hence, remanufacturing is an important strategy that should be promoted towards addressing the issues. However, a review of the implementation of medical equipment remanufacturing in the US and EU showed that the medical equipment remanufacturing is poorly developed and terminological inconsistency was also found. A definition as well as a preliminary process model was proposed in section 2-6 and Figure 2-6 which borrowed information from traditional remanufacturing practice as well as from best practices in the medical device industry. The process model aims to capture the key features that characterise medical equipment remanufacturing. This model serves as the basis for the development of the process model in this chapter.

The basic model represents the features of the definition proposed in section 2.6 along with best practice remanufacturing process for medical equipment. It had leveraged information from notable sources in the remanufacturing literature including: (Lund, 1984; Ijomah, 2008; Paterson, Ijomah and Windmill, 2017; Paterson *et al.*, 2018).

6.5.2 Phase 1 validation of the proposed process model

Validation of research outputs is necessary to enhance its industrial relevance. Research output without validation may be of little industrial relevance. To avoid this pitfall, the preliminary decision support framework and process model developed in this work are validated by experts in the field. Review by a small sample of expert is a well-known technique for validating findings of a research (Beecham *et al.*, 2005). Validation by expert review has been used in several studies, examples including risk assessment, clinical supervision, patient behaviour and software process improvement studies (Priyono, 2015; Paterson, Ijomah and Windmill, 2017).

6.5.3 Results of the phase 1 process model validation

Participants' assessment of how the framework represents the activities that are necessary to ensure that remanufactured medical equipment is of high quality was first solicited. Six participants gave the framework scores in the range 9 – 10 on this basis; three other participants scored it 7 – 8 while another three gave it a score in

the range 5 – 6. The major concerns included that medical equipment refurbishment should comply with relevant regulatory standards and emphasis on quality management standard. Another respondent noted that mere replacement of damaged parts does not bring about product renewal as other parts may damage subsequently. One other participant noted that “sorting” is not included in the framework. In view of these observations, regulatory control was included in the updated framework. The regulatory control would ensure that the disassembly, inspection, testing, replacement of damaged and worn parts, optional upgrade and packaging complies with appropriate international standards. The provision of warranty and optional financing arrangements like those applied to equivalent new products included in the framework will also, further allay quality concerns. It is assumed that by implementing a quality management system, the issue of correctly sorting components would be inherently addressed. Hence, sorting is not included in the framework.

The participants strongly opposed the remanufacturing of single use devices; noting mostly that they are disposables and cannot be restored to “as good as new” quality due to design and lack of capability. For the first five participants, the extent of disagreement to the possibility of remanufacturing SUDs is in the range 9 – 10 while the second five indicated extents in the range 7 – 8. One of the participant’s strength of opposition was 3. However, his reason which is that medical device class as well as regulatory requirements needs to be considered in selecting equipment to refurbish does not seem to agree with the extent he indicated. Thus, his input is assumed to be inconsistent. Another participant that scored 6 to this expression noted that SUDs may have been manufactured in such a way that remanufacturing them would be impossible. His reason shows a clear disagreement to the possibility of remanufacturing SUDs. Hence, his score is assumed to be incongruent.

The participants agreed that refurbished equipment should be marketed with the same level of professional post sale technical support as with new. Eight participants rated their agreement in the range 9 – 10 while three have their own rating in the range 7 – 8. The most important reason for agreeing to this is that it would help to ensure that users have greater chance of deriving utility from the refurbished/remanufactured equipment. One participant specifically expressed the fear that having remanufactured/refurbished an equipment increases the need for providing such services. One of the participant’s rating is 5 because according to him, electronic products have specific lifetime which may necessitate replacing most components; thus, making post sales technical service support difficult and

expensive to realise. However, it is expected that a remanufacturer will have the capacity to address such challenges and in fact, this could add to its revenue stream. The responses to the importance of providing post sales technical support are provided in Table 6-23.

Table 6-23: Responses to the extent to which it is necessary to provide post sales technical support for refurbished medical equipment.

Respondents	***Extent***	***Rationale***
A	10	This will help prolong the period of use of the medical equipment
B	5	Electronic products have definite lifespan which may negate cost-effective provision of post sales services
C	7	Agree but should be made optional.
D	10	Post sales services would help remanufacturers to keep up with necessary regulatory requirements.
E	9	Users will believe that servicing and post-sales services for a refurbished medical device would be more rampant compared to a new equivalent. By agreeing to provide such services, remanufacturers will allay their fears.
F	8	Post-sale technical support should be given more attention compared with new equivalent.
G	10	This will validate the claim that the refurbishment has successfully restored the product to as good as new quality
H	10	Ability to provide technical support is central to buyer confidence for remanufactured products as the buyer knows that they can be assisted if machines ever fail
I	10	To ensure that finished products are of high quality
J	10	Providing such services will be excellent in addressing the medical equipment needs of the developing countries.
K	9	To ease maintenance and servicing of the equipment and to demonstrate the equipment is equal to new equivalent in all respects

The participants also agreed that refurbished/remanufactured equipment claimed to have been upgraded or changed in the process should be subjected to pre-market evaluation for verification. They stressed that the fact that medical equipment is said to be refurbished increases the need for pre-market verification and also points to the need for establishing an objective way of establishing that the claimed upgrade will not alter the safety and performance of the finished product. Annex D1 presents a complete data on this validation. Recommendations from the validation exercise were implemented to develop an improved version of the model.

6.5.4 Other features identified for inclusion- improved model.

The proposed process model already shows that medical equipment returned for remanufacturing are first cleaned, disinfected, and disassembled to least manageable components. However, a participant for the validation specified that the activity in this stage needs to be made more explicit by identifying that there would be need for at least, two levels of cleaning and disinfection: pre-disassembly and post-disassembly. The researcher thus, included that the components would be further cleaned and disinfected after disassembly, to mitigate infection hazards. Also, since it is only possible to conduct parts inspection following disassembly which gives access to parts and components, the researcher therefore, included part inspection process after the post-disassembly disinfection and cleaning. Hence, parts are inspected against preformulated baselines and/or OEM and relevant standards to determine possible deviations. Maintenance data, field service notices and use conditions are also considered at this stage in order to accurately determine all possible issues in the history of the equipment. Records reflecting findings are maintained. Parts that still comply with OEM specifications and standards are kept aside for direct reuse while those ones that do not comply but can be restored are reworked to get them to comply. Parts which cannot be restored are removed from the remanufacturing process. These parts may be used for refurbishment, repair or they may be recycled.

One of the participants also noted that the rework should follow a comprehensive plan, that the plan should have a requirement for validation of reworked parts against OEM and/or relevant standards. According to the participant, all the indices such as geometry, voltage, e.tc. contained in the relevant standard is compared against the part. The parts are then assembled, and all necessary software and updates installed. The participant noted that the equipment can only be tested as a whole product against OEM performance and safety specifications after parts and subsystems have been shown to be compliant. If the finished product satisfies all

the specifications, it is then labelled remanufactured and either stored or shipped if already ordered. On the other hand, if significant deviation from standard is recorded, then the equipment would go back to the initial stages of the process. These activities are all represented in the improved process model.

As suggested by one of the participants, the issue of standards was addressed further. Considerations for whether to recertification will be required are also included, these requirements which depend on the market have been analysed in section 2.6. Thus, if an equipment is remanufactured outside the EU following this procedure and is intended for the EU market, it will have to be recertified. On the other hand, if the process is conducted for US market or for most developing countries' markets, the evidence showing that OEM safety and performance specification is not compromised would eliminate the need for recertification. The entire process should conform to acceptable quality and risk management standards such as ISO 13485 and ISO 14971 and other device-specific standards. For instance, if the device is an electromedical or electromechanical equipment, then requirements of EN 60601 group of standards should be fulfilled.

As one of the highlights in the proposed definition of remanufacturing was post-sales support and this need have been further stressed in the findings from the study on purchase intentions from this work, the researcher therefore, expanded on the types of support available for medical equipment. Hence, for large equipment, installation and post-installation inspection and testing should accompany supply. In all cases, the remanufacturer should provide service manuals, training, similar optional financing to equivalent new medical equipment and have a system for collecting and monitoring performance data to ensure performance does not deviate. This will help to address some of the short comings of refurbished equipment being sent to developing countries without manuals and technical support (Gatrad, Gatrad and Gatrad, 2007). Post sales technical support should also be optionally made available for durations typical of comparable new equipment. Some of the participants in the purchase intentions study noted that it is important to make this provision an option as it would potentially drive product price high and so make it unattractive for some users. Thus, post-sales maintenance and servicing of the equipment including provision of spare parts will be made optional. Finally, the remanufacturer should keep record of adverse effects that may occur due to the use of the remanufactured equipment. This is currently a requirement for medical equipment manufacturers in both the EU and the US. This was discussed in section 2.6. For the medical equipment remanufacturer this will provide up to date information of potential risks

associated with remanufactured products and provide a source of information for addressing them. It will also ensure that adverse incidents related to the process of remanufacturing are eliminated or at least, mitigated.

After including these improvements in the basic model, an improved version shown in figure 6-8 was produced. As this new model was substantially different from the first basic one, it was programmed for a second-phase validation.

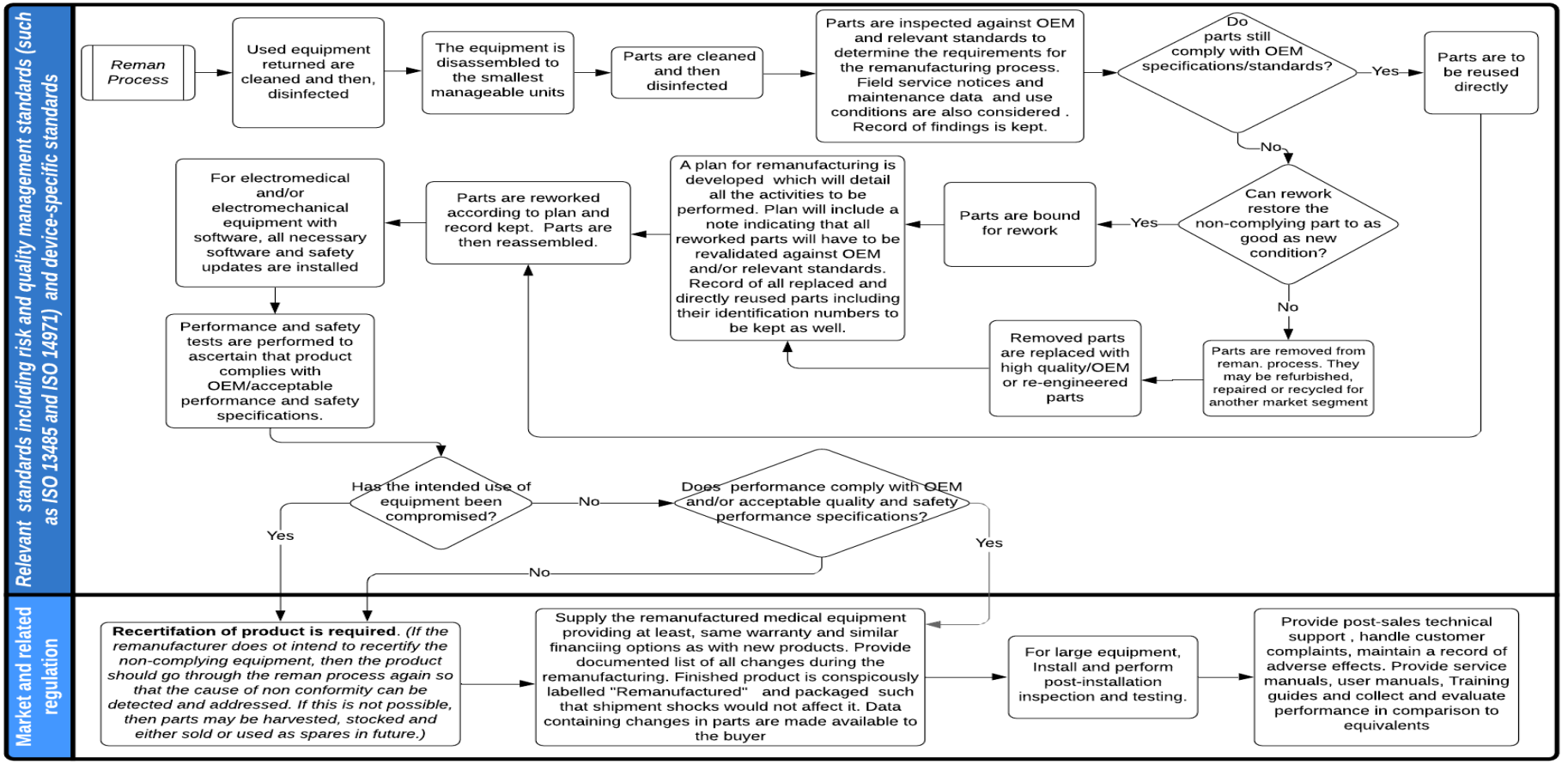

Figure 6-8: Improved framework for medical equipment remanufacturing

6.6 Development of the preliminary decision support tool

Expanding the features of the basic process model for medical equipment remanufacturing in section 2.6 obviously made it more explicit but added some other features. Similarly, there are other context-specific factors that need to be considered in deciding to implement medical equipment remanufacturing in a developing country. These factors were already determined in the preceding chapters but how to apply them needs to be understood.

It therefore becomes relevant to develop a tool to support potential practitioners, academics and governments in managing, establishing, studying or promoting medical equipment remanufacturing. For the practitioner, a preliminary decision support tool will be invaluable in ensuring that the right preparation precedes the process of remanufacturing medical equipment and that the process can be controlled to ensure high quality products. In developing the preliminary decision support tool, I applied the factors affecting remanufacturing that were already identified in chapters 2, assessed and prioritised in chapter 6. Broadly, these factors are grouped into incentives, institutional and technological factors.

6.6.1 Incentives

The factor with identified to have the greatest impact on medical equipment remanufacturing is municipal infrastructure which is an institutional factor that impact on the incentive to carry out remanufacturing. Hence, “incentives“ is the first consideration in the consideration to implement medical equipment remanufacturing. The incentive could be profit driven and could depend on several factors including cost of acquiring tools and technologies, alternative energy sources, labour costs and market potential for remanufactured equipment. The market potential depends on whether remanufactured equipment will be accepted by health care professionals and how much they are willing to pay for them. An important factor which may determine acceptability include patient population needs which may create market gap or potential demand and acceptability of the product. As remanufactured medical equipment may not possess the latest technologies, potential users would often be inclined towards prolonged use of medical equipment during which case they may be interested in remanufactured parts and sub-assemblies, or the use of obsolete medical equipment. Most of the requirements in this stage can be satisfied in many developing countries and frugal developed countries. Therefore, medical equipment remanufacturing would contribute significantly to the access of high-quality medical equipment for people in those categories. It is important to note that remanufacturing may still be implemented

even if there is no incentive but may not be necessary or profitable. This means that access to the market and demand must exist and the remanufacturer must be able make profit.

6.6.2 Technological factors

The technological factors such as skills, product design considerations, ease of upgrade, wide variety of equipment models, residual value of recovered used equipment, obsolescence and technologies for remanufacturing are represented in the space between incentives and institutional factors. It is important that technological factors are taken very seriously to ensure that remanufactured products are of high quality. This is because the risk perception of remanufactured products is related to both the technologies available to the remanufacturer and the profit derivable (Zhang *et al.*, 2011; Hazen *et al.*, 2012). While the perceived risk is found not to directly influence purchase intention in this study, indirect negative association between perceived risk and other factors such as perceived risk was found. Diminishing the perceived risk will therefore, be critical to the success of medical equipment remanufacturing enterprise. Technological advancement will play a key role in achieving this. A remanufacturer's technological advancement will also help to minimise warranty returns by improving the efficiency of the remanufacturing process.

Hence, key indicators of technological capability from section 2,5 such as "skills and technologies requirement" are included in the tool to account for the technological factors. These indicators will address considerations for skills and technologies needed to provide the right degree of proficiency to carry out the activities involved in the remanufacturing process to the required degree of quality. This includes disassembly, cleaning, rework, upgrades. The technological consideration will also cater for the remanufacturing of wide variety of equipment available in the local market. Alternatively, a potential remanufacturer may identify specific equipment models and develop remanufacturing technologies for them. In any of these cases, the technological consideration will include how to provide some new features to equipment that are older technologies. The new features may be software upgrade, as this will reduce the negative impact of obsolescence in the decision to choose remanufactured medical equipment.

6.6.2.1 Availability of skill set

A medical equipment remanufacturer acts as a manufacturer if the product will be placed in the EU market or in the US, if the process would significantly change the intended use, safety or performance specifications of the product. These countries'

regulations represent best practices. Hence, the remanufacturer should therefore have skills necessary to excel in this capacity to re-engineer some components or sub-systems if necessary. This is particularly necessary as one of the incentives for conducting medical equipment remanufacturing is to facilitate the use of old or obsolete equipment; some of which manufacturers have stopped providing technical support for. It is therefore necessary that the remanufacturer can use emerging technologies such as additive manufacturing (3D printing) and have expertise in electronics including circuit design and production. The remanufacturers should also have strong awareness of international quality standards to ensure that products comply with international quality standards.

Achieving the necessary skills may require focused training programmes in areas such as practical medical device design. As there is significant need for programming in the medical device industry, the training should also involve Firmware programming and software development. Firmware programming is particularly necessary in the design of circuit boards, especially when circuit components such as motherboards or integrated circuit (IC) components are to be replaced locally. Such a skill level would enable remanufacturers to remanufacture even medical equipment whose manufacturers no longer provide support in the form of spare parts supply. It will help the remanufacturer to attain the level of competence required to succeed in applying cost-effective remanufacturing to the benefit of developing countries where the use of older and/or obsolescent equipment is common.

6.6.2.2 Product Characteristics

To remanufacture a medical equipment, several product-specific characteristics are to be considered. These include the device intended use, design characteristics and lifecycle. A device intended use is the purpose for which it was made. It includes not only the health conditions which the equipment is used to diagnose, treat or ameliorate, but extends to the use pattern of the equipment. For instance, the FDA notes that the intended use of a SUD is violated if it is reused. This is because the manufacturers have specified that the device is only safe to be used once for the medical purpose for which it is designed. This principle would constitute a significant consideration in remanufacturing of SUDs since their OEM's intended use would no longer hold. It would then be the responsibility of the remanufacturer to demonstrate safety and effectiveness if such a product is remanufactured. This complies with the UK MHRA position as well as the FDA medical device approval system about entities that change the intended use of medical devices.

This explains why the proposed process map puts a requirement for demonstrating compliance of remanufactured products whose original intended non-medical purpose has changed by remanufacturing them.

Another important product-specific consideration is the amenability of the medical equipment to remanufacture. This is often referred to as design for remanufacture in the remanufacturing literature. In this instance, the question would be “would the design of the equipment permit it to be remanufactured?” This consideration includes determining whether the equipment design would permit disassembly, cleaning, disinfection/sterilisation, inspection, and testing, to the extent required during the remanufacturing process. Disassembly is only feasible for products with modular design. The higher the modularity, the easier disassembly would be. However, both disassembly and cleaning require physical strength in addition. Consequently, medical equipment for remanufacture should be made of materials that can withstand associated stress. Some designs such as those with very narrow and long lumens make cleaning and disinfection difficult if not impossible. For such products, strategies for cleaning and disinfection must be validated.

A major risk area which may affect purchase intentions for remanufactured medical technologies is cybersecurity. This is because some medical equipment are vulnerable to cyber-attack. Potential users of remanufactured medical equipment may have worries regarding the remanufacturer’s capability to continue to provide protection against cyber-attacks. Thus, remanufactured equipment should also be safeguarded by being defended against the introduction of malicious software, disruption of operation arising from blocked flow of operation, sending false information which may influence inappropriate actions by health care experts or accepting unauthorised changes or commands to its embedded software (Jones and Katzis, 2017).

Cyber-attacks increase patient risks by increasing the likelihood that device functionality is compromised due to inadequate security. It is now a premarket requirement by the FDA, to consider cyber security along with functional safety of medical devices and this requirement applies to devices that contain software (and firmware) or programmable logic; including software that are themselves, considered as medical devices (FDA, 2014). Manufacturers are expected to address cybersecurity at the product design and development phase, detailing as part of software validation and risk analysis, their approach to determining and managing cybersecurity vulnerability of their device.

Just like manufacturers, a remanufacturer that is significantly changing an equipment should thus, provide a cybersecurity documentation showing some of the following elements required during FDA validation:

1. Summary describing the plan for providing validated software updates and patches as deemed necessary for the entire medical device lifecycle in order to guarantee its safety and effectiveness.
2. Summary of the framework put in place to ensure that the medical device software will maintain its integrity and thus remain malware free from the remanufacturer's site to its place of deployment.
3. Instructions for using the device in such a manner that will not compromise the cybersecurity controls for the intended use environment.

For the remanufacturer, these requirements may imply developing capability to provide updates needed to keep up with cyber threats or collaborate with OEM to achieve this. If the remanufacturer is OEM or on contract remanufacturing, then achieving this would be easier compared to an independent remanufacturer (Lund, 1984; Hatcher, Ijomah and Windmill, 2011; Saavedra *et al.*, 2013; Tian *et al.*, 2014).

6.6.3 Institutional factors

Institutional factors can motivate or negatively impact medical equipment remanufacturing. Specifically, institutional factors may exert influence on the potential for incentive derivation but are often aimed at ensuring patient safety through market regulation. Institutional factors include business licensing system, the education and training system which influence the availability of technically skilled individuals as well as the efficiency with which basic infrastructural amenity is made available to ease business. The management of intellectual property rights also needs to be understood to eliminate associated issues.

A potential remanufacturer needs to carefully assess the institutional factors and how it would impact its operation. Institutional factors must be considered, and strategies put in place to ensure that all requirements relating to them are fulfilled. Without the ability to fulfil institutional factors, a finished product may not make it to the market or sustain demand. Hence, appropriate licensing must be secured, and remanufacturing process must be free from intellectual property infringement. Remanufacturers should also formulate strategies to boost confidence in their finished products since regulation is weak and people do not trust that the remanufacturing process has been checked appropriately. These considerations are

very important and as such, are placed as the final decision point in the tool. The preliminary decision tool is shown in Figure 6-9.

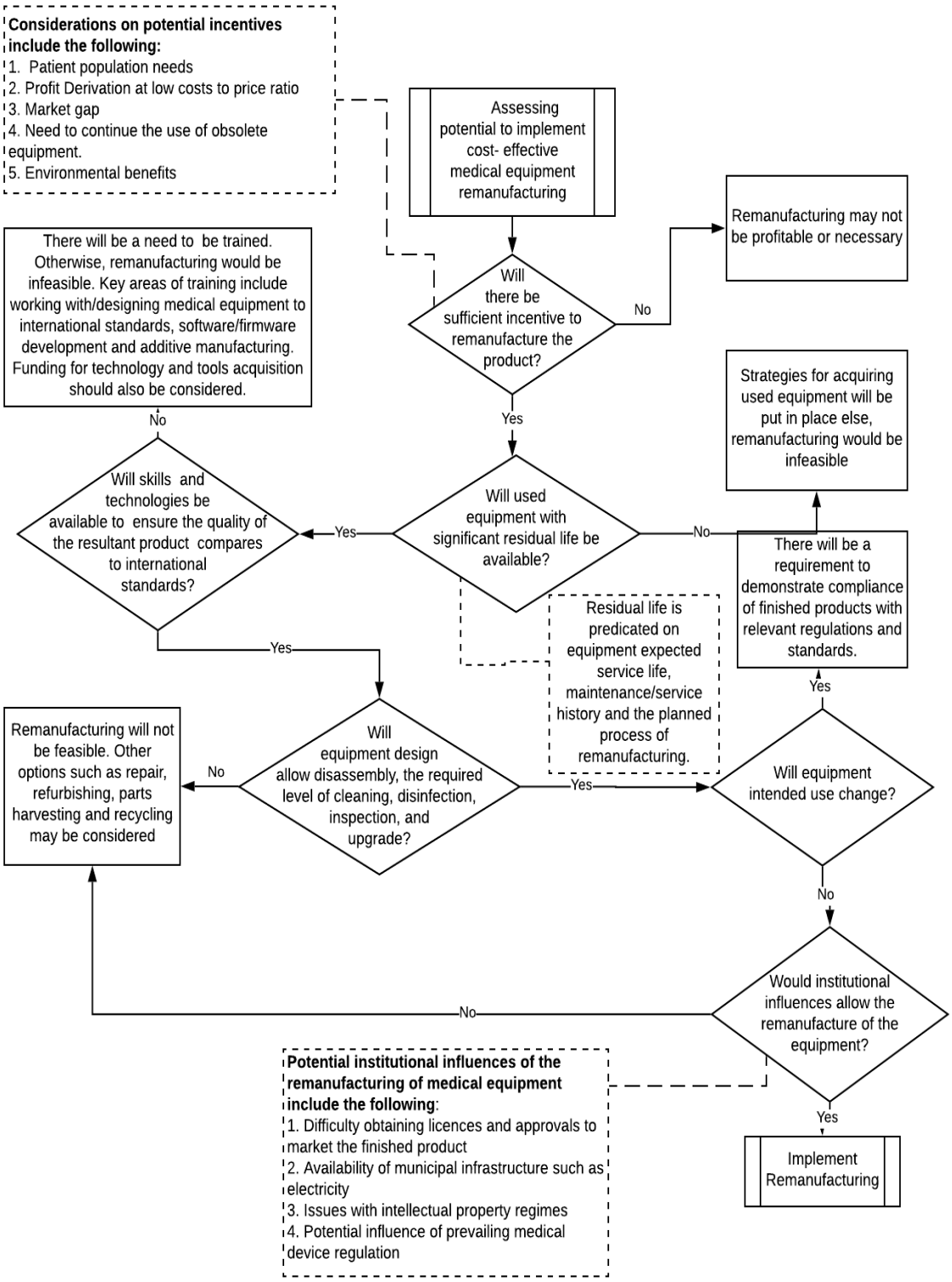

Figure 6-9: Preliminary Decisions in Cost-Effective Medical Equipment Remanufacturing developed in this study.

6.7 Phase 2 validation results

Both the process model and the preliminary decision tool were jointly validated in this section. The results of the validation show that the frameworks satisfy all the criteria itemised above, against which theoretical tools may be assessed. One participant suggested that the Chinese and European models for refurbishment

could be integrated to form a hybrid model. According to the participant, the Chinese create their own parts for equipment under refurbishment especially when OEM parts are no longer available or when it is cheaper to do so. The European model emphasises replacement with OEM parts. This would not be very beneficial to developing countries due to cost and due to decreased environmental benefits. However, the emphasis in quality observable in the EU is desirable. In this framework, not only has the two models been integrated but the US model was also considered.

To ensure that all relevant considerations are made during inspection, participant A suggested looking out for field service notices (FSN) relating to equipment intended for remanufacture. FSN details all the issues of concern about an equipment and could be valuable during inspection, in determining the exact extent of work to be done in remanufacturing the equipment. While acknowledging that this may be difficult particularly for those in developing country, the participant pointed out that the UK government website which is free to access usually publishes such notices. The participant also questioned the ownership of responsibility for adverse effects arising during the use of the equipment. Considerations for the points raised by this participant were already included in the process model. Accordingly, if the equipment has changed during the process, then the remanufacturer will be required to recertify it. Recertification is also applicable when the intended use is altered.

In participant G's opinion, weights should be given to the factors stated in the preliminary decision support framework. While the rationale is understood, such weights would vary depending on the equipment being considered for remanufacturing as well as prevailing circumstances of the potential remanufacturer. Hence, determination of weights would best be addressed through case studies.

The details of the results are presented below and summarised in Table 6-24.

6.7.1.1 Descriptive relevance

Items used to assess the descriptive relevance of the tools are questions 1, 6 and 11. The responses to these items range from "agree" to "strongly agree" for questions 1 and 6. In the case of question 11 which is negatively worded, the responses are expectedly "disagree" and "agree". Thus, the tools meet the criteria for descriptive relevance.

6.7.1.2 Goal relevance

Questions 2, 7 and 12 on the instrument were used to assess the goal relevance criteria for the tools. From the results summarised in Table 6-24, responses for

questions 2 and 12 range from “agree” to “strongly agree”. Responses to question 7 were also mostly “agree” and “strongly agree” except for one participant that responded with “neither”. The participant had already answered “strongly agree” and “agree” to questions 2 and 12 respectively. Since the two questions assess the same criteria using varied expressions, it is assumed that the inconsistency is an error attributable to the participant. Hence, the tools fulfil the goal relevance criteria.

6.7.1.3 Operational validity

Reviewers’ responses to questions 3, 8 and 13 which assess the operational validity show that the framework satisfies the criteria. Specifically, all the participants answered “agree” to question number 3 while answers to question number 13 were split equally between “agree” and “disagree”. All the participants responded “disagree” to question number 8. As the question was negatively worded, “disagree” was the expected input. Hence, the framework may be said to fulfil the operational validity criteria.

6.7.1.4 Non-obviousness

Questions 4, 9 and 14 assess the non-obviousness of the framework, that is the degree to which it meets or exceeds common sense output. To question 4, three participants responded with “strongly agree” while three also responded “agree”. Five participants answered “agree” to question 14 while one answered, “strongly agree”. For question 9 which is negatively worded to ensure participants inputs are not impulsive, participants responses are “neither” answered by one participant, “disagree” which answered by three participants and “disagree” by two participants. The participant that answered “neither” to question 9 gave expected answers to questions 4 and 14 to which he responded with “strongly agree” and “agree” respectively. Hence this response can be assumed to be due to the participant’s inconsistency which means that the framework qualifies for non-obviousness.

6.7.1.5 Timeliness

The timeliness of the proposed tools was assessed using questions 5, 10 and 15. The responses to question 5 which is negatively worded range from “strongly disagree” by 4 participants to “disagree” by only two of them. The responses to questions 10 and 15 are equally split between “strongly agree” and “agree”. Thus, the frameworks satisfy the Timeliness criteria.

Table 6-24: Summary of results of final Validation by experts

Criteria	No. in the instrument	Questions to respondents	Strongly disagree	Disagree	Neither	Agree	Strongly agree
Descriptive relevance	1	The process represented tools is feasible for medical equipment remanufacturing				3	3
	6	The tools are acceptable description of high-level activities necessary in medical equipment remanufacture				2	4
	11	Medical equipment remanufactured based on the tools will be poor	2	4			
Goal relevance	2	The activities represented in the tools are important to medical equipment remanufacturing	3	3			
	7	Failure to implement medical equipment remanufacturing as represented in the tools may introduce unwanted results			1	3	2
	12	Preliminary decisions and process model in the tools are useful in some way				4	2
Operational validity	8	I find the tools difficult to follow		6			
	13	The tools can be used to help medical equipment remanufacturers to make improvements				3	3
	3	The activities represented in tools can be implemented in real practice [3				6	
Non-obviousness	4	The tools will help to understand the various strategies for carrying out medical equipment remanufacturing				3	3
	9	There are many major issues missing from the tools	3	2	1		
	14	The tools have the potential to help medical equipment remanufacturers to make better decisions				5	1
Timeliness	5	The tools are not useful for remanufacturing companies in organising their operations	4	2			
	10	The medical equipment remanufacturing process described in tools is an important area to address				3	3
	15	The tools will be useful for medical equipment remanufacturers in the present time				3	3

Chapter 7:
Discussions

7.1 Introduction

The aim of this chapter is to discuss the results obtained from this study and demonstrate how they answer each research question set out in chapter 1. The chapter will draw on important literature references to enrich the discussion.

7.2 Medical equipment remanufacturing and the medical equipment availability issues.

Several previous studies explored the problems of medical equipment availability in developing countries. These problems were analysed in Chapter 2 of this work. However, most of these studies enumerate the problems without exploring them further. For instance, (Malkin, 2007) only highlights the problems. Some other studies focused on specific medical devices, usually linking the problem to the capacity to carry out specific types of procedures. For instance, Okoye (Okoye *et al.*, 2015) conducted a survey of paediatric capacity to identify that relevant equipment are in acute shortage and McCormick (McCormick and Eltringham, 2007) found that anaesthesia equipment and supplies are often not available in developing countries. Similarly, Shah (Shah, 2014) studied the access to imaging technology in developing countries. The study demonstrated that the poor access to diagnostic imaging modalities such as mammography units to be1 per million people compared to 23 per million in high income countries HIC, CT imaging equipment to be 1 unit per million compared to 44 per million in HIC and also found that this trend of disparity is same with MRI and PET and nuclear imaging devices.

Other researchers studied the suitability of existing strategies for providing medical equipment and assess their merits and/or demerits. For instance, Compton (Compton *et al.*, 2018) highlighted the problems with donated medical equipment that make them inappropriate. Issues identified includes lack access to use manuals and spare parts. Hope (Hope, 2015) studied the different contexts of corruption in developing country health sector. The study found that corruption causes the loss of government's capacity to provide access to quality health, inflates budget for health and poor image and trust of health institutions.

Unlike these studies, current research has taken a proactive stance in identifying all the factors responsible for poor medical equipment availability issues in developing countries. The factors identified were also validated approved by experts in developing

world context, to demonstrate that they represent the reality. In doing so, it has answered the following research question:

RQ1a: What are the main causes of poor medical equipment availability in developing countries?

This study took cognizance of the potential interrelationship among the factors responsible for the medical equipment availability issues and prioritised them using DEMATEL. By extending this DEMATEL prioritization task, this study also found that remanufacturing can potentially address the poor medical equipment availability factors amounting to 43.5% total prominence. This is a measure of how effective remanufacturing could be in addressing the medical equipment availability issues for developing countries and answers the following research question RQ 1d:

*By how much would remanufacturing contribute towards improving medical equipment availability in developing countries**?***

The use of DEMATEL in this study also helped to identify the factors that are in the cause group and those in the effect group. For policy makers, it would be more important to focus on the factors in the "cause" group since addressing these factors will help to minimise the impact of the linked "effect" factors. Hence, policy makers may first focus on providing solutions to F5: Absence of HTM and HTA, F3: Lack of funds to access and/or purchase medical equipment, F1: Corruption, F6: Weak or absent medical device regulation, F9: Lack of clear economic model and F4: Lack of infrastructure such as electricity, water supply, oxygen.

The results of this study indicated that the absence of HTM and HTA is the topmost driving factor. HTA and HTM play key roles in healthcare; yet they are almost weak or absent in many developing countries. While HTA ensures that technologies are appropriate towards addressing prevailing healthcare challenges, HTM guarantees successful utilisation of medical equipment. Implementing HTA and HTM includes gathering reliable information about proposed new equipment; planning and selecting technologies based on prevailing needs and making resources available to ensure the sustainability of equipment; purchasing the right models of equipment and installing them correctly as well as making plans for decommissioning, disposal, and replacement of unsafe or obsolete equipment. Thus, HTA and HTM policies are to be motivated by the type of health care an organisation intends to provide and thus; contributes to the achievement of standardisation, improved maintenance practice as well as resource optimisation (Lenel et al., 2005). Such standardisation facilitates the development of maintenance capability and improved access to spare parts. HTM

policies also ensure that budgetary provision is made for the maintenance of technologies along their life cycles and so, incorporates some economic consideration regarding sourcing of funds. Economic models for medical equipment may include limiting the length of hospital stay and ensuring that expensive procedures and techniques are reserved as last options. Weak or absent regulation also contributes to the influx of poor-quality equipment into the market, lack of skilled maintenance staff as well as lack spare parts and consumables. According to one of the respondents to this study,

"Medical equipment come into the country from many sources without passing through standard pre-entry evaluation. The safety, effectiveness and durability of equipment are thus, not guaranteed and so, they break down too frequently."

Importation of poor-quality medical equipment especially the second-hand ones in this manner increases the risk of not being able to source spare parts. This is mostly the case when the manufacturers have discontinued the production of spare parts (Hutubessy, Hanvoravongchai and Edejer, 2002).

This study also finds that corruption in the health care industry contributes to the inefficiency of medical equipment regulation. One of the respondents to the study observed that policies and frameworks are usually available but not implemented since those responsible are often easily compromised. Governments and relevant organisations should, therefore, take decisive action against corrupt acts which hinder regulatory dispensation as well as formulate and implement robust HTA and HTM policies.

7.3 Addressing terminological inconsistency

Terminological inconsistency issue was found while in search of answers to the following research questions:

RQ1b: How is remanufacturing implemented in the medical device industry?

RQ1c: How can remanufacturing be characterised to solve the medical equipment issues in developing countries?

The issue was first presented in Chapter 2 where it was noted that remanufacturing in the medical device industry is somewhat novel and refers to several activities. The different activities regarded as remanufacturing include refurbishment in the US and the EU, the closest is full refurbishment. These activities were reviewed to ensure that best practices in these developed countries informed the findings of this study. However, terminological inconsistencies were found regarding medical equipment

remanufacturing and only a weak evidence of medical equipment remanufacturing practice was found. It was thus, necessary to address this issue, to provide an acceptable definition for remanufacturing, one which could also help to provide a sustainable supply of medical equipment to developing world by addressing some of the key issues affecting the availability of medical equipment.

In addition to the definition, a basic process model was developed leveraging information from OEM refurbishment and existing literature in remanufacturing. Hence, the focus shifted from just identifying how remanufacturing is implemented in the medical device industry as there appears to be many perspectives, to developing a process model for medical equipment remanufacturing. By enriching the basic model with findings from subsequent phases of this study, a more robust process model was developed which shows how medical equipment remanufacturing should be implemented and so, answers the fourth research question:

RQ4: *How can medical equipment be carried out cost effectively?*

The new definition emphasises post sales technical support. The inclusion of professional post-sales services is important feature of the proposed definition. Professional post-sales services such as the supply of spare parts assures customers that lack of spare parts would not cause abrupt suspension of the product's utility. Therefore, the definition reflects the "crucial role of remanufacturing in the paradigm shift from mere product sales to the sales of services" and/or product service systems (PSS) (Ijomah, 2009; Alabdulkarim, Ball and Tiwari, 2013). This association between remanufacturing and servitisation which is extremely important for remanufactured medical equipment is not included as a requirement in the conventional definition of remanufacturing. Moreover, provision of technical service support is necessary for the sustained use of medical devices in developing countries. This is a feature which current strategies lack but which developing countries require (Gatrad, Gatrad and Gatrad, 2007).

The provision of post sales services by remanufacturers would get them more involved in the equipment lifecycle and offer them access to information necessary for making improved product designs. This is because remanufacturers often get feedback on causes of products failure (Toffel, 2004) and this can be necessary for achieving this objective. Provision of post sales services would also make it easier to keep up with post-sales requirements of medical device regulatory systems such as adverse effects reporting which includes reporting of serious injuries or death due to the use of the device. Finally, post-sales services can increase potential customers' confidence in

remanufactured medical equipment as it would provide easy access to technical support.

In line with the conventional definition, remanufactured medical equipment should retain its intended use. The intended use has an impact on the class to which a medical device may be assigned (European Commission DG Health and Consumer, 2010). Thus, remanufacturing should not create the need for reclassification of a device. Hence, if a medical device is considered remanufacturable, then the resultant product should also retain the intended use of the original product. However, the process must guarantee that the resultant product would be safe and effective.

This rule would ordinarily imply that SUDs cannot be remanufactured according to the FDA since their intended use which is for a single use only would be violated. Hence, it would be necessary to recertify an equipment if its intended use is changed on remanufacturing it. This may be peculiar to medical devise only, especially when compared to Kodak's remanufacture of Single Use Cameras. It remanufactures its single use cameras (Matsumoto and Umeda, 2011; Chaowanapong, Jongwanich and Ijomah, 2017) and markets the finished products as single use cameras.

A common definition is important as it would ensure a standard exists (Ijomah, 2008). A standard definition will also help to estimate market size and monitor the growth of the industry (Paterson, Ijomah and Windmill, 2017). Thus, the definition for remanufacturing developed in this work, which incorporates industry best practices will not only serve these purposes but also help to ensure that resultant products are of high quality and accompanied by relevant post-sales support.

This work also resolved the terminological issue relating to conflicting after-life processes in the medical device industry such as repackaging and reprocessing. For these terms, the presence or absence of disassembly is the key distinguishing feature (Paterson, Ijomah and Windmill, 2017). Disassembly involves decoupling a product into the parts. Unlike remanufacturing or refurbishment, medical equipment reprocessing or repackaging often do not involve disassembly, as in the case of many simple SUDs whose reprocessing and repackaging involve mere cleaning and sterilisation/disinfection. The Code of regulations of medical devices in the US specifies that repackaging may involve even simple activities such as changing the container, wrapper or labelling of a device along the process of its distribution to the person that makes the final delivery or sale to the consumer. Thus, if the device is not disassembled, the process cannot be regarded as remanufacturing. On the other hand, if disassembly is involved, then there is a likelihood that the process could be regarded

as remanufacturing. However, the process could also be refurbishment or repair. Further considerations would then be necessary to determine if the process is remanufacturing indeed. The process model developed in this research highlights other features of medical equipment remanufacturing and will be relevant in finding out if the process could be classified as remanufacturing. Figure 7-1 summarises this argument.

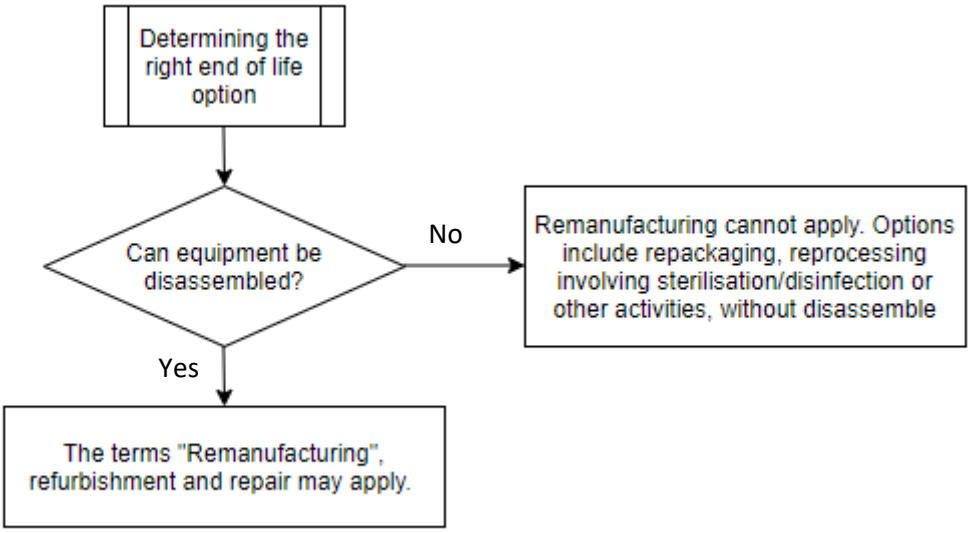

Figure 7-1: Clarification of terminology relating to conflicting activities in the definition of remanufacturing in the medical device industry.

7.4 Implementing medical equipment remanufacturing in the face of challenges

Remanufacturing is a key sustainability strategy with only little uptake in many developing countries. The pioneers of remanufacturing believed that medical equipment sector is one important area where medical equipment remanufacturing could yield great benefits, with potential to contribute towards the sustainable development goals of disease and poverty alleviation for developing countries (Lund, 1984). While remanufacturing is particularly applicable to developing countries, surprisingly, only a few studies in the area are from industries in developing countries (Chaowanapong, Jongwanich and Ijomah, 2018). This study found that remanufacturing has potentials to help address some of the problems of poor medical equipment availability in developing countries. It then progressed to study the factors to be considered in implementing this in a developing country context. By studying the factors, the following research questions were answered:

RQ 2: What key factors predict the purchase intention for remanufactured medical equipment among potential users?

The interplay of the factors might have contributed towards the poor uptake of medical equipment remanufacturing in developing countries. Therefore, a potential medical equipment remanufacturer should have measures in place to address each of the factors. This is the very first study in this area.

Lall's (Lall, 1992) technological capability framework was used as a theoretical framework to guide the identification of relevant factors. The remanufacturing literature has benefited from several theories from other fields. The benefit of applying theories from other fields of study to remanufacturing is that it broadens the theoretical options available for solving practical problems. In applying Lall's theoretical framework, this study became the first to link the key factors in remanufacturing to three broad groups of factors.

The factors were grouped into three broad categories: technological, institutional and incentives. Technological capability factors which may be considered at firm level or national level account for the level of preparedness conduct medical equipment remanufacture considering available skill set, technologies/equipment and associated investment, and product design characteristics. Technologies/equipment which are often necessary in remanufacturing include those used for inspection and testing.

The main benefit of the grouping system generated in this study is that it is particularly applicable to settings where remanufacturing practice is not strong and the factor groupings help to relate the key considerations to practical societal issues. Moreover, by grouping the factors in this manner instead of listing them tiringly, it would become easier to identify and summarise the factors to consider in implementing medical equipment remanufacturing.

Poor municipal infrastructure II2 was found to be of the highest importance. A typical municipal infrastructure assessed in this study is electricity which has the potential to increase the operational cost of remanufacturing since the cost of fuelling power generators can be very high. Electricity is strongly linked to industries and industrialisation. In recognition of its importance, the United Nations Organisation includes access to electricity as the seventh item on its sustainable development goals. The responsibility of generating electricity for own business significantly increases the cost of production and may discourage new businesses or force existing ones to close (Ateba, Prinsloo and Gawlik, 2019).

The factor found to have the least impact is I6: Access to replacement parts. This seems somewhat counter intuitive given that developing countries lack equipment and lack of spare parts was identified as one of the factors causing medical equipment

availability issues. However, there appears to be greater inclination towards developing supply links for spare parts with companies abroad. While this approach has proven to be successful, it will be interesting to determine whether it can increase the cost of remanufacturing or cause delay.

Technological factors with the greatest impacts include P5: Design will not permit remanufacturing, P10: Ease of upgrade to required technology, P11: Wide variety of equipment to develop remanufacturing capability for; P12: Residual value of recovered used product, P13: Obsolescence of recovered used products. To account for P5, P10 and P11, a potential remanufacturer may have to conduct thorough initial planning which would include developing relevant relationships. By examining the design of the product, the remanufacturer may find out if there are means to remanufacture them. Otherwise, other EOL options may be explored while the idea of remanufacturing is given up.

The wide variety of medical equipment models influence the effort necessary to develop mastery of skill set needed to implement remanufacturing. This is because workers only have a mastery of equipment in the market which they have either maintained/repaired/refurbished during its lifecycle. Consequently, if there is great variety of equipment, the probability of getting skilled workforce becomes reduced and the need for training increases. In addition to the challenges associated with skills development, sourcing of spare parts from the market may also become difficult due to the potential for decreased compatibility.

Through supply chain relationship building, information and systems needed to conduct remanufacturing may be achieved. For instance, is a potential remanufacturer may seek to act as a contract remanufacturer on behalf of an OEM so that it may be able to access both the information and systems needed for upgrading equipment and for capacity building. Such relationships will be invaluable in developing capacity to provide necessary upgrade and to remanufacture a wide variety of equipment to serve the market.

On the other hand, the residual value and obsolescence of recovered equipment are attributes of products intended for remanufacture. Residual value is a measure of the quality of returned products which in turn, is a measure of the amount of work or parts to be replaced during the remanufacturing process, contributing to the cost effectiveness of the endeavour. While the residual value influences the cost of remanufacturing, obsolescence influences both the acceptability of remanufactured products and the ease of accessing spare parts for replacements.

Another consideration that has the potential to mitigate the impact of I6 is indigenous capacity development. In this regards, indigenous development of printed circuit board noted in the research represented a big progress in producing spare parts locally. These are vital skills and technologies for remanufacturing.

To successfully implement medical equipment remanufacturing, there should be strategies to address or account for all the factors identified in this study, especially the more important ones. These strategies may vary depending on the equipment being considered for remanufacture. Case studies on the impact of the factors identified in this work would, therefore, make exciting future work.

7.5 Remarks on the acceptance and potential purchase intentions

This study has become the first to study the acceptability and purchase intentions for remanufactured medical equipment. The results obtained show that remanufactured medical equipment has the potential to be an acceptable solution among health care experts with developing country experience. Participants in the survey indicated that a precondition for accepting remanufactured equipment is a reduced price- 30% of the participants would consider remanufactured medical equipment when price reduction is 50% while 21% would consider it when the price reduction is 40%. Cumulatively, 68% of the participants would consider remanufactured medical equipment if the price reduction is up to 40%. This amount may be considered a positive indication for a remanufacturer assuming the remanufacturing of medical equipment would have similar cost profile to that of machine tools where the remanufactured product price is in the range 40-60% of new ones (Du *et al.*, 2012). Potential remanufacturers would have to control their costs to ensure that medical equipment that are remanufactured would compete favourably in the market compared to other options.

Results of the survey also supported the incorporation of post sales technical support into the remanufacturing concept. Accordingly, this would address some of the most important issues affecting the availability of medical equipment in developing countries which includes lack of repair capacity and access to spare parts (Gatrad, Gatrad and Gatrad, 2007). Participants in the survey believed that post-sales support would help address maintenance issues, encourage efficient functioning of equipment, would prove that the remanufactured equipment is truly as good as new and should be made optional. Figure 7-2 shows all participants' opinions concerning post sales technical support being incorporated to medical equipment remanufacturing.

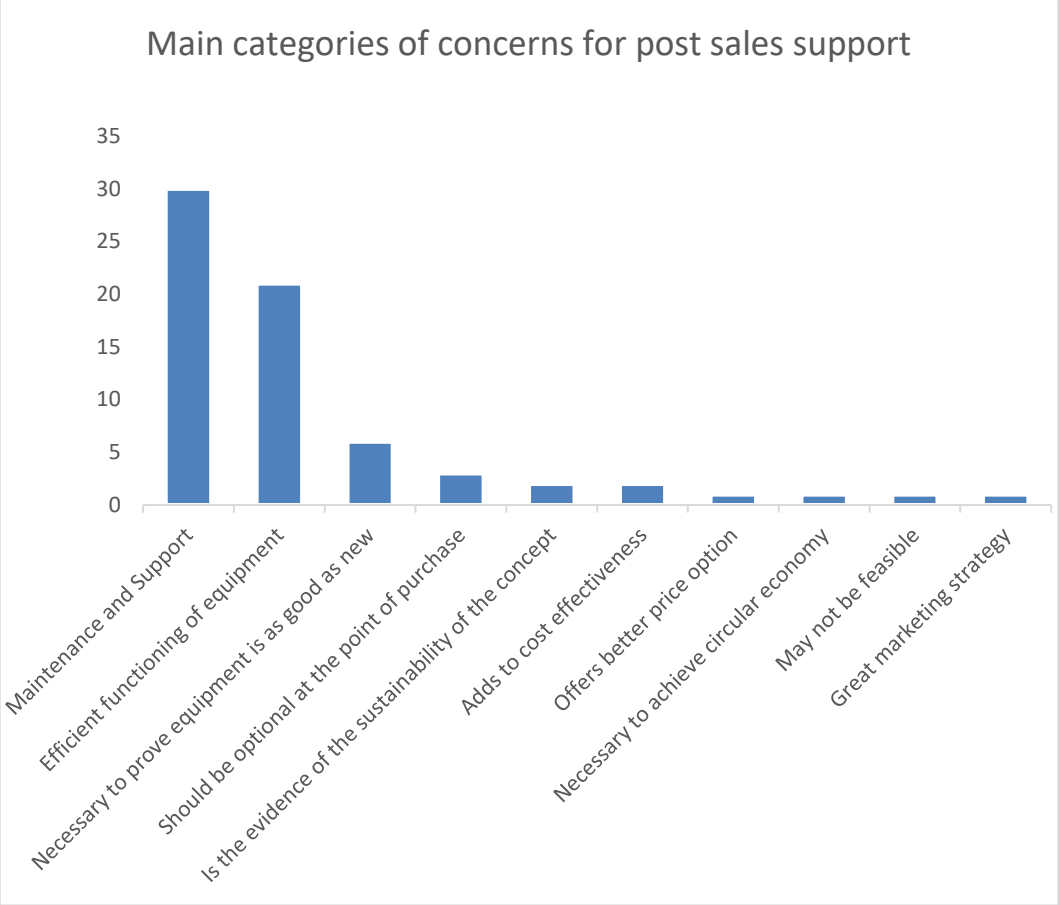

Figure 7-2: Participants' opinions concerning incorporating post sales technical support to medical equipment remanufacturing.

In this study, the theories of planned behaviour, perceived risks and perceived benefits have been used for the first time in relation to medical equipment remanufacturing. While this application is novel in this study, there has been an application of these theories in the remanufacturing literature by Wang (Wang *et al.*, 2013). However, unlike Wang, this study did not include product knowledge since it is arguably represented implicitly in the perceived benefits. Same with Wang's finding, perceived risk in this study has an insignificant direct influence on purchase intentions for remanufactured medical equipment but has indirect effects through subjective norms, perceived benefits, and perceived behavioural control. Same with Wang's findings also, the perceived benefit and subjective norms were found to directly influence the purchase intentions. However, unlike the result in Wang's study, perceived benefit has been found to have strong influence on purchase intentions.

The purchase attitude constructs initially included in the proposed model for this study was removed following factor analysis. The performance of the analyses suggested that other constructs measure the same variances. In Wang's study, the construct

remained, and formed an intermediate link between perceived risks and purchase intentions.

Hence, for remanufactured medical equipment, subjective norms, perceived benefits, and perceived behavioural control (less purchase attitude) have positive influences on purchase intentions. Measures aimed at improving interest in remanufactured medical equipment should therefore focus on promoting positive results with respect to these factors.

The insignificant negative influence of perceived risks on purchase intentions suggests that medical experts' understanding of the risks associated with remanufactured medical equipment is unlikely to cause deterrence in using them. However, it also points to the need to emphasise putting in place measures to ensure that products are safe and of high quality. This will help to dissuade scrupulous operators from participating in the industry and see that quality and safety are not sacrificed to achieve a reduction in price just to entice potential users. The quality of remanufactured equipment can be promoted through effective regulations and standards. Regulations may see that quality and risk management plans are incorporated in the remanufacturing process.

By answering key questions aimed at determining the importance of price reduction, post-sales support e.t.c and by identifying the key factors affecting the purchase intentions for remanufactured medical equipment, this study therefore, answered the following research questions:

RQ3: How would potential users perceive remanufactured medical equipment?

RQ 3a: What key factors predict the purchase intention for remanufactured medical equipment among potential users?

7.6 Notes on the remanufacturing tools developed in this study.

Both the process model and the preliminary decision support tool developed in this work are the first in relation to medical equipment remanufacturing. The tools were developed from patterns and findings from the preceding chapters. Based on the preliminary literature review, the factors affecting medical equipment availability in developing countries were identified and subsequently prioritised using the DEMATEL technique. The findings showed that medical equipment remanufacturing can be an impactful solution to some of the more important factors. A further literature review was carried out to understand the developed world context of medical equipment remanufacturing. Variations in the terminologies used to refer to alternative after life

processes in the medical device industry was found. In the EU context, the term remanufacturing was not found with the regulatory documentation.

As this work was about proposing medical equipment remanufacturing as a solution, the importance of a common definition and a standard process was obvious. The definition proposed in this work got an infusion of the aspects of remanufacturing that address the main problems with medical equipment availability in developing countries such as post sales technical support. This information was from the preliminary literature review and DEMATEL prioritisation of factors. A basic process model of remanufacturing was developed by combining information from OEM refurbishment process found to have some similarities with remanufacturing, and information from the general remanufacturing literature such as Paterson, Windmill and Ijomah (2017).

In the first phase validation of the basic model, some new information were acquired which needed to be incorporated into the model. Similarly, the factors in the cost-effective implementation of medical equipment remanufacturing which were identified in the phase 2 of this study were organised in order of priority in a tool which was aimed at supporting the preliminary decision exercise for potential remanufacturers. Both this decision support tool and the improved process model were validated in the second validation phase to confirm their practical relevance.

The tools developed in this work contribute towards addressing the shortage of remanufacturing-specific tools, particularly the analytic models that help remanufacturers to improve their operational effectiveness (Ijomah, 2008). In addition, the tools can also help academics that are interested in remanufacturing, particularly those interested in medical equipment remanufacturing to gain complete understanding of the remanufacturing concept and so, be able to carry out their research effectively. The usefulness of the tools is demonstrated through validation by experts who deemed them to be so, and their opinions are valid because they are quite knowledgeable in fields of knowledge related to remanufacturing and medical equipment management. The criteria for validation which are based on recommendations from Thomas and Tymon (Thomas and Tymon, 1982 Cited Ijomah, 2008) indicate that the tools provide valid description of a remanufacturing process that will yield high quality equipment and contribute to making medical equipment more available.

Chapter 8:
Conclusions

8.1 Introduction

This research work raised a couple of new knowledge in the previous chapters. The new knowledge includes an idea of how important remanufacturing could be towards addressing the medical equipment availability issues for developing countries. It also provided an understanding of the key factors in the cost-effective implementation medical equipment remanufacturing which ultimately led to the development of tools to guide remanufacturers. This chapter reflects on the choices made throughout this study and the implications they have for the industries and the academia.

8.2 Methodological choices

Several methods were used in this work, to ensure that the research questions are completely and correctly answered. Being a study based on the Pragmatist paradigm, the driving factor for selecting the methods used in this study had been the research questions that needed to be answered.

This study is the first to apply DEMATEL in analysing the factors affecting medical equipment availability in developing countries. DEMATEL has several characteristics that made it an ideal technique to adopt in assessing the impact of medical equipment remanufacturing in addressing developing country medical equipment availability issues. For instance, DEMATEL can be used to analyse complicated interrelationships (Wu and Tsai, 2011). It is also an efficient technique for exploring the interrelationships among factors (Chen and Chi, 2015). Apart from its ability to produce a model of interrelationships, DEMATEL can also measure the impact of each factor on the others and can be used to prioritise factors according to relative impacts or degrees of prominence. Finally, DEMATEL permits group decision making and can be applied to relatively large number of factors. These characteristics made DEMATEL more preferable than other techniques such as Analytic Hierarchy Process (AHP) and Technique for Order of Preference by Similarity to Ideal Solution (TOPSIS).

This study is also the first to apply a combination of Theory of Planned Behaviour, Theory of Perceived Risk and Benefits to the study of purchase intention for remanufactured medical equipment. While this application is novel in this study, these theories have been previously applied in the remanufacturing literature by Wang (Wang

et al., 2013). The choice of this model stems from the fact that combining the theories in this manner brings all the key factors to be considered into the study. This approach is similar to the framework adopted in Wang (Wang et al., 2013) except that product knowledge is not utilised. This does not amount to any significant loss in the number of factors that the theories cover since product knowledge as well as value and trust for remanufactured products which are constructs used in related studies all refer to the relative understanding and trust in the quality, price reduction and environmental benefits of remanufactured products. These areas are well represented in the TPB, Perceived Risks and Perceived Benefits.

8.3 Uniqueness and contributions to theory

While several studies have investigated the problems of poor medical equipment availability issues in developing countries, none of the studies explored potential interrelationships among the factors nor attempted to prioritise them. This study contributed to theory by introducing the use of DEMATEL as a means of prioritising the factors implicated in the poor medical equipment availability in developing countries. It also recognised that remanufacturing could be used to address some of these problems and made an estimate of its potential impact. This study has therefore, opened new perspectives for assessing the problems of medical equipment availability. The implication is that even more innovative prioritisation techniques could be used in future studies. In proposing remanufacturing as a solution to the medical equipment availability issues, this study also demonstrates that remanufacturing can address not just the sustainable development goal of achieving responsible consumption and production but also, that of achieving good health and well-being. The definition for remanufacturing that was proposed, and the tools developed in this study can effectively serve as bases for future research.

Another important contribution of this research to theory is the application of a technology development capability framework. Being the first to apply such theoretical framework to remanufacturing, this study therefore extends the remanufacturing literature, incorporating other perspectives through which important factors can be identified and analysed.

Finally, this study applied the theory of planned behaviour to medical equipment remanufacturing. This theory had only been applied to different context of remanufacturing and the result in this study shows some similarity but marked differences. However, it shows purchase attitude to be a redundant construct when theories of perceived benefit and perceived risks are combined with the theory of

planned behaviour. This result contradicts that which has been found in the other context of remanufacturing literature and therefore, opens opportunities for further investigation.

8.4 Implications for policy and practice

This study has several policy and practice implications It contibutes towards improving developing countries' healthcare outcomes by significantly addressing medical equipment availability issues through remanufacturing. The root factors affecting medical equipment availability were explored while the potential impact of remanufacturing towards addressing the issues was estimated. Lack of HTM and HTA, lack of funds and corruption were found to be among the top driving factors for the availability issue. Hence, policy makers may pay more attention to these driving factors since by so doing, they will mitigate the impact of the driven factors. Hence, policy makers should make deliberate efforts to address corruption, to establish effective HTA and HTM regimes and to develop innovative techniques of maximising available funds for healthcare expenditures.

This study also identifed the key factors that should be considered in implementing medical equipment remanufacturing. As the factors include technical factors, incentives/market and institutional factors, it therefore informs relevant individuals in authority, institutions and businessess on the key factors that need to be considered to implement medical equipment remanufacturing. It therefore, provides those in the industry and policy makers with a holistic means of viewing the key factors to be considered in implementing medical equipment remanufacturing.

For industries and policy experts, this research also provided a decision support tool and process model that can help in pre-planning and implementation of medical equipment remanufacturing. The decision support tool highlights the order in which important factors that need to be considered in implementing medical equipment remanufacturing while the process model presents all the activities in the remanufacturing process that ensures that the resultant product complies with best practice medical device industry standards. Policy makers can integrate the components of the process model into a regulatory document to produce a standard that potential medical equipment remanufacturers can adopt. Currently, the weak regulation in many developing countries implies that only OEM remaunfacturers may be able to gain trust from the people. That is, only products remanufactured by OEMs may be trusted because they made the equipment in the first place and that reputation helps to assure potential users that they will already have the quality management

strategies in place. Independent remanufacturers will then have to work harder to build the potential users' trust. It may however, be difficult for an independent remanufacturer to develop the technology needed. Accessing software updates will also be difficult for the independent remanufacturer unless they have a contract or relationship with OEM, suppliers or are able to develop them inhouse. Hence, OEMs seem to have greater opportunity to benefit from medical equipment remanufacturing, and this is a well known position (Martin, Guide and Craighead, 2010).

8.5 Research limitations

This study aimed to propose remanufacturing as a means of addressing medical equipment availability issues in developing countries. While the researcher paid due attention and strived to make the research bias-free, there were still some limitations which are discussed below.

Some of the participants were used more than once. The study adopted a multiphase mixed methods design. While the purpose of each phase of the research differred, the use of the same participants may introduce some bias, for instance, due to familiarity with the researcher or the main objective of the research.

Since there was no evidence of medical equipment remanufacturing as defined, the researcher used the experience of medical experts through out the study, as actual remanufacturers could not be reached. Without any doubts, these experts would know the best features and operational conditions of medical equipment as well as some of the issues affecting availability in the developing country context. However, there understanding of the industrial factors in the actual remanufacturing context may be limited and only there own evaluation or imagination of the impact of these factors would be provided during the interviews and questionnaire survey.

DEMATEL multicriteria decision making technique was used to rank the factors affecting medical equipment availability. It was chosen because it is able to explore the interrelationship among the factors and also permits the aggregation of inputs from multiple experts. However, DEMATEL technique used does not account for the errors in human judgement which could be inherent in the inputs from the participants in that phase of the study.

In the survey conducted to assess the behavioural factors (purchase intentions), medical doctors were disproportionately higher than experts from the other fields. This was not the researcher's design. The researcher intended for experts from the other professions to be proportionately represented and included this in his sampling plan. But this was not realised within the time frame allotted to data collection. Hence, the

analysis involved could not assess the differences per profession and so, no such insights was made available in this study.

This study makes a claim for the entire developing countries. However, data were mostly from Nigeria, with the assumption that being a developing country, the results and recommendations will also be applicable to other developing countries. However, this may not be a valid argument. It is therefore seems appropriate to advise that the results of this study is for analytic generalisation.

8.6 Future research recommendations

There are several opportunities for future research in this area. The most important future research recommendations may, however, aim to address the limitations highlighted above. So, future research may recruit experts from greater number of developing countries so that more diversified inputs may be obtained and analysed. Case studies of the remanufacture of specific medical equipment may also be conducted and the tools developed in this study may be used as the basis. This will provide greater opportunity to test the validity of the tools.

Instead of using DEMATEL to assess the problems of poor medical equipment availability, a more wide-scale analysis using survey may be conducted. This will provide opportunity to accommodate greater views and analyse associated differences. Similarly, a suitable fuzzzy technique may be incorporated into the DEMATEL approach to account for the potential errors in human judgement.

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Appendix A

ANALYSING THE CAUSES OF POOR MEDICAL DEVICE AVAILABILITY IN DEVELOPING COUNTRIES

Name_____
_____

Organisation_____
_____

Expertise
area_____

Years of
experience_____
_____

Code	Identified causes	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11
F1	Corruption	0										
F2	Attitude/perception		0									
F3	Lack of funds to access and/or to purchase equipment			0								
F4	Lack of infrastructure such as electricity, water supply, oxygen				0							
F5	Absence of HTM and HTA					0						
F6	Weak or ineffective regulation						0					
F7	Lack of trained or skilled users and maintenance staff							0				
F8	Unavailability of equipment, spare parts and consumables								0			
F9	Lack of clear economic model									0		
F10	Equipment are inappropriate for the needs of the people										0	
F11	Ineffective supply chain and communication involving recipients											0

HTA: Health technology assessment; HTM: Health technology management

Appendix B1

Questionnaire No. _A_____

You are invited to participate in this study on the assessment of potential challenges to the implementation of medical equipment remanufacture in Nigeria. The survey is being conducted by Solomon Eze, a student at the University of Strathclyde, Glasgow.

Remanufacturing is an industrial process which returns a used product to at least, as good as new quality and warranty. It involves collection of used products, decontamination, disassembly, inspection, rework/recovery, replacement of worn or damaged parts, upgrade in software and hardware to latest and/or appropriate technology, reassembly and testing to ensure that the equipment has been restored to its original safety and performance specifications.

There is no risk envisaged to arise from participating in this study. Only your responses will be collected and stored under password protection on the University's computer. Thus, your contribution will be anonymous.

By clicking on the 'Agree' button below, you confirm the following:

- That you have read the above information
- That you voluntarily agree to participate in the survey.

Please select your choice below:

☐ Agree

☐ Disagree

Q1. Please, what is your occupation?

☐ Lecturer of Biomedical Engineering

☐ Distributors of medical equipment

☐ Manufacturers/designers of medical equipment

☐ Clinical/Biomedical Engineer/Medical equipment maintenance experts

☐ Regulators/policy makers in relation to medical equipment

☐ Remanufacturers/refurbishers/repairers of medical equipment

☐ Other (please specify) _____

Q2. How many years experience do you have in your career?

Less than 5 ☐

Between 5 and 10 ☐

More than 10 ☐

Q3. Have you heard of the medical equipment remanufacturing concept before?

Yes ☐

No ☐

Q4**. Do you know of anybody that has used/is using remanufactured equipment?**

Yes ☐

No ☐

Q4. Have you used remanufactured equipment before?

Yes ☐

No ☐

Q5. **To what extent do you agree that remanufacturers of medical equipment should offer professional post sales technical service same as for new products?**

☐ Strongly agree

☐ Agree

☐ Neither agree nor disagree

☐ Disagree

☐ Strongly disagree

Please explain the rationale for your opinion

Q6. Using a scale of 1 to 10, Please indicate the extent to which you believe the following activities may make medical equipment remanufacture more difficult. **Please enter the appropriate value.**

S/N	Production capability	scale	Rationale
P1	Availability of equipment and technologies for remanufacturing.		
P2	Availability of skilled workforce		
P3	Potential hazard risks to workmen		
P4	Labour costs		
P5	Design will not permit remanufacture		
P6	Ease of disassembly and reassembly		
P7	Ease of inspection and testing		
P8	Ease of cleaning		
P9	Ease of disinfection/sterilisation		
P10	Ease of upgrade to appropriate technology		
P11	Wide variety of medical equipment models to develop remanufacturing capability for		
P12	Residual value of recovered used products (due to the extent of damage)		
P13	Recovered used products may be obsolete		
P14	Affordability of requisite investments		

Q7. Using a scale of 1 to 10, please rate the adverse impact of the following factors on medical equipment remanufacturing. **Please enter the appropriate value.**

S/N	Incentive derivation and uncertainties	scale	Comments
I1	Willingness to pay for remanufactured medical equipment		
I2	Demand for remanufactured medical equipment		
I3	Availability of marketing or distribution channel		
I4	Availability of used products in acceptable quantity and quality		
I5	Access to design information		
I6	Access to replacement/spare parts		
I7	Availability of lower cost new or second-hand medical equipment		

Q.8 Using a scale of 1 to 10, please rate the adverse impact of the following factors on medical equipment remanufacturing. **Please enter the appropriate value.**

S/N	Institutional influence	scale	Comments
II1	Difficulty obtaining licences to market remanufactured medical equipment		
II2	Municipal infrastructure such as electricity		
II3	Intellectual property management issues		
II4	Obtaining regulatory approvals to set up medical equipment remanufacturing enterprise		
II5	Weak regulation		

Appendix B2: Interviews

Interview with participant C

How is equipment maintenance in your hospital?

I came back from abroad in 2011, at that time; most of the hospital equipment was in states of disrepair. I laboured for 2-3 years and almost got frustrated with the biomedical engineering that was on ground when I took over the hospital. I found there was a Biomedical engineering department but on ground. On investigating further, I however found that there was no qualified Biomedical Engineer within the department. When I asked questions, I noticed that the hospital had a qualified Biomedical Engineer that was ostracised to the Radiology department where his contribution to the hospital was not satisfactory. Since I have executive order to make changes, I quickly redeployed him and mandated him to improve the department. Within 3 months of resumption, the engineer with his group which he put together from all the places they were ostracised had saved the hospital up to 40 million Naira. In fact the engineer had been exceptionally good.

How would you assess Biomedical engineering in Nigeria?

I think it is a growing profession. Currently, one of the main biomedical engineering training institutions is the Lagos University Teaching Hospital which is funded GE Health. The programme was founded by a professor of Cardio Thoracic surgery who went ahead to study Biomedical Engineering and now a professor in the field. Our hospital usually gets slots to train our staff there. Some of our staff members that did very well in training were retained as adjunct staff there. Currently, we have laboratory and ventilation equipment experts who trained in the institution. I think I can comfortably say that I have a viable biomedical engineering department today. So, I would say that Biomedical Engineering training in the country is improving. The engineers have the capacity to read circuit boards to detect faults and provide the first line of maintenance for even complex equipment. They can trouble shoot faults with these equipment and tell us what the problems are and then, they can invite the company that can take over subsequent maintenance or repairs if necessary.

Recently, the University affiliated to our hospital also started a Biomedical Engineering Programme. The programme has focused mainly on capacity development; with students in the department having completed projects such as blood sugar monitor, infant warmer and needle crusher and separator. The programme enjoys local and international support and partnership to achieve the objective. There are also other universities in Nigeria that have Biomedical Engineering programmes. So I would say we are improving in that area.

How do you perceive the remanufacturing concept for medical equipment?

You know that developing countries have much medical equipment that are not functioning. So a lot of questions came to my mind when I first read about remanufacturing in your work. I was definitely sure that we can benefit from the concept. But we have a wide range of medical equipment including radiology, laboratory and nuclear medicine. I do not exactly know how we can take advantage of the remanufacturing process. For equipment like ultrasound, the most important challenge for remanufacturing that I can perceive is availability of software update. The Original equipment manufacturers may not be willing to provide copies of these to potential remanufacturers and this can likely affect the image quality. You know that the software plays a key role on the image quality. You can have two similar equipment giving very different image qualities while the only difference between them is the software. So, unless one knows how to upgrade the software, the output image would still be poor. So for me, remanufacturing can be of great benefit to us if it can help increase access to such updates. We know that there is usually no much difference between these equipment other than the software. External cosmetic designs do not just matter.

If you have a remanufacturer in Nigeria, Do you not think that it would be easy for the person to get access to software updates even at a cost, from the original manufacturers?

It can be possible, as you said, at cost. But most of their middlemen will not do that for you no matter what. This is because they understand that the popular opinion around here, even among distinguished academics, is to buy new equipment. So they want to encourage it to increase their sales. It is absurd that our people usually prefer getting new equipment without seeking to cultivate that habit of carrying out repairs. This is why there are so many out of use equipment everywhere polluting our environment. So for me, I think this is a very good project that is long overdue and should not have come from a developed country that needs remanufacturing the least, as everyone is trying to escape litigation. We should be more interested in maximising the use of equipment. Instead what you get is people pushing to get new ones so that they can get that 10% kickback from the deal.

Given that even low cost medical devices are reused in poorer developing countries, do you think it would be in their interest to remanufacture single use medical devices?

You know, single use devices get denatured by sterilisation and they may end up doing more harm to the patient. Take for instance, bone marrow needle. Some bone marrow needles are made of stainless steel and are reusable after sterilisation. Others however, are single use. Using the single

use needle twice, even if on the same patient is often painful at least, to the patient as it would have blunted out the needle on the first use. Moreover, there far more cases of communicable diseases in the developing world than in the developed world. So it would be risky to encourage reuse or remanufacture of single use medical devices. A similar case is considering the reuse of bone screw. On the first use, the thread usually wears out. So unless it can be rethreaded and efficiently sterilised without damage, then we can begin to think about its reuse. So I would say that single use equipment are usually consumables.

How do you see having equipment from variety of manufacturers which can potentially make the development of remanufacturing technology more involving as technologies for remanufacturing these different equipment will need to be developed?

We do that a lot. Our equipment come from up to 40 different makers. Many of the equipment are basically the same principle, only slight design changes and aesthetic improvements. In recognition of the potential challenges associated with using equipment from a multiplicity of manufacturers, the Federal Government has brought out a gazette listing the companies from where medical equipment can be purchased. Under each item, there are usually not more than for options of manufacturers to choose from. For instance, for radiological equipment, it is GE, Siemens or Philips. This will help to limit variety and improve expertise. GE, Philip and Siemens have maintenance units in Nigeria.

How do you ensure the radiation safety of radiation emitting equipment such as X-ray equipment?

We have medical physicists that it is their responsibility to do that. The hospital has about six of them, in the Radiation oncology, radiology and nuclear medicine departments. Among them, two have already obtained their PhD in the field while one is currently on his. One of the medical physicists also underwent a United Nations sponsored IEA training in Egypt.

Has your hospital benefited from medical equipment donation?

Yes, from two sources. The one in Atlanta Georgia has a weigh house that is about the same size as two football fields. They put equipment on their Website that they have and when you indicate interest, after prior assessments, their biomedical engineer will examine and certify the equipment safe for use before sending it to you. What was intriguing was that some of the equipment were actually brand new, only with damaged carton. I am very sceptical about equipment donations, but these two companies are registered companies in the US and they have trademark stamps on the donated equipment. But most of the time, other donations are not compatible with electricity, humidity to mention a few. But there is no hospital in Nigeria that will say they don't have donated equipment.

Imagine a scenario where remanufacturing is used to rationalise donation by having an accredited remanufacturer within the country communicating with potential donors, approving and assessing remanufactured medical equipment before it gets to the recipients. What do you think of this arrangement?

I think it sounds as a very good idea, even though Nigeria does not have any law about medical equipment donations. Most medical equipment donors are actually registered to donate medical equipment and most of these equipment are marked not for sale. But there are also some "smart" people that put up the name of a hospital and go these equipment, repackage them and sell them. So if anything happens, most times, you find it difficult to catch them. Some of these guys are in Lagos where you have loads of used equipment brought into the country from all parts of the world. There was also a young man around us here, who used to bring in loads of surgical equipment that he had no clue what they are. I went to him once and started pricing a set of cardio-thoracic surgery equipment. I ended up buying it from him for N50,000 and gave them to my boss then. In fact, if I were to buy those equipment in Europe, I would probably be spending close to N500,000. But the man did not know what they were, so he just said I should take them.

So if your suggestion has to work, then there will be a need for policy to ensure that whatever equipment coming into the country as donation is certified at the border; even though over there, it is certified because those countries' governments do not allow the export of poor quality equipment. This will help provide donors with information on voltage and humidity requirements of equipment used in the recipient countries. Yes I agree with you 100% but it will require legislation.

Interview with participant B1

Please what is the nature of the organisation where you work

I work in a Federal government public hospital

Please what is your position in the organisation

I am an assistant chief radiographer

What is the cheapest and most expensive procedures you do ?

That will be like the routine X-ray such as for hand which is about N750 to N800. But there is usually special considerations for children who in most cases are charged half the same price as adults. The most expensive scans are CT scans. CT scan of the abdomen, brain and cervix are the most

expensive. Angiography was not done in the hospital because the CT available is just 2-slice but a new CT is just being installed with which such procedures can be done.

On the average, approximately how many procedures are done in the hospital

This depends on the number of equipment functional. If it is when the mobile unit is functional, then an average of 30 cases can be done in a day with X-ray equipment, other days we do about 20 scans. With the CT scanner when it is functional, about 8-12 scans are done. Our X-ray equipment are Analogue.

Do you think your equipment break down more than usual?

Yes, that is our major challenge in the hospital and when such a breakdown happens, the downtime lasts for very long times. The causes are from the equipment and unnecessary bureaucracy. For instance, when a breakdown is not appropriately repaired, then in no distant time, the equipment would break down again. Equipment are usually purchased without involving the users. Other times it is donations. But the bottom line is usually that the users are not always involved. If they involved the users, then considerations of the workload and parts replacement would be considered. These happen with newer equipment but the older ones often worked very reliably.

In your opinion, is the local capacity able to carry out repairs of broken-down equipment?

In our hospital we have biomedical equipment department. In my opinion, I do not think they have experience enough to handle such repairs. But when there is a breakdown, they have to be the ones to escalate to the need to invite experts. They first assess the damage to see if it is within their capacity, otherwise escalate. So, they would continue trying to repair, wasting time. So, the amount of time lost before the equipment is finally repaired becomes unduly prolonged. Upon escalation, experts from Lagos who are proper engineers often have the capacity to carry out the repairs. So considering local to be the hospital, I would answer no but if referring to the country as a whole, I would answer yes.

Are there programmed quality assurance testing in the hospital to ensure that equipment are safe for staff and patients?

We select the parameters. The parameters determine the radiation exposure to the patients. We do not have an objective way of checking it. We use the subjective means. So when the image comes out, if it is darker or lighter than normal, then it will give us an indication of what is going on with the equipment- whether the patient has received more radiation than necessary or not. We do not have

a dosimeter to measure the dosage. Since we only have analogue equipment, we try to make sure that the chemical used for development of the image is of high quality.

Given your expertise in the field, how many would like to use an X-ray equipment before considering buying a new one

A good X-ray equipment should be able to work for more than 10 years without any issues. So I would expect to replace an equipment between 10 to 15 years of use.

Within this period, do you think it would be possible to break even on the investment in the purchase of the equipment?

If there are patients, yes. We work in a public hospital so I believe it is possible. The best would be to use buy as new, use efficiently, and sell out or trade in for upgrade. The idea of looking at the contract price of equipment is deceptive; the key should always be to consider how long it would serve. With new equipment, there is much higher likelihood of achieving long service at little or no cost of maintenance.

When do you think is most appropriate to dispose an equipment?

I would say when it breaks down frequently and engineers find it very difficult to repair or recommend replacing them.

What are your major concerns about a remanufactured X-ray equipment?

Reading about remanufacturing, I think it is a good thing. I have only known about refurbishment and second hand. But I think remanufacturing is a good concept, particularly since the warranty would be as good as new and the price would be cheaper. So I would definitely want to give it a try.

Do you think the local capacity in Nigeria can carryout remanufacturing of medical equipment given their work repairing equipment in your hospital?

I think there are people who can do it. Those engineers in Lagos are quite knowledgeable and will definitely be able to remanufacture medical equipment. But they are not many.

Would you purchase or recommend purchase of equipment remanufactured in Nigeria, -say by those experts from Lagos?

They have to prove themselves first. They need to show that price is encouraging, that maintenance is actually provided. I think it will be better because they will be able to understand the relationship between predominant failures and the parts of the equipment. So personally, I would prefer it if it is done in Nigeria.

Interview with participant B3

Please what is the nature of your job?

I am a senior diagnostic radiographer at XXXX hospital. My responsibilities as a senior radiographer include using and overseeing the application of diagnostic imaging equipment such as X-ray, CT scanners and MRI in the hospital for patient diagnoses. My task also includes ensuring the radiation safety of all the equipment and looking after younger members of staff in the department.

Please what is the cheapest procedure you carry out in your department?

I would say that the cheapest procedure we do in the unit is paediatric chest X-ray scan which is costed N750 per patient.

Please what is the most expensive procedure you carry out in your department?

Angiography CT is the most expensive procedure costing N86,400 per patient

How many X-ray based procedures do you do in a day?

It is difficult to say exactly how many procedures we do in a day. But I think it will be about 500 procedures on average.

How often do you get patient requiring the complex procedures?

About 20-30 complex cases in a day are usually complex cases.

Do you think that your equipment breaks down more than normal?

I would say yes, because at any point in time, there is at least one equipment that has broken down of the 7 Planar X-ray equipment and CT scanner in our department. The problem is not even that they break down but it usually takes a long time to get them back to functioning state.

What is the longest possible time an equipment can stay down without repair

This varies. There was a time our CT scanner was down for almost 10 months because of damaged tube. It was a massive job which was done by the suppliers who are also the producers.

Are the suppliers that carried out the repair from Nigeria?

Yes. I suppose the work for the OEM and have been trained.

In your opinion is the local capacity sufficient for carrying out repairs promptly and efficiently?

Local capacity is employed in repairing minor damages. I do not think that they can carry out major repairs. More complicated problems are usually beyond their expertise and the manufacturers or suppliers are contacted by our organisation.

If trained indigenous technicians and engineers may have the technical know-how to carry out repair and refurbishment but there is no facility to support them within the country and that may be a problem.

In the case of the CT scanner which involved a complex repair, was it trained indigenous people that carried out the repair or were they foreigners?

They are resident in Nigeria but have been trained by the foreign companies who are also original manufacturers of the equipment. The damaged equipment was made by Toshiba and their experts are on ground to provide technical assistance when the need arises.

So, these guys are from the country, working for foreign companies but have been trained to carry out repairs?

Yes

Am I right to say that someone who has already been trained by an OEM but who no longer works for the OEM can carry out remanufacturing?

Yes, but OEMs usually get them to agree that they will not leave the company before a specific time period to preserve their trade secret.

How about quality assurance for radiation safety?

There are some QA procedures that are done every morning. Example is phantom test to ensure the quality of the image is good. There is also tube warming. Those ones are done monthly or

immediately after repair. We also have our internal radiation physicists and biomedical engineers that carry out such procedures.

How long do you think it is proper to use an equipment before replacing them

I think an equipment can serve very long period of time if properly maintained unless recalled by the company. For Planer X-ray equipment, I would say 20 years but for CT scanners10 to 15 years since the technology changes rapidly.

How long have the equipment in your dept served?

The oldest CT scanner was installed in 2005, it is faulty now and I would say it has been abandoned. The other one was installed in 2011. There are also many of the Planer X-ray equipment installed in 2005.

How would you determine when an equipment requires replacement?

When it requires more frequent work or when the image quality is no longer acceptable. When an equipment breaks down frequently, it becomes expensive to maintain them. Also, since the repair usually takes long to complete, you find that such equipment will only be used sparingly. Under such circumstances, it would be difficult to break even on the investment in the equipment.

On the other hand, if the image quality of an equipment is so poor that it would diagnosis would be misinterpreted, then the safety of patients would be in danger. If it is obvious that the reason for such poor quality is as a result of equipment age, then the best thing to do is to decommission the equipment.

Of the equipment acquired in 2005, do you think they are due for replacement?

Yes, because they have started exhibiting these unwanted properties: poor quality images and frequent need for repairs.

What is your major concern with remanufactured X-ray equipment?

I still feel it is not possible to restore used equipment to be as good as the ones that are new from the factory.

Assuming you have an OEM remanufacturing, would you be happier with the product?

Of course, since they are the manufacturers, they will be able to do a lot better work in bringing the equipment back to new. So people will trust them when they say the remanufactured equipment is new because they know what new means and what it takes for an equipment to be new

Do you think X-ray equipment are currently being remanufactured in Nigeria whether by independents or by OEMs?

No.

Interview with participant A4

Please, what is the nature of your organisation?

I work in a teaching hospital as a Biomedical Engineer.

What are your qualifications please?

I hold a Bachelor of Engineering and a Master of Engineering degree in Biomedical Engineering.

How would you assess the level of biomedical engineering capability in your organisation and the country?

I cannot tell you about the level of Biomedical Engineering in Nigeria because I may not have the right information. I can only say about biomedical engineering in my hospital. The hospital is fully digitised. Images are transferred through Picture archiving service (PACS). I received my biomedical engineering training abroad and am a capable hand for the hospital. I lead my team to provide efficient maintenance of all the equipment except when spare parts are not available. I think so far, this is the best standard anywhere in the world and we sustain it. So you can see where we are in terms of development.

I have explained remanufacturing to you. Do you think that it can be conducted in the country given the available skillset?

I can talk about refurbishment which is familiar to me and I think the concept you are talking about is refurbishment. There are people already doing it in the country. I also refurbish equipment. A lot of machine coming into the country are refurbished; especially the very expensive ones. The MRI acquired by the National Hospital Abuja was refurbished; I was there during the installation.

A lot of work in the area of medical equipment refurbishment is going on in Aba, Onitsha and Lagos. If the people doing the job are respected and patronised they will be able to do a lot more. These operators can even refurbish equipment to a specification better than that of the OEM.

What are the most common causes of breakdown?

The equipment breakdown we experience are normal, such that OEMs foresee and have plans for making parts available for necessary replacement. You know, when machines are designed, OEMs usually know the parts that will require replacement along the product's lifespan. They make provision for spares to carry out such replacements.

How do you carry out the repair? Do you do it in-house or with external assistance?

We do most of our maintenance in-house. The only delay we experience is due to the difficulty accessing funds for maintenance and repairs. Management often do not allocate funds until it is time

for maintenance or repairs. This may take a lot time in some cases, especially when there is already a breakdown of expensive equipment.

Do you have easy source of spares for repair?

We deal with manufacturers directly, to obtain spare parts. Some OEMs however, do not agree to send their parts to Nigeria for intellectual property violation issues but we always find a way out in such situations. It is easy for us to have such an international network with manufacturers but others may find it difficult to do so. Some hospitals contact us to help them source their parts.

Are there programmed quality assurance processes in place in your hospital to detect equipment that are no longer safe to staff and patients?

We have different analysers used for calibration and quality assurance. For X-ray and CT equipment, we use them to know the amount of radiation exposure that patients and staff are at risk of. Our team is highly trained, so we know and implement what is required. Same may not however, be said of other hospitals.

Do you think there is sufficient incentive for medical equipment remanufacturing in Nigeria?

Yes. But there is a major challenge especially with low cost products from China. If the price of the finished product is high, people are likely to opt for lower price options from China. Some parts I purchase at N1.9 million from Germany sell for less than N200 thousand in China. China gives you whatever specification of product you request and lower the price accordingly. Nigerians are usually not very interested in quality. Take for instance, Innoson cars made in Nigeria; does it sell in Nigeria more than others? This is because the manufacturer eventually spends more manufacturing the car and must sell at higher prices. So, the products cannot compete favourably. In a nutshell, people will likely not go for costly products when there are lower cost options; even if quality is sacrificed to some extent. This may affect the profitability of medical equipment remanufacturing business in Nigeria unless the process drives down price considerably.

Does Nigeria have a national regulatory framework for determining the standard of equipment and products being imported?

There are specific agencies that regulate medical equipment. There is also the Standards Organisation of Nigeria that should see to the quality of product being imported to the country. Sadly, the Standards organisation of Nigeria does not provide any standards. They do not even have people that are appropriately skilled in checking standards. Besides, people usually “pay them for their time”, so no one bothers about standards.

Do you conduct equipment decommissioning in you hospital?

Yes. People carrying out medical equipment refurbishment are usually interested in them as trade-in with manufacturers is not yet common. Those buying decommissioned equipment may get a certain number, cannibalise/harvest parts from some of them in order to fully refurbish a few of them.

Would you purchase an equipment remanufactured locally?

For me to consider purchasing refurbished or remanufactured equipment, there has to be significant price reduction. Some dubious people in the refurbishment business would sell refurbished equipment to you at the price of new ones; they would not let you know the equipment is refurbished.

Interview with participant A1

1. What are the major causes of equipment failure in your hospital?

When there is a disconnect between workers, you find that staff that do not know how to use an equipment always fiddle with them. They would not like to own up their lack of experience in using the equipment so that training will be organised for them; so they end up causing damages to equipment. I think the quality of training in the educational sector is no longer as good as it used to be. So most people coming from the university do not have idea of how equipment works. So human error due to equipment use by untrained personnel is one of the most important causes of equipment failure we experience.

You often get them learning by trial and error on expensive equipment. Even if the equipment is not damaged in the process of unsupervised learning, the lifespan would be decreasing with each attempt. Take for instance the CT scanner or X –ray. Each scan is takes a lot from the equipment life. Wrong use of the equipment which leads to repeated scan can cause a decrement in the equipment lifespan without commensurate value. It would also expose a patient to greater radiation dosage. So this may also result in wrong patient diagnosis in some cases and delivery of wrong dose.

2. Are you able to provide prompt maintenance service for the Hospital?

My answer to the question is a “yes”. But it has been a struggle all along, especially with the hospital management. First, the time of response to getting spare parts has been an issue for us. This is because funds for conducting maintenance services and repairs are usually not made available by the management until it gets late or even too late. One other factor that was an issue for long is the integration of biomedical unit with the works department. For many years, that has been the structure. It is only recently that biomedical engineering department was carved out from the overall works department of the hospital and this has allowed us to focus on the core task of providing medical equipment maintenance.

It was difficult to achieve this independence, and it was as a result of the Federal Ministry of Health's intervention. But as soon as we were set up as a department, the hospital started seeing the value we can deliver; I can tell you that my team has saved the hospital a lot of money. We have been able to easily bring equipment wrongly marked beyond economic repair (BER) back to life. It baffles me how equipment are discarded in Nigeria. I have been to more developed African countries such as Egypt and Algeria. I can tell you that they do not throw equipment away like we do in the country.

Without biomedical engineers taking part in negotiations preceding equipment procurement, manufacturers have been able to supply equipment whose technical details are not well scrutinised. We have managed to put a stop to that in the hospital. Now we assess the technical details of all equipment the hospital proposes to acquire.

We have also recently developed a database for all the equipment in the hospital. This has helped us in planning preventive maintenance. So our maintenance service is good.

Are the equipment you recover or maintain yet obsolete?

The most important thing for us is to have available equipment functioning especially when replacement is not in sight. From experience however, it seems that older equipment give us longer performance. I can tell you about very old Ultrasound equipment that we recovered like that; it is still operational till data. There are however, many that were bought new, recently that have damaged BER.

Are there regulatory systems I place to help ensure the quality of medical equipment used in the country?

Currently, the regulatory system is very weak. Medical equipment importers often take advantage of the situation to import equipment with spurious quality. The biomedical engineering profession may help in this regard, but it is still in its infancy. We may currently have a few qualified biomedical engineers for the regulatory roles. Developing and implementing robust medical equipment regulatory framework would require the collaboration of with the Federal Ministry of Health.

How do you source for medical equipment spare parts?

We usually conduct online search of medical equipment manufacturers. We contact them for the spares in many cases; provide the specifications of the equipment for which we need a spare part. They usually deliver the parts to us when we satisfy their quotation. So we troubleshoot to identify the damaged parts and then contact the suppliers.

Sourcing the parts may be a challenge when the production of the equipment has been discontinued by the manufacturers. In such cases, we first try to identify the manufacturers of the parts, that is, the people that supply them to the equipment maker. Such suppliers have helped us out several times

but the parts usually come very expensive. This is because the benefit of mass supply which drives the price down is no longer considered in this situation. So, in some cases, it may cost for instance, up to USD 1500 to produce only a printed circuit board.

I have seen some of the stockpiled equipment you have. Do you think that some many of them would still have substantial value?

We have successfully repaired and brought back to life, some equipment that would have been thrown away. In most cases, this was achieved just by identifying and replacing damaged parts. So it means that the hospital has been throwing away equipment with significant residual value until we intervened.

What types of equipment do you consider suitable for remanufacturing?

I would say the more expensive equipment such as Nuclear medicine equipment, imaging equipment such as ultrasound, CT, MRI, CATLAB. Others include diathermy equipment, laboratory equipment such as centrifuges, PCV, and chemistry analysers. Dental chair should also be considered.

Interview participant E

The safety of remanufactured medical equipment is important to the success of the operation. With respect to radiation emitting medical equipment, are there currently, any regulatory framework in place, to ensure that medical equipment function within prescribed safety limits.

NNRA (Nigerian Nuclear Regulatory Authority) which was instituted in 2001 is responsible for radiation equipment in Nigeria, including X-ray equipment, CT scan. They regulate whatever comes into the country that has to do with radiation especially in manufacturing and medical sectors but also in oil and gas. The Act establishing the agency came up in 1995 and so, NNRA replaced the federal radiation protection service.

The NNRA gives licence to importers of radiation equipment. When installed, part of their work is to ensure that performance of the equipment is optimal. They insist that each organisation with installed equipment appoints a radiation officer. I have been one. However, they have not been able to cover the whole country. They should have a task force going round the country, taking inventory of radiation emitting equipment in order to achieve their objectives. But sadly, this is not the case. They don't even know the number of CT equipment in the country. They have ambitious objectives but do not have the will and machinery to implement them. Cobalt 60 radiotherapy equipment mostly used

for nuclear medicine in the country is also being regulated by the agency. There are only 9 radiotherapy equipment in Nigeria including just about 3 Linacs. Cobalt 60 equipment usually come as donations. The in our hospital usually gets damaged but there are biomedical technicians that fix them. There has also been issues with improper disposition of damaged cobalt 60 equipment (radioactive materials are often disposed together with the equipment) among operators that collect them for recycling.

Does the licence issued by NNRA apply to only distributors?

Anyone who intends to import such equipment is expected to work along with them, whether individual or organisation.

Do you think the NNRA can be improved to better address its responsibilities?

Yes, it always depends on leadership. The institution once had a vibrant leader that mobilised task force for intensive monitoring of compliance with the regulation. Some hospitals were even sealed off in Lagos at that time, where patients spend up to 10 times more than they should, under X-ray exposure. There are also several independent X-ray diagnostic centres where the building are not designed appropriately to protect the staff and nearby people from radiation exposure. Since the leader left, there has not been any meaningful supervision from the organisation. The current Director General seems to be quiet on radiation safety. Whereas in the dispensation I just told you about, every establishment with X-ray equipment usually keeps searching for radiation safety advisers whose responsibility it would be to ensure that the equipment in their possession comply with standard. That is how it is done in developed world.

Are there laid down quality control and acceptability criteria for radiation emitting equipment?

It is the responsibility of the RSA and RSO to carry out quality control measures. This includes ensuring that acceptable radiation exposures result when the X-ray tube is energised.

In the EU, there are acceptability criteria which are broadly divided into qualitative and quantitative. Examples of qualitative criteria being the inclusion of automatic exposure control for paediatric equipment. Are such criteria available to RSO and RSA as guide?

I would say we normally only carry out the quantitative QC measurements then. The hospital has a radiation survey meter which is privately owned; with which we carry out radiation measurements.

Do you think the regulations on ground are sufficient for implementing remanufacturing of medical equipment effectively?

The regulations and laws on ground would be very effective if properly implemented. So I think that mostly implementation efforts should be improved. This will involve elimination of corruption in the system so that no one bypasses it.

Appendix C

Potential purchase intentions and willingness to pay for remanufactured X-ray equipment.

Start of Block: Default Question Block

Q1 You are invited to participate in this web-based study aimed at assessing the perceptions on remanufactured medical equipment. The survey is being conducted by Solomon Eze, a student of the University of Strathclyde, Glasgow and should take approximately 10 minutes. Remanufacturing is an industrial process which returns a used product to at least, an "as good as new" quality; with warranty same or better than that available to equivalent new product. It is different from refurbishment which yields equipment with less quality and warranty. Remanufactured products are characteristically cheaper than new equivalents since some durable parts with longer life are reused. Being an industrial process, appropriate quality control measure is implemented to ensure that resultant products comply with relevant safety and performance specifications. No risk is associated with participating in this study. Your responses will be directed to an online survey system where the data will be stored in an electronic format under password protection. The survey has not sought for your personal details and will not collect the IP address of your machine. Thus, your contribution will be anonymous.

By clicking on the 'Agree' button below, you confirm the following: 1. That you have read the above information 2. That you voluntarily agree to participate in the survey. Please select your choice below:

☐ Agree

☐ Disagree

Skip To: End of Survey If You are invited to participate in this web-based study aimed at assessing the perceptions on rem... = Disagree

Q2 *Which of the following correctly describes your experience with medical equipment?*

- I work in a Public hospital
- I work in a Private hospital
- I work in an Independent diagnostic imaging centre or laboratory
- I am a student
- Other (Please specify)

  _____

Q3 *Which of the following best describes your current position*

- Manager
- Medical doctor
- Radiographer
- Biomedical/Clinical Engineers/technician/Clinician
- Other (Please specify)

  _____

Q4 *How many years of experience do you have in your profession?*

- 3 - 5 years
- 5 - 10 years
- Over 10 years

Q5 *Please choose from the following, the option that applies to you:*

- I have used only new equipment
- I have used only second hand medical equipment
- I have used both new and second hand equipment
- Others (Please specify)

  _____

Q6 *Have you heard of the medical equipment remanufacturing concept before?*

- Yes
- No

Q7 *Do you know of anybody that has used/is using remanufactured medical equipment?*

- Yes
- No

Q8 *Have you used remanufactured medical equipment before?*

- Yes
- No

Q9 Do you think that post sales technical service support such as maintenance, spare parts supply and training should be sold together with remanufactured medical equipment? **Please tick in the appropriate cell below.**

- **Strongly agree** (Please explain the rationale for your opinion)
  _____
- **Agree** (Please explain the rationale for your opinion)
  _____
- **Neither agree nor disagree** (Please explain the rationale for your opinion)
  _____
- **Disagree** (Please explain the rationale for your opinion)
  _____
- **Strongly disagree** (Please explain the rationale for your opinion)
  _____

Q10 *Assuming you were to purchase an X-ray equipment, what is the least price reduction that would likely make you decide to purchase a remanufactured alternative?* Please tick in the appropriate cell below.

- 10%
- 20%
- 30%
- 40%
- 50%
- Other (Please specify)
  _____
- None

Q11 *On a scale of 1 to 10, please indicate the extent to which you would be more inclined to purchase remanufactured X-ray equipment if it is given the same warranty as that of equivalent new one.* ***Please tick in the appropriate box***

1	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Q12 *Would you purchase direct second hand X-ray equipment instead of a remanufactured one?* Please tick in the appropriate cell below

- Yes
- No

Please state your reason(s) below

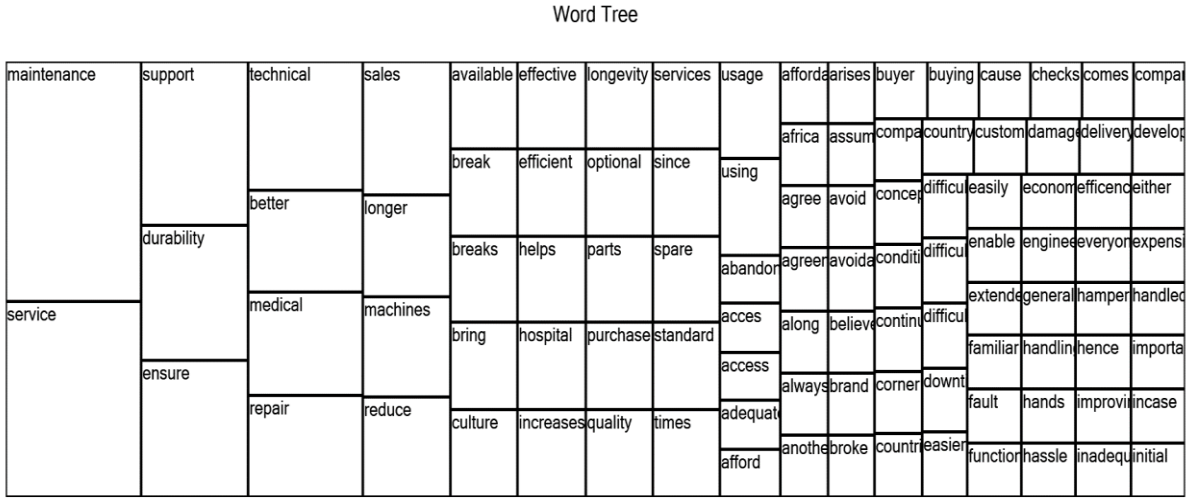
Page Break

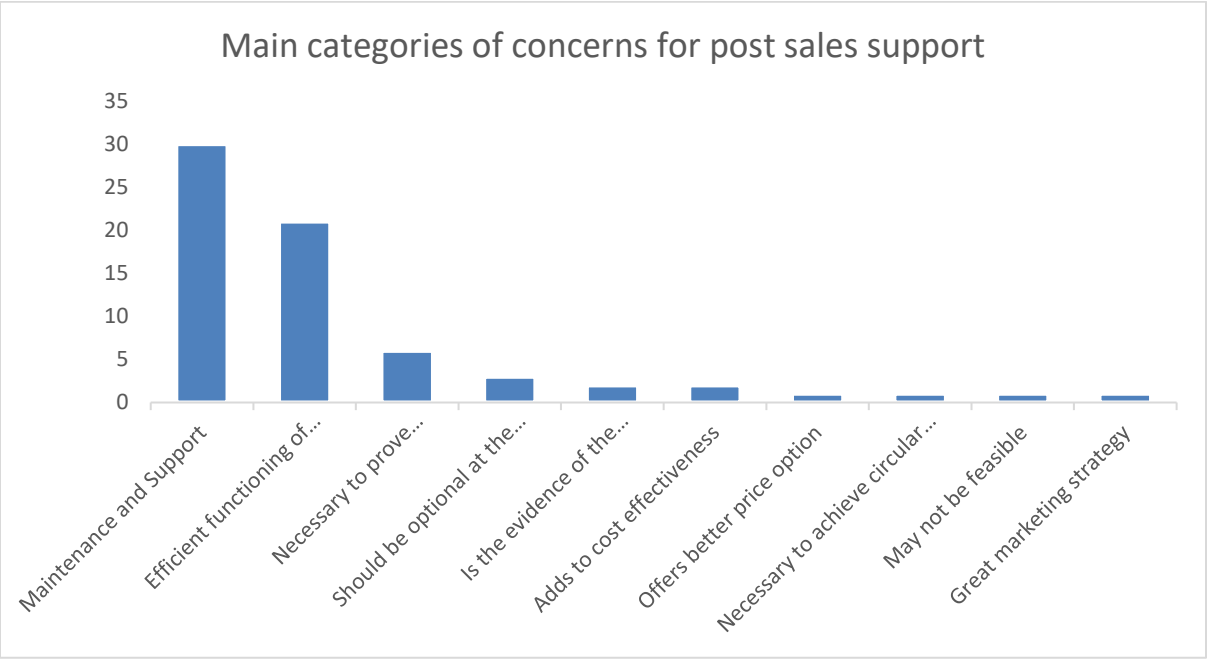
Q13 *In the statements below, please rate your opinion regarding remanufactured medical equipment,* **from strongly disagree to strongly agree**. ***Please tick in the appropriate cell*** **below**

Statements	Strongly disagree	Disagree	Somewhat disagree	Neither disagree nor agree	Somewhat agree (5)	agree (6)	Strongly agree (7)
Purchasing remanufactured X-ray equipment will give access to reliable and durable products.	•	•	•	•	•	•	•
Purchasing remanufactured X-ray equipment will reduce purchasing cost compared to new X-ray equipment.	•	•	•	•	•	•	•
I will be satisfied with the appearance of remanufactured X-ray equipment	•	•	•	•	•	•	•
The performance of remanufactured X-ray equipment can satisfy my expectations.	•	•	•	•	•	•	•
Purchasing remanufactured X-ray equipment can help reduce patient safety issues in our hospitals.	•	•	•	•	•	•	•
I like the idea of using remanufactured X-ray equipment	•	•	•	•	•	•	•
Purchasing remanufactured X-ray equipment is a wise decision	•	•	•	•	•	•	•
It is possible for me to purchase remanufactured X-ray equipment	•	•	•	•	•	•	•
I cannot purchase remanufactured X-ray equipment	•	•	•	•	•	•	•
If I have the option, I will choose to purchase remanufactured X-ray equipment	•	•	•	•	•	•	•

Given the opportunity, I would encourage my colleagues to purchase remanufactured X-ray equipment	•	•	•	•	•	•	•
Those that have important influence on me would approve my purchase and use of remanufactured X-ray equipment	•	•	•	•	•	•	•
My colleagues and friends would also like to purchase remanufactured X-ray equipment if given the option	•	•	•	•	•	•	•
I fear that remanufactured X-ray equipment may not be as safe as new ones and may have some safety risks	•	•	•	•	•	•	•
I am afraid that remanufactured X-ray equipment may not perform as good as new ones and may have safety risks	•	•	•	•	•	•	•
I am afraid that remanufactured X-ray equipment will not perform like new ones such that I may spend more time on repairs.	•	•	•	•	•	•	•
I fear it will not be possible to derive commensurate utility for monetary investment in purchasing remanufactured X-ray equipment.	•	•	•	•	•	•	•
I am afraid that the provision of after sales services for remanufactured X-ray equipment cannot be enforced.	•	•	•	•	•	•	•

Participants' perspectives with respect to including post sales technical support with medical equipment remanufacturing




Main categories of concerns for post sales support
35
30
25
20
15
10
5
0
Maintenance and Support
Efficient functioning of...
Necessary to prove...
Should be optional at the...
Is the evidence of the...
Adds to cost effectiveness
Offers better price option
Necessary to achieve circular...
May not be feasible
Great marketing strategy

Summary of responses to part 4 of the questionnaire

S/N	Statements	Strongly agree	Agree	Somewhat agree	Neither	Somewhat disagree	Disagree	Strongly disagree	
Q1	Purchasing remanufactured X-ray equipment will give access to reliable and durable products.	9%	34%	28%	12%	8%	4%	3%	116
Q2	Purchasing remanufactured X-ray equipment will reduce purchasing cost compared to new X-ray equipment.	28%	41%	18%	1%	5%	2%	4%	114
Q3	I will be satisfied with the appearance of remanufactured X-ray equipment.	10%	41%	16%	19%	7%	4%	4%	113
Q4	The performance of remanufactured X-ray equipment can satisfy my expectations	10%	36%	27%	17%	4%	3%	4%	114
Q5	Purchasing remanufactured X-ray equipment can help reduce patient safety issues in our hospitals.	3%	28%	16%	31%	8%	12%	3%	113
Q6	I like the idea of purchasing remanufactured X-ray equipment	8%	32%	31%	15%	3%	8%	4%	114
Q7	Purchasing remanufactured X-ray equipment is a wise decision	7%	34%	29%	14%	5%	7%	4%	112
Q8	It is possible for me to purchase remanufactured X-ray equipment	5%	47%	20%	14%	4%	4%	4%	113
Q9	I cannot purchase remanufactured X-ray equipment	1%	6%	5%	16%	11%	47%	14%	111
Q10	If I have the option, I will choose to purchase remanufactured X-ray equipment	4%	30%	26%	17%	7%	11%	4%	112
Q11	Given the opportunity, I would encourage my colleagues to purchase remanufactured X-ray equipment	4%	41%	18%	20%	4%	11%	3%	112
Q12	Those that have important influence on me would approve my purchase and use of remanufactured X-ray equipment	4%	26%	23%	31%	6%	9%	2%	111

Q13	My colleagues and friends would also purchase remanufactured X-ray equipment if given the option	4%	27%	27%	32%	4%	4%	2%	112
Q14	Remanufactured X-ray equipment will not be as safe as new ones.	6%	26%	37%	6%	10%	12%	2%	110
Q15	Remanufactured X-ray equipment will not perform as good as new ones	5%	24%	33%	13%	9%	13%	4%	111
Q16	Remanufactured X-ray equipment will not perform as good as new ones such that I may spend more time on repairs.	6%	22%	28%	13%	12%	15%	4%	110
Q17	It will not be possible to derive commensurate utility for monetary investment in purchasing remanufactured X-ray equipment.	5%	14%	24%	17%	15%	20%	4%	111
Q18	I am afraid that after sales services for remanufactured product will not be possible	7%	22%	24%	18%	5%	20%	4%	111

Appendix D1: Validation tool

Validation tool

Start of Block: Framework Validation

You are invited to participate in validating a proposed framework (shown below) for characterising medical equipment remanufacture/refurbishment. Validation from the industry is sought to determine the usefulness and usability of the framework. The validation is being conducted by Solomon Eze, a student of the University of Strathclyde, Glasgow. There is no risk envisaged to arise from participating in this study. Your responses will be collected and stored under password protection on the University's computer. They will be used anonymously and deleted after the validation.

Please contact Solomon at solomon.eze.strath.ac.uk if you have any questions. Thank you.

By clicking on the 'Agree' button below, you confirm the following:

- That you have read the above information
- That you voluntarily agree to participate in the survey.

Please select your choice below:

- Agree (1)
- Disagree (2)

Skip To: End of Survey If You are invited to participate in validating a proposed framework (shown below) for characterisin... = Disagree

Q1 Please state your name

_____

Q2 Please state the name of your organisation

_____

Q3 Please state your organisation's /company's core business

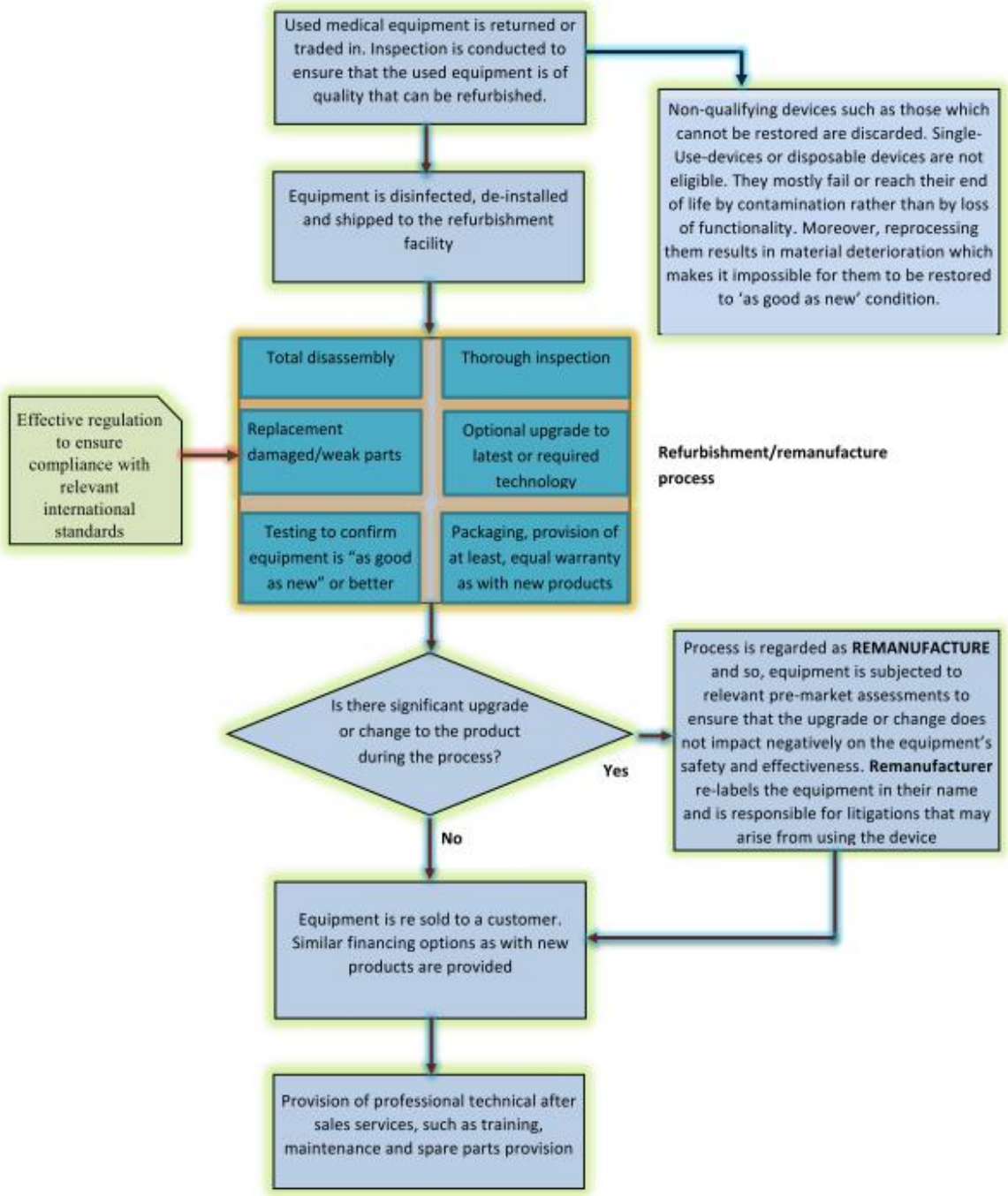
_____

Q4 Please state the length of experience you have in your role in years

_____

End of Block: Framework Validation

Start of Block: Block 1



Tool proposed for proposed

Q5 To what extent do you agree that the above chart clearly represents activities that should be involved in medical equipment refurbishment?

0 1 2 3 4 5 6 7 8 9 10

Please slide the bar accordingly ()

Please state the rationale for your opinion in question Q5; including additional measures or activities that can increase the quality of refurbished medical devices.

_____

Q6 To what extent do you agree that medical equipment regarded as 'refurbished' should be restored to "as good as new" condition?

0 1 2 3 4 5 6 7 8 9 10

Please slide the bar accordingly ()

Q7 To what extent do you agree that single-use devices cannot be restored to 'as good as new' condition?

0 1 2 3 4 5 6 7 8 9 10

Please slide the bar accordingly ()

Please provide the rationale for your opinion in question Q7

_____

Q8 To what extent do you agree that the processes as conveyed by the chart, represents the current practice with medical device refurbishment/remanufacture?

0 1 2 3 4 5 6 7 8 9 10

Please slide the bar accordingly ()

Please provide the rationale for your opinion in question Q8.

_____

Q9 To what extent do you agree that the processes represented by the chart will yield high quality medical devices for developing countries if implemented successfully?

0 1 2 3 4 5 6 7 8 9 10

Please slide the bar accordingly ()

Please provide the rationale for your opinion in question Q9 including any other subprocesses or measures that should be taken to improve quality of resultant product

_____

Q10 To what extent do you agree that refurbished/remanufactured medical devices should be marketed with the same level of professional post-sale technical support as with new equivalents?

0 1 2 3 4 5 6 7 8 9 10

Please slide the bar accordingly ()

Please provide the rationale for your opinion in question Q10 and whether you think it is realistic to provide such services?

_____

Q11 To what extent do you agree that refurbished equipment claimed to have been upgraded in the process needs to be subjected pre- and post-market requirements for verification?

0 1 2 3 4 5 6 7 8 9 10

Please slide the bar accordingly ()

Please provide the rationale for your opinion in question Q11

_____

Q12 Please provide your e-mail address.

_____

End of Block: Block 1

Appendix D2: Summary of inputs in Validation phase 1

Participants' Names	Q5 To what extent do you agree that the above chart clearly represents activities that should be involved in medical equipment refurbishment? - Please slide the bar accordingly	Q5b Please state the rationale for your opinion in question Q5; including additional measures or activities that can increase the quality of refurbished medical devices.	Q6 To what extent do you agree that medical equipment regarded as 'refurbished' should be restored to "as good as new" condition? - Please slide the bar accordingly	Q7 To what extent do you agree that single-use devices cannot be restored to 'as good as new' condition? - Please slide the bar accordingly	Q7b: Please provide the rationale for your opinion in question Q7
	10	Every measure necessary to eliminate risk is important during refurbishment. Regulation is also very important to ensure that what is claimed is actually what is done.	6	10	They are sterilised not repaired and this is a different operation
Dr ChrXXXX	7	the aim of medical devices companies is producing high quality devices with lower price hence I think this proposal can achieve this aim to an extent	6	9	I think using personal tools and devices as new brand is not accepted by most people, in addition to the reasons of being reached their life end and may be used under abnormal conditions by their owners.
AbdXXXX	5	the chart clearly related the function of medical devices between the Users and manufacturer	4	10	somehow agree

IbrXXXX	5	Medical devices refurblishment should conform to regulatory standards. There is no mention of ISO 13485 which enshrines quality management procedure(s)	8	3	Yes, a good number of medical devices can be restored to "as good as new" but the class of the device should be considered and the regulatory standards must be strickly adhered to.
IdoXXXX	6	Replacing major components of a medical device alone does not qualify it to become a new device, other components which may be at the time of testing may not show any form of weakness, it does not mean these parts will still function as expected by the end of their expected life span.	3	8	Single-use devices are expected to go back to the manufacturer for decommissioning and/or recycling.
DanXXXX	7	The block diagram do not adequately represents the proper flow diagram of the concept in medical equipment refurbishment. For example after the inspection is conducted, the equipment should be categorized according to types and functions e.g Lab equipment ofr Radiology equipment.	8	8	My opinion is that a single use devices cannot be restored to as good as new with out much compromise to the specific function of such device.
Dr. KarXXXX	10	This can make if more affordable for low income countries	9	10	It is single use for a purpose. Contamination can leave debris which cannot be removed completely.

CariXXXX	10	The remanufactured equipment should follow strict regulations and also have similar warranty and finance arrangements as new ones.	10	10	Sometimes machines are just thrown away because newer ones have been produced and the older models become useless. Remanufacturing will reduce waste and ultimately itâ€™s impact on the environment by bringing the older models up to the level of new and also certifying them to be functional and reliable.
Dr. AuXXXX	9		10	8	sterlisation, maintenance are based on other devices and skills of the personnel conducting the restoration activity, and these people don't have same skills as manufacturers
EdXXXXX	10	It covers to a large extent what should be done.	10	8	They are disposables
ObeXXXX	9		9	7	
OyeXXXX	8		10	6	Such devices might be manufactured in such a way that remanufacturing them would be impossible

Participants' Names	Q8 To what extent do you agree that the processes as conveyed by the chart, represents the current practice with medical device refurbishment/remanufacture? - Please slide the bar accordingly	Q8b: Rationale for Q8	Q9 To what extent do you agree that the processes represented by the chart will yield high quality medical devices for developing countries if implemented successfully? - Please slide the bar accordingly	Q9b Please provide the rationale for your opinion in question Q9 including any other subprocesses or measures that should be taken to improve quality of resultant product	Q10 To what extent to you agree that refurbished/remanufactured medical equipment should be marketed with the same level of professional post sales techical support as with new equivalent?	Q10b Please provide the rationale for your opinion in question Q10 and whether you think it is realistic to provide such services?
Dr ChrXXXX	10	Because there is effective regulation.	10	It includes options for eliminating poor quality parts. Regulation supports this. Moreover, if the refurbisher offers same post market warranty and services as with new equipment, then they will most likely be sure of the quality.	10	It would help to make prolong the use of the equipment

AbdXXXX	3	I think there are eithical conditions that prevent using the refurbished medical devices as new goods, in addition, there are a strong competetion between the medical devices companies in the developed companies and I think users will choose the new brands rather than restored or refurbished	7	I thinks using this chart will yield an accepted quality devices that can be used in the developing countries stipulating sale them with lower cost than the real new brand in these developing countries as the living cost is much lower than these in the developed countries.	5	I believe that most of the electronic components have a specific life span, hence the refurbished devices will have most of their parts as old components with some exceptions of these damaged. that will need more post sale technical support after sale
IbrXXXX	6	strongly agree	8	strongly agree	7	agree
IdoXXXX	4	Not sure this is the practice	2	Developing countries should not be dumping grounds for substandard (refurblished) products. Medical products refurblishment should be done with much consideration to the class of the device.	10	The current EU changes in medical devices regulatory provides for post-sale survelliance through the use of barcode for each product. Hence, such service is realistic
DanXXXX	6	Medical facilities with such medical devices would use a chart as this to refurbish their devices, especially for hospitals/facilities that do not have the financial clout to replace such expensive equipment.	5	The refurbish devices in no time become white elephants with no spare parts.	9	Servicing and post-sales services for a refurbished medical device would be more rampant compared to a new equivalent

Dr. KarXXXX	7	The intergrity of the current practice is at stake.	7	The chart will yield high quality medical devices for the developing countries if implemented successful with adequate training and quality control and with original parts and components.ly	8	Post-sale technical support should be given more attention compared with new equivalent.
CariXXXX	3	This seems to occur rarely compared to its global potential	9	Compliance and Quality assurance needs to be strict and respected, if not penalised.	10	I believe the refurbishment is to be done to the same standard as the orginal manufacturing process
Dr. AuXXXX	6	Most times the refurbished machines have shorter manufacturer warranty though there can be an option to purhase extended warranty for these	10	Developing countries may still struggle to raise enough money to purchase newer machines but can be encouraged if they know that hey can buy older ones that can provide same services as the new. Furthermore, it will be very reassuring to know that should they wish to change to the newer models, their older ones can be easily resold to the remanufacturing factories who will then use them to make better machines that other people can purchase	10	Ability to provide technical support is central to buyer confidence for remanufactured products as the buyer knows that ghey can be assisted if machines ever fails
EdXXXXX	9	based on ISO and CE marking procedures	10	it has major areas required in in re-manufacturing	10	to ensure safety and quality results

ObeXXXX	10	Compliant with the literature in some aspects and more advanced in others.	10		10	Providing such services will be excellent in addressing the medical equipment needs of the developing countries.
OyeXXXX	9		10		9	
IkoXXXX	5	Because I have not seen another to double check	9	The chart looks technical realistic and could stand test of time	9	The post-sale technical support will go a long way to sustain the remanufactured equipment

Participants' Names	Q11 To what extent do you agree that refurbished equipment claimed to have been upgraded in the process needs to be subjected pre- and post-market requirements for verification? - Please slide the bar accordingly	Q11b Please provide the rationale for your opinion in question Q11
Dr ChrXXXX	10	Serves as validation for what is claimed.
AbdXXXX	8	I think any medical device should be subjected to pre- and post- market requirements whether was new brand or refurbished, but being refurbished or upgraded will increase the need of this verification.
IbrXXXX	8	strongly agree
IdoXXXX	10	See the current EU changes Medical Devices Regulation
DanXXXX	9	The refurbished equipment must be able to perform as specified by the manufacture when it was first subjected to verification requirements.
Dr. KarXXXX	8	The process needs to be subjected to pre- and post market requirements for verification because human life is involved and the quality of life must be improved.
CariXXXX	10	Sounds like right next step for verification.
Dr. AuXXXX	10	We all know that newer machines are generally safer than older models. If the remanufacturer claims that they have managed to make the older model as safe and as effective as the newer models then there should be an objective wat of testing this out.
EdXXXXX	10	to ensure there are within safe limits as per international rules and regulations
ObeXXXX	5	Not in all cases
OyeXXXX	9	
IkoXXXX	9	This will ensure quality and boost consumer confidence

Appendix D3: Final validation instrument and participant inputs

QUESTONNAIRE

This questionnaire is constituted as follows:

Part I: Brief background information of the respondent

Part II: Description of the framework

Part III: Validation of the framework against correctness, completeness, relevance, ease of implementation

Part IV: Recommendations for improving the framework

PART I: BRIEF BACKGROUND INFORMATION OF RESPONDENT

Could you please, briefly describe your yourself and your expertise in relation to medical devices?

Name (Optional): _____

Job Title: _____

How long have you been working in this profession? _____

Do you understand medical device/equipment refurbishment process associated standards? _____

PART II: DESCRIPTION OF MEDICAL EQUIPMENT REMANUFACTURING FRAMEWORKS PRESENTED

Given the inconsistencies associated with terminologies related to the restoration of used medical equipment, a definition for remanufacturing which captures the peculiarities and requirements of medical devices becomes expedient. Recognising the importance of complying with appropriate quality standards, requirements of prevailing national regulations of medical devices on key issues such as “intended use”, the provision of post sales technical support and optional financing options for new device manufacturers, it becomes pertinent to require remanufacturers to also do the same. Hence, the frameworks developed in this research highlight the importance of standards and ensures that “intended use” is maintained. Key regulatory requirements such as traceability responsibilities, observance of key standards such as Quality management and Risk

management standards as well as other device-related standards. It therefore expands the definition as follows:

"The industrial process by which a used equipment is restored to at least, original equipment manufacturer's performance and safety specifications from customers' and regulatory perspectives; with the resultant product capable of performing its intended use and given a warranty as well as provision for professional post-sales services that are at least as good as those given to an equivalent new one."

The processes leading to the achievement of this definition is presented in the frameworks in the Appendix. Figure 1 assesses the key factors that should be considered prior to implementing remanufacturing. Figure 2 details the processes for medical equipment remanufacturing which has the IEC 62077 Standard for Good Refurbishment Practice as backbone but includes other features.

PART III: VALIDATION OF THE FRAMEWORKS

Please provide your assessment of the framework against the questions listed below. Please provide your input by crossing the boxes corresponding to your chosen answers. For the purpose of this exercise, the decision support framework and process model are collectively referred to as "tools".

S/N	Statement	Strongly disagree	Disagree	Neither	Agree	Strongly agree
1	The process represented tools is feasible for medical equipment remanufacturing					
2	The activities represented in the tools are important to medical equipment remanufacturing					
3	The activities represented in tools can be implemented in real practice					
4	The tools will help to understand the various strategies for carrying out medical equipment remanufacture					
5	The tools are not useful for remanufacturing companies in organising their operations					
6	The tools are acceptable description of high-level activities necessary in medical equipment remanufacture					
7	Failure to implement medical equipment remanufacturing as represented in the tools may introduce unwanted results					
8	I find the tools difficult to follow					

9	There are many major issues missing from the tools					
10	The medical equipment remanufacturing process described in tools is an important area to address					
11	Medical equipment remanufactured based on the tools will be poor					
12	Preliminary decisions and process model in the tools are useful in some way					
13	The tools can be used to help medical equipment remanufacturers to make improvements					
14	The tools have the potential to help medical equipment remanufacturers to make better decisions					
15	The tools will be useful for medical equipment remanufacturers in the present time					

PART IV: RECOMMENDATIONS FOR IMPROVING THE RELEVANCE OF THE FRAMEWORK

I would like to ask your general opinion regarding how to improve the framework presented in the attached document. Any comment would be highly appreciated. Please provide your comments below

1. Could you please write in the space below, any comments regarding possible improvement to the framework?

2. Could you please provide any suggestions for how to make the above framework more relevant to practice?

QUESTONNAIRE

This questionnaire is constituted as follows:

Part I: Brief background information of the respondent

Part II: Description of the framework

Part III: Validation of the framework against correctness, completeness, relevance, ease of implementation

Part IV: Recommendations for improving the framework

PART I: BRIEF BACKGROUND INFORMATION OF RESPONDENT

Could you please, briefly describe your yourself and your expertise in relation to medical devices?

Name (Optional): [redacted]

Job Title: Academic researcher in medical devices remanufacturing

How long have you been working in this profession? 3 years

Do you understand medical device/equipment refurbishment process associated standards?

Yes

PART II: DESCRIPTION OF MEDICAL EQUIPMENT REMANUFACTURING FRAMEWORKS PRESENTED

Given the inconsistencies associated with terminologies related to the restoration of used medical equipment, a definition for remanufacturing which captures the peculiarities and requirements of medical devices becomes expedient. Recognising the importance of complying with appropriate quality standards, requirements of prevailing national regulations of medical devices on key issues such as "intended use", the provision of post sales technical support and optional financing options for new device manufacturers, it becomes pertinent to require remanufacturers to also do the same. Hence, the frameworks developed in this research highlight the importance of standards and ensures that "intended use" is maintained. Key regulatory requirements such as traceability responsibilities, observance of key standards such as Quality management and Risk management standards as well as other device-related standards. It therefore expands the definition as follows:

"The industrial process by which a used equipment is restored to at least, original equipment manufacturer's performance and safety specifications from customers' and regulatory perspectives, with the resultant product capable of performing its intended use and given a warranty as well as provision for professional post-sales services that are at least as good as those given to an equivalent new one."

The processes leading to the achievement of this definition is presented in the frameworks in the Appendix. Figure 1 assesses the key factors that should be considered prior to implementing remanufacturing. Figure 2 details the processes for medical equipment remanufacturing which has the IEC 62077 Standard for Good Refurbishment Practice as backbone but includes other features.

PART III: VALIDATION OF THE FRAMEWORKS

Please provide your assessment of the framework against the questions listed below. Please provide your input by crossing the boxes corresponding to your chosen answers. For the purpose of this exercise, the decision support framework and process model are collectively referred to as "tools".

S/N	Statement	Strongly disagree	Disagree	Neither	Agree	Strongly agree
1	The process represented tools is feasible for medical equipment remanufacturing				✓	
2	The activities represented in the tools are important to medical equipment remanufacturing				✓	
3	The activities represented in tools can be implemented in real practice				✓	
4	The tools will help to understand the various strategies for carrying out medical equipment remanufacture				✓	
5	The tools are not useful for remanufacturing companies in organising their operations	✓				
6	The tools are acceptable description of high-level activities necessary in medical equipment remanufacture					✓
7	Failure to implement medical equipment remanufacturing as represented in the tools may introduce unwanted results				✓	
8	I find the tools difficult to follow		✓			
9	There are many major issues missing from the tools	✓				
10	The medical equipment remanufacturing process described in tools is an important area to address					✓
11	Medical equipment remanufactured based on the tools will be poor	✓				
12	Preliminary decisions and process model in the tools are useful in some way				✓	
13	The tools can be used to help medical equipment remanufacturers to make improvements				✓	
14	The tools have the potential to help medical equipment remanufacturers to make better decisions				✓	
15	The tools will be useful for medical equipment remanufacturers in the present time				✓	

PART IV: RECOMMENDATIONS FOR IMPROVING THE RELEVANCE OF THE FRAMEWORK

I would like to ask your general opinion regarding how to improve the framework presented in the attached document. Any comment would be highly appreciated. Please provide your comments below

1. Could you please write in the space below, any comments regarding possible improvement to the framework?

The tool covers the key steps involved in medical equipment remanufacturing.

2. Could you please provide any suggestions for how to make the above framework more relevant to practice?

None

QUESTONNAIRE

This questionnaire is constituted as follows:

Part I: Brief background information of the respondent

Part II: Description of the framework

Part III: Validation of the framework against correctness, completeness, relevance, ease of implementation

Part IV: Recommendations for improving the framework

PART I: BRIEF BACKGROUND INFORMATION OF RESPONDENT

Could you please, briefly describe your yourself and your expertise in relation to medical devices?

Name (Optional): [redacted]

Job Title: [redacted]

How long have you been working in this profession? 22 YEARS.

Do you understand medical device/equipment refurbishment process associated standards?

YES.

PART II: DESCRIPTION OF MEDICAL EQUIPMENT REMANUFACTURING FRAMEWORKS PRESENTED

Given the inconsistencies associated with terminologies related to the restoration of used medical equipment, a definition for remanufacturing which captures the peculiarities and requirements of medical devices becomes expedient. Recognising the importance of complying with appropriate quality standards, requirements of prevailing national regulations of medical devices on key issues such as "intended use", the provision of post sales technical support and optional financing options for new device manufacturers, it becomes pertinent to require remanufacturers to also do the same. Hence, the frameworks developed in this research highlight the importance of standards and ensures that "intended use" is maintained. Key regulatory requirements such as traceability responsibilities, observance of key standards such as Quality management and Risk management standards as well as other device-related standards. It therefore expands the definition as follows:

"The industrial process by which a used equipment is restored to at least, original equipment manufacturer's performance and safety specifications from customers' and regulatory perspectives; with the resultant product capable of performing its intended use and given a warranty as well as provision for professional post-sales services that are at least as good as those given to an equivalent new one."

The processes leading to the achievement of this definition is presented in the frameworks. The first part of framework 1 addresses terminological issue associated with remanufacturing in the industry; namely: "if the used product is not disassembled in the process, then the process cannot be considered as remanufacturing. The second part of framework 1 assesses the key factors that should

PART III: VALIDATION OF THE FRAMEWORKS

Please provide your assessment of the framework against the questions listed below. Please provide your input by crossing the boxes corresponding to your chosen answers. For the purpose of this exercise, the decision support framework and process model are collectively referred to as "tools".

S/N	Statement	Strongly disagree	Disagree	Neither	Agree	Strongly agree
1	The process represented tools is feasible for medical equipment remanufacturing				✓	
2	The activities represented in the tools are important to medical equipment remanufacturing				✓	
3	The activities represented in tools can be implemented in real practice				✓	
4	The tools will help to understand the various strategies for carrying out medical equipment remanufacture					✓
5	The tools are not useful for remanufacturing companies in organising their operations	✓				
6	The tools are acceptable description of high-level activities necessary in medical equipment remanufacture				✓	
7	Failure to implement medical equipment remanufacturing as represented in the tools may introduce unwanted results					✓
8	I find the tools difficult to follow		✓			
9	There are many major issues missing from the tools			✓		
10	The medical equipment remanufacturing process described in tools is an important area to address				✓	
11	Medical equipment remanufactured based on the tools will be poor		✓			
12	Preliminary decisions and process model in the tools are useful in some way				✓	
13	The tools can be used to help medical equipment remanufacturers to make improvements				✓	
14	The tools have the potential to help medical equipment remanufacturers to make better decisions				✓	
15	The tools will be useful for medical equipment remanufacturers in the present time				✓	

PART III: RECOMMENDATIONS FOR IMPROVING THE RELEVANCE OF THE FRAMEWORK

I would like to ask your general opinion regarding how to improve the framework presented in the attached document. Any comment would be highly appreciated.

Follow life cycle of Medical Devices.

1Could you please write in the space below, any comments regarding possible improvement to the framework?

Target your customer correctly. Understand the regulatory frameworks and their limitations. Remember that by remaining factoring you become to some degree the manufacturer.

Could you please provide any suggestions for how to make the above framework more relevant to practice?

- Understand the Chinese Model
- Understand the European model
- And build a hybrid model to meet your needs.

QUESTONNAIRE

This questionnaire is constituted as follows:

Part I: Brief background information of the respondent

Part II: Description of the framework

Part III: Validation of the framework against correctness, completeness, relevance, ease of implementation

Part IV: Recommendations for improving the framework

PART I: BRIEF BACKGROUND INFORMATION OF RESPONDENT

Could you please, briefly describe your yourself and your expertise in relation to medical devices?

Name (Optional): [redacted]

Job Title: [redacted]

How long have you been working in this profession? 10 years

Do you understand medical device/equipment refurbishment process associated standards?

Yes

PART II: DESCRIPTION OF MEDICAL EQUIPMENT REMANUFACTURING FRAMEWORKS PRESENTED

Given the inconsistencies associated with terminologies related to the restoration of used medical equipment, a definition for remanufacturing which captures the peculiarities and requirements of medical devices becomes expedient. Recognising the importance of complying with appropriate quality standards, requirements of prevailing national regulations of medical devices on key issues such as "intended use", the provision of post sales technical support and optional financing options for new device manufacturers, it becomes pertinent to require remanufacturers to also do the same. Hence, the frameworks developed in this research highlight the importance of standards and ensures that "intended use" is maintained. Key regulatory requirements such as traceability responsibilities, observance of key standards such as Quality management and Risk management standards as well as other device-related standards. It therefore expands the definition as follows:

"The industrial process by which a used equipment is restored to at least, original equipment manufacturer's performance and safety specifications from customers' and regulatory perspectives; with the resultant product capable of performing its intended use and given a warranty as well as provision for professional post-sales services that are at least as good as those given to an equivalent new one."

The processes leading to the achievement of this definition is presented in the frameworks in the Appendix. Figure 1 assesses the key factors that should be considered prior to implementing remanufacturing. Figure 2 details the processes for medical equipment remanufacturing which has the IEC 62077 Standard for Good Refurbishment Practice as backbone but includes other features.

PART III: VALIDATION OF THE FRAMEWORKS

Please provide your assessment of the framework against the questions listed below. Please provide your input by crossing the boxes corresponding to your chosen answers. For the purpose of this exercise, the decision support framework and process model are collectively referred to as "tools".

S/N	Statement	Strongly disagree	Disagree	Neither	Agree	Strongly agree
1	The process represented tools is feasible for medical equipment remanufacturing					✓
2	The activities represented in the tools are important to medical equipment remanufacturing					✓
3	The activities represented in tools can be implemented in real practice				✓	
4	The tools will help to understand the various strategies for carrying out medical equipment remanufacture					✓
5	The tools are not useful for remanufacturing companies in organising their operations		✓			
6	The tools are acceptable description of high-level activities necessary in medical equipment remanufacture					✓
7	Failure to implement medical equipment remanufacturing as represented in the tools may introduce unwanted results					✓
8	I find the tools difficult to follow		✓			
9	There are many major issues missing from the tools		✓			
10	The medical equipment remanufacturing process described in tools is an important area to address					✓
11	Medical equipment remanufactured based on the tools will be poor		✓			
12	Preliminary decisions and process model in the tools are useful in some way					✓
13	The tools can be used to help medical equipment remanufacturers to make improvements					✓
14	The tools have the potential to help medical equipment remanufacturers to make better decisions				✓	
15	The tools will be useful for medical equipment remanufacturers in the present time					✓

PART IV: RECOMMENDATIONS FOR IMPROVING THE RELEVANCE OF THE FRAMEWORK

I would like to ask your general opinion regarding how to improve the framework presented in the attached document. Any comment would be highly appreciated. Please provide your comments below

1. Could you please write in the space below, any comments regarding possible improvement to the framework?

2. Could you please provide any suggestions for how to make the above framework more relevant to practice?

QUESTONNAIRE

This questionnaire is constituted as follows:

Part I: Brief background information of the respondent

Part II: Description of the framework

Part III: Validation of the framework against correctness, completeness, relevance, ease of implementation

Part IV: Recommendations for improving the framework

PART I: BRIEF BACKGROUND INFORMATION OF RESPONDENT

Could you please, briefly describe your yourself and your expertise in relation to medical devices?

Name (Optional): [redacted]

Job Title: [redacted]

How long have you been working in this profession? 20 years in medical profession

Do you understand medical device/equipment refurbishment process associated standards?

Yes

PART II: DESCRIPTION OF MEDICAL EQUIPMENT REMANUFACTURING FRAMEWORKS PRESENTED

Given the inconsistencies associated with terminologies related to the restoration of used medical equipment, a definition for remanufacturing which captures the peculiarities and requirements of medical devices becomes expedient. Recognising the importance of complying with appropriate quality standards, requirements of prevailing national regulations of medical devices on key issues such as "intended use", the provision of post sales technical support and optional financing options for new device manufacturers, it becomes pertinent to require remanufacturers to also do the same. Hence, the frameworks developed in this research highlight the importance of standards and ensures that "intended use" is maintained. Key regulatory requirements such as traceability responsibilities, observance of key standards such as Quality management and Risk management standards as well as other device-related standards. It therefore expands the definition as follows:

"The industrial process by which a used equipment is restored to at least, original equipment manufacturer's performance and safety specifications from customers' and regulatory perspectives; with the resultant product capable of performing its intended use and given a warranty as well as provision for professional post-sales services that are at least as good as those given to an equivalent new one."

The processes leading to the achievement of this definition is presented in the frameworks in the Appendix. Figure 1 assesses the key factors that should be considered prior to implementing remanufacturing. Figure 2 details the processes for medical equipment remanufacturing which has the IEC 62077 Standard for Good Refurbishment Practice as backbone but includes other features.

PART III: VALIDATION OF THE FRAMEWORKS

Please provide your assessment of the framework against the questions listed below. Please provide your input by crossing the boxes corresponding to your chosen answers. For the purpose of this exercise, the decision support framework and process model are collectively referred to as "tools".

S/N	Statement	Strongly disagree	Disagree	Neither	Agree	Strongly agree
1	The process represented tools is feasible for medical equipment remanufacturing					X
2	The activities represented in the tools are important to medical equipment remanufacturing					X
3	The activities represented in tools can be implemented in real practice				X	
4	The tools will help to understand the various strategies for carrying out medical equipment remanufacture				x	
5	The tools are not useful for remanufacturing companies in organising their operations	X				
6	The tools are acceptable description of high-level activities necessary in medical equipment remanufacture				X	
7	Failure to implement medical equipment remanufacturing as represented in the tools may introduce unwanted results			X		
8	I find the tools difficult to follow		X			
9	There are many major issues missing from the tools	X				
10	The medical equipment remanufacturing process described in tools is an important area to address					X
11	Medical equipment remanufactured based on the tools will be poor	X				
12	Preliminary decisions and process model in the tools are useful in some way				X	
13	The tools can be used to help medical equipment remanufacturers to make improvements				X	
14	The tools have the potential to help medical equipment remanufacturers to make better decisions				X	
15	The tools will be useful for medical equipment remanufacturers in the present time					X

PART IV: RECOMMENDATIONS FOR IMPROVING THE RELEVANCE OF THE FRAMEWORK

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1. **Could you please write in the space below, any comments regarding possible improvement to the framework?**

A good framework. A little overwhelming on first glance. The main suggestion would be explicit reference to acceptability testing of remanufactured products in appendix 1 as one of the criteria that informs decision to engage in remanufacturing (Decision Support Tool)

2. **Could you please provide any suggestions for how to make the above framework more relevant to practice?**

Being able to put weights on the importance of different incentive criteria (e.g. population need versus market gap , depending on context and purpose of remanufacturing in appendix 1 (decision support tool) may be useful in guiding practitioners in deciding on feasibility of cost effective medical remanufacturing.

QUESTIONNAIRE

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Part III: Validation of the framework against correctness, completeness, relevance, ease of implementation

Part IV: Recommendations for improving the framework

PART I: BRIEF BACKGROUND INFORMATION OF RESPONDENT

Could you please, briefly describe your yourself and your expertise in relation to medical devices?

Name (Optional): [redacted]

Job Title: LECTURER I - PUBLIC HEALTH & ENVIRONMENTAL ENGINEERING.

How long have you been working in this profession? 5 YEARS

Do you understand medical device/equipment refurbishment process associated standards?

YES

PART II: DESCRIPTION OF MEDICAL EQUIPMENT REMANUFACTURING FRAMEWORKS PRESENTED

Given the inconsistencies associated with terminologies related to the restoration of used medical equipment, a definition for remanufacturing which captures the peculiarities and requirements of medical devices becomes expedient. Recognising the importance of complying with appropriate quality standards, requirements of prevailing national regulations of medical devices on key issues such as "intended use", the provision of post sales technical support and optional financing options for new device manufacturers, it becomes pertinent to require remanufacturers to also do the same. Hence, the frameworks developed in this research highlight the importance of standards and ensures that "intended use" is maintained. Key regulatory requirements such as traceability responsibilities, observance of key standards such as Quality management and Risk management standards as well as other device-related standards. It therefore expands the definition as follows:

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13	The tools can be used to help medical equipment remanufacturers to make improvements					✓
14	The tools have the potential to help medical equipment remanufacturers to make better decisions					✓
15	The tools will be useful for medical equipment remanufacturers in the present time					✓

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Part III: Validation of the framework against correctness, completeness, relevance, ease of implementation

Part IV: Recommendations for improving the framework

PART I: BRIEF BACKGROUND INFORMATION OF RESPONDENT

Could you please, briefly describe your yourself and your expertise in relation to medical devices?

Name (Optional): [redacted]

Job Title: General Clinical Engineer[redacted]

How long have you been working in this profession? 10 year

Do you understand medical device/equipment refurbishment process associated standards?

Yes

PART II: DESCRIPTION OF MEDICAL EQUIPMENT REMANUFACTURING FRAMEWORKS PRESENTED

Given the inconsistencies associated with terminologies related to the restoration of used medical equipment, a definition for remanufacturing which captures the peculiarities and requirements of medical devices becomes expedient. Recognising the importance of complying with appropriate quality standards, requirements of prevailing national regulations of medical devices on key issues such as "intended use", the provision of post sales technical support and optional financing options for new device manufacturers, it becomes pertinent to require remanufacturers to also do the same. Hence, the frameworks developed in this research highlight the importance of standards and ensures that "intended use" is maintained. Key regulatory requirements such as traceability responsibilities, observance of key standards such as Quality management and Risk management standards as well as other device-related standards. It therefore expands the definition as follows:

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3	The activities represented in tools can be implemented in real practice				✓	
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5	The tools are not useful for remanufacturing companies in organising their operations	✓				
6	The tools are acceptable description of high-level activities necessary in medical equipment remanufacture					✓
7	Failure to implement medical equipment remanufacturing as represented in the tools may introduce unwanted results				✓	
8	I find the tools difficult to follow		✓			
9	There are many major issues missing from the tools	✓				
10	The medical equipment remanufacturing process described in tools is an important area to address				✓	
11	Medical equipment remanufactured based on the tools will be poor		✓			
12	Preliminary decisions and process model in the tools are useful in some way					✓
13	The tools can be used to help medical equipment remanufacturers to make improvements					✓
14	The tools have the potential to help medical equipment remanufacturers to make better decisions				✓	
15	The tools will be useful for medical equipment remanufacturers in the present time				✓	

PART IV: RECOMMENDATIONS FOR IMPROVING THE RELEVANCE OF THE FRAMEWORK

I would like to ask your general opinion regarding how to improve the framework presented in the attached document. Any comment would be highly appreciated. Please provide your comments below

1. Could you please write in the space below, any comments regarding possible improvement to the framework?

   The Diagram is quite informative at high level as it covers important considerations.

2. Could you please provide any suggestions for how to make the above framework more relevant to practice?

   None

LIST OF PUBLICATIONS

***Eze, S., Ijomah, W. & Wong, T.C. Accessing medical equipment in developing countries through remanufacturing. *Jnl Remanufactur* **9,** 207–233 (2019). https://doi.org/10.1007/s13243-018-0065-7

Eze, S., Ijomah, W. & Wong, T. Remanufacturing: a potential sustainable solution for increasing medical equipment availability. *Jnl Remanufactur* **10,** 141–159 (2020). https://doi.org/10.1007/s13243-020-00080-0

Nwankpa N, Eze, S, Ijomah , W, Gachagan, A, Marshal S. Deep Learning Based Vision Inspection System for Remanufacturing Application. IOS Press, *Advances in Transdisciplinary Engineering Ebook: Advances in Manufacturing Technology* **9,** 535-546 (2019). DOI: 10.3233/ATDE190094

Eze, S., Ijomah, W. & Wong, T. A Decision Support Tool for Medical Equipment Remanufacturing in a Developing Country. International conference on remanufacturing (2019). Amsterdam 23-25 June.

Eze, S., Ijomah, W. & Wong, T. A new definition and framework for medical equipment remanufacturing. Submitted to the Journal of Cleaner Production- under review.

*** First presented at the International conference on remanufacturing at Linkoping 24-26 October, 2017