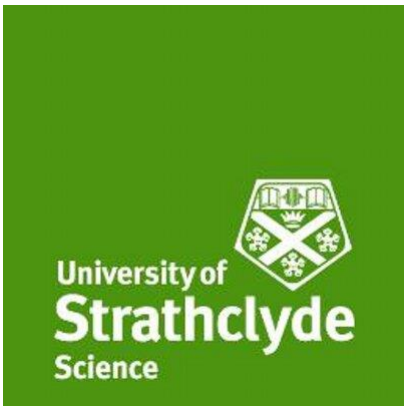

The application of implementation science to the design, test and scale up of high risk medicine care bundles

Natalie McFadyen Weir

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Copyright declaration

Signed:

Date:

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List of publications, reports and presentations

Publications

- Weir NM, Newham R, Corcoran ED, Bennie M. Factors influencing national implementation of innovations within community pharmacy: a systematic review applying the Consolidated Framework for Implementation Research. Forthcoming in Implement Sci pending minor revisions. 2018 Sept 18.
- Weir NM, Newham R, Corcoran ED, Ali Atallah Al-Gethami A, Mohammed Abd Alridha A, Bowie P et al. Application of process mapping to understand integration of high risk medicine care bundles within community pharmacy practice. Res Social Adm Pharm. 2017 Nov 21. Available from: https://www.sciencedirect.com/science/article/pii/S1551741117303303?via%3Dihub. DOI: 10.1016/j.sapharm.2017.11.009.

Reports

- Bennie M, Corcoran ED, Weir NM, Newham R, Watson A, Bowie P. Scottish Patient Safety Programme – Pharmacy in Primary Care Collaborative Final Evaluation Report. Glasgow: University of Strathclyde; 2016. 104 p.

Presentations

- Weir NM, Newham R, Corcoran ED, Bennie M. What barriers and facilitators influence the implementation of new high-risk medicine services in Scottish community pharmacies? Poster presented at: 62nd Annual Scientific Meeting of the Society of Social Medicine; 2018 Sept 7-9; Glasgow, Scotland.
- Easton M, Weir NM (2018). NSAID communication care bundle [Webinar]. Scotland, UK; NHS Education for Scotland; 2018 Mar 08 [cited 2018 Sept 18]. Available from: https://learn.nes.nhs.scot/3077/pharmacy/cpd-resources/nsaid-communication-care-bundle-webinar
- Weir NM, Corcoran ED, Newham R, Watson A, Bowie P, Bennie M. Quality Improvement tools to improve the safe use of high risk medicines – a theory based evaluation. Poster presented at: Royal Pharmaceutical Society National Seminar; 2017 Oct 01; Stirling, Scotland; and at: European Drug Utilisation Research Group (EuroDURG) Conference; 2017 Nov 15-17; Glasgow, Scotland.

- Weir NM, Corcoran ED, Bennie M. Application of consensus methods to refine high risk medicines care bundles. Poster presented at: 10th Health Services Research UK (HSRUK) Symposium; 2017 July 6-7; Nottingham, England.
- Weir NM, Newham R, Corcoran ED, Ali Atallah Al-Gethami A, Mohammed Abd Alridha A, Bowie P et al. Is there scope for rapid implementation of pharmacoepidemiology findings using quality improvement methods? Poster presented at: 32nd International Conference on Pharmacoepidemiology & Therapeutic Risk Management; 2016 Aug 24-27; Dublin, Ireland.

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Abbreviations

ACEi	**angiotensin converting enzyme inhibitor**
ARB	angiotensin receptor blocker
AKI	acute kidney injury
BTS	Breakthrough Series
CFIR	Consolidated Framework for Implementation Research
CI	confidence intervals
CPS	Community Pharmacy Scotland
ERIC	Expert Recommendations for Implementing Change
GG&C	Greater Glasgow and Clyde
GI	gastro-intestinal
GP	general practitioner
HIS	Healthcare Improvement Scotland
INR	international normalized ratio
LLE	Local learning event
NHS	National Health Service
NLE	National learning event
NSAIDs	non-steroidal anti-inflammatory drugs
OAT	oral anti-coagulant therapy
PDSA	Plan-Do-Study-Act
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analysis
SPSP-PC	Scottish Patient Safety Programme – Primary Care
SPSP-PPC	Scottish Patient Safety Programme – Pharmacy in Primary Care
UK	United Kingdom
US	United States

Glossary

Care bundle	**A set of structured interventions which, when consistently delivered, improve patient outcomes and/or health service processes**
Cosmopolitanism	The degree to which an organization is networked with other external organizations.
Relative advantage	Stakeholders' perception of the advantage of implementing the intervention versus an alternative solution.
Symptomology	the set of symptoms characteristic of a medical condition or exhibited by a patient

Thesis abstract

Warfarin and non-steroidal anti-inflammatory drugs (NSAIDs) result in preventable adverse effects and hospital admissions. Internationally, the community pharmacy setting is evolving to offer more patient-facing services. Therefore, the aim of this thesis was to design warfarin and NSAIDs interventions – termed 'care bundles' – and to test their implementation within the Scottish community pharmacy setting. To design the care bundles (Stage 1), consensus methods were applied. A six-item warfarin care bundle and a six-item NSAIDs care bundle were developed, with the NSAIDs care bundle stratified into two parts: a Communication Care Bundle and a Safer Care Bundle. The second stage of this thesis evaluated their pilot implementation within 24 community pharmacies. This involved a postal questionnaire; task-analysis techniques conducted during on-site visits; and telephone interviews with patients. Stage 2 identified that the determinants of implementation success differed between the care bundles. On-site visits to pharmacies evidenced that both care bundles penetrated well within community pharmacy practice and integrated within the dispensing process. However, the care bundles were not always delivered as intended in practice. When patients were interviewed about the warfarin care bundle, none of the warfarin patients recalled receiving a care bundle and its necessity was queried. Conversely, the NSAID participants were satisfied with their experience of the NSAIDs care bundle and it mostly had a positive impact. Overall, these findings indicated that scale up efforts should centre on the NSAIDs care bundle. Stage 3 of this thesis informed this through active dissemination of the results to key stakeholders, which shaped the national implementation strategy for the NSAIDs Communication Care Bundle in 2018. To achieve maximal improvements in the safer use of NSAIDs, national implementation of the NSAIDs Safer Care Bundle should also be realised. Future research should explore the attainment of intended outcomes of the NSAIDs care bundles.

Thesis summary

Background: The use of warfarin and non-steroidal anti-inflammatory drugs (NSAIDs) can result in preventable adverse effects and hospital admissions. Furthermore, risky prescribing practices in relation to these high risk medicines have been identified within Scottish GP practices. Within Scotland and internationally, the role of community pharmacy is evolving from a supply-oriented discipline to one which provides a public health benefit through the provision of patient-facing services. Therefore, in an effort to reduce the harm caused by warfarin and NSAIDs whilst utilising the skillset of community pharmacies, warfarin and NSAIDs care bundles were developed within this setting. The overall aim of this thesis was to further design and test these care bundles to inform their intended national implementation throughout Scotland.

Methods: The design, evaluation and scale up of the warfarin and NSAIDs care bundles involved a three stage process, which was informed by implementation guides stemming from the field of implementation science. These were: the Consolidated Framework of Implementation Research (CFIR); Proctor's taxonomy of implementation outcomes; and the Expert Recommendations for Implementing Change (ERIC) taxonomy.

Stage 1 utilised consensus methods to develop warfarin and NSAIDs care bundles. These were then implemented and refined in 24 community pharmacies across Scotland in February 2017. Stage 2 involved a mixed method evaluation of the care bundles within community pharmacy practice. Firstly, a questionnaire was disseminated (Jun 2017) which explored community pharmacy staff perceptions of the barriers and facilitators influencing the successful implementation of the care bundles. Secondly, the penetration of the care bundles within routine community pharmacy practice and whether they were delivered as intended were explored through the use of a questionnaire (Jun 2017) and task analysis techniques during on-site visits (Oct – Nov 2017). Thirdly, patient perceptions of the care bundles were sought by telephone interviews using a patient satisfaction questionnaire and a semi-structured interview schedule (Apr - Jun 2018). In Stage 3, the findings of Stage 2 were used to develop key recommendations for the national implementation of the warfarin and NSAIDs care bundles.

Results: Stage 1 resulted in the development of a six-question warfarin care bundle focusing on patient knowledge and understanding, and a six-question NSAIDs care bundle

focussing on communication and prescribing risk. The NSAIDs care bundle was stratified into two parts: the NSAIDs Communication Care Bundle, and the NSAIDs Safer Care Bundle. Following their implementation in 24 community pharmacies, the evaluation conducted in Stage 2 identified that the determinants of implementation success differed between the care bundles. The success factors for the NSAIDs care bundle were the pharmacy staff having sufficient knowledge of NSAIDs, perceiving the funding and incentives to be sufficient, and not perceiving the bundle to negatively impact workload. Whereas, for the warfarin care bundle, patient perceptions and the compatibility of the care bundle were success factors. On-site visits to pharmacies (n=8) identified that both care bundles penetrated well within community pharmacy practice, and both integrated similarly within the dispensing process. However, the care bundles were not always delivered as intended in practice. When patients were interviewed about their perceptions of receiving the care bundle, none of the warfarin patients recalled receiving a care bundle and its necessity was queried. Conversely, the NSAIDs participants were satisfied with their experience of the NSAIDs care bundle. It mostly had a positive impact on patients' knowledge and attitudes, their behaviour, and in some instances instigated changes in prescribed medication. However, a minority of patients reported unintended consequences, including increased concerns and reluctance to take their NSAID.

Conclusion: These findings indicated that scale up efforts should focus on the NSAIDs care bundle considering the positive patient perceptions, contrasted with a lack of perceived need for the warfarin care bundle. In November 2017, The Scottish Government announced that the NSAIDs Communication Care Bundle would progress onto national implementation through its incorporation within the community pharmacy contractual framework in May 2018. Stage 3 of this thesis involved disseminating the key evaluation findings to stakeholders. This shaped the national implementation strategy, which included supporting whole team involvement, ensuring pharmacy staff sufficiency in knowledge, and incentivising engagement. To achieve maximal improvements in the safer use of NSAIDs, efforts should focus on also securing the national implementation of the NSAIDs Safer Care Bundle, which can be supported by the findings of this thesis. Future research should explore the attainment of intended outcomes of the national implementation of the NSAIDs care bundles.

Research team

A number of individuals offered valuable contribution throughout this thesis. These individuals and their job role are listed below. Their specific input is referred to throughout this thesis where appropriate.

Marion Bennie (MB)	Professor of Pharmacy Practice (University of Strathclyde) and Chief Pharmacist (Information Services Division)
Rosemary Newham (RN)	Research Fellow (University of Strathclyde)
Emma Dunlop Corcoran (EDC)	Research Associate (University of Strathclyde)
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Ansu Joseph (AJ)	PhD Candidate (University of Strathclyde)
Yvonne Semple (YS)	PhD Candidate (University of Strathclyde) and Lead Pharmacist Medicines Information (NHS Greater Glasgow & Clyde)
Alison Thomson (AT)	Senior Lecturer (University of Strathclyde)
Andrew Laird (AL)	Pharmacist (NHS Greater Glasgow & Clyde)

Chapter 1: Introduction

This thesis describes the development and evaluation of warfarin and non-steroidal anti-inflammatory drugs (NSAIDs) care bundles within the Scottish community pharmacy setting, and poses recommendations for their scale up throughout Scotland. A care bundle is defined as a set of structured interventions which, when consistently delivered, improve patient outcomes and/or health service processes [1, 2]. It is hypothesised that when healthcare interventions are collectively applied as part of a packaged bundle, the changes are more likely to be implemented [3]. To appreciate the surrounding contextual factors that could impact aspects of these care bundles within community pharmacy practice, this chapter outlines the community pharmacy setting in Scotland, and describes the emergence of patient safety and quality improvement within Scotland's national healthcare strategies. Thereafter, the development and evaluation of early iterations of the warfarin and NSAIDs care bundles are described.

1.1 Pharmaceutical care

Pharmaceutical care has been defined by Hepler and Strand as 'the responsible provision of drug therapy for the purpose of achieving definitive outcomes that improve a patient's quality of life' [4]. The World Health Organisation has expanded upon this by stating that pharmaceutical care does not just affect patients directly on a one-on-one basis. Rather, the pharmacy profession can have an impact on communities as a whole through preventative action and health promotion, and recognises their collaboration with the wider, multi-disciplinary healthcare team [5]. This definition is instrumental in demonstrating the evolution of the pharmacy profession from a supply-oriented discipline to one that provides a valuable contribution to patient care [6]. Within community pharmacies, this transcends from the supply of medicinal products to the provision of healthcare information to the public and fellow healthcare professionals, participation in health promotion activities, and responding to minor ailments [5].

1.2 Relevant healthcare strategy in Scotland

Following the devolution of healthcare responsibilities in the UK in 1999, strategies set forth by the Scottish Government govern healthcare delivery within Scotland. These strategies underpin the concepts relating to the warfarin and NSAIDs care bundles which are the focus of this thesis. This includes an emphasis on patient safety by reducing avoidable harm, and an emphasis on providing reliable healthcare to the Scottish population. New services have

also been introduced within the Scottish community pharmacy context which have shaped their evolving patient-facing role within primary care. An overview of the national strategies of relevance to this thesis is presented in Figure 1.1 and are described in more detail in Sections 1.2.1 to 1.2.5.

Year	National strategy	Key areas of interest to this thesis
2000	Our National Health: A plan for action, a plan for change	This strategy emphasised the necessity of a collaborative approach with patients, providers and other stakeholders to drive continuous improvements within healthcare. The potential to extend the clinical role of community pharmacy was proposed.
2006	The Right Medicine: A strategy for Pharmaceutical Care in Scotland	Extension of the role of community pharmacy was realised through the implementation of four pharmaceutical care services: 1. the Minor Ailments Service 2. the Acute Medication Service 3. the Public Health Service 4. the Chronic Medication Service
2010	Healthcare Quality Strategy for NHS Scotland	This strategy strived to deliver person-centred, safe and effective care. Key developments included the establishment of the 'Scottish Patient Safety Programme' within primary care with an emphasis on patient safety and quality improvement.
2013	Prescription for Excellence	This strategy saw the introduction of the Scottish Patient Safety Programme within the community pharmacy setting. Greater clinical contribution of community pharmacy was proposed to be achievable through prescribing pharmacists and adoption of automated dispensing technology.
2017	Achieving Excellence in Pharmaceutical Care: A Strategy for Scotland	Within community pharmacy, this strategy strived to introduce continuous quality improvement, a patient safety climate survey, tools and resources for safer use of high risk medicines, and a medicines reconciliation programme.

Figure 1.1. Overview of relevant healthcare strategies in Scotland (2000-2017)

1.2.1 Our National Health: A plan for action, a plan for change (2000)

In 2000*, Our National Health: A plan for action, a plan for change* was published [7]. This was the first Scottish healthcare strategy following the devolution of healthcare responsibilities in 1999. A collaborative approach to improving the nation's health was proposed by involving patients in the design of healthcare services, working in partnership with NHS staff, and working collaboratively with other stakeholders such as Local

Authorities, independent providers and voluntary bodies. Continuous improvement of healthcare delivery was advocated, and three clinical areas were prioritised: coronary heart disease, cancer, and mental health. The potential to extend the role of community pharmacy to better contribute within the wider healthcare setting was also acknowledged.

1.2.2 The Right Medicine: A strategy for Pharmaceutical Care in Scotland (2006)

This strategy in 2006 contextualised *Our National Health: A plan for action, a plan for change* (2000) to the pharmacy profession, and further emphasised the necessity to strengthen the contribution of pharmacy within healthcare [8]. In Scotland, community pharmacies are autonomous businesses which are contracted to provide NHS pharmaceutical care services. It is through this community pharmacy contractual framework that national strategies are realised through their implementation as contractual obligations. This strategy resulted in the implementation of four new pharmaceutical care services within the community pharmacy contractual framework: the Minor Ailments Service, the Acute Medication Service, the Public Health Service, and the Chronic Medication Service, which are described in greater detail Figure 1.2. This represented a noticeable shift in the funding model of community pharmacies within Scotland, as previously the money allocated was primarily based on dispensing volume and not service provision. This exemplifies the profession's deviation from a supply-orientated discipline within Scotland to one that is patient-facing [6].

Pharmaceutical service	Description
Minor Ailments Service	For this service, eligible patients can register with their pharmacy and receive free advice and treatment for a variety of minor ailments. To be eligible, patients must be registered with a Scottish general practitioner (GP) and fulfil a certain criteria (e.g. be under 16 years of age or over 60 years of age or have a medical exemption certificate).
Acute Medication Service	The Acute Medication Service involves the electronic transfer of prescription information between GP surgeries and community pharmacies using a barcode printed on prescriptions. This barcode is scanned within pharmacies to allow the transfer of information including: patients details, medicine to be dispensed, dosage instructions, GP details and the date of the prescription.
Public Health Service	The Public Health Service consists of the provision of three services: 1. supply of emergency hormonal contraception to eligible patients 2. a smoking cessation service with nicotine replacement therapy 3. displaying health promotion campaigns within pharmacies
Chronic Medication Service	The Chronic Medication Service saw the introduction of serial dispensing, with pharmacists having greater involvement with patients' repeat medication. Patients opt-in and the pharmacist develops a pharmaceutical care plan for them. A serial prescription for the patient's repeat medication is then generated for 24 or 48 weeks following their GPs approval. Support tools were developed for patients on the high risk medicines lithium, methotrexate and warfarin. These act as a guide for a community pharmacist to discuss these medicines with patients, focusing on concordance; interactions and precautions; adverse reactions; and monitoring.

Figure 1.2. Overview of the four pharmaceutical care services introduced in 2006 [8]

1.2.3 The Healthcare Quality Strategy for NHS Scotland (2010)

Our National Health: A plan for action, a plan for change (2000) was updated a decade later in 2010 with the *Healthcare Quality Strategy for NHS Scotland* (2010) [9]. The ambition of this updated healthcare strategy was to deliver the highest quality healthcare services to people in Scotland by making healthcare person-centred, safe, and effective. This was driven by thee quality ambitions, shown in Figure 1.3.

Key drivers	Quality ambitions
Person-centred	"Mutually beneficial partnerships between patients, their families and those delivering healthcare services which respect individual needs and values and which demonstrate compassion, continuity, clear communication and shared decision making."
Safe	"There will be no avoidable injury or harm to people from healthcare they receive, and an appropriate clean and safe environment will be provided for the delivery of healthcare services at all times."
Effective	"The most appropriate treatments, interventions, support and services will be provided at the right time to everyone who will benefit, and wasteful or harmful variation will be eradication"

Figure 1.3. The quality ambitions of the *Healthcare Quality Strategy for NHS Scotland* (2010) [9]

Compared with the preceding national healthcare strategy, the *Healthcare Quality Strategy for NHS Scotland* (2010) emphasised the necessity to improve the safety and quality of the NHS in Scotland. This led to the national roll-out of the Scottish Patient Safety Programme (SPSP) [9] which was initially introduced in the acute sector, and later within primary care. To drive improvements in patient safety, a Quality Improvement Hub was developed to help facilitate collaborative working between NHS organisations and to upskill staff on quality improvement tools and techniques [9]. A bottom-up approach was advocated to identify pockets of good practice for scale up throughout Scotland. System-wide commitments to patient safety using consistent and reliable improvement methods were advocated to reduce unjustified and potentially harmful variation [9]. The *Healthcare Quality Strategy for NHS Scotland* also advocated the routine collection of patient-reported outcomes and their experience of NHS services to drive improvements [9].

1.2.4 Prescription for Excellence (2013)

The *Healthcare Quality Strategy for NHS Scotland* was contextualised to the pharmacy profession through a strategy entitled *Prescription for Excellence*, published in 2013 [10]. The focus of *Prescription for Excellence* was based upon a report by Wilson and Barber commissioned by the Cabinet Secretary for healthcare [11], which aimed to review the appropriateness of NHS Scotland pharmaceutical services. The recommendations included strengthening the contribution of pharmacists; better utilising the skills of pharmacy support staff; more collaborative working with other professions; and adopting technology

to improve service delivery [10]. Wilson and Barber also identified the opportunity for community pharmacies to become part of the Scottish Patient Safety Programme and to focus on high risk medicines and prescribing [10]. *Prescription for Excellence* (2013) acknowledged these key recommendations, and the national strategy strived for pharmacists to have a greater role in prescribing and to implement pharmacovigilance services as part of the Scottish Patient Safety Programme [10]. To allow for these advancements, the dispensing process was proposed to be managed by pharmacy technicians and supported by automated dispensing technology [10].

1.2.5 Achieving Excellence in Pharmaceutical Care: A Strategy for Scotland (2017)

In 2017, an updated strategy for pharmaceutical care in Scotland was published following the appointment of a new Chief Pharmaceutical Officer in June 2015 [12]. *Achieving Excellence in Pharmaceutical Care: A Strategy for Scotland* (2017) builds upon the ethos set forth by *Prescription for Excellence*, with continued focus on extending the clinical role of pharmacy. Key aims were to improve NHS pharmaceutical care and enable transformation, with nine commitments (Figure 1.4).

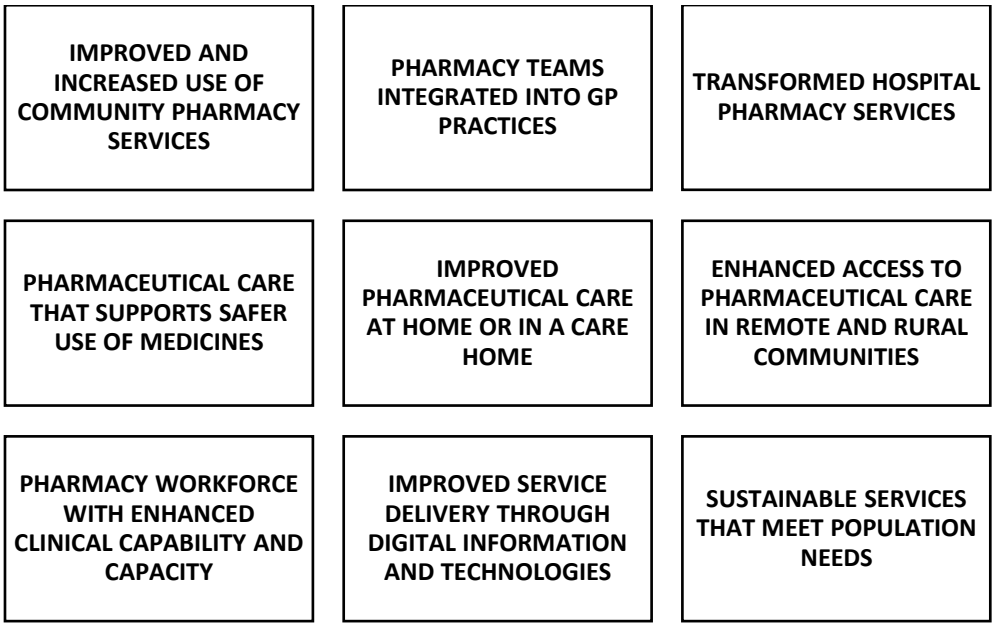


Figure 1.4. The nine commitments of *Achieving Excellence in Pharmaceutical Care: A Strategy for Scotland* (2017) [12]

The strategy advocates continued delivery of the four pharmaceutical care services presented in Figure 1.2 - the Minor Ailments Service, the Acute Medication Service, the Public Health Service, and the Chronic Medication Service, and indicated plans to expand these to meet emergent healthcare needs. This included the proposed expansion of the Minor Ailments Service, and the introduction of the Pharmacy First service to allow community pharmacies to provide antibiotic treatment for impetigo and urinary tract infections [13]. Patient safety continued to be on the national pharmaceutical care strategy, with a commitment to continue the operation of the Scottish Patient Safety Programme within the community pharmacy setting. A number of safety and quality related innovations were proposed to be introduced within community pharmacies: a patient safety climate survey, high risk medicine care bundles, and a medicines reconciliation programme.

1.3 The Scottish Patient Safety Programme

The Scottish Patient Safety Programme (SPSP) is a national quality improvement initiative which launched in 2008, with an overarching aim to improve the safety of healthcare services in Scotland [8]. Since then, it has remained on the Scottish Government's national agenda as a mechanism through which improvement initiatives can be tested prior to wider-scale implementation. NHS Scotland collaborated with the Institute of Healthcare Improvement on the programme, who are an independent organisation based in Massachusetts which partnership with healthcare organisations to drive improvements. The SPSP initially focused on the acute healthcare sector and achieved a number of successes: a 7% reduction in hospital standardised mortality rates, a 70% reduction in *Clostridium difficile* infections since 2007, and an avoidance of 125,000 bed days in two years for those over 65 years old [14].

As an output of the national healthcare strategies previously described, the SPSP migrated into primary care [9, 10], with the programme managed by NHS Healthcare Improvement Scotland (HIS). Following a two-year pilot phase in GP practices, the programme instigated a number of changes in the 2013/14 and 2014/15 GP contract for provision of NHS services. These included: continuous quality improvement with an emphasis on the safe prescribing of warfarin, methotrexate and azathioprine; participation in a safety climate survey; and applying a trigger tool to detect patient safety incidents [15]. Within GP practices, the SPSP was considered a success by achieving focused and co-ordinated action on patient safety concerns [16]. The trigger tool successfully identified previously undetected patient safety incidents, and clinical outcomes were observed with improvements in warfarin international normalized ratio (INR) control [17, 18].

1.3.1 The Breakthrough Series collaborative model

A defining feature of the SPSP was its application of the Breakthrough Series (BTS) collaborative model [19]. In healthcare, collaborative models bring individuals together in a structured way to focus on areas of improvement, and are being increasingly used in both the United Kingdom (UK) and the United States (US) [20]. Typically, they encourage healthcare staff to share their experiences, learn about quality improvement methods, and formulate change packages so that best practice can be achieved [20]. A change package is defined as a context-sensitive intervention which is in early developmental stages [21]. The

BTS collaborative model was initially developed in the early 1990s by the Institute of Healthcare Improvement, and has been refined following its application in various contexts - including the UK primary care setting [19]. The BTS collaborative model comprises structured learning events broken up by action periods, where change packages are tested in practice, as presented in Figure 1.5 [19]. The SPSP operationalised the BTS model through local and national learning events which were attended by front-line healthcare practitioners and strategists alike.

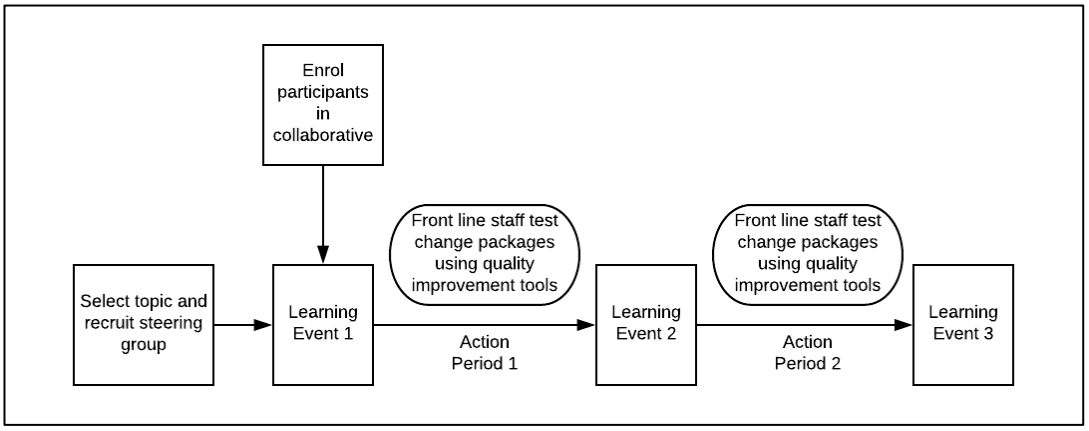


Figure 1.5. Overview of the Breakthrough Series (BTS) collaborative model initially developed by the Institute of Healthcare improvement in the US [19]

1.3.2 Care bundles

The concept of 'care bundles' was developed by the Institute of Healthcare Improvement, and is defined as a set of structured interventions which, when consistently delivered, improve patient outcomes and/or health service processes [1, 2]. A care bundle's ability to improve care outcomes was first demonstrated by the introduction of a ventilator care bundle within 35 intensive care units in the US [3]. This care bundle consisted of peptic ulcer disease prophylaxis, deep vein thrombosis prophylaxis, elevation of the head off of the bed, and a 'sedation vacation', which resulted in 44.5% reduction in ventilator-associated pneumonia [3]. Following this, it was hypothesised that when healthcare interventions are collectively applied as part of a packaged care bundle, the changes are more likely to be implemented than if they were implemented individually [3].

The concept of care bundles was then tested in different settings. A central line care bundle, a ventilator care bundle, a severe sepsis care bundle, and a perinatal care bundle were tested in both US and UK settings with positive improvements in care demonstrated [2].

Guidelines for care bundle design were iteratively formulated [2]: it was suggested that care bundles be developed for well-defined patient populations, and that each bundle element has strong clinical agreement; be developed by a multidisciplinary care team; and be descriptive in nature as opposed to prescriptive [2]. Key factors which were considered instrumental in the success of the care bundle is that they strive for care to be delivered reliably to every patient, every time; in general they promote awareness within the setting they are applied; and lastly, they promote the use of quality improvement tools [2]. The SPSP adopted care bundles as mechanisms to produce safer, reliable care, where front-line staff were involved in the development and test of care bundles iteratively.

1.3.3 The use of quality improvement tools

Within the SPSP, quality improvement tools were used by both strategists and front-line healthcare practitioners. Quality improvement tools are part of the broader field of improvement science, which has been described as an emerging field of study which focuses on the scientific study of methods, theories and approached designed to facilitate efforts to improve quality [22]. The field originated from management and organisation theory, with Jurans' *Quality Handbook* first published in 1951 which focused on the design and management of work processes [23]. Improvement Science was later applied within healthcare, and Don Berwick applied the Model for Improvement during his work with the Institute of Healthcare Improvement [22]. The Model for Improvement (Figure 1.6) is a guiding quality improvement framework which consists of three preceding questions, followed by operation at practitioner level through Plan-Do-Study-Act (PDSA) cycles [24]. PDSA cycles typically involve rapid testing of small-scale changes, and can be described as a trial-and-learning approach to iteratively developing and testing a change package [24, 25]. PDSA cycles have been used within acute and primary care settings in numerous countries including the US, UK, Canada, Australia and the Netherlands [25].

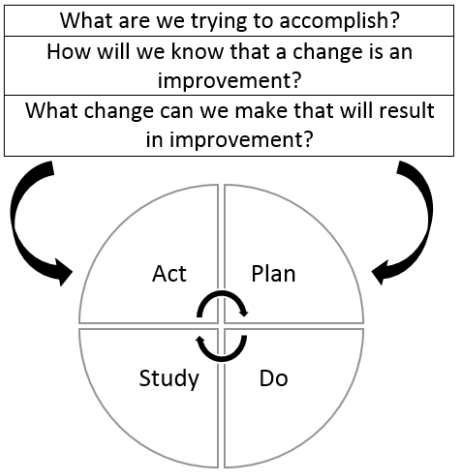


Figure 1.6. The Model for Improvement [24]

A driver diagram is a quality improvement tool which is used to answer the three initial questions of the Model for Improvement (Figure 1.6). They are operationalised at strategic level to direct the focus of quality improvement collaboratives, and are visual representations of how intended aims of a programme can be achieved. The overarching aim of a quality improvement collaborative is developed and linked to primary drivers (problems which need to be addressed to meet this aim) and secondary drivers (specific areas for improvement) [24]. They have been applied when deriving key focuses of the *NHS Healthcare Quality Strategy for NHS Scotland* and in the various avenues of the SPSP [8, 9].

To operationalise quality improvement initiatives at front-line healthcare practitioner level, PDSA cycles are assisted by run charts. Run charts are line graphs of data plotted over time, and can allow improvements to be visualised so that trends in the data can be assessed over time [24]. These can be used to assess the impact of PDSA cycles on an intended outcome to identify if a test of change resulted in an improvement or not.

1.4 The Scottish Patient Safety Programme – Pharmacy in Primary Care collaborative

The SPSP expanded from the acute sector and the GP setting into the community pharmacy setting, launching in November 2014 the SPSP - Pharmacy in Primary Care (SPSP-PPC) collaborative. The overarching aim of the SPSP-PPC collaborative was to improve patient safety by strengthening the contribution of community pharmacy and improving communications within the primary care team [26]. Four NHS Health Boards were recruited

to be involved in the collaborative following a competitive application process: NHS Greater Glasgow and Clyde (GG&C), NHS Highland, NHS Fife and NHS Grampian.

Also via a competitive application process, 27 community pharmacy sites initially opted to participate in the collaborative from the four NHS Health Boards. One pharmacy in NHS GG&C withdrew participation early within the collaborative. See Figure 1.7 for characteristics of the 26 community pharmacies.

Pharmacy characteristics	N
Pharmacies within each NHS region	
Highland	5
Grampian	5
Fife	7
Greater Glasgow & Clyde	9
Pharmacy type	
Large chain	13
Medium chain	4
Small chain	2
Independent	7
Rurality	
Urban setting	21
Rural setting	5

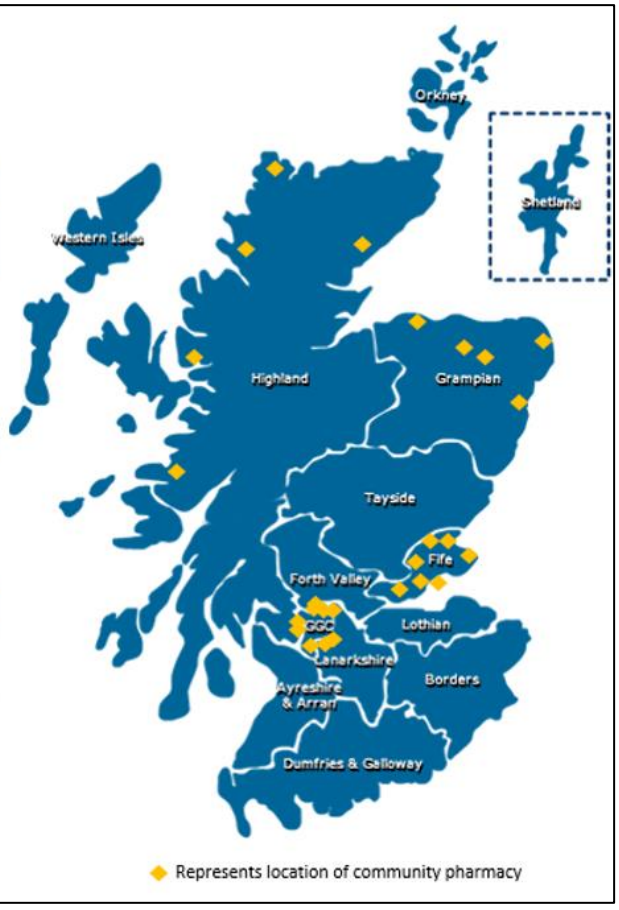


Figure 1.7. Brief demographics of pharmacies involved in the SPSP-PPC collaborative (n=26) (2015)

Large chain = >30 pharmacies, medium chain = 5-30 pharmacies, small chain = 2-4 pharmacies, independent pharmacy = one, single pharmacy

In November 2014, a steering group was set up for the SPSP-PPC collaborative which met approximately every two months until November 2016 to share information on the progress of the collaborative. Two National Leads were appointed to steer the collaborative, with eight Regional Leads also appointed – two for each of the four

participating NHS Health Boards. An evaluation team was set up comprising representatives from NHS Education for Scotland (n=2) and the University of Strathclyde (n=3).

The BTS model was operationalised through three national learning events, and two local learning events within the respective NHS Health Boards, which were delivered throughout the timeline of the collaborative (Nov 2014 – Nov 2016). Attendees included representatives from the participating community pharmacies, the SPSP-PPC steering group, the SPSP-PPC evaluation team, and in some instances other invited stakeholders. At the first national learning event in November 2014, the representatives from the participating community pharmacies were introduced to the Model for Improvement, driver diagrams, PDSA cycles, and run charts. During action periods in between the learning events, the participating community pharmacies tested the SPSP-PPC change packages within their practice using PDSA cycles and run charts. These change packages are described in the upcoming Section 1.4.1. The run charts developed by the community pharmacies were presented and discussed at the SPSP-PPC steering group meetings. Two SPSP-PPC Regional Leads from each NHS Health Board provided local support to participating community pharmacy during the action periods.

1.4.1 SPSP-PPC change packages

To meet the objectives of the collaborative and those of the wider pharmaceutical care strategy [10, 12], three change packages were developed and tested as part of the SPSP-PPC collaborative, which are described in Figure 1.8. The ambition was for these change packages to become nationally implemented throughout Scotland following their initial testing. The change packages were a safety climate survey, high risk medicine care bundles, and a medicine reconciliation care bundle.

SPSP-PPC change package	Description
High risk medicine care bundles	Warfarin and NSAIDs care bundle were developed which involved the community pharmacy undergoing clinical assessment of these medicines, and discussing these medicines with patients to ensure their understanding and awareness of their associated risks.
Medicines reconciliation care bundle	A medicines reconciliation care bundle was developed to ensure that patients discharged from hospital with medication changes had their medicines accurately reconciled. Hospital discharge letters were sent to the community pharmacy and through communication with GPs the pharmacy staff ensured changes were appropriately actioned. Pharmacy staff also had a discussed with patients to ensure they had adequate understanding of changes made.
Safety climate survey (SafeQuest-CP)	A validated questionnaire called SafeQuest-CP was developed to measure the safety climate within community pharmacies [27], which focused on teamwork; leadership; safety systems and learning; communication; and working conditions [27]. After completing the questionnaire, pharmacy staff held a reflective discussion on the results which aimed to raise awareness of the importance of a positive safety culture [27].

Figure 1.8. The three change packages of the SPSP-PPC collaborative

SPSP-PPC = Scottish Patient Safety Programme – Pharmacy in Primary Care, NSAIDs = non-steroidal anti-inflammatory drugs, GPs = general practitioners

The timeline of when these change packages were tested within the pilot community pharmacies and when the learning events occurred is presented in Figure 1.9.

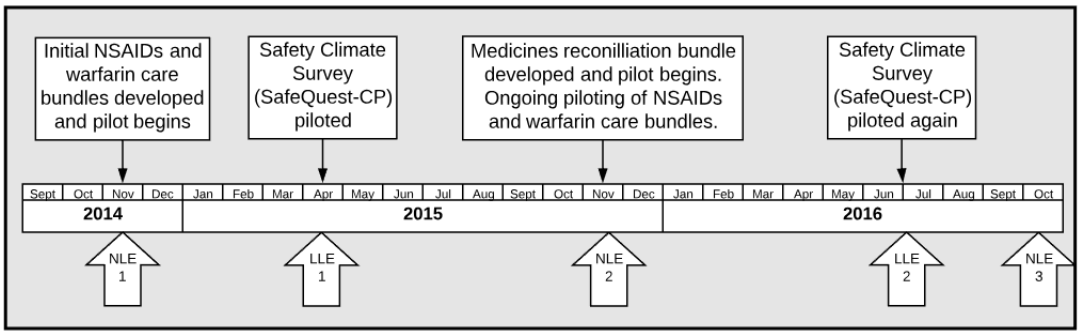


Figure 1.9. Timeline of the change package testing and the learning events within the SPSP-PPC collaborative (2014-2016)

NSAIDs = non-steroidal anti-inflammatory drugs, NLE = national learning event, LLE= local learning event

1.4.2 Warfarin and NSAIDs care bundles

The warfarin and NSAIDs care bundles are the focus of this thesis, thus will be described in greater detail. Warfarin and NSAIDs are considered high risk medicines frequently associated with adverse drug events. In the UK, preventable adverse drug related hospital admissions have been quantified using analysis of patient records, with an identified prevalence ranging from 3.1% to 6.0% [28-32]. Internationally, anticoagulants (i.e. warfarin) and NSAIDs are attributed to 27% of preventable drug related admissions alongside anti-platelets and diuretics [33], and their association with preventable adverse events has also been identified in primary care [34, 35]. Furthermore, risky prescribing practices related to warfarin and NSAIDs have been identified as relatively common in Scottish GP practices (Table 1.1) [36]. Based on this data, an advisory group in NHS Scotland in 2014 recommended that future improvement initiatives should focus on warfarin and NSAIDs [37].

Table 1.1. High risk prescribing of warfarin and NSAIDs identified in Scottish GP practices (2011) [36]

High risk medicine	Prescribing safety indicator	Percentage of patients % (95% CI)
Warfarin	Antiplatelet prescribed to current warfarin user	9.6 (9.2 – 10.1)
	High risk antibiotic prescribed to current warfarin user	7.9 (6.4 – 9.3)
	Oral azole antifungal prescribed to current warfarin user	0.7 (0.6 – 0.8)
NSAIDs	NSAID prescribed in patient with peptic ulcer disease without gastroprotection	8.8 (8.6 - 9.1)
	NSAID prescribed in patients 75 and over without gastroprotection	50.5 (49.5 - 51.5)
	NSAID prescribed in patients aged 65 and over prescribed ACEi or ARB and diuretic	8.8 (8.5 - 9.0)
	NSAID prescribed in patients aged 65 and over with estimated glomerular filtration rate <60	8.2 (7.1 - 9.3)
	NSAID prescribed to current warfarin user	3.4 (3.1 - 3.7)
	NSAID prescribed to patient with heart failure	11.4 (11.0 - 11.9)

NSAIDs = non-steroidal anti-inflammatory drugs, ACEi = angiotensin converting enzyme inhibitor, ARB = angiotensin receptor blocker, GP = general practitioner

1.4.3 Development of warfarin and NSAIDs care bundles

To address these highlighted safety concerns associated with the medicines warfarin and NSAIDs, the SPSP-PPC collaborative chose to focus their efforts on reducing this avoidable harm through the development of warfarin and NSAIDs care bundles within community

pharmacy. Introduction of the care bundle was intended to ensure that community pharmacy staff reliably inform patients about their NSAIDs or warfarin medication, their associated risk, and routinely identify and act upon any interactions. The ultimate aim of introducing the care bundles was to observe reductions in the associated adverse effects of NSAIDs and warfarin.

Two of the participating health boards focused on warfarin (NHS Grampian and NHS Fife), and two on NSAIDs (NHS GG&C and NHS Highland). As they were developed regionally, each had different aims and areas of focus, as presented in Figure 1.10. These care bundles were piloted in the participating sites from November 2014 onwards and iteratively developed through the use of PDSA cycles and run charts. Facilitative resources for pharmacy staff to aid care bundle delivery in practice were also developed which are presented in Appendix 1.1.

NHS Highland - NSAIDs care bundle
1. Has the patient been informed to take it with or after food?
2. Has the patient been informed to report any GI side effects to their pharmacist or GP?
3. Is the patient aware of the Medicine Sick Day Rules?
4. Is the patient in a high risk group requiring gastroprotection? If yes, has gastroprotection been prescribed?
5. Is the patient prescribed the triple whammy combination? If yes, has the triple whammy combination been highlighted to the prescriber?
NHS GG&C - NSAIDs care bundle
1. Have you checked that the patient is concordant with taking their NSAID?
2. Have you checked if the patient is experiencing adverse drug reactions or side effects?
3. Has gastroprotection been prescribed for high risk patients?
4. For patients identified as taking other high risk drugs, has this risk been highlighted to the prescriber?
5. If the prescriber was contacted, was the resulting review communicated back to the pharmacy?
6. Has this change been discussed by the pharmacist with the patient/carer?
NHS Fife - warfarin care bundle
1. Does the patient have an up to date Oral Anti-Coagulant Therapy (OAT) record book (indication, duration of treatment and therapeutic range)?
2. Does the patient carry an up to date alert card (indication, duration of treatment and target range)?
3. Does the patient know what to do if they have missed a dose of warfarin?
4. Is the patient aware that they should inform the team responsible for their warfarin care of any significant changes that may affect their warfarin? E.g. Newly prescribed medicines, certain over-the-counter medicines and changes to food/alcohol.
5. Is the patient aware of what to do if they are suffering from signs and symptoms of over/under-coagulation?
6. Is the patient aware that they should have an INR test 3 days after starting a course of antibiotics?
NHS Grampian - warfarin care bundle
1. Is the yellow Oral Anti-Coagulant Therapy (OAT) record booklet up to date / current including completed information (indication, duration of treatment and therapeutic range)?
2. Is the OAT alert card up to date / current including completed information (indication, duration of treatment and target range)?
3. Is the patient / carer aware that the Yellow OAT record booklet is taken to EVERY healthcare intervention?
4. Is the patient / carer aware that they should carry the Alert Card at all times?

Figure 1.10. The four high risk medicine care bundles developed (2014) [38]

NSAID(s) = non-steroidal anti-inflammatory drug(s), GI = gastro-intestinal, GP = general practitioner, INR = international normalized ratio

1.4.4 Evaluation of the warfarin and NSAIDs care bundles

An evaluation of the warfarin and NSAIDs care bundles was conducted by the SPSP-PPC evaluation team [38]. This evaluation focused on the implementation of the care bundles and their integration into routine practice. A mixed methods approach was adopted involving questionnaires, semi-structured interviews (one-to-one, paired and focus groups), observational case studies, process mapping and documentary evidence [38].

The evaluation identified that the community pharmacies adopted the warfarin and NSAIDs care bundles with confidence [38]. There was continuing staff understanding and acceptance of the care bundles, and they were viewed as appropriate within the context of the role of community pharmacy [38]. Furthermore, it was identified that the care bundles could successfully penetrate within different community pharmacy contexts [39]. However, although *scope* for whole pharmacy team involvement with the care bundles was evidenced [39], delivering the warfarin and NSAIDs care bundles was often seen as the responsibility of the pharmacist and did not always involve the wider team [38]. Feedback from community pharmacy staff on patient satisfaction also flagged mixed perceptions, yet overall the community pharmacy staff perceived that patients appreciate the opportunity the care bundles offered to communicate with the pharmacy staff [38].

The SPSP-PPC evaluation team identified that the early iterations of the care bundle may require further development to enable their national implementation, as the necessity of two different warfarin care bundles and two different NSAIDs care bundles was queried [38]. A key recommendation posed by the SPSP-PPC evaluation team was to consolidate the care bundles in a single warfarin care bundle and a single NSAIDs care bundle, building upon the learning from the initial testing phase. This was considered to offer equality of patient care if they were to progress onto national implementation through Scotland.

1.4.5 Influence of the SPSP-PPC collaborative on the national strategy

Pilot testing of the SPSP-PPC collaborative's change packages and the use of quality improvement methodology within community pharmacies resulted in a number of national outputs. In July 2016, it was announced that the 2016/17 community pharmacy contract would include an additional Quality Improvement Methodology pool of £2M [40]. Later, in September 2016, this was further elaborated upon and four sets of activities were added to the community pharmacy contract (Figure 1.11) with an associated single flat payment of

£1600 offered to each community pharmacy in Scotland [41]. This provided funding to the pilot pharmacies to further develop and test consolidated warfarin and NSAIDs care bundles, in line with key recommendations posed by the SPSP-PPC evaluation team (Section 1.4.4).

Activity	Description
Activity A: Understanding improvement - knowledge	This activity involved community pharmacy staff completing six learning modules which offer an introduction to quality improvement methodology to support continuous improvement in community pharmacies.
Activity B: Building a safety culture - space, time and context	This activity involved community pharmacy staff completing two learning modules which encourages pharmacies to create space and time for reflective learning and peer discussion.
Activity C: Safety Climate Survey (SafeQuest-CP)	This activity involved community pharmacy staff completing a safety climate survey (SafeQuest-CP), followed by reflection and a discussion of the results.
Activity D: On-going testing of the medicines reconciliation care bundle and consolidated warfarin and NSAIDs care bundles	This activity involved the pharmacies pilot testing the SPSP-PPC's change packages to continue to test the medicines reconciliation care bundle and consolidated warfarin and NSAIDs care bundles. As these pharmacies has been involved in the SPSP-PPC collaborative and have learnt about quality improvement techniques they were not required to complete activities A and B.

Figure 1.11. Quality improvement focus within the 2016/17 community pharmacy contract [41]

NSAID(s) = non-steroidal anti-inflammatory drug(s), SPSP-PPC = Scottish Patient Safety Programme – Pharmacy in Primary Care

1.5 Implications for present research

Through reflection of the term 'pharmaceutical care' and the definitions set forth by the World Health Organisation and Hepler and Strand [4, 5], it is evident that the warfarin and NSAIDs care bundles align with the international vision of the evolving role of the pharmacy profession. For example, the warfarin and NSAIDs care bundles exemplify the migration of the pharmacy profession from being a supply-oriented discipline, to one which provides a public health benefit through the provision of key safety interventions with the intentions of preventing avoidable harm to patients [6]. This supports the ongoing development of these care bundles as part of a wider international remit of progressing the pharmacy profession.

In the context of Scotland, the SPSP-PPC collaborative aligns with the current healthcare strategy by its focus on improving patient safety and quality of care, and the use of improvement methods and collaborative approaches to drive change [9, 12]. Therefore, the care bundles position well within the Scottish healthcare strategy as a mechanism through

which improvements in patient safety can be realised. National implementation of the safety climate survey (SafeQuest-CP) and the learning modules on quality and safety (Activities A and B within Figure 1.11), may influence community pharmacies' readiness to adopt other safety-related initiatives - such as the warfarin and NSAIDs care bundles - and help create a culture of engaged pharmacy staff willing to improve. Furthermore, by exploring the incidence of preventable adverse drug events and related admissions to hospital of warfarin and NSAIDs [33-35], as well as the identification of associated risky prescribing practices in Scotland [36], there appears a sufficient quality gap in the safety of NSAIDs and warfarin to support national implementation of the care bundles.

However, further refinements to the care bundles are required. *The Healthcare Quality Strategy for NHS Scotland* advocates reducing unjustified variation and providing reliable care to the Scottish population [9], which supports the SPSP-PPC evaluation team's recommendation that a single warfarin care bundle and a single NSAIDs care bundle would offer equality of patient care throughout Scotland. Therefore, the initial trajectory of this thesis focuses on the development of consolidated care bundles (Chapter 4). Thereafter, the consolidated warfarin and NSAIDs care bundles developed require to be further evaluated within community pharmacy practice (Chapters 5-9). To inform the progression and evaluation of the consolidated care bundles, the following chapter (Chapter 2) explores the field of implementation science and details the selection of suitable implementation guides which informed this process.

Chapter 2: Implementation science and selection of suitable implementation guides

Implementation science is a broad field of study encompassing all aspects of the implementation of innovations. Encompassed within the field is the design of innovations; the evaluation of implementation and innovation outcomes; development and evaluation of implementation strategies; and the development and application of theory relevant to implementation research which spans across patient, provider, organisation and policy levels [42, 43]. The field of implementation science is explored within this thesis chapter to better structure the progression, evaluation, and intended national implementation of the warfarin and NSAIDs care bundles. This chapter concludes with the selection of suitable implementation guides which were applied to direct the evaluation of the care bundles and pose recommendations for their possible scale up throughout Scotland.

2.1 Background and evolution of implementation science

Within the opening letter which marked the beginning of the journal *Implementation Science* (2006), Eccles and Mittman defined implementation science as the 'scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services' [44]. A more recent definition of implementation science derived from expert opinion is the 'study of theories, process, models and methods of implementing evidence-based practice', which demonstrates the flexibility of the field to various settings [45]. The similarities between implementation science and improvement science (discussed earlier in Section 1.3.3) is evident [44]. Both share a common goal of driving healthcare improvements with similar underlying principles [22]; Figure 2.1 compares their definitions.

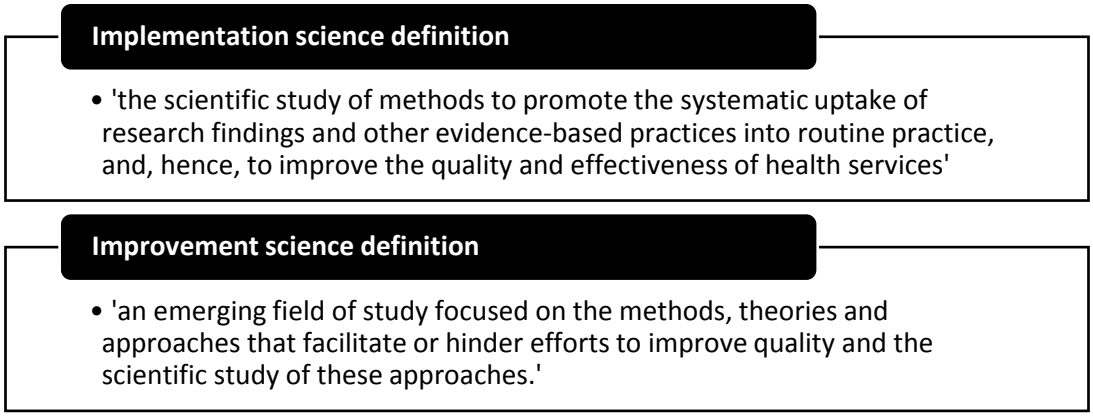


Figure 2.1. Comparison of improvement science and implementation science definitions [22, 44]

Some academics advocate the alignment of the two sciences [46]. For example, in a recent lecture Øvretviet discussed the possibility of establishing a journal combining the two approaches [47]. However, others consider the disciplines to be separate. Bauer et al suggests that the distinct feature of improvement science is that it focuses on very specific areas of improvement as identified at the front line [42], whereas implementation science typically identifies quality gaps and areas of focus within the healthcare service at a higher level. Therefore, quality improvement methodology may best be considered as an implementation intervention through which change is achieved, in a similar way to audit and feedback [42]. For example, Trietsch et al applied techniques derived from implementation science to evaluate the implementation of a quality improvement initiative in the Netherlands [48]. This latter approach will be adopted for this thesis, whereby implementation science informed the design, evaluation and scale up of the warfarin and NSAIDs care bundles, whereas the front-line staff applied quality improvement methodology, as described in Section 1.3.3.

The theoretical basis of implementation science spans wider than its application within the health sector. Everett Rogers' *Diffusion of Innovations* was published first in 1962 as a theory explaining how and why new ideas or technology spread throughout social systems. It was developed following a synthesis of over 500 studies from various different disciplines [49], and has been continually updated with its fifth version published in 2003. Case exemplars discussed by Rogers include the adoption of mobile telephones and farming technology. A key output of Rogers' Diffusion of Innovations was the categorisation of adopters into 5 types: innovators, early adopters, early majority, late majority, and laggards, which are terms which continue to be applied within the field of implementation science [21].

Later, implementation science was predominately applied within the field of public policy. Pressman and Wildavsky in 1973 published their book entitled *Implementation* based upon their evaluation of an employment program [50]. Pressman and Wildavsky concluded that even apparently simple implementation projects are convoluted and complex [50]. These earlier studies exploring policy implementation have been criticised for focusing too heavily on implementation failures [51], and relying on a number of assumptions including presumed transferability of research findings to different contexts [52]. Furthermore, a top-down perspective was traditionally adopted within policy implementation research, which meant that researchers lacked awareness of the myriad of factors affecting implementation at the front line [51]. The science of policy implementation has since progressed to encompass various bottom-up and top-down theories and approaches [51], where bottom-uppers tend to focus on implementation process at the front line, and top-downers typically attempt to develop generalizable advice for policy setting [51].

Within healthcare, the Veterans Affair's Quality Enhancement Research Initiative (QUERI) began in 1998 and is considered one of the first healthcare programs with an emphasis on the implementation process [53]. The program is ongoing, and its overarching aim is to improve the health of veterans by facilitating rapid implementation of effective treatments into practice [53]. It is now US-wide and encompasses multiple ongoing programs and partnered evaluation initiatives. Shortly after initiation of the QUERI project, the UK Department of Health in 2002-2003 commissioned a systematic literature review by Greenhalgh et al to identify how innovations within the healthcare sector could be successfully spread [52]. The review developed a conceptual framework (Figure 2.2) of the various influential aspects during implementation. Greenhalgh et al acknowledged that at this time few studies empirically explored the complexities of spreading and sustaining innovations, and that the subjective judgments of the authors influenced the review process and its conclusions [52].

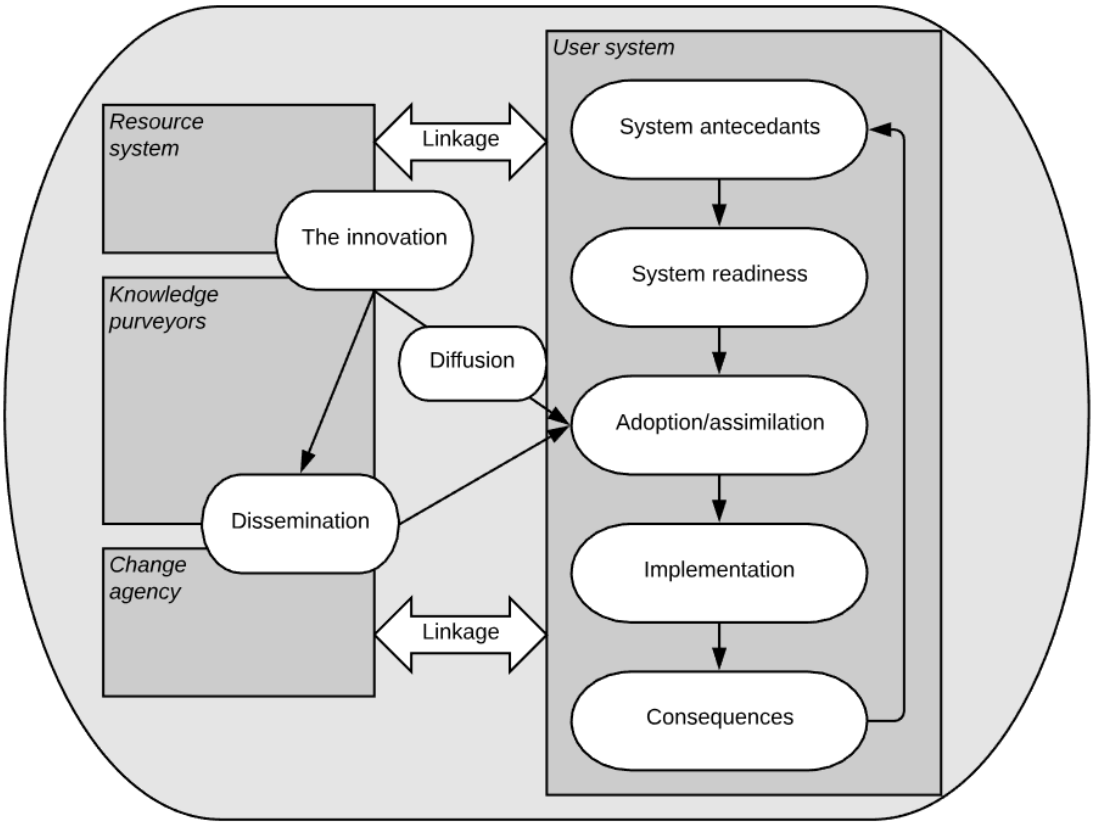


Figure 2.2. Conceptual framework of the diffusion, dissemination, and implementation of innovations in health service delivery and organization, adapted from Greenhalgh et al (2003) [52]

Since then, implementation science has been extensively applied within healthcare to explore the implementation of guidelines. A systematic review on the effectiveness of guideline implementation strategies published in 2006 identified 235 studies which compared guideline implementation strategies, indicating a sizable amount of research within this area [54]. However, only four studies were suitable for data extraction due to overall poor quality. A systematic meta-review in 2008 of guideline implementation similarly found that the current evidence base was poor in quality [55]. It concluded that multifaceted implementation strategies were more effective, and that a number of influences can affect implementation and guideline compliance [55]. These included characteristics of the guideline (e.g. easiness to understand); professionals' awareness of the guideline; external environment (e.g. support from superiors); sufficient resources (e.g. staff and time); and patient characteristics (e.g. co-morbidities).

Within the community pharmacy setting, Watkins et al conducted a review in 2015 on the effectiveness of implementation strategies used for the implementation of guidelines [56].

Twenty-two studies in total were included, yet variation in guideline content meant it was not possible to draw conclusions about the impact of the guideline characteristics on implementation success. Furthermore, as the implementation strategies were mostly multifaceted it was not possible to identify which specific implementation tactics drove success. Of the strategies, two were tailored strategies - which are when an implementation strategy has been developed following an assessment of barriers and facilitators during pilot phases [57, 58]; however, neither displayed positive outcomes. Six further implementation strategies were theory-based focusing on behaviour change theories, with four showing positive outcomes. However, the outcome measures were heterogeneous, primarily process outcomes derived from non-validated or modified validated instruments, and there was a high degree of bias, notably the self-selection recruitment process. Additionally, only half of included studies involved implementation strategies targeted towards pharmacy support staff, with the remaining targeting only pharmacists.

Other studies within the community pharmacy setting have explored the implementation of more complex innovations, as opposed to guidelines, such as the introduction of pharmacy prescribing rights or novel patient-facing innovations [59, 60]. Complex innovations are defined as a 'deliberately initiated attempt to introduce new, or modify existing, patterns of collective action in healthcare' which have elements of complexity [61]. This can include the number of groups or organisational levels targeted by the innovation, the number of outcomes, and the degree of flexibility and tailoring of the innovation [61, 62]. Within this thesis, the warfarin and NSAIDs care bundles to be studied may be best described as complex innovations, as opposed to guidelines.

One study of interest exploring the introduction of pharmacist's prescribing rights - which can be considered a complex innovation - is a qualitative study by Makowsky et al [59]. This study applied a theory driven approach to understand factors influencing prescribing uptake [59], drawing upon Greenhalgh et al's conceptual framework presented in Figure 2.2 [52]. Application of the theory was considered useful to offer understanding to the complexity of the topic, and allowed characterisation of the different prescriber types, identification of the factors affecting adoption (such as the professional relationship with physicians, the influence on routine practice and the legitimisation of previous practice), and found comparable findings to similar studies in different countries.

A study in English community pharmacies conducted by Latif et al in 2016 explored the implementation of the New Medicine Service, an innovation which was considered multifaceted and complex [60], which again used pre-defined theory to guide the qualitative exploration [63]. Latif et al identified variation in the delivery of the New Medicine Service, and identified factors influencing the innovation's successful implementation to include workflow, infrastructure, and public and professional relationships [60]. Latif et al concluded that better engagement and collaboration with the pharmacy workforce alongside a phased rollout may have maximised implementation success [60].

Overall, there is a paucity of research on *which* implementation strategies result in successful implementation of complex innovations within community pharmacy. The scarcity of research on this area is also pertinent within the wider primary care setting. In 2015, Lau et al conducted a systematic review of complex innovations in primary care [64], which excluded the community pharmacy setting from the analysis. The review could not pin-point which implementation strategies were most successful, and instead concluded that a 'one-size fits all' implementation strategy does not exist. However, the authors did advocate that an implementation strategy should be tailored and based on context-specific identified barriers.

2.1.1 Definitions and terminology

The use of consistent terminology within the field of implementation science is advocated to facilitate the knowledge-translation gap [45, 65]. Although similar in concept, the term implementation is not synonymous with diffusion, dissemination and adoption. Diffusion is the spread of new practices through passive, untargeted and unplanned means usually by imitation or replication [66], and is suggested only to be effective if the recipient is engaged [67]. Dissemination is the active and planned spread of new strategies to the target audience; mechanisms can be passive (such as guideline and policy development) or more active in nature (such as behavioural and social approaches) [68]. Adoption itself is defined as the adopters 'decision to make full use of an innovation as the best course of action available' [49], whereby implementation is the process by which the new practice or innovation becomes integrated within a setting [52, 68]. Sustainability is considered the state when an innovation is continued indefinitely or considered routine practice [49, 52].

To describe the tactics used to maximise implementation success, there is a difference between implementation intervention and strategy. An implementation intervention is a singular technique or method to instil a change in practice – such as an educational session or audit and feedback [69]. An implementation strategy is a multifaceted change effort with numerous components, which are often selected in a defined effort to overcome known implementation barriers or exploit known facilitators within given settings [42, 57]. Within the literature lies scope for confusion, as an intervention can relate to the above definition, but also to a new service which is being implemented [64, 66, 70]. New services are most commonly referred to as innovations, which is either an idea, a practice, or an object that is perceived as new by those implementing it [49].

2.2 Applying implementation science frameworks, theories, models and taxonomies

In the absence of empirical evidence of which implementation strategies affect the successful implementation of innovations [64], implementation science is operationalized through a plethora of frameworks, theories, models and taxonomies which guide or offer understanding to implementation [43, 71, 72]. For simplification within this thesis, implementation related taxonomies, theories, frameworks and models will collectively be termed 'implementation guides', as the terms themselves are not interchangeable [43]. Many implementation guides are generic and designed to be applied to a broad range of settings [49, 52]. Others are context-specific and are designed for use within a specific setting - such as within the primary care setting, or for specific innovation types [73] - such as innovations focused on diabetes care [74].

Through a narrative review process, Nilsen identified that the implementation guides have one of three aims [43]. Firstly, implementation guides which offer understanding or explanation on the factors which can affect the implementation process can be classified as either 'determinant frameworks', 'classic theories' or 'implementation theories' [43]. Secondly, implementation guides which describe or offer guidance on the implementation process are termed 'process models' [43]. And thirdly, implementation guides which offer guidance on evaluating an implemented innovation are 'evaluation frameworks' [43]. See Figure 2.3 for elaboration of the five sub-sets of implementation guides with examples.

Determinant frameworks
Determinant frameworks identify barriers and facilitators to implementation. The Consolidated Framework of Implementation Research (CFIR) is an example, which was developed following a comprehensive review of previous frameworks and theories. Factors attributed to successful implementation are categorised to five domains: innovation characteristics, outer setting, inner setting, characteristics of individuals and implementation process. Other examples include the Theoretical Domains Framework and the PARIHS framework.
Classic theories
Classic theories originate from fields out with implementation science, such as sociology and organisational theory, and includes Rogers' 'Diffusion of Innovations', which theorises that there are different adopter categories (innovators, early adopters, early majority, late majority and laggards), and stresses the importance of various innovation characteristics such as its' relative advantage and compatibility with pre-existing systems.
Implementation theories
Implementation theories have been developed by implementation scientists and offer understanding or explanation to the implementation process. An example is the Normalization Process Theory, developed following a review of numerous qualitative studies within healthcare setting. It offers theory to the process by which new practice can become integrated and embedded into the surrounding social context.
Process model
Process models offer actionable guidance of how to implement innovations. An example is the Replicating Effectiveness Framework, which offers a roadmap of how to implement innovations within community based settings[75]. The Expert Recommendations for Implementing Change (ERIC) taxonomy is another example, which is a taxonomy of implementation interventions which can be applied when developing an innovation's implementation strategy.
Evaluation frameworks
Evaluation frameworks guide the evaluation of new innovations which have been implemented, by identifying outcomes which can determine implementation success. The RE-AIM framework is an example, which was developed to evaluate public health innovations[76], and focuses on five domains: reach, efficacy, adoption, implementation, and maintenance. Building upon this, Proctor at al developed a taxonomy of inter-related implementation outcomes: adoption, appropriateness, feasibility, fidelity, cost, penetration, and sustainability, alongside service and client outcomes.

Figure 2.3. An overview of implementation guides with examples, adapted from Nilsen [43]

Due to the well-known complexity of implementation, it is acknowledged that using just one implementation guide may not offer comprehensive support [43]. This is echoed by the results of a systematic review of implementation guides by Moullin et al [71], whereby most implementation guides were identified as being descriptive or explanatory in nature, offering little actionable guidance on the implementation processes or aspects which increase implementation success [71]. Therefore, a combination of implementation guides may be most suitable, which is being increasingly observed within the literature [77].

Birken et al reviewed the rationale given for studies combining the Consolidated Framework for Implementation Research (CFIR) and the Theoretical Domains Framework (TDF) [78], both of which are classified as determinant frameworks. Their systematic review identified five protocols and seven completed studies. Not all studies stated the rationale for this approach, which made the authors advocate better reporting and justification of the use of implementation guides [78]. Of the eight studies which did offer a rationale, this centred on the different conceptual levels covered by each framework: the CFIR offered an overarching perspective on the factors influencing implementation, whilst the TDF offered more practical guidance [78].

Currently, there is no consensus on the best approach to applying implementation guides or how they are best combined [45]. Furthermore, due to the extensive library of implementation guides, the difficulty in choosing the most appropriate one(s) for a given setting and context is acknowledged [43, 65]. As researchers have been criticised for the underuse or inappropriate use of implementation guides [79], Birken et al in 2017 conducted a survey with self-identified implementation scientists to identify which implementation guides are used, how they are used, and why they were selected [79]. From the 223 respondents, over 100 implementation guides were used, some of which were developed in-house. Table 2.1 presents the top 10 implementation guides used, the top 10 criteria for selecting implementation guides, and how they were used by implementation scientists [79]. Overall, Birken et al identified lack of consensus on the most important criteria for selecting an implementation guide, and qualitative responses indicated that the selection process may be driven by convenience and/or prior exposure [79]. Therefor, the authors suggested that implementation scientists should transparently report their criteria for selecting the implementation guides used and specifically how they were applied [79].

Table 2.1. Top 10 implementation guides used by implementation scientists, common applications and selection criteria (n=223 participants) [79]

Top 10 Implementation guides	**%**
Consolidated Framework for Implementation Research (CFIR)	20.6
Reach Effectiveness Adoption Implementation Maintenance (RE-AIM)	13.9
Diffusions of Innovation	9.0
Theoretical Domains Framework	5.4
Exploration, Preparation, Implementation, Sustainment	4.9
Proctor's Implementation Outcomes	4.9
Organizational Theory of Implementation of Innovations	3.6
Knowledge to Action	3.1
Implementation Drivers Framework	3.1
Active Implementation Framework	2.7
Top 10 criteria for selection implementation guide	**%**
Analytic level (e.g. individual, organizational, system)	58.0
Logical consistency/plausibility (e.g. face-valid explanations)	56.1
Description of a change process (i.e. provides an explanation of how changes in process factors lead to changes in implementation-related outcomes)	53.8
Empirical support (i.e. use in empirical studies)	52.8
Generalizability	47.2
Application to a specific setting or population	44.3
Inclusion of change strategies/techniques (e.g. provision of specific methods)	44.3
Outcome of interest (i.e. conceptual centrality of the variable to which included constructs are thought to be related)	41.0
Inclusion of a diagrammatic representation (i.e. a clear and useful figure representing the concepts and their interrelations)	41.0
Recommended or implied research method (e.g. interviews/questionnaire) to be used in an empirical study that uses the framework or theory	40.1
Applications of implementation guides	**%**
To identify key constructs that may serve as barriers and facilitators	80.1
To inform data collection	77.1
To guide implementation planning	66.2
To enhance conceptual clarity	66.2
To specify the process of implementation	63.2
To frame an evaluation	61.0
To inform data analysis	59.7
To guide the selection of implementation strategies	58.9
To specify outcomes	55.8
To clarify terminology	48.1
To convey the larger context of the study	48.1
To specify hypothesized relationships between constructs	47.6

2.3 Selection of implementation guides for this thesis

As previously described, numerous implementation guides exist to help steer implementation scientists to systematically approach the implementation of innovations, yet this is complicated by the lack of consensus on how to select and apply these guides. Furthermore, as many implementation guides focus on single aspects of implementation, with no 'one-size fits all' multifaceted implementation guide in existence, using more than one implementation guide may be beneficial.

Therefore, three implementation guides were selected to facilitate an informed evaluation of the consolidated warfarin and NSAIDs care bundles during their testing phase, and to pose key recommendations for their future scale up. As per the categorisation of implementation guides presented in Figure 2.3, those selected included a determinant framework, an evaluation framework, and a process model [43].

The determinant framework selected for application in this thesis was the Consolidated Framework for Implementation Research (CFIR), whilst the evaluation framework selected was a taxonomy of implementation outcomes proposed by Proctor et al [63, 70]. These were both selected to inform the evaluation of the consolidated warfarin and NSAIDs care bundles as they each have different purposes. The CFIR facilitates the identification of key barriers and facilitators influencing the successful implementation of innovations [63], whereas the taxonomy of implementation outcomes proposed by Proctor et al is used to inform the evaluation of outcomes [70]. The third implementation guide selected was the Expert Recommendations for Implementing Change (ERIC) taxonomy, which is a process model that lists all known possible implementation interventions [69, 80]. It was applied in this thesis to structure the recommendation posed for the national scale up of the warfarin and NSAIDs care bundles.

The use of transparent reporting of the criteria used to select implementation guides is advocated by Birken et al [79]. Therefore, an overview of the three implementation guides selected will be presented, followed by an explanation of how they were to be applied, and why they were selected.

2.3.1 Consolidated Framework for Implementation Research (CFIR)

The Consolidated Framework for Implementation Research (CFIR) developed by Damschroder et al (2009) is an example of a determinant framework, which stratifies factors

known to influence implementation success into 5 domains: innovation characteristics, the inner setting, the outer setting, characteristics of the individual, and implementation process [63]. Each domain has a number of constructs, which are presented in Figure 2.4 with full definitions available within Appendix 2.1.

CFIR Domains	CFIR Constructs
Innovation Characteristics	Intervention Source, Evidence Strength & Quality, Relative Advantage, Adaptability, Trialability, Complexity, Design Quality & Packaging, Cost
Outer Setting	Patient Needs & Resources, Cosmopolitanism, Peer Pressure, External Policy & Incentives
Inner Setting	Structural Characteristics, Networks & Communications, Culture Implementation Climate (*Tension for Change, Compatibility, Relative Priority, Organizational Incentives & Rewards, Goals and Feedback, Learning Climate),* Readiness for Implementation (*Leadership Engagement, Available Resources, Access to Knowledge & Information)*
Characteristics of Individuals	Knowledge & Beliefs about the Intervention, Self-efficacy, Individual Stage of Change, Individual Identification with Organization, Other Personal Attributes
Implementation Process	Planning, Engaging (*Opinion Leaders, Formally Appointed Internal Implementation Leaders, Champions, External Change Agents),* Executing, Reflecting & Evaluating

Figure 2.4. Overview of CFIR domains and constructs [63]

CFIR = consolidated framework of implementation research

As the name suggests, the CFIR is a consolidation of previous implementation guides. The authors first referred to Greenhalgh et al's conceptual model on the implementation of innovations in healthcare as a starting point (presented in Figure 2.2), followed by snowball sampling to identify implementation guides published following this. The content of 19 identified implementation guides were synthesised and presented as the CFIR in 2009 by Damschroder et al [63]. In 2016, a systematic review identified 26 studies which applied the CFIR [81]. Most (73.1%) used it to gain an understanding of practitioners' experiences of implementing an innovation, commonly during implementation or post-implementation. The setting where it has been applied varied, as did the innovations of interest, including those relating to mental health, obesity, and blood pressure [81]. Six studies used it to guide data collection, twelve used it to guide data analysis, and four to guide both data collection and analysis [81].

For the evaluation of the warfarin and NSAIDs care bundles, the CFIR was selected to identify key factors acting as barriers and facilitators to their successful implementation from the

perspectives of the front line community pharmacy staff. The CFIR was selected to inform the data collection and analysis, and the use of a framework to do so as opposed to a purely inductive approach was purposeful to better position the work within the wider implementation science literature and to ensure consistency of terminology used. Furthermore, identifying barriers and facilitators influencing implementation success was considered to facilitate the development of tailored implementation strategies, whereby salient barriers and facilitators can be acknowledged and addressed during scale up of the care bundles [81].

The CFIR was purposefully selected for application in this thesis for a number of reasons. Firstly, it presents determinants of implementation success at five domain levels (see Figure 2.4), thus it was considered broad enough to cover all possible influences. Secondly, it is easy to understand and at face-value appears plausible. Thirdly, as the CFIR was developed from a consolidation of 19 implementation guides, this suggests it to be credible. Lastly, as it is commonly applied, findings derived from it can be easily cross-compared to other studies to facilitate eventual theory generation [79].

2.3.2 Proctor et al's taxonomy of outcomes

A taxonomy of outcomes developed by Proctor et al was selected to identify outcomes of interest to evaluate in relation to the care bundles [70]. Proctor et al developed this taxonomy of outcomes following a literature review and narrative synthesis, which concluded with a three-tiered stratification of outcomes: implementation outcomes, service outcomes, and client outcomes [70]. An overview of the taxonomy of outcomes proposed by Proctor et al is presented in Figure 2.5. The importance of delineating the implementation outcomes from service and client outcomes is well established [82]. Rossi and Freeman stressed that if an innovation revealed no impact on service and clinical outcomes, without attention to its implementation outcome it is not possible to conclude whether the innovation was ineffective, or instead it was unsuccessfully implemented [83].

Implementation outcomes	Service outcomes	Client outcomes
Acceptability	Efficiency	Satisfaction*
Adoption	Safety	Symptomology*
Appropriateness	Effectiveness	Function
Costs	Equity	
Feasibility	Patient-centeredness	
Fidelity*	Timeliness	
Penetration*		
Sustainability		

Figure 2.5. Proctor et al's conceptualisation of outcomes in implementation research [70]
** denotes outcomes of interest explored within this thesis.*

Previous studies applying Proctors et al's conceptualisation of outcomes have focused more so on the implementation outcomes. A study by Young et al specifically explored the implementation outcomes fidelity and adoption for an HIV screening programme, which identified that the guidelines were not being applied as intended [84]. A study by Ware et al specifically explored the implementation outcomes adoption, penetration, feasibility and fidelity of a mobile phone-based tele-monitoring programme for patients with heart failure [85]. Exploring these implementation outcomes identified that the innovation's implementation was considered an overall success [85].[1]

For this thesis, an exploration of all of Proctor et al's outcomes presented in Figure 2.5 would not have been possible given resource and time constraints. Therefore, specific outcomes of interest were selected to be explored. In relation to the implementation outcomes, cost and sustainability were outwith the scope of this thesis. The initial SPSP-PPC evaluation evidenced positive findings in relation to the warfarin and NSAIDs care bundles' acceptability, adoption, appropriateness and feasibility within community pharmacy practice [38]. Therefore, these were not a priority to explore. As the findings in relation to penetration and fidelity identified scope for improvements [38], these outcomes were selected to be explored for the purpose of this thesis. This purposeful selection of the specific Proctor et al's outcomes to be explored overcomes limitation of the initial SPSP-PPC evaluation conducted of the warfarin and NSAIDs care bundles [38], which can be criticised for retrospectively aligning the data to this implementation guide following data collection [79].

[1] Similarly to this thesis, Ware et al also adjunctively explored the barriers and facilitators of this innovation using the CFIR.

Implementation fidelity is defined as 'the degree to which an intervention was implemented as it was prescribed in the original protocol or as it was intended by the program developers' [86]. Achievement of intended clinical outcomes is dependent on the care bundles being delivered as intended when introduced within real-world community pharmacy settings (6). Therefore, exploring implementation fidelity is a pre-requisite in instances where service or client outcomes are to be explored. Penetration, defined as *'*the integration of a practice within a service setting and its subsystems', was selected to be evaluated in tandem with implementation fidelity [87]. This was because identifying if the care bundles were delivered as intended may be of limited value without also understanding how they penetrated within the community pharmacy setting. Therefore, exploring penetration was considered beneficial to offer further useful information to aid their intended national roll out.

The implementation outcome penetration encompasses two facets. The first facet of penetration encompasses if and how innovations become incorporated within routine practice. Exploring this is particularly salient for this thesis, as moving away from a variable set of warfarin and NSAIDs care bundles and developing consolidated care bundles may influence their ability to penetrate into routine community pharmacy as previously identified [39]. The second facet of penetration is the number of healthcare providers which deliver an innovation in practice (15). Again, this is of particular interest for the care bundles, as the SPSP-PPC evaluation identified limited whole team involvement within pharmacies, despite scope for whole team involvement being evidenced [38].

The ability of the warfarin and NSAIDs care bundles to achieve intended service and client outcomes has not yet been evidenced [38]. However, considering that consolidated care bundles would be tested within a small-scale pilot phase within this thesis, the statistical power to identify changes in service outcomes, such as reduced high risk prescribing, was not considered attainable. Therefore, only client outcomes were selected to be explored. Obtaining client feedback (referred to hereon as patient perceptions) would seek their satisfaction with the care bundles and their self-reported improvements in symptomology (e.g. any impact the care bundle may have on participants' side effects). Exploring these patient perceptions would offer insight into their perceived value and impact of the care bundles, which is advocated by the *Healthcare Quality Strategy for NHS Scotland* [9]. The necessity to explore this is also supported by the fact that the earlier SPSP-PPC evaluation

identified mixed patient perceptions of the care bundles as reported by the community pharmacy staff (see Section 1.4.4) [38].

Proctor's taxonomy of outcomes was purposefully selected in order to frame the evaluation of outcomes of the warfarin and NSAIDs care bundles, thus it was used to inform both data collection and analysis. It was purposefully selected over other evaluation frameworks for many of the same reasons as the CFIR was chosen. Similarly to the CFIR, it is a consolidation of previous work meaning it was presumed to have greater credibility; it was easy to understand and appeared plausible, and lastly, it is commonly applied which allows the findings of this thesis to be cross-compared to other studies.

2.3.3 Expert Recommendations for Implementing Change (ERIC) taxonomy

The Expert Recommendations for Implementing Change (ERIC) taxonomy, developed in 2015, is a process model which offers actionable guidance of how to implement innovations within practice. However, unlike other process models which provide a prescriptive roadmap of steps to be undertaken to successfully implement an innovation, the ERIC taxonomy lists all known possible implementation interventions. It was developed by Powell et al [69] and Waltz et al [80] in response to the lack of conceptual clarity of how implementation interventions and strategies are defined. The use of consistent language when describing implementation interventions and strategies was considered important to allow for cross comparison between studies [69, 80]. A consensus approach was used to develop the taxonomy involving 71 implementation science experts. This resulted in the development of 73 discrete implementation interventions with associated definitions, termed hereon the ERIC taxonomy [69]. These 73 discrete implementation interventions were then conceptually mapped into 9 classifications [80], as presented in Figure 2.6. A full compilation of the taxonomy developed is presented in Appendix 2.2.

Nine classifications of implementation interventions	Examples of implementation interventions (n=73)
1. Use evaluative and iterative strategies	• Develop and implement tools for quality monitoring • Audit and provide feedback
2. Provide interactive assistance	• Provide clinical supervision • Provide local technical assistance
3. Adapt and tailor to context	• Tailor strategies • Promote adaptability
4. Develop stakeholder interrelationships	• Inform local opinion leaders • Capture and share local knowledge
5. Train and educate stakeholders	• Develop educational materials • Create a learning collaborative
6. Support clinicians	• Facilitate relay of clinical data to providers • Remind clinicians
7. Engage consumers	• Use mass media • Involve patients/consumers and family members
8. Utilise financial strategies	• Fund and contract for the clinical innovation • Develop disincentives
9. Change infrastructure	• Mandate change • Change liability laws

Figure 2.6. The nine classifications of implementation interventions as described by Waltz et al with examples [80]

Studies applying the ERIC taxonomy have used it similarly to report and describe the implementation strategies applied for a variety of different innovations types. Swindle et al used the taxonomy to describe the implementation strategy for an educational innovation aimed to improve the nutrition of preschool children, which included making training dynamic and distributing educational materials [88]. For a complex innovation for children at risk of attachment problems [89], selected implementation interventions based on the ERIC taxonomy included organising clinician implementation team meetings, mandating change, and conducting ongoing training. And lastly, for a toolkit designed to reduce the cardiovascular risk of women veterans [90], interventions selected to facilitate its implementation included identifying and preparing champions and providing local technical assistance.

Within this thesis, the ERIC taxonomy was applied to frame the recommendations posed for the scale up the care bundles in response to the evaluation results. The ERIC taxonomy was selected because of its generalisability, which was considered beneficial for two reasons. Firstly it appeared to be broad enough to be applicable to describe implementation

interventions which could be used within the Scottish community pharmacy setting, despite the fact it does not appear to have been used in this context before. Secondly, its generalisability means that it is applied in a myriad of different contexts [88-90], which allows for the opportunity to cross compare different implementation strategies used within different settings. Due to its informed design though consensus methodology with 71 implementation science experts, it was considered both a plausible and exhaustive list of implementation interventions. And lastly, at face value, its simplicity meant it was considered easy to apply.

Chapter 3: Thesis aims and objectives

This thesis describes the design and evaluation of consolidated warfarin and NSAIDs care bundles which informed their scale up throughout the Scottish community pharmacy setting through the application of implementation science guides. This was achieved through a three stage process as presented in Figure 3.1.

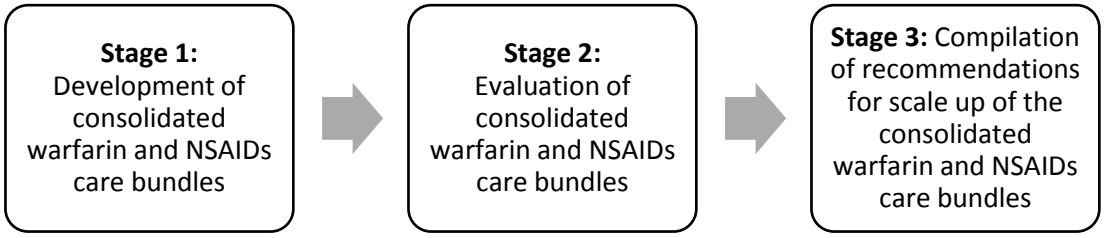


Figure 3.1. Overview of the three stages of this thesis

Stage 1 of this thesis involved the development of consolidated warfarin and NSAIDs care bundles, which was borne from a key recommendation posed by the SPSP-PPC evaluation team (Section 1.4.4). Stage 2 then involved a multifaceted evaluation of the consolidated care bundles developed. This explored the barriers and facilitators influencing their successful implementation where the CFIR was applied [63], which was informed from a preliminary systematic review conducted as part of this thesis. Specific outcomes of interest as defined by Proctor et al were also explored: penetration, fidelity, and client outcomes (i.e. patient perceptions) [70]. Due to the lack of empirical evidence on which implementation strategies are most effective within the community pharmacy setting, in Stage 3 the evaluation findings were used to develop recommendations for the scale up of the consolidated warfarin and NSAIDs care bundles. Each of the three stages had a number of corresponding aims and objectives which are presented.

Stage 1: Development of consolidated warfarin and NSAIDs care bundles

Aim 1: Develop and validate consolidated warfarin and NSAIDs care bundles (Chapter 4), with the following objectives:

- Define the core components and adaptable peripheries of the care bundles
- Scope the extent of variation of the existing care bundles
- Develop consolidated care bundles
- Validate the consolidated care bundles within community pharmacy practice

Stage 2: Evaluation of consolidated warfarin and NSAIDs care bundles

Aim 2: Identify barriers and facilitators to the national implementation of community pharmacy innovations (Chapter 5), with the following objectives:

- Identify studies exploring the factors influencing the national implementation of community pharmacy innovations from the perspectives of community pharmacy staff
- Synthesise reported barriers and facilitators

Aim 3: Develop a questionnaire to explore the barriers and facilitators influencing implementation success for the warfarin and NSAIDs care bundles and their penetration into routine community pharmacy practice (Chapter 6), with the following objectives:

- Develop questionnaire items to identify:
    - implementation success of the consolidated NSAIDs and warfarin care bundles
    - barriers and facilitators influencing implementation success
    - penetration of the care bundles into routine practice
- Conduct validity and reliability testing for the questionnaire
- Pilot the questionnaire
- Disseminate the final questionnaire to the participating pharmacies

Aim 4: Identify the barriers and facilitators influencing successful implementation of the consolidated warfarin and NSAIDs care bundles (Chapter 7), with the following objectives:

- Identify pharmacy staff perspectives of implementation success
- Identify causative barriers and facilitators influencing implementation success
- Develop recommendations to inform the national implementation of the warfarin and NSAIDs care bundles

Aim 5: Explore penetration and fidelity of the consolidated warfarin and NSAIDs care bundles (Chapter 8), with the following objectives:

- Conduct a fidelity assessment of the care bundles' core components
- Examine penetration of the care bundles in relation to their incorporation within routine community pharmacy practice and the resources used

- Examine penetration in relation to extent of pharmacy staff involvement with the care bundles

Aim 6: Elicit patient perceptions of the warfarin and NSAIDs care bundles (Chapter 9), with the following objectives:

- Seek patients' self-reported delivery of the care bundles
- Explore patient satisfaction with the care bundles
- Identify patient-reported impact of the care bundles.

Stage 3: Compilation of recommendations for scale up of consolidated warfarin and NSAIDs care bundles

Aim 7: Compile the recommendations for the national implementation of the warfarin and NSAIDs care bundles to inform tailored implementation strategies. (Chapter 10)

An overview of where these three stages positioned within the timeline of this thesis is presented in Figure 3.2.

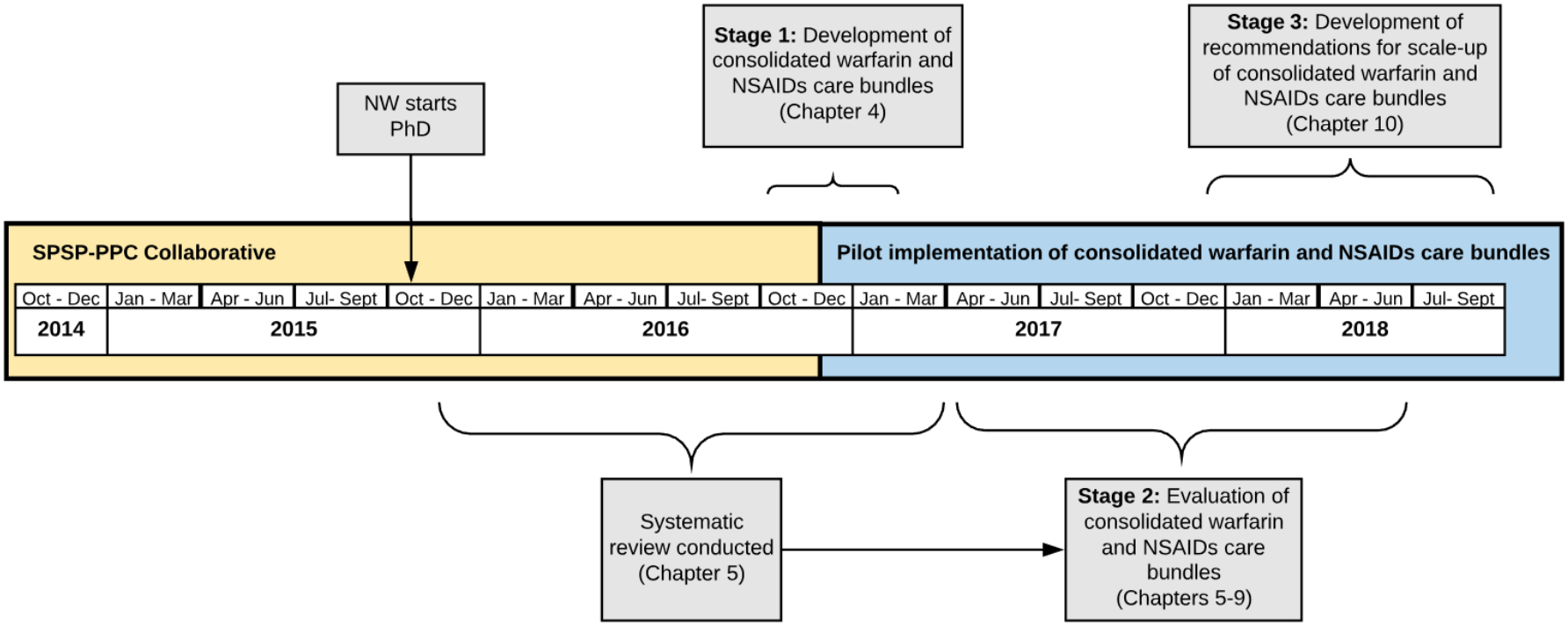


Figure 3.2. Timeline of thesis (Oct 2015- Oct 2018)

NW = Natalie Weir, SPSP-PPC = Scottish Patient Safety Programme – Pharmacy in Primary Care, NSAIDs = non-steroidal anti-inflammatory drugs

Chapter 4: Development and validation of consolidated warfarin and NSAIDs care bundles

4.1 Summary of Chapter

Background

Within the SPSP-PPC collaborative, two different NSAIDs care bundles and two different warfarin care bundles were developed. These differences were considered to constitute unnecessary variation, thus the aim of this study was to consolidate the four care bundles into a single NSAIDs care bundle and a single warfarin care bundle.

Methods

This study first involved defining what the core components of the care bundles should be (Phase 1), followed by scoping the extent of existing care bundle variation (Phase 2). Phase 3 applied the nominal group technique consensus method [91] to develop consolidated NSAIDs and warfarin care bundles involving a range of stakeholders (n=16). Lastly, Phase 4 involved early piloting of the consolidated care bundles within a cohort of 24 community pharmacies in four NHS Health Boards to ensure their usability in real-world settings (Feb 2017).

Results

A six-question NSAIDs care bundle focussing on communication and prescribing risk was developed (93% agreement); and a six-question warfarin care bundle focusing on patient knowledge and understanding was developed (100% agreement). Final refinements made to the care bundles ensured the wording, guidance and reference material were nationally applicable throughout Scotland in light of their intended scale up.

Conclusions

The method adopted in this study harnessed engagement of multiple stakeholders. The development of consolidated care bundles has allowed for their logical progression, and if scaled up nationally may offer equality of care to the Scottish population on these high risk medicines. Unanswered questions remain including the barriers and facilitators to implementing the care bundles, their integration into practice, and patient perceptions.

4.2 Background

Preventable adverse effects and hospital admissions are associated with the medicines warfarin and NSAIDs [28-35], and risky prescribing practices related to these high risk medicines have been identified as relatively common in Scottish GP practices [36]. In an effort to reduce this harm, in November 2014 community pharmacies (n=26) from across four regions in NHS Scotland iteratively developed and piloted warfarin and NSAIDs care bundles. These focused on improving the safer use of these medicines by prompting community pharmacy staff to check for interactions and to educate patients on the risks of these medicines. National implementation of these care bundles within all Scottish community pharmacies was intended to achieve wide-scale improvements in the safety of these medicines [92, 93] and to prevent only small pockets of best practice existing [9, 94].

However, national implementation of the care bundles was challenged by the fact that they were developed regionally; NHS Grampian and NHS Fife focused on warfarin, and NHS GG&C and NHS Highland focused on NSAIDs. Therefore, two different NSAIDs care bundles and two different warfarin care bundles were developed, which differed in relation to their aims, eligible patient cohort, and areas of risk covered by the care bundles (see Figure 1.10 of Chapter 1). Strategists within the SPSP-PPC collaborative considered these differences to constitute unnecessary variation – that is, the disparity in the provision of healthcare services and/or resources – which could negatively impact intended outcomes [93]. Furthermore, the *Healthcare Quality Strategy for NHS Scotland* (2010) emphasises the necessity to reduce inappropriate and unnecessary health service variation [9]. Thus, it was agreed that consolidation of the four care bundles into a single NSAIDs care bundle and a single warfarin bundle would ensure equality of care delivered to eligible patients once scaled up in Scotland [9, 94].

Implementing such standardized services and adopting top down implementation approaches is not without its challenges [82], as innovations can deviate from their intended operation when applied in real-world settings [95]. This is particularly evident in healthcare settings which are autonomous in nature (such as community pharmacies, general practitioner surgeries and dental practices) [92, 96], which adopt their own work processes and govern their own service delivery [97, 98]. Furthermore, contextual adaptations during scale up is known to facilitate successful implementation [99, 100], and in some instance an innovation's success is dependent on local level adaptations [101].

Resultantly, a meet-in-the-middle approach has been proposed whereby an innovation's core components and adaptable peripheries are identified [52, 63, 82]. Core components of an innovation are those which, if modified, are expected to compromise intended outcomes, with consistent application thought to ensure that an innovation will result in equitable outcomes [99]. Adaptable peripheries are modifiable parts of an innovation which allow it to successfully integrate within different contexts [99]. For example, in the Florida Health Literacy Study - which aims to improve patients' disease-specific knowledge - a core component was the specific patient incentives used [102]. The training schedule for participating healthcare staff was considered an adaptable periphery which varied depending on differing staff needs [102].

Ideally, identifying the core components of an innovation, such as the warfarin and NSAIDs care bundles, would involve sensitivity analysis using clinical outcome data and/or implementation fidelity data [98, 103]. However, clinical outcome data was unobtainable given the small scale nature of their pilot implementation in 26 pharmacies only, and the care bundle's run-chart data (which can be considered a measure of fidelity) were not truly representative as it only captured data for up to 10 patients per month. A cross-comparison of the run-chart data between the participating SPSP-PPC NHS Health Boards was also not possible as differing data collection methods were adopted. This inability to objectively measure success within quality improvement initiatives is a challenge previously encountered within the Scottish primary care setting [104]. Alternative attempts to identify an innovation's core components include qualitative interviews with stakeholders [105], yet such methods don't allow for collaborative agreement. Therefore, to address the existing variation of the high risk medicine care bundles, the purpose of this study was to apply an appropriate methodology to develop consolidated warfarin and NSAIDs care bundles using a collaborative approach with key stakeholders.

4.3 Aims and objectives

The aim of this study was to design and validate consolidated warfarin and NSAIDs care bundles. Specific objectives were to:

1. Define the core components and adaptable peripheries of the care bundles (Phase 1)
2. Scope the extent of variation of the existing care bundles (Phase 2)

3. Develop consolidated care bundles (Phase 3)
4. Validate the consolidated care bundles within community pharmacy practice (Phase 4)

4.4 Subjects and settings

The SPSP-PPC Steering Group (n=20), the SPSP-PPC pilot pharmacies (n=24), and other stakeholders (n=3) were invited to participate throughout the various phases of this study (Figure 4.1). The SPSP-PPC National Leads included a national clinical lead and a healthcare improvement lead. The SPSP-PPC Regional Leads included a local clinical lead and a primary care administrative lead for each of the four NHS regions (NHS GG&C, NHS Highland, NHS Fife, and NHS Grampian). Within the SPSP-PPC evaluation team, two of the representatives were from NHS Education for Scotland (NES) including a Professor of Pharmacy and the NES Lead for Patient Safety Research. The remaining three were from the University of Strathclyde and included a PhD candidate (the author of this thesis), a Professor of Pharmacy Practice, and a Research Associate.

Recruited participants	Phase 1: Defining core components and adaptable peripheries	Phase 2: Scoping the extent of variation of the existing care bundles	Phase 3: Developing consolidated care bundles	Phase 4: Validating the consolidated care bundles
SPSP-PPC Steering Group (n=20)				
SPSP-PPC National Leads (n=2)	✔		✔	
SPSP-PPC Regional Leads (n=8)		✔	✔	
SPSP-PPC evaluation team (n=5)	✔		✔	
HIS Project Administrator (n=1)			✔	
HIS Project Officer (n=1)			✔	
NES representative (n=1)			✔	
Patient representative (n=1)			✔	
Data and measurement Advisor (n=1)			✔	
Other stakeholders (n=3)				
National lead SPSP-PC collaborative (n=1)			✔	
Patient representative (n=1)			✔	
Scottish Government representative (n=1)			✔	
SPSP-PPC community pharmacies (n=24)				✔

Figure 4.1 Participants recruited for the four phases of developing consolidated care bundles

SPSP-PPC = Scottish Patient Safety Programme - Pharmacy in Primary care, HIS = Healthcare Improvement Scotland, NES = NHS Education for Scotland, SPSP-PC = Scottish Patient Safety Programme - Primary Care

The characteristics of the 24 participating SPSP-PPC community pharmacies involved in piloting the consolidated care bundles are presented in Table 4.1. Except from NHS Highland where two pharmacies withdrew participation to focus solely on the medicines reconciliation aspect of the SPSP-PPC collaborative, the pharmacies testing the care bundles remained the same as those previously involved in the SPSP-PPC collaborative.

Table 4.1. Characteristics of the 24 pilot pharmacies (2017)

Pharmacy characteristics	N (%)
High risk medicine of interest	
Warfarin	12 (50.0%)
NSAIDs	12 (50.0%)
Location	
NHS GG&C	9 (37.5%)
NHS Highland	3 (12.5%)
NHS Fife	7 (29.1%)
NHS Grampian	5 (20.8%)
Type of pharmacy	
Large chain pharmacy (>30 pharmacies)	12 (50.0%)
Medium chain pharmacy (5-30 pharmacies)	4 (16.7%)
Small chain pharmacy (2-4 pharmacies)	1 (4.2%)
Single, independent pharmacy	7 (29.2%)
Rurality	
Urban setting	21 (87.5%)
Rural setting	3 (12.5%)

GG&C = Greater Glasgow and Clyde, NSAIDs = non-steroidal anti-inflammatory drugs, NHS = National Health Service

4.5 Study design

A multi-method approach was selected to meet the objectives of the study, which is not uncommon when applying consensus methods [106, 107]. Phase 1 involved defining the core components and adaptable peripheries of the care bundles. This was followed by Phase 2 where the scope of the existing variation of the care bundles was identified. Phase 3 resulted in development of refined, consolidated NSAIDs and warfarin care bundles with agreed core components. Lastly, Phase 4 involved validation of the consolidated care bundles, conducted within a cohort of community pharmacies to ensure their appropriateness and usability in real-world settings. See Figure 4.2 for an outline of the study design.

Phase	Study objective	Method	Participants (n)
Phase 1: Defining core components and adaptable peripheries *(October 2016)*	To define the core components and adaptable peripheries of the care bundles	Teleconference 'Web-ex' meeting	SPSP-PPC National Leads (n=2) and SPSP-PPC evaluation team (n=5)
Phase 2: Scoping the extent of variation of the existing care bundles *(November 2016)*	To scope the extent of variation of the existing care bundles	Open-ended survey	SPSP-PPC NHS Regional Leads (n=8)
Phase 3: Developing consolidated care bundles *(November 2016-January 2017)*	**Phase 3a: Consensus workshop** (November 2016)		
	To gain consensus on warfarin and NSAIDs care bundles' core components	Nominal group techniques	SPSP-PPC Steering Group and other stakeholders (n=16)
	Phase 3b: Care bundle refinement (January 2017)		
	To refine the care bundles and agree on the final wording of the care bundle questions, guidance, and rationale.	Teleconference 'Web-ex' meeting	SPSP-PPC Steering Group (n=10)
Phase 4: Validating the consolidated care bundles *(February 2017)*	To validate the consolidated care bundles within community pharmacy practice	Pilot implementation of consolidated care bundles, with note-taking at formal SPSP-PPC meetings and review of documents used to report results.	SPSP-PPC community pharmacies (n=24)

Figure 4.2. Outline of the four phases conducted to develop consolidated care bundles (Oct 2016 - Feb 2017)

SPSP-PPC = Scottish Patient Safety Programme – Pharmacy in Primary care, NSAIDs = non-steroidal anti-inflammatory drugs, NHS = National Health Service

4.6 Phase 1: Definition of the core components and adaptable peripheries

4.6.1 Methods

In October 2016, three members of the SPSP-PPC evaluation team (NW, MB and EDC) from the University of Strathclyde held a teleconference meeting with the SPSP-PPC National Leads (n=2). This was to propose and discuss the definitions of the core components and adaptable peripheries of the warfarin and NSAIDs care bundles, which was done through discussion and reflection of the earlier evaluation results of the original warfarin and NSAIDs care bundles [38]. Prior to the teleconference call, information on the four care bundles which were collated from earlier evaluation results [38]. Due to the nature of the topic, a traditional meeting approach was adopted over qualitative methods, such as a focus groups or interviews, as allowing for free flowing conversation was considered most conducive to achieve the intended aim.

4.6.2 Results

It was agreed that there would be two high level core components for both the warfarin and NSAIDs care bundles: the care bundle questions and the eligible patient cohort who would receive the care bundles. The adaptable peripheries included which staff members were involved in delivering the care bundles to patients, the specific communication methods used (e.g. face-to-face or telephone conversation), and the use of resources. See Figure 4.3 for a description of these high-level core components and adaptable peripheries.

Core components	Description
Care bundle questions	• Which risk factors and/or interactions should be assessed for and what information should be provided to patients by the community pharmacy staff
Patient cohort	• Which cohort of patients should be considered eligible for the care bundle
Adaptable peripheries	**Description**
Pharmacy staff delivery	• Which pharmacy staff member(s) deliver the care bundle to eligible patients (e.g. pharmacist, dispenser) depending on staff competencies and local configurations of staff mix
Communication method	• Where and how communication with the patient occurs (e.g. in the pharmacy, telephone conversation) depending on patient and/or pharmacy preference
Use of resources	• The use and supply of patient resources developed (e.g. NSAIDS safety information cards, the warfarin YouTube video), depending on patient preference and/or pharmacy staff's judgement of suitability • The use of pharmacy resources (e.g. pharmacy stickers, reminder prompts) depending on pharmacy preference

Figure 4.3. Description of proposed core components and adaptable peripheries of the consolidated care bundles (Oct 2016)

NSAIDs = non-steroidal anti-inflammatory drugs

4.7 Phase 2: Extent of variation of existing care bundles

4.7.1 Methods

Tackling unwarranted variation in healthcare first requires systematic exploration and documentation of variation [93]. A survey was developed to collate up-to-date information on the operationalization of the four warfarin and NSAIDs care bundles. As the SPSP-PPC collaborative applied quality improvement methods such as PDSA cycles, iterative adaptations to the care bundle questions and patient cohort were anticipated since their initial design.

Information on each of the care bundle questions and patient cohorts were gathered from formal SPSP-PPC evaluation findings (i.e. on-site visits), informal means (i.e. steering group discussions), and from information disseminated to the pilot pharmacies. For each NHS Health Board, this information was collated into a word document and sent to the SPSP-PPC Regional Leads (n=8) accompanied by a series of open-ended questions to elicit if there have been any adaptations to the original care bundles. See Figure 4.4 for the survey questions.

Each scoping survey was sent to the respective SPSP-PPC Regional Leads two weeks prior to the consensus workshop (Phase 3a) in November 2016 via email. Participants were asked to complete it electronically. A response deadline of one week was given, with a reminder email sent on the last day for those who hadn't yet responded.

1. Are there any changes to the care bundle questions?
2. Are there any changes to the care bundle guidance?
3. Are there any changes to the care bundle rational?
4. Are there any changes to the care bundle patient cohort?
5. Are there any other changes in relation to the care bundle?
6. Are there any examples of variation within your Health Board? Specifically, are there any pharmacies which do anything differently – i.e. ask different questions/have a different patient cohort?

Figure 4.4. Survey questions exploring extent of variation of the pre-consolidated care bundles

4.7.2 Results

An SPSP-PPC NHS Regional Lead from each participating NHS Health Board completed the survey. There was one instance where a care bundle question had changed, and various instances where there was clarification of the patient cohort (Table 4.2). These up-to-date care bundle questions and their respective patient cohorts were disseminated to the participants involved in the consensus workshop (Phase 3a).

Table 4.2. Results of survey on extent of care bundle variation

Care bundle	Care bundle changes	Patient cohort changes
NSAIDs care bundle 1	The question wording, guidance and rational had been changed for question 3. For question 1a, the question remained the same but the guidance and rationale had changed.	There was clarification of the patient cohort, that it was all NSAID patients who were eligible and not those over 60, and that there is repetition of the care bundle to all patients (although it was noted that the way the information is provided is adapted).
NSAIDs care bundle 2	It was confirmed that there had been no changes to the care bundles questions, guidance, rational or cohort, and that there was no variation between the pharmacies.	There was clarification of the patient cohort - in this region the care bundle is repeated to all patients.
Warfarin care bundle 1	It was confirmed that there had been no changes to the care bundles questions, guidance, rational or cohort, and that there was no variation between the pharmacies.	There was clarification of the patient cohort, that there was repeated reiteration of the advice, education at every interaction, and that all patients (including 'one offs') were eligible for the care bundle.
Warfarin care bundle 2	It was confirmed that there had been no changes to the care bundles questions, guidance, rational or cohort, and that there was no variation between the pharmacies.	There was clarification of the patient cohort. There was no reliance on patients bringing in their warfarin recording book. It was clarified that a 'one time visitor' to a pharmacy would not be delivered the care bundle, only regular patients develop from a list generated by the PMR system.

NSAIDs = non-steroidal anti-inflammatory drugs, PMR = patient medication record

4.8 Phase 3: Development of consolidated care bundles

To effectively reduce unwarranted variation, collective engagement of healthcare professionals, patients and policy makers is required [108], and strategic decision making should involve engagement of a variety of stakeholders [106, 109]. Therefore, Phase 3 of the study was conducted which invited key stakeholders to agree the detail for the core components of the care bundles (see Figure 4.1 for information on these participants). This was separated into two sub-phases. Firstly, Phase 3a involved a consensus workshop to obtain consensus on the specific core components with the SPSP-PPC steering group and other stakeholders. As consensus methods are rarely considered the endpoint [110], this was followed by Phase 3b which involved refining the consolidated care bundles developed via a teleconference 'Web-ex' meeting with the SPSP-PPC Steering Group.

4.8.1 Phase 3a: Consensus workshop methods

A consensus method was considered most appropriate to agree on the core components of the care bundles. This was due to the absence of clinical data pertaining to the care bundles, or verifiable empirical data evidencing the fidelity of the care bundles' operation in practice. Consensus methods can be used to aid decision making within healthcare if there is lack of, or conflicting, empirical evidence (29). Consensus methods seek to determine the extent a group of people agree about a specific issue [110], and it is argued that they are an underutilised method within the area of service development and complex organisational change (30). Furthermore, using a consensus approach with a multi-speciality group maintains the collaborative ethos advocated by the BTS collaborative model employed by the SPSP-PPC collaborative [19].

A review of different consensus methods was first conducted to identify the most suitable method, presented in Appendix 4.1, with the nominal group technique (NGT) selected as the most appropriate. The NGT is a method used for decision-making and consensus generating [91, 111, 112], which involves group interaction and discussion with equal input of all participants who are termed the nominal group [113]. The NGT involves a nominal question being posed [114], with the nominal group then involved in five NGT stages which concludes with formally identifying if consensus has been achieved (see Figure 4.5) [114].

1. Introduction and explanation
2. Silent generation of ideas
3. Sharing of ideas
4. Group discussion
5. Voting and ranking.

Figure 4.5. Summary of the Nominal Group Technique stages

4.8.1.1 The nominal questions

The four nominal questions posed within this study focused on the care bundle questions and eligible patient cohorts which were the core components of the care bundles:

Nominal question 1: *What should the consolidated NSAID care bundle questions be?*

Nominal question 2: *What should the consolidated NSAID care bundle patient cohort be?*

Nominal question 3: *What should the consolidated Warfarin care bundle questions be?*

Nominal question 4: *What should the consolidated Warfarin care bundle patient cohort be?*

4.8.1.2 Participants

A multi-specialty group of 23 participants comprising the SPSP-PPC Steering Group and other stakeholders were purposefully invited to participant within the SPSP-PPC consensus workshop to ensure a wide range of opinions (see Figure 4.1) [115]. Their selection was based on their involvement in the SPSP-PPC collaborative as an SPSP-PPC Steering Group member or their expertise in a relevant area of interest

4.8.1.3 NGT method

The application of the NGT stages for this study are described in Figure 4.6. Two SPSP-PPC evaluation team members moderated these - EDC and NW (who is the author of this thesis). Each nominal question formulated a separate NGT with one hour dedicated to each [113]. The four NGTs took place at a one day consensus workshop on the 22nd of November 2016. Participants received an information pack by email one week prior to the event. This enclosed a two page 'Fact Sheet' of the NGT process and anonymous information on each of the four NHS Health Boards care bundle questions and patient cohorts updated where appropriate following the survey (Phase 2). The topic, scope and workshop agenda were verbally reintroduced with the aid of a PowerPoint presentation on the day, followed by opportunity for questions. The setup of the room was purposefully arranged with the tables and seats in a U-shaped setting as this was considered most conducive for group discussion by allowing all participants to easily see each other. An information sheet was provided, demographics of the participants were collected and informed consent obtained.

NGT Stage	Elaboration
Silent generation of opinion and/or thoughts (10 minutes)	• The nominal questions were posed verbally and presented on a power point slide and within participant workbooks (see Appendix 4.2 for example workbook). • The different care bundle questions or patient cohorts identified from the scoping survey were presented within participant workbooks. • Participants silently wrote their thoughts or opinions of each. • Participants were asked not to start a discussion.
Round robin feedback (15 minutes)	• Each participant had the opportunity to share their opinions and/or thoughts. A moderator (EDC) transcribed and projected these onto a screen. Participants were instructed that feedback could be specific or general, and that it was not mandatory to offer comments. • A wooden 'talking spoon' was used to indicate whose turn it was to speak to prevent interruption or discussion.
Discussion (15 minutes)	• Open discussion commenced to allow participants to elaborate, dispute, or discuss the opinions and/or thoughts presented during the round robin feedback.
Ranking (5 minutes)	• Within the workbooks, participants ranked each of the care bundle questions or patient cohort difference from 'most-to-least favourable'. • Depending on the number of elements for each NGT, the top ranked item was given the highest number and the least favourable the lowest. • Participants were asked to keep their ranking confidential.
Break (5 minutes)	• The ranking was collated and tallied by the moderators using Microsoft Excel 2013 as suggested by McMillan et al [113]. The moderators did this together to cross-validate data entry.
Ranking presented back & consensus (10 minutes)	• The summative ranking results were presented back to the participants in order of highest to lowest ranked. • For the NGTs focusing on care bundle questions, the top six were visually highlighted, as within NHS Scotland care bundles are typically between four to six measures [37]. • Whilst the ranking results were presented to the participants, a pre-consensus discussion occurred for participants to comment on the ranking results. As a group, there was a discussion about which items which would be retained within the care bundle. • Following the pre-consensus discussion of which items would be retained within the care bundle, formal consensus was sought. • Consensus was achieved if >70% of participants were in agreement with the final proposed care bundle. This was determined anonymously by asking participants to close their eyes and signify agreement by putting their thumbs up.

Figure 4.6. Application of the nominal group technique (NGT) for this study

As the evaluation team were formatively evaluating the pilot programme and were considered steering group members it was deemed that the participants might value true anonymity during the consensus workshop. Therefore, participants' written opinions and/or thoughts and ranking within the NGT workbooks were kept anonymous and could not be attributed to certain individuals or demographic characteristics throughout the analysis. Therefore, analysis is summative to show how the nominal group in its entirety responded.

4.8.2 Phase 3a: Consensus workshop results

4.8.2.1 NGT participants

Of the 23 participants invited, sixteen individuals participated within the NGTs. The full demographics of participants are shown in Table 4.3. The patient representative could only participant during the warfarin NGTs only.

Table 4.3. Demographic details of the consensus workshop participants (n=16, Nov 2016)

Participants role	**n**
SPSP-PPC National Lead	1
SPSP-PPC Regional Leads	8
SPSP-PC National Lead	1
SPSP-PPC evaluation team representative	1
HIS Project Administrator	1
HIS Project Officer	1
NES representative	1
Scottish Government representative	1
Patient representative*	1
Gender	**n**
Male	5
Female	11
Age (years)	**n**
16-24	0
25-34	1
35-44	4
45-54	10
55-64	1
65+	0

** Participant participated in the warfarin NGTs only*

SPSP-PPC = Scottish Patient Safety Programme – Pharmacy in Primary care, SPSP-PC = Scottish Patient Safety Programme – Primacy Care, HIS = Healthcare Improvement Scotland, NES = NHS Education for Scotland

4.8.2.2 NGT ranking results and pre-consensus discussion

Tables 4.4 and 4.5 present the results of the NGT ranking and the pre-consensus discussion for the warfarin and NSAIDs care bundles, whereby the items are presented in order of highest to lowest ranked. Maximum rankings for each items were calculated by multiplying the number of items by participants. For example, for NGT1 relating to the NSAIDs care bundle questions (Table 4.4), as eleven item were ranked by 15 participants the highest ranking score possible is 165 (11x15), and the lowest is 15 (1x15).

During the pre-consensus discussion for the NSAIDs care bundle, participants discussed that two of the care bundle questions which were ranked within the top six were conceptually similar. These were: 'Have you checked if the patient is experiencing adverse drug reactions or side effects?' (which was ranked second) and 'Has the patient been informed to report any GI side effects to their pharmacist or GP?' (which was ranked sixth). Therefore, through discussion it was suggested that only the former of these be retained as it attained the higher ranking score. This meant that the six items to be retained within the NSAIDs care bundle were the top five ranked items and the seventh ranked item. Some suggested refinement were also made to these six items in relation to the items wording, as presented in Table 4.4.

During the pre-consensus discussion for the warfarin care bundle, participants noted that the sixth and seventh ranked care bundle questions were conceptually similar to items which were highest ranked. Therefore, it was agreed that neither of these would be retained. The next care bundle question ranked eight was 'Is the patient aware that they should have an INR test 3 days after starting a course of antibiotics?'. Although this was the lowest ranked, during the pre-consensus discussion some participants stressed its importance. Other reported that they ranked it low due to the lack of national consensus in Scotland on how many days after starting a course of antibiotics a patient on warfarin should have their INR tested. This was easily overcome by a participant suggesting wording refinements with the removal of '3 days'. Participants were agreeable to this and this question was therefore selected to be retained within the consolidated warfarin care bundle.

Table 4.4. Results of the NSAIDs care bundle consolidation (n= 15, November 2016)

NGT Questions	Items	Ranking Score	Pre-consensus discussion comments	Retained
NGT1: What should the consolidated non-steroidal anti-inflammatory drugs (NSAIDs) care bundle questions be?	**Has the patient been informed to take it with or after food?**	118/165	No suggestions – to be retained	**Yes**
	Have you checked if the patient is experiencing adverse drug reactions or side effects?	107/165	No suggestions – to be retained	**Yes**
	Has gastro-protection been prescribed for high risk patients?*	100/165	To be retained but refined to focus on adding in gastroprotection if required or stopping the NSAID. Proposed wording: *'For high risk patients, has gastroprotection been prescriber OR the NSAID been stopped, if appropriate?*	**Yes**
	a) Is the patient in a high risk group requiring gastroprotection? (Yes/No) **b) If yes, has gastroprotection been prescribed? (Yes/No)***			
	a) Is the patient prescribed the triple whammy combination? (Yes or No) **b) If yes, has the triple whammy combination been highlighted to the prescriber? (Yes or No)^**	95/165	No suggestions – to be retained	**Yes**
	Have you checked that the patient is concordant with taking their NSAID?	93/165	To be retained but refined to be more specific and focus on whether patients still require their NSAID and assessing their need. Proposed wording: *'Has the patient's use and/or need of their NSAID been assessed?'*	**Yes**
	Has the patient been informed to report any gastro-intestinal side effects to their pharmacist or general practitioner?	88/165	Not to be retained as overlap with above retained question.	**No**
	Is the patient aware of the Medicine Sick Day Rules? (Yes or No or Not applicable)	85/165	To be retained but refined to no longer rely on the 'medicine sick day rules' but highlighting risk of dehydrating illness. Proposed wording: *'Has the patient been made aware of the risk of a dehydrating illnesses?'*	**Yes**
	For patients identified as taking other high risk drugs, has this risk been highlighted to the prescriber?^	81/165	Not to be retained.	**No**
	a) If the prescriber was contacted, was the resulting review communicated back to the pharmacy? **b) Has this change been discussed by the pharmacist with the patient/carer?**	38/165	Not to be retained.	**No**
	Have all measures been met?	15/165	Not to be retained.	**No**
NGT2: What should the consolidated NSAIDs care bundle patient cohort be?	**Eligible patients are those who are prescribed an NSAID, over-the-counter (OTC) and Minor Ailments Service supplies.**	28/30	No suggestions – to be retained. Although, agreement in the room that it should be 'monitored early' and if 'push back' then will moderate this.	**Yes**
	Eligible patients are those who are prescribed an NSAID.	17/30	Not to be retained.	**No**
	The following was the same for both the NSAID care bundles and resultantly no consolidation was required: • All NSAID patients are eligible (i.e. no restriction to high risk groups) • The care bundle is repeated to patients			

**,^ These questions from the original NSAID care bundles were deemed interchangeable and for the purpose of the NGT method they were grouped together.*

Table 4.5. Results of the warfarin care bundle consolidation (n= 16, November 2016)

NGT Questions	Items	Ranking Score	Pre-consensus discussion comments	Retained
NGT 3: What should the consolidated warfarin care bundle questions be?	**Is the OAT alert card up to date / current including completed information (indication, duration of treatment and target range)?***	98/160	To be retained but refined to focus more on patient's awareness of the importance to carry an up to date alert card. Proposed wording: *'Is the patient aware of the importance of carrying an up to date alert card?'*	**Yes**
	Does the patient carry an up to date alert card (indication, duration of treatment and target range)?*			
	Is the yellow OAT record booklet up to date / current including completed information (indication, duration of treatment and therapeutic range)?*	91/160	To be retained yet refined to not focus on specific information sources as these are variable between regions, and to include if patient has up-to-date information on current dose. Proposed wording: *'Does the patient have up to date information on their indication, duration of treatment, therapeutic range and current dose of Warfarin?.* Updated guidance included making patients aware to bring this information to every healthcare intervention.	**Yes**
	Does the patient have an up to date Oral Anti-Coagulant Therapy (OAT) record book (indication, duration of treatment and therapeutic range)?*			
	Does the patient know what to do if they have missed a dose of warfarin?	84/160	No suggestions – to be retained	**Yes**
	Is the patient aware that they should inform the team responsible for their warfarin care of any significant changes that may affect their warfarin? E.g. Newly prescribed medicines, certain OTC medicines and changes to food/alcohol.	70/160	No suggestions – to be retained	**Yes**
	Is the patient aware of what to do if they are suffering from signs and symptoms of over/under-coagulation?	68/160	No suggestions – to be retained	**Yes**
	Is the patient / carer aware that they should carry the Alert Card at all times?	66/160	Not to be retained – overlap with above retained question regarding alert card.	**No**
	Is the patient / carer aware that the Yellow OAT record booklet is taken to EVERY healthcare intervention?	49/160	Not to be retained – overlap with above retained question regarding up to date information.	**No**
	Is the patient aware that they should have an International Normalised Ratio (INR) test 3 days after starting a course of antibiotics?	48/160	Commented to be crucial, and to be retained with '3 days' to be removed due to variable local protocols. Proposed wording: *'Is the patient aware that they should have an INR test after starting a course of antibiotics?'*	**Yes**
NGT4: What should the consolidated warfarin care bundle patient cohort be?	**All regular and non-regular (i.e. 'once off') patients prescribed Warfarin (even if they don't have their Warfarin record book)**	32/32	No suggestions – to be retained	**Yes**
	All regular patients prescribed Warfarin (even if they don't have their Warfarin record book on hand)	16/32	Not to be retained.	**No**
	Patients are repeatedly delivered the care bundle	32/32	No suggestions – to be retained	**Yes**
	Patients are not repeatedly delivered the care bundle.	16/32	Not to be retained.	**No**

** These questions from the original warfarin care bundles were deemed interchangeable and for the purpose of the NGT method they were grouped together.*

4.8. NGT consensus agreement

For the items suggested to be retained following the ranking process and pre-consensus discussion, formal consensus was sought to ensure agreement with the proposed care bundles. Consensus was attained for each of the care bundles, as is presented in Table 4.6. For the NSAIDs care bundle questions, 93% (n=14) of participants agreed with the six care bundle questions and for the NSAIDs care bundle's eligible patient cohort. For the warfarin care bundle questions, all participants (100%) agreed with the care bundle questions, and 88% agreed with the warfarin care bundle's eligible patient cohort.

Table 4.6. Nominal group technique (NGT) consensus results (Phase 3a)

Agreed consolidated care bundle questions and patient cohort	**% (n) in Agreement**
NGT1: What should the consolidated NSAID care bundle questions be?	**93% (n=14)**
1. Has the patient been informed to take it with or after food?	
2. Have you checked if the patient is experiencing adverse drug reactions or side effects?	
3. Has the patient been made aware of the risk of a dehydrating illnesses?	
4. Has the patient's use and/or need of their NSAID been assessed?	
5. For high risk patients, has gastroprotection been prescriber OR the NSAID been stopped, if appropriate?	
6. Is the patient prescribed the triple whammy combination? If yes, has the triple whammy combination been highlighted to the prescriber?	
NGT2: What should the NSAID care bundle patient cohort be?	**93% (n=14)**
• Eligible patients are those who are prescribed an NSAID, over-the-counter (OTC) and Minor Ailments Service supplies.	
• Patients are repeatedly delivered the care bundle	
NGT3: What should the consolidated Warfarin care bundle questions be?	**100% (n=15)**
1. Is the patient aware of the importance of carrying an up to date alert card?	
2. Does the patient have up to date information on their indication, duration of treatment, therapeutic range and current dose of Warfarin?	
3. Does the patient know what to do if they have missed a dose of warfarin?	
4. Is the patient aware that they should inform the team responsible for their warfarin care of any significant changes that may affect their warfarin? E.g. Newly prescribed medicines, certain OTC medicines and changes to food/alcohol.	
5. Is the patient aware of what to do if they are suffering from signs and symptoms of over/under-coagulation?	
6. Is the patient aware that they should have an INR test after starting a course of antibiotics?	
NGT4: What should the Warfarin care bundle patient cohort be?	**88% (n=14)**
• All regular and non-regular (i.e. "once off") patients prescribed Warfarin (even if they don't have their Warfarin record book on hand).	
• Patients are repeatedly delivered the care bundle	

NSAIDs = non-steroidal anti-inflammatory drugs, INR = international normalized ratio

4.8.3 Phase 3b: Care bundle refinement methods

Consensus methods are rarely considered the endpoint [110], and suggested refinements following the consensus workshop were welcomed to ensure the usability and appropriateness of the consolidated warfarin and NSAIDs care bundles in routine practice. This occurred during a videoconference 'WebEx' on January 12th 2017 approximately 6 weeks following the consensus workshop with the SPSP-PPC Steering Group and the SPSP-PPC evaluation team (see Figure 4.1). The purpose of the videoconference 'WebEx' was to refine the intricacies of the care bundle core components and ensure that the care bundle wording, guidance and rationale was applicable to all settings within Scotland. Following the videoconference WebEx, the agreed changes were made to the care bundles and disseminated to the SPSP-PPC steering group with critical amendments welcomed within a one-week deadline before final dissemination to the participating pharmacies.

4.8.4 Phase 3b: Care bundle refinement results

Fifteen members of the SPSP-PPC Steering Group and Evaluation Team participated in the videoconference 'WebEx'. This included the SPSP-PPC National Leads from HIS (n=2), the SPSP-PPC NHS Regional Leads with representation from all of the four NHS regions involved (n=7), representatives from the SPSP-PPC evaluation team (n=3), HIS project officers (n=2), and a Data & Measurement Advisor from HIS (n=1). Three of the SPSP-PPC steering group members could not attend (an SPSP-PPC NHS Regional Lead and two representatives from NHS Education for Scotland). Twelve (80%) of the participants also participated in the NGTs (Phase 3a). The inclusion of only the SPSP-PPC steering group and SPSP-PPC evaluation team and not a wider multi-speciality group was purposeful as this phase focused on more intricate details relating to the care bundle's operationalization, and the external parties (e.g. representatives from Scottish Government) would have had limited knowledge within this area to input.

The suggested final refinements to the consolidated care bundles are shown in Table 4.7.

Table 4.7. Refinement of the consolidated care bundles (Phase 3b)

NSAIDs care bundle refinements

• Reword care bundle question 2 to:
  ○ 'Has the patient been informed to report any potential adverse drug reactions to the pharmacist and/or prescriber?'
• Reword care bundle question 3 to:
  ○ 'Has the patient been informed to stop the NSAID medication during periods of dehydrating illness (e.g. sickness and diarrhea)?"
• Deliver the care bundle questions 1 to 3 to all patients (i.e. prescribed, over-the counter purchases, minor ailments service applied) which would be termed the 'NSAIDs Communication Care Bundle'.
• Deliver the care bundle questions 4 to 6 to patients on additional medication which would be termed the 'NSAIDs Safer Care Bundle'.

Warfarin care bundle refinements
• Reword all care bundle questions to check pharmacist's compliance not patient responses (e.g. 'Is the patient aware of the importance of carrying an up to date alert card?' changed to 'Has the patient been told of the importance in carrying an up-to-date alert card?')

NSAID(s) = non-steroidal anti-inflammatory drug(s)

4.9 Phase 4: Validation of the consolidated care bundle

4.9.1 Phase 4 methods

The refined, consolidated warfarin and NSAIDs care bundles progressed onto testing within the SPSP-PPC community pharmacies on the 6th of February 2017, funded via the 2016/17 community pharmacy contractual framework [116]. The purpose of this testing phase was to validate their usability in routine practice. The SPSP-PPC pharmacies which had previously tested the warfarin care bundles swapped to test the consolidate NSAIDs care bundle, and vice versa. This was purposeful to understand the appropriateness of an NSAIDs or a warfarin care bundle in different localities before wider roll-out. Except from NHS Highland – where two pharmacies focused solely on the medicines reconciliation care bundle – the pharmacies testing the care bundles remained the same as those previously involved in the SPSP-PPC collaborative (n=24). Twelve pharmacies piloted the NSAIDs bundle within NHS Grampian and NHS Fife, and twelve pharmacies piloted the warfarin bundle within NHS GG&C and NHS Highland. A timeline of the events following consolidation of the warfarin and NSAIDs care

bundles is shown in Figure 4.7. Resources developed from the initial pilot phase were disseminated to the pilot pharmacies (Appendix 1.1), and pharmacies were asked to continue to complete quality improvement run charts using a standardised excel sheet developed by HIS and to routinely send these to respective health board leads.

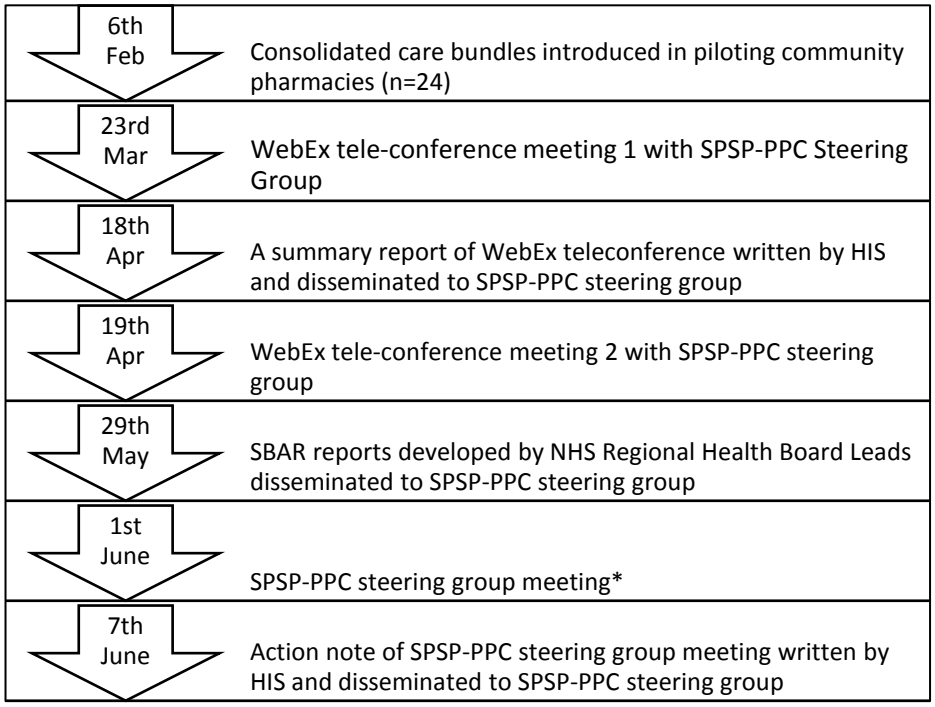


Figure 4.7. Timeline of events following consolidation of the care bundles in 2017

** The SPSP-PPC evaluation team provided an update on the progress based on interim findings from note-taken during the WebEx teleconferences*
SPSP-PPC = Scottish Patient Safety Programme – Pharmacy in Primary Care, HIS = Healthcare Improvement Scotland, NHS =National Health Service, SBAR = situation, background, assessment, recommendation

Reviews of documents and note-taking during regular teleconferences and steering group meetings during February to June 2017 were conducted to reflect upon the operation of the core components and adaptable peripheries, and note amendments to the consolidated care bundles in practice. Hand-written notes made during meetings were typed into a written transcript using a purposefully developed template shown in Figure 4.8, as previously described by Sunstein and Chiseri-Strater [117]. To corroborate and ensure consistency of reporting and interpretation, EDC who also attended the teleconferences and steering group meetings read summaries of the written transcripts.

Detailed account: Based on the hand written notes, a detailed account of the meetings was transcribed as soon as possible following the meetings.

Reflection/my involvement: NW reflected on her experience, her involvement and how it may have influenced events during the meetings.

Analysis: A brief paragraph was written on the reflections of what the mood was like in each meeting and the outputs.

Future action: Areas to best focus future evaluation activities on were noted.

Figure 4.8. Template for typing up hand written notes taken during meetings [118]

Deductive content analysis of the written transcripts and circulated documents was conducted. Data were extracted from the data sources if it related to the operation of the core components and adaptable peripheries, and/or any posed amendments to the consolidated care bundles. The data sources included: written transcript of notes of WebEx teleconferences (n=2), a Flash-Report written by HIS (n=1), Situation-Background-Assessment-Recommendation (SBAR) reports written by the SPSP-PPC NHS Regional Leads for each participating NHS Health Board (n=4), written transcript of notes taken from a face-to-face steering group meeting (n=1), and an action note developed by HIS (n=1).

4.9.2 Phase 4 results

4.9.2.1 Consolidated care bundles' core components

Following application in routine pharmacy practice, the SPSP-PPC NHS Regional Leads from Fife and Grampian collaborated to refine the core components of the consolidated NSAIDs care bundle. For the NSAIDs care bundle patient cohort, early piloting identified that the two-part care bundle resulted in variable processes within the pharmacies with respect to who was receiving the care bundle. Based on pharmacy staff feedback, the most pragmatic and feasible solution was for the 'Communication Bundle' to be delivered to all patients (either prescribed, on the minor ailments services, or via an over-the-counter purchase), and the 'Safer Care Bundle' to be delivered only to patients prescribed an NSAID. These changes were agreed by the entire SPSP-PPC steering group at the first WebEx hosted on the 23rd of March 2017, and the amended care bundle was disseminated to the pharmacies participating in the NSAIDs care bundle in April 2017.

There were no suggestions to refine the consolidated warfarin care bundle core components, however it was noted that the care bundle questions duplicated with the existing High Risk Medicines Intervention Pharmacy Care Record tool [119]. This tool allows community pharmacists to document a high risk medicine risk assessment for patients receiving the medicines warfarin, methotrexate or lithium. This explores patients' concordance with their medication; interactions and precautions; adverse drug reactions; and monitoring. An image of the warfarin risk assessment is presented in Appendix 4.3

The final warfarin and NSAIDs care bundles developed from this validation phase are presented in Figure 4.9, with full rationale and guidance for the care bundles presented in Appendix 4.4.

Care bundle	Care bundle questions	Eligible patients
NSAIDs care bundle	**Communication Care Bundle**	
	1. Informing patient to take NSAID with or after food	All OTC, eMAS and Rx supplies of an NSAID.
	2. Informing patient to report of potential adverse drug reactions	
	3. Informing patient to stop NSAID medication during dehydrating illness	
	Safer Care Bundle	
	4. Assessing use/need of NSAID	All Rx supplies of an NSAID.
	5. Identifying if patient is in high risk group	
	6. Identifying triple whammy interactions	
Warfarin care bundle	1. Informing patient of importance of carrying alert card	All Rx supplies of warfarin.
	2. Reviewing patients' information on indication, duration of treatment, therapeutic range and current dose of warfarin	
	3. Informing patient of what to do if missed a dose of warfarin	
	4. Informing patient to report any significant changes which may affect their warfarin	
	5. Discussing common signs and symptoms of over/under-coagulation	
	6. Informing patient that the need INR test if starting antibiotics	

Figure 4.9. Core components of the consolidated warfarin and NSAIDs care bundles

OTC = over the counter, eMAS = minor ailments service, Rx = prescription, NSAID(s) = non-steroidal anti-inflammatory drug(s), INR = international normalised ratio

4.9.2.2 Consolidated care bundles' adaptable peripheries

An adaptable periphery of the care bundles included which pharmacy staff were involved in delivering the care bundle. Early feedback suggested this to facilitate implementation of the consolidated warfarin bundles in different pharmacies by allowing them to adopt different workflow models; some community pharmacy staff felt it would have to be delivered by a pharmacist, whereas others involved pharmacy technicians. Overall, whole team engagement was reported for the NSAIDs bundle, especially with the NSAIDs Communication Care Bundle which was delivered to all supplies of an NSAID.

The adaptability of the communication methods which could be adopted (e.g. if the care bundle is delivered in person or over the phone) was evidenced for the warfarin bundle, although there was no emergent data on this for the NSAIDs bundle. In response to challenges cited with delivering the warfarin care bundle to patients who do not attend the pharmacy, some pharmacies attached labels to prescription bags asking patients to phone the pharmacy.

For the NSAIDs bundle, the resources were commented to be valued by the pharmacies and had been used. For the warfarin bundle, the resources were commented to be useful, patient friendly, and colourful. However, within NHS GG&C where warfarin is managed by clinic nurses, it was noted that there was duplication of supply of the warfarin related resources.

Although it was asked of all participating community pharmacies to undergo data collection for the purpose of developing run charts, it was reported during the WebEx meetings that data was not submitted by all pharmacies to the SPSP-PPC regional leads. For the warfarin care bundle, it was reported that low patient numbers meant it was difficult to develop meaningful run charts, which was thought reflective of the prescribing shift from warfarin to the use of newer direct oral anti-coagulants.

4.10 Discussion

Implementation scientists and strategists have long debated top-down versus bottom-up implementation approaches (1, 15). Developing innovations with core components and adaptable peripheries is considered a meet-in-the-middle approach, yet there is a scarcity of methods on how to do so where there is lack of empirical evidence [98, 103]. The consensus method applied in this study harnessed positive engagement from a diverse array of

stakeholders, and was successful in developing consolidated warfarin and NSAIDs care bundles with agreed core components. Early feedback was obtained from the 24 piloting pharmacies, with final refinements and early testing supporting the evidence that they are operational in routine community pharmacy practice. Overall, the study has allowed for logical progression of the warfarin and NSAIDs care bundles in preparation for their anticipated national implementation within Scottish community pharmacies.

The consolidated care bundles developed in this study focused on educating patients on the risks associated with the high risk medicines warfarin and NSAIDs, with the NSAIDs bundle additionally focusing on identifying high risk patients and interactions (e.g. triple whammies). Interestingly, both care bundles developed had a similar every patient, every time approach, whereby all patients taking these high risk medicines were to be delivered the care bundle. This approach differs from other warfarin and NSAIDs services identified within the literature which stratify eligible patients to those in high risk categories [120, 121]. For a NSAIDs service in NHS Crawley pharmacies, NSAIDs-related medicine use reviews were delivered only to patients prescribed an NSAID who were either over the age of 55 or were not concomitantly prescribed a gastro-protective agent [120]. For a warfarin-related education service delivered by medical staff within the UK, eligible patients were stratified to those over the age of 65 with identified unstable INR control [121]. Thus, the care bundles developed in this study may have wider scope to improve safety-related outcomes of these high risk medicines given their notable inclusivity.

The purposeful development of the care bundles' core components was in an effort to develop services which can offer equality of care to patients if scaled up throughout Scotland. Potential implications of the care bundles include reducing risky prescribing practices and preventable adverse drug-related events once scaled-up, which could be quantitatively captured at scale via existing data infrastructure in Scotland [122]. This is an important consideration for any quality improvement initiative as the ability to show an improvement has been made is a fundamental component of the Model for Improvement [24]. The level of standardisation offered by defined core components may also facilitate scale up efforts as nationally applicable training resources and events could be developed. Furthermore, the development of defined core components of the care bundles may facilitate their implementation, as there is some evidence which indicated that the more clearly defined an

innovation's core components are the greater the likelihood of successful implementation [82].

Meanwhile, the care bundles' adaptable peripheries may allow for flexibility in their delivery and ensure that they can integrate within different community pharmacy contexts. Ensuring integration within variable processes is of notable importance within the Scottish community pharmacy context due to the variation in pharmacy ownership and the introduction of novel eHealth technology, such as automated dispensing technology [123-125]. For example, task delegation within pharmacies can be dependent on local staff configuration and/or competencies – which was observed within earlier evaluation where whole team involvement was observed to varying degrees [38]. Additionally, the use of pharmacy-specific resources can be dependent on local preference and/or need.

The existence of adaptable peripheries may also allow for a degree of patient-centeredness as the delivery can be adapted to different patients [92]. For example, the communication method can be tailored depending on patient preference or needs; patients who cannot leave their homes may appreciate a telephone conversation as opposed to face-to-face contact, as was seen in the example with the warfarin bundle where labels were attached to prescription bags asking patients to phone the pharmacy. The supply of patient resources (e.g. information cards) is also dependent on pharmacy staff judgment of suitability and patients' perceived needs and desire for such resources. This was evidenced in these early stages of testing, as the warfarin resources were not always supplied by the pharmacies to patients as they had reported receiving these resources elsewhere.

4.10.1 Strengths and limitations

A strength of the methods used in the study was its ability to harness engagement from a range of stakeholders throughout: national strategists influenced the concept and content in line with national strategy; regional leads commented on the feasibility of the bundles; a patient representative offered input from their perspective of the warfarin care bundle; and front-line staff refined the care bundles following application in routine community pharmacy practice. The use of a collaborative approach to develop consolidated care bundles also aligns with the BTS model applied throughout the SPSP-PPC collaborative. This approach in itself may constitute a facilitator to harness support for the next phases of implementation, as the implementers' knowledge of how an innovation was developed is believed to influence

successful implementation [99]. However, Phase 1 (Section 4.6) of this study, which centred on defining the high level core components and adaptable peripheries, may have benefitted from wider stakeholder engagement. Although the SPSP-PPC National Leads (n=2) were purposefully selected due to their seniority in the SPSP-PPC programme, it may have been valuable for other national strategists to have been involved, such as those from the Scottish Government or NES.

This is the first study to report a systematic, transparent and inclusive multi-stakeholder approach used to develop the specific core components of an innovation which were then refined in practice. Studies which have adopted similar consensus methods have in general only focused on identifying areas of importance to direct future service development and improvement initiatives at a higher policy level [106, 126]. For example, Hutten et al used a multistage process to identify six high priority areas relating to the care of patient with depression [106], which were used to steer policy and not to govern the intricacies of a specific service. A study which used an inclusive method to develop the vital elements of an education and physical training programme, conducted separate focus group interviews with different stakeholders and thus formal attainment of consensus or agreement was not obtained [105]. Furthermore, the study did not describe if and how the innovation was implemented and refined in practice [105].

Transferability of the methods used in this study is suggested as the same method was successfully applied for both the high risk medicines of interest. This was corroborated by further application of this study's method within a dental quality improvement collaborative [127], which successfully consolidated three different medication reconciliation care bundles into a single care bundle. This indicates that a replicable method has been developed which is able to converge unnecessary variation and develop consolidated innovations in different healthcare settings. However, it should be noted that both settings (community pharmacy and dentistry) were actively involved in a collaborative project and therefore the appropriateness of the method in settings lacking engaged stakeholders and a collaborative ethos is unknown as of yet. Additionally, other settings may require more exploratory methods to identify the extent of variation, such as qualitative or ethnographic approaches, as opposed to a survey used in this study.

The validity of consensus methods, in general, can be compromised by the tendency of participants within the groups to adopt normative views [128]. It is possible this may have

occurred within this study as some participants may have known about the strategic desire to developed consolidated care bundles. However, the outputs of the consensus workshop (Phase 3a) were revisited during the post-consensus videoconference 'WebEx' (Phase 3b) where there was no strong objection expressed to deviate from the consensus outputs, which may suggest that true consensus was indeed achieved. Also during the consensus methods, there was an inherent risk of investigator-bias as the moderators (NW and EDC) had on-going involvement within the SPSP-PPC collaborative as part of the SPSP-PPC evaluation team. To circumvent this, they attempted to maintain a facilitative role rather than lead on the discussions and offer their opinions.

For the NGTs relating to the development of the warfarin and NSAIDs care bundle questions, some of the care bundle questions overlapped in their concept (see Tables 4.3 and 4.4) which complicated the ranking process. Therefor, although the ranking was collated and presented back to participants in order of highest to lowest ranked items, there was less reliance on these ranking results during the pre-consensus discussion to decide what items would be retained within the care bundles. Regardless, the ranking was still considered a useful exercise to stimulate discussion and decision-making.

These results of the warfarin NGT relating to the care bundle questions also exemplifies the necessity of the interactive discussion element during decision making. Within this NGT, the following question obtained the lowest ranking – 'Is the patient aware that they should have an INR test 3 days after starting a course of antibiotics?'. However, during the pre-consensus discussion participants stressed its importance, and its reason for low ranking was due to lack of national consensus in Scotland on when INR testing should be conducted, which was easily overcome by suggested wording refinements with the removal of '3 days' (see Table 4.5).

4.10.2 Future directions

This study has successfully developed consolidated care bundles and has allowed for their logical progression in anticipation for their national roll out in Scotland. However, this study presents only a starting point and further evaluation activities are necessary to inform future developments of these care bundles. The validation phase (Phase 4) did not result in any amendments to the warfarin care bundle, yet the validation phase resulted in refinements to the NSAIDs care bundle's patient cohorts. This final amended NSAIDs care bundle was disseminated to the pharmacies involved in the NSAIDs care bundle in April 2017 by the

respective SPSP-PPC regional lead. Further evaluation activities to be conducted for the care bundles are as follows:

- Obtain generalizable data on the emergent barriers and facilitators to inform appropriate national implementation strategies (Chapter 7)
- Evaluate implementation fidelity of the consolidated warfarin and NSAIDs care bundle to identify if the care bundles are delivered as intended in practice [103] (Chapter 8)
- Evaluate penetration of the care bundles by exploring their (i) integration within routine community pharmacy practice including the use of resources, as well as (ii) the involvement of various community pharmacy staff with the care bundles (Chapter 8)
- Explore the perceptions of patients who have been delivered the care bundles (Chapter 9)

4.11 Conclusion

Through a multi-phase process, consolidated warfarin and NSAIDs care bundles were successfully developed and refined following their pilot implementation within 24 community pharmacies. The method adopted to develop these care bundles was novel and harnessed engagement of multiple stakeholder in the absence of implementation fidelity data or clinical outcomes [98, 103], with scope that it could be applied in other settings. The development of the care bundles' core components has allowed for their logical progression in preparation for their anticipated national implementation within Scottish community pharmacies, yet unanswered questions remain including whether or not they are successfully implemented in practice, the barriers and facilitators influencing this, and patient perceptions of the care bundles.

Chapter 5: Factors influencing the national implementation of innovations within community pharmacy: a systematic review[2]

[2] A manuscript of this systematic review has been accepted for publication and is forthcoming in *Implementation Science* pending minor revisions

5.1 Summary of Chapter

Background

Community pharmacy is increasingly considered a setting through which innovations can be implemented to meet emergent healthcare needs, yet innovations often need scaled up nation-wide to affect population level change. This systematic review aims to identify facilitators and barriers to the national implementation of community pharmacy innovations.

Methods

A systematic review exploring pharmacy staff perspectives of the barriers and facilitators to implementing innovations at a national level was conducted. The databases Medline, EMBASE, PsycINFO, CINAHL and Open Grey were searched. Eligible studies underwent quality assessment, and a directed content analysis approach to data extraction was conducted and aligned to the Consolidated Framework for Implementation Research (CFIR).

Results

Thirty-nine studies were included: 16 were qualitative, 21 applied a questionnaire design, and two were mixed methods. Overarching thematic areas spanning across the CFIR domains were: pharmacy staff engagement (e.g. their positive and negative perceptions), operationalisation of innovations (e.g. insufficient resources and training); and external engagement (e.g. the perceptions of patients and other healthcare professionals, and their relationship with the community pharmacy).

Conclusions

The findings highlight the myriad of factors affecting successful implementation within community pharmacies, yet similarities with other reviews suggest the field is closer to developing a causal theory of this within this setting. Findings can be used to develop a questionnaire able to identify barriers and facilitators within community pharmacy.

5.2 Background

The primary care sector needs to continually adapt to meet emergent healthcare needs, and improved population health is found in nations with a strong primary care system [129, 130]. Community pharmacies have veered away from traditional dispensing-focused roles as their ability to offer enhanced services within primary care has been recognised [131]. Existing contributions within primary care include the administration of vaccinations [132], smoking cessation support [133], and medication reviews [134, 135]. Additionally, the introduction of pharmacy technicians performing accuracy checks on dispensed medication and the implementation of novel technologies, such as automated dispensing, are considered facilitators to improve efficiency and workflow [123, 136]. This can allow pharmacies more time to offer more patient-focused services.

The accessibility of a healthcare professional without the need for an appointment render community pharmacies unique to other primary care settings, which enhances the scope of exposure of new services to a greater number of patients [137-139]. Successful implementation of innovations within healthcare systems underpins the achievement of intended outcomes – for example, improvements in efficiency, safety or symptomology [70]. For maximal impact within primary care, and to improve population-level healthcare, local innovations need to be scaled up nation-wide [140]. In the case of the consolidated warfarin and NSAIDs care bundles, national implementation would be required in order to achieve meaningful improvements in the safety of these medicines.

The complexity of national implementation is well known [45]. Within community pharmacies, service delivery can be dependent on ownership [141], partly due to the autonomous nature of community pharmacies and their requirement to be profitable. Previous reviews have attempted to identify which implementation strategies are effective within community pharmacy [56] and the primary care setting in general [64]. However, neither of which were able to identify which specific implementation strategies may have driven successful implementation. Without knowing which implementation strategies are effective, Lau et al suggest that an implementation strategy should be based on identified barriers and facilitators [64].

Two previous reviews have explored the barriers and facilitators to the implementation of innovations within the community pharmacy setting. Organisational and individual

facilitators to practice change in relation to cognitive pharmacy services have been identified by Roberts at al in 2006 [142]. As few empirical studies at this time explored implementation within the community pharmacy setting, the results mostly centred on hypothetical facilitators. More recently in 2017, Shoemaker et al identified barriers and facilitators to the implementation of three services common in the US: Medication Therapy Management, immunisations and rapid HIV testing [143].

However, methodological approaches adopted by these reviews and associated limitations warrant further exploration within this area. The reviews by Shoemaker et al and Roberts et al explored barriers and facilitators only for a subset of innovation types. Neither review focused specifically on national implementation and included the evaluation of innovations limited to pilot stages. Additionally, neither critically appraised the included studies, and the reviews included studies which sought perspectives from individuals with no involvement in implementation, meaning the results may not reflect barriers and facilitators truly experienced in practice.

5.3 Aims and objectives

This systemic review addresses the limitations of the reviews by Shoemaker et al and Roberts et al, and aims to identify barriers and facilitators to the national implementation of community pharmacy innovations, with the following objectives:

1. Identify studies exploring the factors influencing the national implementation of community pharmacy innovations from the perspectives of community pharmacy staff
2. Synthesise reported barriers and facilitators

5.4 Methods

This systematic review is presented according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) 2009 Checklist [144]. A protocol for this systematic review was developed with reference to the Cochrane collaboration and PRISMA-Protocols guidelines [145, 146], and uploaded onto the PROSPERO register of systematic reviews (Registration number: CRD42016038876) [147].

5.4.1 Eligibility criteria

Eligible studies sought pharmacy staff's perspectives on barriers and facilitators to implementing national innovations. An innovation was considered a practice, object or idea perceived to be new to the setting in which it was implemented [49]. Studies involving participants from mixed disciplines (e.g. general practitioners as well as community pharmacy staff) were included if it was possible to extract the data solely pertaining to community pharmacy staff perspectives. Studies were excluded if they focused on:

- undefined innovations (e.g. concepts such as "pharmaceutical care")
- participants who chose not to adopt an innovation (as this reports on barriers to adoption and not implementation)
- barriers and facilitators to implementing innovations for specific pharmacy characteristics (e.g. barriers to implementation within independently-owned pharmacies), or to delivering services to a specific sub-set of eligible patients (e.g. barriers to delivering medication review services to Aboriginal populations specifically)
- anticipated barriers or facilitators during pre-implementation phases

Qualitative, quantitative and mixed methods studies were included from peer-reviewed journal articles, conference proceedings, poster presentations and unpublished literature. Books, editorials, lecture commentaries and studies reporting non-original research were excluded.

5.4.2 Search strategy

The databases Medline, EMBASE, PsycINFO and the Cumulative Index of Nursing and Allied Health Literature (CINAHL) were searched from their inception til the 17th of December 2015. Unpublished literature was searched within the Open Grey database [12]. See Appendix 5.1 for the full Medline search strategy. The search was limited to the English language and covered all studies available up until the search date. Supplementary searches (see Figure 5.1) were applied from December 2015 onwards until data analysis concluded in March 2017.

1.	Screening the reference list of included studies
2.	Email alerts from the Zetoc database (a monitoring and search service for global research publications) when new articles were published in the following journals: • Accreditation and Quality Assurance • BioMed Central Health Services Research • British Medical Journal Quality and Safety • Implementation Science • International Journal for Quality in Health Care • International Journal of Health Care Quality Assurance • International Journal of Pharmacy Practice • International Journal of Quality And Innovation • Joint Commission Journal on Quality and Patient Safety • Quality Management in Health Care • Research in Social and Administrative Pharmacy
3.	Hand searches of The Pharmaceutical Journal

Figure 5.1. Supplementary search strategy (Dec 2015 - Mar 2017)

5.4.3 Study selection

Titles and abstracts were screened within the online software Covidence [81], with potentially relevant studies progressing onto full-text screening. The primary reviewer (NW) completed study selection, with a 20% randomly-selected subset of the title/abstracts independently screened by AL, and a 20% randomly-selected subset of full-texts screened independently by NA. A percentage of agreement was calculated and categorised using the following thresholds: <70% poor; 70-79% fair; 80-89% good; and >90% excellent [148]. Anything over 80% was considered adequate [149]. Where the data were published in more than one format, the format which underwent the most extensive peer-review process was included (e.g. a journal article would be selected for data extraction over a conference proceeding).

5.4.4 Data extraction

A data extraction table was devised following consultation of the Supplementary Guidance for Inclusion of Qualitative Research in Cochrane Systematic Reviews of Interventions [146]. It was adapted where appropriate and piloted in approximately 10% of studies. Piloting identified that delineating the data to barriers and facilitators was over-simplistic as the studies also reported on suggestions of what would have facilitated implementation. These were termed 'hypothetical facilitators' and were extracted separately to facilitators.

5.4.5 Quality assessment

Quality assessment tools were used specific to the method(s) employed. They consisted of a series of questions exploring aspects such as the clarity of the aim, appropriateness of the methodology, recruitment of participants and data analysis. The 34-item Critical Appraisal Skills Programme (CASP) tool was used to appraise qualitative studies [150]. For questionnaire design studies, the Boynton and Greenhalgh Quality Checklist (BGQC) tool was used [151]. The mixed method studies all applied interviews alongside a questionnaire. Existing mixed method quality assessment tools did not assess questionnaires to the same depth as the BGQC tool [152] and would not offer comparable quality assessment. Therefore, the mixed methods studies were assessed using the initial screening questions within the Mixed Methods Appraisal Tool (MMAT) [153], which explores the appropriateness of the mixed method approach, with each method then assessed by the CASP or BGQC tool [150, 151]. The full quality assessment tools used are presented within Appendix 5.2.

The quality assessment tools used each have screening questions on the clarity of the aim and appropriateness of the research design. Studies were excluded if these initial criteria were not met. Questionnaire studies which used only closed-ended questions were excluded unless based on previous qualitative work or wider literature as the researchers would have introduced bias based on their a priori assumptions of influential factors [154]. To generate the quality assessment result for each study, each question within the quality assessment tool was attributed a score of two if the study fully met the criteria, one if partially met, and zero if not met or unclear. The quality assessment results are represented as percentages as not all questions were applicable to every study [155, 156]. The quality assessment results for the mixed method studies were calculated from the lowest scoring method to ensure the final result did not exceed the quality of the studies weakest component [153]. The quality assessment was conducted by the primary reviewer (NW), with clarification from a mediator when required (EDC).

5.4.6 Synthesis of results

The Consolidated Framework for Implementation Research (CFIR) was selected to synthesise the data [63], and has been previously been described in Section 2.3.1 and is presented in its entirety in Appendix 2.1. The CFIR is a determinant implementation framework of factors influencing implementation among five domains: intervention characteristics; the inner

setting; the outer setting; characteristics of the individual; and implementation process [157]. It is commonly applied [79], which facilitates cross comparison of results [81].

A directed content analysis approach [158] was applied where data extraction was conducted inductively, with the synthesis afterwards deductively aligned to the CFIR [159, 160]. This allowed data capture of barriers and facilitators not within the CFIR to test its applicability within the community pharmacy context. As the CFIR constructs are conceptually broad (e.g. one construct is 'Knowledge and Beliefs'), data within each CFIR construct was explored for emergent sub-constructs [161]. A table quantifying the barriers, facilitators and hypothetical facilitators within each CFIR construct was developed, with overarching thematic areas identified from visual analysis of this table [161]. A descriptive narrative synthesis method was chosen to present commonly reported CFIR constructs to facilitate integration of the qualitative and quantitative results [162].

To examine the robustness of the results, a sensitivity analysis involved the removal of studies with a quality assessment result of <50% to observe what effect this had on the reporting frequency of the barriers, facilitators and hypothetical facilitators [163]. As different studies evaluated the same innovation, the results were categorised both by study and by innovation to assess how this affected reporting frequency.

5.5 Results

5.5.1 Study selection

Thirty-nine studies were included from the 5,874 studies which had titles and abstracts screened (Figure 5.2). The percentage of agreement of the titles and abstracts independently screened was 94% (excellent), and for full-texts was 88% (good).

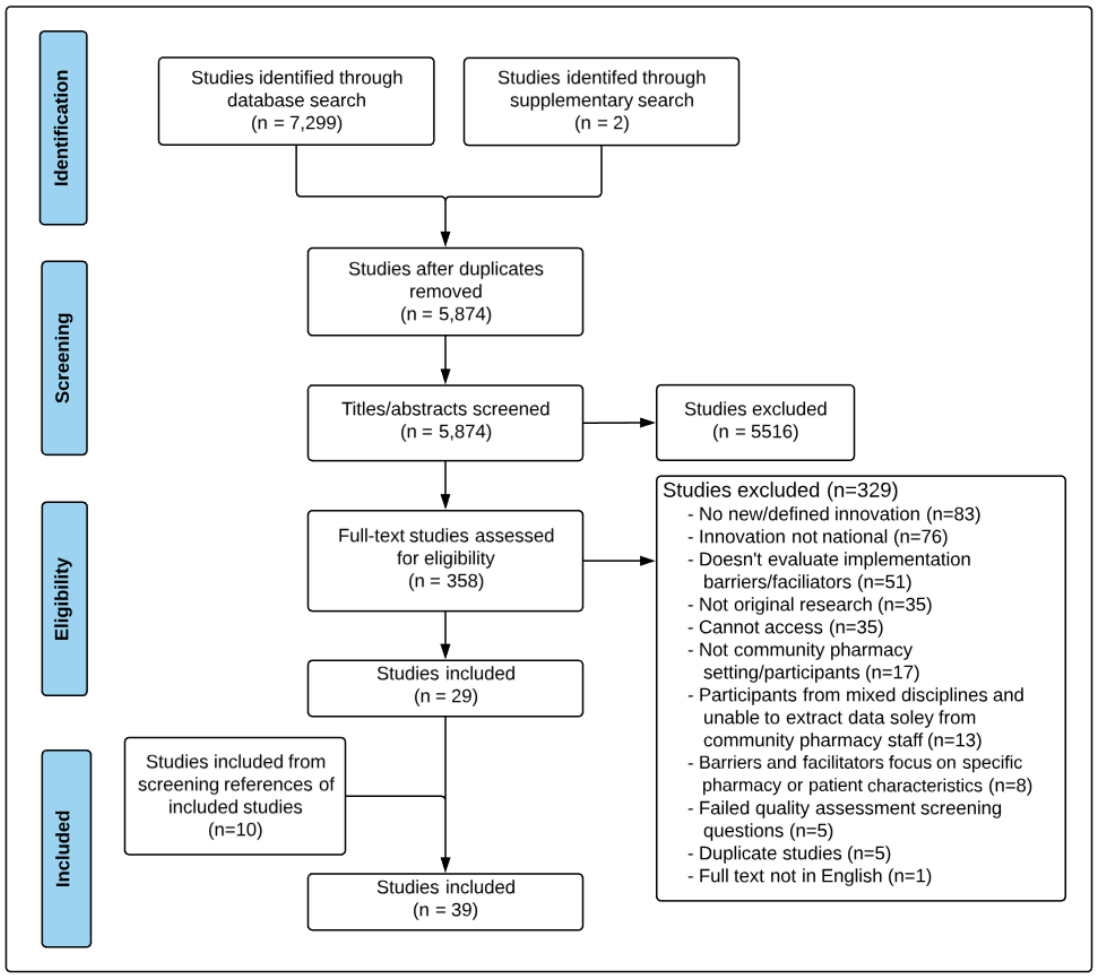


Figure 5.2. Flow chart of screening process to identify relevant studies (Dec 2015 - Mar 2017)

5.5.2 Study characteristics

All studies were published from 2002 onwards, with most published since 2010 (n=28, 71.8%). Approximately half (n=20, 51.3%) originated from the UK. Ten studies originated from other European countries and the other nine were from Australia (n=3), Malaysia (n=2), New Zealand (n=2), Saudi Arabia (n=1) and Cambodia (n=1). The innovation types can be categorised into four subtypes: Clinical Innovation (n=21); Pharmacovigilance (n=6); e-Technology (n=2); and Legislative Change (n=10), such as policy changes and reclassification of medicines. Some studies evaluated the same innovation: the UK "Healthy Living Pharmacy" framework (n=5), the UK "New Medicines Service" (n=3), the "Danish' Inhaler Technique Assessment Service" (n=2), the UK "Medicines Use Review" (n=3), the Malaysian spontaneous adverse drug reporting system "MADRAC" (n=2), and the Swedish implementation of ePrescribing (n=2). Resultantly, the 39 studies report on 28 innovations.

Excluding one study which did not provide participant numbers [164], the total number of participants included from the studies is 12,172. Only 10 studies (25.6%) explored perspectives of community pharmacy support staff [164-173] and two did so exclusively [168, 172]. The full characteristics of included studies are within Table 5.1.

Table 5.1. Characteristics of included studies in systematic review

Author, year, country	Quality assessment result	Aim	Innovation details	Evaluation method	Sample participants	Response
Legislative Change						
Allenet et al, 2003, France [174]*	38%	To describe the opinion and behaviour of pharmacists towards generic substitution.	New law passed permitting substitution between brand and generic drugs based on a list developed by the French Drug Administration alongside a new reimbursement model.	Postal questionnaire	Pharmacy owners sampled through a national pharmacy magazine.	N=1000 questionnaires randomly selected for analysis
Chee Ping et al, 2010, Australia [175]*	79%	To evaluate the impact of reforms of a pharmaceutical benefits scheme on pharmacist perceptions and practices regarding generic medicines.	Generic substitution policy reform which saw the development of a "brand innovation" and generic medicine formularies in, pricing reforms, including a fee of AUD $ 1.50 when a generic medicine was dispensed.	Online questionnaire	Pharmacists including proprietors, managers, employees and locums sampled, via direct mailing and link to questionnaire posted within newsletters.	N=157
Guald et al, 2010, New Zealand [176]*	63%	To elucidate how non-prescription supply of oseltamivir worked in practice and whether improvements were necessary.	Reclassification of oseltamivir (Tamiflu) for it to be available off prescription under set criteria (e.g. patients over the age of 12 presenting in person during influenza season).	Semi-structured interviews	Pharmacists from a purposive sample of 903 community pharmacies	N=26

Author, year, country	Quality assessment result	Aim	Innovation details	Evaluation method	Sample participants	Response
Gröber-grätz et al, 2010, Germany [165]*	50%	To investigate the implementation of Drug Discount Contracts and their impact.	A reformed health insurance act which aimed to reduce expenses saw the entitlement of health insurance companies to make Drug Discount Contracts with pharmaceutical manufactures. If patients had prescriptions for a brand name drug from a different manufacturer than the contract partner, pharmacist are not to supply the prescribed drug but the contract partners. Substitution rules include identical active ingredient, dosage, pack size, indication, and same or exchangeable galenics.	Postal questionnaire	Pharmacy staff (pharmacists, pharmacy assistants, pharmaceutical sales assistants and "others") sampled through a pharmacy journal.	N=804
Hamrosi et al, 2014, Australia [177]*	70%	To identify the barriers and facilitators to the utilisation of Consumer Medicine Information.	Standardized Consumer Medicine Information was introduced within Australia, which is brand specific written information for patients about medicines developed by pharmaceutical manufacturers. Guidelines were developed regarding the provision for doctors and pharmacists.	Postal questionnaire	Stratified random national sample (of metropolitan and rural settings) of 1100 pharmacists in New South Wales *NB. GPs were also sampled but this data was not extracted.*	N=349 (34%)
Hansford et al, 2007, Great Britain [178]*	64%	To describe community pharmacists' views, attitudes and early experiences of over the counter simvastatin.	Simvastatin 10mg was reclassified from a prescription only medication to pharmacy status, making it available for over the counter supply. Licensing restricts sales to those with moderate 10 year risk of a first coronary event. A cardiovascular risk assessment should be conducted by pharmacists.	Postal questionnaire	The main pharmacist with most responsibility for over the counter supply of medicines from a random sample of 2000 pharmacies.	N=1156 (58%)

Author, year, country	Quality assessment result	Aim	Innovation details	Evaluation method	Sample participants	Response
Paudyal et al, 2012, Scotland (UK) [179]*	64%	To understand pharmacists' perceived integration into practice, and attitudes to over the counter simvastatin 5 years post reclassification.	See above (Hansford et al)	Postal questionnaire	The main pharmacist with most responsibility for over the counter supply of medicines from all community pharmacies in Scotland (N=1138)	N=563 (50%)
Lonergan et al, 2012, Ireland (UK) [166]^	41%	To explore the opinions and experiences of pharmacy staff and patients to guidelines controlling the sale and supply of non-prescription codeine medications in Ireland.	Guidelines developed for pharmacists and retail pharmacy businesses on the safe supply of non-prescription codeine products were developed which restricts supply to improve patient safety.	Semi-structured interviews	Purposive sampling of pharmacy staff (pharmacists, pre-registration pharmacists and pharmacy assistants) from a range of pharmacy types and geographical location. *NB. Patients were also sampled but this data was not extracted.*	N=10
Weidmann et al, 2011, Great Britain [180]*	64%	To investigate the experiences, views and attitudes of community pharmacists towards the sale of orlistat.	Orlistat was approved for over the counter sale as a weight loss medication for those over 18 years old, with a BMI of >28kg/m2. Good practice guidelines issued recommends which included BMI testing and the use of additional multivitamin supplements.	Postal questionnaire	Pharmacists from a random selection of 13200 community pharmacies	N=4026 (32.4%)
Thomas et al, 2009, England (UK) [181]^	25%	To evaluate community pharmacists' views and understanding of amendments to the controlled drug's regulations and the challenges faced, and to explore community pharmacists' perception of the regulations in relation to the disposal of patient-returned controlled drugs.	Amendments to controlled drugs regulations.	Postal questionnaire and semi-structured interviews	Pharmacists from 120 pharmacies in three regions were sampled for questionnaire. For the qualitative part, pharmacists from 77 community pharmacies in the two primary care trusts were sampled.	N= 63 (32%) for the questionnaires N=10 for the interviews

Author, year, country	Quality assessment result	Aim	Innovation details	Evaluation method	Sample participants	Response
Clinical Innovations						
Donovan et al, 2016, England (UK) [168]*	70%	To explore the views, attitudes and perceptions of pharmacy support staff on the Health Living Pharmacy initiative.	The concept of Healthy Living Pharmacies was developed, which were too support the health and wellbeing of patients to improve health outcomes through provision of public health services. Features included a criteria for quality and performance, and having a trained healthy living champion in each pharmacy. Advice on health issues are offered to patients (e.g. smoking cessation and physical activity), services included emergency hormonal contraception and needle exchange schemes.	Semi-structured interviews	Up to three support staff (medicine counter assistants, dispensing assistants, pharmacy technicians, accuracy checking technicians) from accredited Health Living Pharmacies located in the Northumberland region.	N=21
Brooks et al, 2013, England (UK) [167]^	47%	To explore the perspectives and experiences of community pharmacy staff who provide public health services on becoming a "Healthy Living Pharmacy".	See above (Donovan et al)	In-depth interviews	Pharmacy staff (pharmacists, Healthy Living Champions and technicians) located in the Staffordshire region.	N=18
Firth et al , 2015, England (UK) [169]*	63%	To explore the barriers to the implementation and progression of the Health Living Pharmacy framework.	See above (Donovan et al)	Structured interviews	Pharmacists and Healthy Living Champions working in Healthy Living Pharmacies purposively sampled based on varying deprivation classifications and plans for the pharmacy to progress to next tiers of the Heathy Living Pharmacy framework.	N=22 (n=11 pharmacists, n=11 healthy living champions)

Author, year, country	Quality assessment result	Aim	Innovation details	Evaluation method	Sample participants	Response
Rutter et al, 2015, England (UK) [172]*	68%	To understand the Healthy Living Champions' perspective of their role and explore the barriers and facilitators to their performance	See above (Donovan et al)	Semi-structured interviews	Healthy Living Champions sampled in the region of Dudley (n=29).	N=14 (48%)
Shevket et al, 2015, England (UK) [170]^	35%	To explore Healthy Living Pharmacy staff perspectives on their pharmacy being a Healthy Living Pharmacy and whether this changed over the course of a year	Health and wellbeing service developed within Community pharmacy	In-depth interviews	Purposive sampling of pharmacy staff (pharmacists, healthy living champions and technicians) from Healthy Living Pharmacies from a range of different pharmacy types (i.e. independents/chains) in the Staffordshire region .	N=18, 9 of which had follow up interviews
Latif et al, 2016, England (UK) [60]*	62%	To investigate the "New Medicines Service" implementation process and how it is translating and transformation in practice.	The New Medicines Service was introduced as an advanced service within the community pharmacy contractual framework. This service offers support to improve patients' adherence of new medicines for specified long term conditions. Patients are invited to the service if they present with a prescription for a new medicine for a long-term condition, and can self-refer, be referred by a GP or nurse or pharmacists initiate the service. There are two patient-pharmacist consultations (either face to-face or via telephone). Guidance questions were provided to the pharmacists to facilitate the patient discussion.	Observations and semi-structured interviews (including short "exit" interviews and full length interviews)	Purposive sample of community pharmacists providing the New Medicine Service who were recruited in the region of East-Midland, South Yorkshire and London, encompassing different ownership types, geographic areas and social deprivation. *NB. GPs were also sampled but this data was not extracted.*	Observations in 23 community pharmacies N=27 full length interviews N=20 shorter "exit" interviews

Author, year, country	Quality assessment result	Aim	Innovation details	Evaluation method	Sample participants	Response
Corlett et al, 2013, England (UK) [182]^	33%	To explore community pharmacists' views and experiences of providing the "New Medicines Service".	See above (Latif et al)	Focus groups	Convenience sample of pharmacists (locums and managers) in the Kent region.	N=9 (from two focus groups conducted)
Lucas et al, 2015, England (UK) [183]*	71%	To explore community pharmacists' experiences and perceptions of the "New Medicines Service".	See above (Latif et al)	Semi-structured interviews	20 community pharmacists from an area in West Yorkshire (with 123 community pharmacies), purposively chosen to have a range of deprivation categories and pharmacy sites and have provided at least one New Medicine Service.	N=14 (70%)
Kaae et al, 2010, Denmark [171]*	66%	To describe the implementation of the "Inhaler Technique Assessment Service" and factors influencing the sustainability of the service.	The Inhaler Technique Assessment Service included a demonstration of corrected inhaler use for patients with asthma and chronic obstructive pulmonary disease, with a manual describing the technical aspects of inhalation. It was intended for newly diagnosed and existing patients when they hand in an inhaler prescription. Documentation was mandatory, and monthly reports are sent to the Danish Medicines Agency. It takes approximately 10 minutes, with a reimbursement fee of 9 dollars.	Observations, semi-structured interviews, and collection and review of documentary material	Purposive sampling of pharmacies based on stable, increasing or declining provision of the Inhaler Technique Assessment Service.	N=7 pharmacies involved N= 29 interviews (n=7 pharmacy owners, n=5 pharmacists, n=17 pharmacy assistants)

Author, year, country	Quality assessment result	Aim	Innovation details	Evaluation method	Sample participants	Response
Kaae et al, 2011, Denmark [164]*	65%	To investigate how organisational factors, particularly leadership style, influence sustainability of the Inhaler Technique Assessment Service	See above (Kaae et al)	Observations, interviews, and collation of written materials that illustrated the implementation process.	Purposive sampling of pharmacy staff from pharmacies of with different geographical range, varying achievements of sustainability and where the pharmacy owner owned the pharmacy during the entire period since the Inhaler Technique Assessment Service launch.	N=4 pharmacies, unclear how many interviewed.
Latif et al, 2008, UK [184]*	55%	To explore factors that affect the number of "Medicine Use Reviews" and investigate attitudes towards its implementation and value.	Medicine Use Reviews are services which involved a consultation to establish patient understanding of their medications. A report was generated and provided to the patient and to their GP, if necessary. Pharmacies can opt in to deliver this service if they meet accreditation requirements.	Postal questionnaire	Convenience sample of 280 accredited pharmacists within one pharmacy chain.	N=167 (60%)
Latif et al, 2010, UK [185]^	37%	To compare views of "Medicine Use Reviews" to previous results.	See above (Latif et al)	Questionnaire	Pharmacists sample from 300 accredited pharmacies in one pharmacy chain.	N=189 (From 146 pharmacies, 49%)
Wilcock et al, 2008, England (UK) [186]*	42%	To explored perceptions of community pharmacists' on "Medicines Use Reviews" and its impact on patients.	See above (Latif et al)	Interviews	A purposive sample of 10 community pharmacists from pharmacies providing Medicines Use Reviews, selected based on rurality and if multiple or independent pharmacies. *NB. GPs were also sampled but this data was not extracted.*	N=10

Author, year, country	Quality assessment result	Aim	Innovation details	Evaluation method	Sample participants	Response
Lee, 2008, New Zealand [134]*	48%	To identify where "Medicines Use Review" services are provided by pharmacist and explore the processes and pharmacists' perceptions of the service.	See above (Latif et al)	Postal questionnaire	A sample of all Medicines Use Review accredited pharmacists in New Zealand who had contact details available (n=68)	N=54 (79%)
Blenkinsopp et al, 2007, England and Wales (UK) [187]^	19%	To investigated community pharmacists' experience of providing the "Medicines Use Review" and prescription intervention service and the future plans of those not currently providing it.	See above (Latif et al)	Postal questionnaire and focus groups.	Pharmacists from a random stratified 10% sample from 31 regions in England and Wales.	N=767 (71%) Purposefully selected pharmacists participates in four focus groups in case study primary care organisations. N=25
Bell et al, 2012, Cambodia [173]*	65%	To investigate the attitudes and practices of pharmacy-initiated tuberculosis referral service	Pharmacy-based assessment of people with tuberculosis symptoms and referral to treatment centres, including provision of information, counselling and referral documentation. Pharmacies register with the Municipal Health Department to join the programme.	Focus groups	Purposive sampling of pharmacist owners, pharmacists and assistants based on years of experience providing referral services.	N=54 (71%)
Hodson et al, 2014, Wales (UK) [188]^	29%	To capture views on the "Wales Discharge Medicines" review service.	A Discharge Medicine Review service was introduced to improve the management of medication post-discharge from a care setting.	Online questionnaire	Pharmacists sampled from all community pharmacies in Wales (n=704)	N=143 (20%)

Author, year, country	Quality assessment result	Aim	Innovation details	Evaluation method	Sample participants	Response
Kansana-hoa et al, 2005, Finland [189]*	65%	To assess implementation of the "TIPPA" patient counselling project.	The TIPPA project promoted patient counselling in community pharmacies. It included an electronic database on medication to support the verbal counselling, a manual on good practice counselling, a website with access to 1600 website links to medical and drug information in three language, a handbook of guidelines for OTC medication, and a handbook of communication skills.	Postal questionnaire	734 pharmacists randomly sampled from two registers representing 90% of all Finnish pharmacists.	N=376 (51%)
Loo et al, 2011, England (UK) [190]^	31%	To derive information concerning community pharmacists' activities and attitudes towards the "National Health Service Health Check".	The National Health Service Health Check involved risk assessment (e.g. lifestyle assessment and measurement of blood pressure and cholesterol) and risk management (e.g. offering advice on weight management, alcohol consumption) of cardiovascular disease.	Postal questionnaire	Purposive sampling of pharmacists working in pharmacies in areas with higher deprivation and earlier deaths in heart disease and strokes than national standards (N=1301).	N=442 (34%)
Paudyal et al, 2010, Scotland (UK) [191]*	68 %	To obtain pharmacists' views on the implementation of the "Minor Ailment Service" in Scotland, with objectives to determine the level of service delivery and the barriers and facilitators related to its implementation.	The Minor Ailment Service was initiated as part of the core contract to promote the public to utilize community pharmacies instead of GPs. It involves the provision of free advice for minor ailments, product supply and referral if appropriate for patients' exempt for prescription payments. It is supported by a national IT network which facilitates remuneration.	Postal questionnaire	Pharmacists with main responsibly in non-prescription medicine supply sampled from all community pharmacies in Scotland excluding those involved in qualitative phase of this evaluation (N=1138).	N=563 (50%)

Author, year, country	Quality assessment result	Aim	Innovation details	Evaluation method	Sample participants	Response
Chaar et al, 2013, Australia [192]*	74%	To investigate factors affecting provision of opioid substitution treatment in New South Wales pharmacies, with objectives to explore motivators for provision, and factors influencing the success of the provision.	The Australian government developed an opioid substitution treatment programme, involving regular dosing of long action opioid substitutes under supervision free of charge except with a small dispensing fee to pay. Pharmacists can opt-in to deliver this service.	Semi-structured interviews	Purposive selection of owners and pharmacists based on location and type of business setting.	N=35
Pharmacovigilance						
Irujo et al, 2007, Spain [193]*	57%	To identify the factors that influence community pharmacists' adverse drug reaction reporting.	As part of a WHO programme for international drug monitoring, community pharmacies participated in reporting adverse drug reactions through spontaneous reporting according to pharmacovigilance regulations developed.	Questionnaire administered in person	Sample of community pharmacists working in the 546 pharmacies in Navarra.	N=78
Bawazir, 2006, Saudi Arabia [194]*	74%	To assess attitude and behaviour of private community pharmacists towards adverse drug reaction reporting	The Ministry of Health developed a program to early detect unexpected and serious adverse drug reactions, detect increase in frequency of known adverse drug reactions, quality defects of registered products and to publish and disseminate reports. For community pharmacies, adverse drug reaction reporting forms were distributed, databases were developed for recording and storing reports, and an advisory committee established.	Questionnaire administered in person	Stratified random sample of 25% (n=24) of Riyadh private community pharmacies.	N=172 (72%)

Author, year, country	Quality assessment result	Aim	Innovation details	Evaluation method	Sample participants	Response
Duarte et al, 2015, Portugal [195]*	76%	Evaluate the habits of spontaneous reporting of adverse drug reactions by community pharmacists, their knowledge of the new legislation, and reasons behind potential issues.	The National Pharmacovigilance System has been established since 1992 to allow spontaneous reporting of adverse drug reactions. New legislation was introduced in 2010 which included new definition of what an adverse drug reaction is, the provision of risk management data, and inclusion of patients as reporters.	Open-ended telephone or email questionnaire	Community pharmacists working within the 301 community pharmacies in Southern Portugal.	N=154 (57% of the 271 contactable pharmacies)
Elkalmi et al, 2011, Malaysia [196]*	62%	Evaluate community pharmacists' attitudes and perceptions to the Malaysian adverse drug reaction programme and determine awareness, involvement, reasons for under-reporting, and what might encourage more ADR reporting.	The adverse drug reporting system involved voluntary reporting, submitted electronically or by post or fax. Both healthcare professionals and patients can report adverse reactions either directly to the Malaysian Spontaneous Adverse Drug Reporting System (MADRAC) or the company marketing the product.	Semi-structured interviews	Purposive and snowball sampling of community pharmacists (proprietors, managers and employee pharmacists) in Penang Island.	N=16
Elkalmi et al, 2014, Malaysia [197]*	78%	To examine the attitudes, perception and barriers to adverse drug reactions reporting.	See above (Elkalmi et al)	Postal questionnaire	470 pharmacists (proprietors, managers, employee and "other" pharmacists) practicing in four northern Malaysian states.	N=116 (25%)
Van Grootheest et al, 2002, The Netherlands [198]*	62%	To gain insight into the attitudes and reporting behaviour of community pharmacist in the Netherlands to adverse drug reactions reporting.	The reporting of suspected adverse drug reaction is a WHO programme for international drug monitoring. Reports are collected and analysed by the Netherlands Pharmacovigilance Centre. Pharmacist reporting of adverse drug reactions is not compulsory.	Postal questionnaire	Stratified random sample of pharmacists (owner, managers, and second pharmacists) from 200 community pharmacies.	N=147 (74%)

Author, year, country	Quality assessment result	Aim	Innovation details	Evaluation method	Sample participants	Response
e-Technology						
Rahimi et al, 2011, Sweden [199]*	50%	To examine the introduction of an ePrescribing into the practice of pharmacy.	The Swedish IEPS (Integrated electronic prescribing system) was developed which allowed prescriptions generated in wards or physician offices to be transmitted electronically to pharmacies. ePrescriptions are transmitted electronically and stored online with patient and pharmacy access. The dispensing process is preformed from the computer screen. Patients can choose any pharmacy to collect their medication, and the new prescriptions were retrieved by entering the patient's social security number.	Postal questionnaire	All pharmacists (N=74) in the Linkoping region.	N=52 (70%)
Hammar et al, 2010, Sweden [200]*	61%	To evaluate Swedish pharmacists' attitudes towards ePrescribing.	See above (Rahimi et al)	Online questionnaire	Random sample of 500 pharmacists employed within the approximated 900 community pharmacies which handles prescription medicines and had an employee e-mail address (4674 pharmacists met inclusion criteria).	N=259 (52%)

5.5.3 Quality assessment results

The quality assessment results are presented within Table 5.2. Five studies were excluded as they applied questionnaires with only closed-ended questions which were not reported to be developed from reference to literature or previous qualitative findings [201-205].

Table 5.2. Summary of quality assessment results of included studies (n=39)

Qualitative studies (n=16)	Result (%)	Questionnaire studies (n=21)	Result (%)	Mixed method studies (n=2)	Result (%)
Chaar 2013* [192]	74	Chee Ping 2010* [175]	79	Thomas 2009^ [181]	25
Lucas 2015* [183]	71	Duarte 2015* [195]	76	Blenkinsopp 2007^ [187]	19
Donovan 2016* [168]	70	Bawazir 2006* [194]	74		
Rutter 2015* [172]	68	Hamrosi 2014* [177]	70		
Kaae 2010* [171]	66	Elkalmi 2014* [197]	68		
Bell 2012* [173]	65	Paudyal 2010* [191]	68		
Kaae 2011* [164]	65	Kansanahoa 2005* [189]	65		
Firth 2015* [169]	63	Paudyal 2012* [179]	64		
Gauld 2011* [176]	63	Weidmann 2011* [180]	64		
Elkalmi 2011* [196]	62	Hansford 2007* [178]	64		
Latif 2016* [60]	62	Hammar 2010* [200]	61		
Brooks 2013* [167]	47	Van Grootheest 2002* [198]	62		
Wilcock 2008* [186]	42	Irujo 2007* [193]	57		
Longergan 2012^ [166]	41	Latif 2008* [184]	55		
Shevket 2015^ [170]	35	Rahimi 2011* [199]	50		
Corlett 2013^ [182]	33	Gröber-grätz, 2010* [165]	50		
		Lee 2008* [134]	48		
		Allenet 2003* [174]	38		
		Latif 2010^ [185]	37		
		Loo 2011^ [190]	31		
		Hodson 2014^ [188]	29		

** peer-reviewed journal paper, ^ conference abstract*

The Critical Appraisal Skills Programme (CASP) tool [150] appraised the qualitative studies, the Boynton and Greenhalgh Quality Checklist (BGQC) tool [151] appraised the questionnaire studies, and the mixed methods studies were assessed using the Mixed Methods Appraisal Tool (MMAT) screening questions [153], with each method then assessed by the CASP or BGQC tool [150, 151]. Each question within the quality assessment tools were attributed a score of two if the study fully met the criteria, one if partially met, and zero if not met or unclear. The quality assessment results are represented as percentages as not all questions were applicable to every study.

5.5.3.1 Qualitative studies

All qualitative studies (n=16) detailed the research aims and rationalised the study's importance and relevance. Six justified why a qualitative design was chosen [167, 170, 171, 183, 192, 196], and three justified the specific method adopted [164, 169, 183]. For one study which employed two qualitative methods, only one method was explicitly justified [60]. Six studies made the methods fully explicit by including the interview or focus group guide [60, 168, 169, 173, 183, 192]. No studies offered a full account of reflexivity as none adequately considered the researcher-participant relationship, however four studies reflected on potential bias during data collection and sampling [168, 172, 176, 183]. No study sufficiently discussed the credibility of their findings as per the quality assessment criteria.

5.5.3.2 Questionnaire design studies

All questionnaire design studies (n=21) had a clear research question. Six studies did not attain a response rate of >50% [177, 179, 180, 190, 191, 197], and three employed sampling methods which made it not possible to determine response rates [165, 174, 175]. Two studies sampled a single pharmacy chain [184, 185], and six sampled participants within specific geographical locations [165, 193-195, 197, 199]. Twelve studies piloted the questionnaire in a representative cohort [134, 175, 177-180, 188, 191, 194, 195, 197, 200]. Four studies did not offer sufficient detail to determine if the pilot sample was representative of study participants [165, 174, 193, 198], and for one study the pilot sample was not representative [184]. One study modified an existing questionnaire but did not re-pilot this [185], and three studies did not state if the questionnaire was piloted [189, 190, 199]. Three studies had claims for both validity and reliability [175, 194, 197], ten had claims for neither [134, 165, 174, 177, 185, 188, 189, 193, 195, 198], and the remaining eight conducted face and/or content validity testing [178-180, 184, 190, 191, 199, 200].

5.5.3.3 Mixed methods studies

The mixed method studies were low in quality due to insufficient details as both were conference proceedings [181, 187]. One study did not explain the rationale for integrating qualitative and quantitative methods [187], and neither offered explanation as to how the data were integrated [181, 187].

5.5.4 Barriers, facilitators and hypothetical facilitators

The reporting frequency of the barriers, facilitators and hypothetical facilitators aligned to the CFIR constructs is shown in Table 5.3. A full presentation of constructs and sub-constructs is in Appendix 5.3. No changes were identified to the most commonly reported CFIR constructs amongst the barriers, facilitators and hypothetical facilitators when removing studies with a quality assessment score of <50% (n=12, 30.8%), or when categorising results by innovation and not study. Therefore, for completeness all studies were retained within the analysis.

Table 5.3. Frequency table of cited Consolidated Framework for Implementation Research (CFIR) constructs (n=39 studies)

CFIR domains (n=5) and constructs (n=39)	**Barrier** n (%) of studies	**Facilitator** n (%) of studies	**Hypothetical facilitator** n (%) of studies
Intervention Characteristics			
Intervention Source	0 (0.0)	0 (0.0)	0 (0.0)
Evidence Strength & Quality	1 (2.6)	0 (0.0)	0 (0.0)
Relative Advantage	7 (17.9)	12 (30.8)	0 (0.0)
Adaptability	7 (17.9)	1 (2.6)	2 (5.1)
Trialability	0 (0.0)	0 (0.0)	0 (0.0)
Complexity	12 (30.8)	2 (5.1)	3 (7.7)
Design Quality & Packaging	10 (25.6)	2 (5.1)	11 (28.2)
Cost	6 (15.4)	0 (0.0)	0 (0.0)
Outer Setting			
Patient Needs & Resources	21 (54)	9 (23)	0 (0.0)
Cosmopolitanism	15 (38)	4 (10)	5 (12.8)
Peer Pressure	0 (0.0)	0 (0.0)	1 (2.6)
External Policy & Incentives	6 (15.4)	2 (5.1)	11 (28.2)
Inner Setting			
Structural Characteristics	0 (0.0)	3 (7.7)	0 (0.0)
Networks & Communications	2 (5.1))	2 (5.1)	0 (0.0)
Culture	0 (0.0)	0 (0.0)	0 (0.0)
Implementation Climate			
Tension for Change	1 (2.6)	0 (0.0)	0 (0.0)
Compatibility	9 (23.1)	12 (30.7)	1 (2.6)
Relative Priority	3 (7.7)	0 (0.0)	0 (0.0)
Organizational Incentives & Rewards	1 (2.6)	15 (38.5)	0 (0.0)
Goals and Feedback	2 (5.1)	2 (5.1)	6 (15.4)
Learning Climate	0 (0.0)	0 (0.0)	0 (0.0)
Readiness for Implementation			
Leadership Engagement	3 (7.7)	2 (5.1)	0 (0.0)
Available Resources	28 (71.7)	7 (17.9)	10 (25.6)

CFIR domains (n=5) and constructs (n=39)	**Barrier** n (%) of studies	**Facilitator** n (%) of studies	**Hypothetical facilitator** n (%) of studies
Access to Knowledge & Information	8 (20.5)	5 (12.8)	17 (43.5)
Characteristics of Individuals			
Knowledge & Beliefs about the Intervention	22 (56.4)	21 (53.8)	0 (0.0)
Self-efficacy	4 (10.3)	6 (15.4)	0 (0.0)
Individual Stage of Change	6 (15.4)	9 (23.1)	0 (0.0)
Individual Identification with Organization	0 (0.0)	0 (0.0)	0 (0.0)
Other Personal Attributes	4 (10.3)	5 (12.8)	0 (0.0)
Process			
Planning	1 (2.6)	0 (0.0)	3 (7.7)
Engaging			
Engaging Stakeholders*	1 (2.6)	0 (0.0)	12 (30.8)
Engaging Innovation Participants*	3 (7.7)	1 (2.6)	12 (30.8)
Opinion Leaders	0 (0.0)	0 (0.0)	0 (0.0)
Formally Appointed Internal Opinion Leaders	0 (0.0)	0 (0.0)	0 (0.0)
Champions	0 (0.0)	0 (0.0)	0 (0.0)
External Change Agents	0 (0.0)	0 (0.0)	0 (0.0)
Executing	0 (0.0)	0 (0.0)	1 (2.6)
Reflecting & Evaluating	0 (0.0)	0 (0.0)	1 (2.6)

NB. Shaded rows are those where the CFIR constructs were cited by at least nine of the 39 studies (23.1%) as a barrier, facilitator or hypothetical facilitator.

**The CFIR construct "Engaging" has been subdivided into "Engaging Stakeholders" and "Engaging Innovation Participants" as per the CFIR qualitative codebook guidelines (http://cfirguide.org/wiki/index.php?title=Engaging).*

Fourteen (35.8%) CFIR constructs were cited by at least nine studies (23.1%) as a barrier, facilitator or hypothetical facilitator. Within these fourteen CFIR constructs, overarching thematic areas spanning across the CFIR domains were identified: operationalisation of the innovation, pharmacy staff engagement, and external engagement (Table 5.4).

Table 5.4. Overarching thematic areas identified from included studies (n=39) across commonly reported Consolidated Framework for Implementation Research (CFIR) constructs

Thematic areas	Description	CFIR construct (CFIR domain)
Operational-isation of the innovation	Innovation attributes such as design/complexity and surrounding factors including resources; compatibility with pharmacy systems; and pharmacy staff access to knowledge and information about the innovation.	• Available Resources *(Inner Setting)* • Design Quality and Packaging *(Innovation Characteristics)* • Complexity *(Innovation Characteristics)* • Compatibility – with systems *(Inner Setting)** • Access To Knowledge and Information *(Inner Setting)*
Pharmacy staff engagement	Pharmacy staff knowledge and beliefs relating to an innovation; it's compatibility with their roles and values; whether it poses advantages or not; and the incentives and strategies which engage community pharmacy staff.	• Knowledge and Beliefs about the Intervention *(Characteristics Of Individuals)* • Individual Stage of Change *(Characteristics of Individuals)* • Compatibility – with roles or values *(Inner Setting)** • Relative Advantage *(Innovation Characteristics)* • External Policy and Incentives *(Outer Setting)* • Organisational Incentives And Rewards *(Inner Setting)* • Engaging Innovation Participants *(Process)*
External engagement	The relationship with patients and other healthcare professionals, their perceptions, and strategies to engage these stakeholders.	• Cosmopolitanism *(Outer Setting)* • Patient Needs And Resources *(Outer Setting)* • Engaging Stakeholders *(Process)*

**The compatibility construct of the CFIR was delineated into 'Compatibility – with roles and values' and 'Compatibly – with systems'*

5.5.4.1 Operationalisation of the innovation

Available Resources

Lack of time [134, 166-171, 173, 174, 177, 184-187, 189-191, 193-199] and increased workload [167, 169, 170, 174, 181] associated with an innovation was common. Staffing issues included insufficient staffing [179, 184, 185, 190] and losing staff to training events [169], and one study reported the benefits of having two pharmacists on duty [60]. Two studies reported a general lack of operational resources [171, 191]. Studies mostly reported innovation-specific barriers such as a lack of printers [177] and reporting forms for adverse drug reporting [194-198]. Lack of access to clinical information was cited for both the legislative and clinical innovations [178, 179, 184, 188, 191] as was a lack of suitable space [168, 179, 184, 190]. Two studies cited adequate pharmacy facilities, such as a consultation room [185, 189]. Six studies reported valued resources associated with an innovation [60, 168, 169, 176, 189, 200] and nine suggested resources which would facilitate implementation [134, 177, 181, 184, 186, 191, 192, 194, 199], including access to clinical information about patients [186, 191], reporting forms [194], improved IT systems [134, 177, 191, 192, 199], a consultation area [184], and a 'fact sheet' to facilitate implementation [181].

Design Quality and Packaging

Poor design was most common amongst clinical innovations. This included the requirement of patient consent devaluing the innovation and patients' perception of the pharmacist as a professional [182], being unaware of a patient's discharge for hospital [188], lapsing of customer registration [191], and inappropriate patient referrals [192]. For a service where medication information was legislated to be supplied to all patients, information was not available in other languages and considered too long to print [177]. For a pharmacovigilance program, centralisation of the reporting system was a barrier [197]. Poor quality of the innovation mainly pertained to IT or system issues [60, 169, 179, 195, 199] or the nature of the paperwork involved [188, 195]. Eleven studies suggested improvements to the design and quality of the innovations [177, 180, 184, 188, 192, 194-198, 200].

Complexity

Complex operationalisation of innovation [191, 196], difficultly of the innovation [60, 165, 168, 174, 179, 182], and complex remuneration or reporting processes [60, 134, 182, 194, 197, 198] were reported. One study reported barriers relating to the complexity of the implementation process itself [181]. Three studies suggested simplifying reporting procedures [194, 197, 198].

Compatibility – with systems

Incompatibility with work systems [177] or applicability in certain settings [168] was reported. Three studies cited compatibility with working systems as a facilitator [60, 168, 189], and work process changes was suggested in one study to facilitate [177].

Access to Knowledge and Information

Two studies cited training received to be useful [168, 180]; however, a lack of appropriate training was cited by other participants for one of these studies [168]. Inadequacy of the training was cited by five studies, including the training not meeting the needs of staff [180], lack of appropriate training [168, 189, 192], or the training focusing on filling out forms rather than skills-based [186]. Whilst three studies cited a lack of information available on the innovation [60, 168, 191], four had participants comment positively on information received [168, 176, 179, 189]. Better access to information and training was a suggested hypothetical facilitator reported by seventeen studies [60, 168, 174-177, 181, 183, 189, 190, 192-198], including suggestions of continuous training [174, 176, 194, 196, 197], mentoring and peer review [60], and incorporating training within undergraduate pharmacy degrees [195, 196, 198].

5.5.4.2 Pharmacy staff engagement

Knowledge & Beliefs about the Intervention

Positive and negative views of the innovation by the pharmacy staff were commonly cited factors influencing implementation. Nine studies had mixed views from participants [168, 173, 176, 179, 180, 184, 185, 192, 198]. The negative perceptions were varied and in many instances context specific, but included concerns and a lack of belief in/support for the innovation [60, 164, 168, 173, 175, 176, 178-180, 184-186, 192, 194-198]. Positive perceptions included a belief in/support for the innovation [134, 166, 168, 169, 173, 174,

176, 179, 180, 182, 184, 185, 188, 192-198] and positivity about the way the innovation was implemented [181].

In four studies, good awareness and understanding surrounding the innovation was cited [173, 176, 193, 198]. Notably for two of these, lack of knowledge was also cited by some participants [176, 198]. Lack of awareness [181, 193, 194, 196, 197] and operational knowledge [168, 176, 181, 190, 193-198] was common, and lack of appropriate clinical knowledge was cited by five studies [171, 194, 195, 197, 198]. All pharmacovigilance studies cited a lack of awareness and knowledge [193-198].

Individual Stage of Change

Within this review, findings within this construct centred upon the motivation of the pharmacy (or lack of) to engage with an innovation. Only the legislative changes or pharmacovigilance innovations reported a reluctance or lack of motivation [174, 176, 177, 194, 197, 198], and willingness and enthusiasm was common within the clinical innovation studies [164, 167, 168, 170, 172, 173, 189], with two citations from legislative change studies [175, 176].

Compatibility – with roles/values

An innovation's compatibility with the roles and values of a pharmacist was reported. This included alignment with ambitions [179], the innovation recognising the potential of pharmacy to adopt enhanced or professional roles [60, 169], or being considered integral to a pharmacists role [182, 186, 193, 194, 196-198].

Relative Advantage

An innovation offering an advantage was evident within 12 studies [166, 167, 169, 170, 174, 175, 183, 186, 191, 198-200]. General advantages included enhanced engagement or relationship with patients [169, 174, 186, 191], improvement in workforce capability - such as improved education, awareness or confidence [166, 167, 169, 198], better relationship with surrounding healthcare professionals [170, 191], and the innovation benefitting patients [166, 170, 175, 183, 191, 200]. Some were context specific, for example the time saving aspect of the Swedish ePrescribing system [199, 200] and the Scottish Minor Ailments Service [191] meaning product cost is no longer considered during consultations

[191]. Six studies reported that the innovation presented disadvantages [165, 176, 191, 192, 199, 200], and three cited both advantages and disadvantages to the innovation [191, 199, 200].

External Policy and Incentives

Reported barriers included the innovation not being aligned with policy [177] and lack of/insufficient funding [134, 170] or remuneration [174, 190, 191]. However, ten studies suggested hypothetical facilitators including extending the scope of innovations [134, 173, 177], and making participation in pharmacovigilance innovations compulsory [194-196, 198]. Other suggestions were primarily financial [173, 174, 177, 184, 190, 194, 196, 198], but also included the provision of awards, certifications, journal subscription, conference attendance [196] or penalising other healthcare professionals for lack of co-operation [174].

Organizational Incentives and Rewards

One study cited negative perceptions of targets, which were perceived as income-focused rather than patient-focused [186]. For clinical innovations and legislative changes, personal rewards included improved professional recognition [169, 174, 182, 191], enhanced influence or role [174, 179, 180, 183, 184, 191] and personal or professional satisfaction [60, 172, 173, 182, 190]. Commercial benefits spanned across all innovations, including financial betterment for the pharmacy [168, 169, 179, 191, 200] and increased customer footfall [170, 173].

Engaging Innovation Participants

There was little data pertaining to how the implementation strategy influenced the implementation. Better informing and engaging the pharmacy workforce was a suggested hypothetical facilitator [60, 167, 189, 192-194, 196-198], with suggestions including better collaboration between pharmacies [167], educational campaigns [189], mentoring and networking opportunities [60, 192], culture change [193], better advertising [194, 198], and promotion [196-198].

5.5.4.3 External engagement

Cosmopolitanism

Pharmacy staff perceived that other healthcare professionals held negative views for the legislative and clinical innovations. Seven studies cited negative response [60, 134, 173, 174, 183, 184, 191], which included reluctance [174], lack of support [179], or general negative views [60, 134, 173, 183, 184]. Lack of referral was a cited barrier for clinical innovations [167, 183, 188, 192], and lack of collaboration and communication with healthcare professionals was also apparent [60, 179, 183, 186, 189, 191, 196]. Facilitators included doctor referrals [176], establishment of new contacts [167], and having pre-existing relationships with other healthcare professionals [183].

Patient Needs and Resources

Although there were no reports from studies evaluating pharmacovigilance innovations within this construct, other innovation types had numerous citations. Patients' support and acceptance of the innovation [166, 170, 175, 183] and positive feedback [167, 168, 170, 172] was contrasted by negative perceptions [165, 166, 173, 174, 179, 183]. These included resistance to change or advice [165, 166, 174, 179], perceiving the innovation as lacking in value [183], and perceiving "pharmacists as drugs suppliers only" [173]. Two studies reported patient demand [168, 192], and pharmacy staff generally reported low public demand [60, 168, 176, 179, 180, 183, 191] or that patients were uninterested or reluctant [134, 177, 183, 184]. For the clinical innovations, there was difficulty recruiting patients [182], reaching targets [169, 183], retaining patients [182], or patients couldn't attend appointments [60, 183, 187]. One study reported public awareness [168], yet lack of public knowledge or awareness was more commonly reported [60, 165, 167-169, 172, 183, 200]

Engaging Stakeholders

Although three studies cited lack of advertising or promotion of the innovation as a barrier to engagement of patients [60, 191, 197], twelve studies across all innovation types suggested better informing and engaging patients [134, 167-169, 173-175, 177, 190, 193, 198, 200]. One study reported that banners and displays increased customer awareness [170]. Suggested facilitators included patient education programmes [175, 177, 191, 200] and local publicity and media campaigns [167-169, 173]. Five studies suggested better engagement with other healthcare professionals [60, 174, 183, 193, 200].

5.6 Discussion

This systematic review evaluated a heterogeneous mix of innovations to identify the factors influencing national implementation within the community pharmacy setting. Three key thematic areas were identified from the most commonly represented CFIR constructs: (i) pharmacy staff engagement, including the perceptions of pharmacy staff and their belief that the innovation was beneficial; (ii) operationalisation of the innovation, such as lack of resources; and (iii) external engagement, including perceived negative views of patients and other healthcare professionals. Each thematic area is discussed in turn with cross comparison to previous reviews conducted by Roberts et al [142] and Shoemaker et al [143]. A comparison of the emergent CFIR constructs within these reviews is presented in Table 5.5.

Table 5.5. Consolidated Framework for Implementation Research (CFIR) constructs represented in current review and those conducted Roberts et al [142] and Shoemaker et al [143]

CFIR Constructs	Current review	Shoemaker et al's review [143]			Robert et al's review^ [142]
	National innovations	MTM	Immuniz-ations	HIV testing	CPS
Intervention Characteristics					
Intervention Source	-	-	-	-	-
Evidence Strength & Quality	✔	✔	-	-	-
Relative Advantage	✔	✔	✔	✔	✔
Adaptability	✔	✔	✔	✔	-
Trialability	-	-	✔	-	-
Complexity	✔	✔	✔	-	-
Design Quality & Packaging	✔	-	-	✔	-
Cost	✔	✔	✔	✔	-
Outer Setting					
Patient Needs & Resources	✔	✔	✔	✔	✔
Cosmopolitanism	✔	-	✔	✔	✔
Peer Pressure	✔	✔	-	✔	-
External Policy & Incentives	✔	✔	✔	✔	✔
Inner Setting					
Structural Characteristics	✔	✔	✔	✔	✔
Networks & Communications	✔	-	-	-	✔
Culture	-	✔	-	✔	✔
Implementation Climate	✔	✔	✔	✔	✔

CFIR Constructs	Current review	Shoemaker et al's review [143]			Robert et al's review^ [142]
	National innovations	MTM	Immuniz-ations	HIV testing	CPS
Tension for Change	✔	†	†	†	-
Compatibility	✔	†	†	†	-
Relative Priority	✔	†	†	†	-
Organizational Incentives & Rewards	✔	†	†	†	✔
Goals and Feedback	✔	†	†	†	-
Learning Climate	-	†	†	†	-
Readiness for Implementation	✔	✔	✔	✔	✔
Leadership Engagement	✔	†	†	†	✔
Available Resources	✔	†	†	†	✔
Access to Knowledge & Information	✔	†	†	†	✔
Characteristics of Individuals					
Knowledge & Beliefs about the Intervention	✔	✔	✔	✔	✔
Self-efficacy	✔	✔	✔	-	✔
Individual Stage of Change	✔	-	-	-	✔
Individual Identification with Organization	-	-	-	-	-
Other Personal Attributes	✔	✔	-	-	✔
Process					
Planning	✔	✔	✔	-	-
Engaging	✔	✔	✔	✔	✔
Engaging (Stakeholders)	✔	†	†	†	-
i. Opinion Leaders	-	†	†	†	-
ii. Formally Appointed Internal Opinion Leaders	-	†	†	†	-
iii. Champions	-	†	†	†	✔
iv. External Change Agents	-	†	†	†	✔
Engaging (Innovation Participants)	✔	†	†	†	✔
Executing	✔	✔	✔	-	-
Reflecting & Evaluating	✔	-	✔	-	-

✔Represents that the CFIR construct was observed within the literature, - Represents that a CFIR construct was not observed within the literature, ^ Mapping of the facilitators identified by Roberts et al review is available upon request, †As the tabulation of results by Shoemaker et al's study was based on the overarching construct and not the sub-construct as with the current review (e.g. "Implementation Climate" and not "Tension for Change", "Compatibility" etc.) cross comparison not possible, MTM – medication therapy management, CPS - cognitive pharmacy services

In relation to pharmacy staff engagement, mixed positive and negative perceptions of innovations by pharmacy staff were apparent. This is in contrast to a previous review exploring the personality traits of pharmacy staff which found pharmacists generally favourable towards new services [206]. It has also been previously identified that pharmacists' positive beliefs and attitudes about a service facilitate successful implementation [142, 143]. This study's more conservative findings may be reflective of the inclusion of national innovations only, as there may be greater representative of people who are less engaged when compared to studies conducted in pilot phases limited to 'early adopters' [21].

Innovations were considered advantageous by pharmacy staff if they enhanced the relationship with patients, improved relationships with surrounding healthcare professionals, benefitted patients, or improved workforce capability. Personal incentives included professional satisfaction, recognition and influence. Shoemaker et al's review also identified that improving patient health and the patient's relationship with the pharmacy to be considered advantageous [143], and that demonstration of skillset and perceived value to the public was an incentive [143]. Shoemaker at al additionally found the acquisition of new patients attending the pharmacy as a facilitator of implementation [143], and the positive influence of monetary incentives and financial betterment identified within the current review mirrors previous findings [142, 143]. This highlights the well-known challenge of balancing the professional, clinical and commercial obligations within the community pharmacy setting [207]. Exploring the cognitive processes underpinning decisions to implement innovations in light of financial and personal incentives, and how these weigh against patient-related benefits, would be an interesting area for future research [208].

The most commonly reported barrier in relation to the operationalisation of an innovation was the lack of available resources, which centred on time and workload constraints, which echoed Shoemaker et al's findings [143]. Beyond staff recruitment, the promotion of whole team engagement and delegation of tasks to pharmacy support staff may facilitate more efficient workflow [6, 209-212] and practice change [142]. Barriers relating to insufficient resources and training were common, as was poor design, complexity, and incompatibly of the innovation, with the latter two also identified by Shoemaker et al [143]. Bottom-up

implementation strategies with front-line staff involved in the design and testing of innovations may overcome resource insufficiencies and design flaws [213, 214].

External engagement centred on the perceptions of other healthcare professionals and patients. Negative perceptions of other healthcare professionals, and lack of both communication and collaboration with pharmacy staff, was a barrier. Roberts et al also identified that communication with doctors and their attitudes influenced successful implementation of cognitive pharmacy services [142], whilst Shoemaker et al identified cosmopolitanism and engagement of the wider healthcare setting to be a facilitator [143]. General practitioners have previously reported lack of collaboration with community pharmacies [215], with evidence that they are cautious about their adoption of new services [216] and clinical roles [217-220].

The influence of perceived patient acceptance was also prominent - community pharmacy staff cited lack of patient demand and their resistance towards innovations. Conversely, a review of patient-reported satisfaction with community pharmacy services found high satisfaction [221], and a disparity between how pharmacists perceive patient satisfaction and how patients report satisfaction has been previously identified [222]. Shoemaker et al identified patient demand for vaccination services and acceptance of Medication Therapy Management, with no barriers identified relating to patient engagement [143]. Additionally, low public awareness of innovations was commonly cited, and there have been mixed findings in relation to patient awareness of community pharmacies roles [223-226]. Informing the public was a commonly reported hypothetical facilitator reported by the studies within this review, suggesting that poor public engagement is perceived as a limitation of the implementation strategies adopted.

5.6.1 Strengths and limitations

Alignment of the results to the CFIR firmly positions the research within the wider implementation science literature. However, the inclusion of qualitative and quantitative studies and the varying level of reporting detail meant it was not possible to weight identified barriers and facilitators and deduce relative influences. The results instead were presented based on the number of reporting studies, which is not uncommon for reviews of this nature [142, 143, 227-229]. Primary studies would benefit from applying the CFIR rating rules which explores the valence (i.e. positive or negative impact) and strength of

influence of emergent CFIR constructs [155]. Nevertheless, tabulation of the results facilitated consideration of the relationship between constructs and allowed for useful cross-comparison [161].

To the authors' knowledge, using a directed content analysis approach when applying the CFIR is novel, and helped assess its applicability to the community pharmacy setting. The CFIR constructs captured most emergent data, except for two instances within the CFIR Outer Setting domain. Patients' perceptions, awareness and engagement is not explicitly encompassed within the Patient Needs and Resources construct - which has been criticised elsewhere [72] – as the construct focuses more so on the ability of an organisation to identify and prioritise patients' needs. The Cosmopolitanism construct overlooks the impact of external healthcare professionals' engagement as it centres on networking with external organisations. Both of these factors would not appear relevant in any other CFIR domain or construct, thus widening the scope of these CFIR constructs accordingly is required.

Limiting the search to the English language compromised the ability to identify implementation facilitators and barriers internationally. However, 41.0% (n=16) of included studies were from non-English speaking nations. During full text screening, thirty-five studies could not be accessed. As only 8.1% (n=29) of the 358 studies screened were included, it is estimated that only three of these would be eligible for inclusion. On reflection, alternative strategies could have been adopted to obtain access to full text articles which were not accessible, such as contacting the authors personally. Although the study selection process underwent independent peer-review, alignment of the results to the CFIR was not conducted independently. However, a dedicated CFIR codebook and technical assistance guide was routinely accessed to ensure appropriate alignment to CFIR constructs [230]. Studies of poor quality were retained to allow for broad data capture, yet removal of the lower quality studies did not affect the representation of the most commonly cited CFIR constructs thus were retained for completeness. Conference abstracts obtained the lowest quality scores – likely to be reflective of their reporting depth – although retaining these ensured representation of the latest research [229].

The emergent CFIR constructs complemented those from related reviews which suggests our findings are valid and that the field is closer to developing a causal theory of how the most salient barriers and facilitators influence successful implementation within the

community pharmacy setting [142, 143]. However, given the methodological differences in the review approaches this should be interpreted with a degree of caution. Two CFIR constructs cited by Shoemaker et al and Roberts et al were not emergent in this review: Culture [142, 143] and Trialability [143]. As Roberts et al only reported "culture of the pharmacy" and did not elaborate [231], it is difficult to hypothesis why in relation to this review. Shoemaker et al coded "alignment with missions/priorities" and "commitment to providing preventive services" within the construct Culture [232], which the current review would have coded within Compatibility (i.e. how the innovation "aligns with individuals' own norms and values") [63]. With regards to Trialability, Shoemaker et al identified that slow expansion of immunization services facilitated implementation, which would unlikely be salient within scaled-up, national services [143]. It was more common for differences to emerge in the valence of the reported CFIR constructs. For example, the current review identified negative patient perceptions (Patient Needs & Resources) and lack of engagement of external healthcare professional (Cosmopolitanism), whereas Shoemaker et al only reported facilitators within these CFIR constructs [143]. This may suggest that emergence of barriers and facilitators at national level are comparable to those in small-scale pilot stages, yet the strength of influence they have on implementation may differ, which would be an interesting area for further research to explore.

5.6.2 Future directions and recommendations

In line with previous work, this review identified that adopted implementation strategies are poorly reported in the literature [140, 143]. It remains unknown how specific implementation interventions in the community pharmacy setting influence implementation. It is recommended that future studies explicitly report both the implementation strategies adopted and specific details of the innovation being implemented [233, 234] to facilitate eventual theory generation in this area.

Potential applications of the results include better directed evaluations building upon the three key thematic areas identified within this study. There is also scope for the results to be used to develop a questionnaire to explore the emergence of barriers and facilitators within any community pharmacy setting, where the use of a questionnaire over qualitative approaches may foster greater response rates and obtain more generalizable findings. Specifically, a questionnaire could explore the barriers and facilitators experienced when implementing novel innovations, which ideally would occur during the earlier stages of an

innovation's implementation for the results to be used to develop a tailored implementation strategy. For this thesis, the development of such a questionnaire is described in Chapter 6, and later applied to evaluate of the consolidated and warfarin care bundles (Chapter 7).

5.7 Conclusion

Pharmacy staff perceptions of the barriers and facilitators to the implementation of national innovations within the community pharmacy setting have been identified. Commonly reported factors which influence implementation include: insufficient resources, the views of patients and other healthcare professionals, pharmacy staff perceptions and acceptance of innovations, and belief that innovations were beneficial. Lack of detail on implementation strategies adopted meant it was not possible to develop a causal theory of how different implementation strategies influenced implementation. It is recommended that future studies explicitly report implementation strategies used and apply the CFIR to facilitate cross comparison and eventual theory generation. Potential applications of the results include better directed evaluations. For example, developing a diagnostic questionnaire able to identify barriers and facilitators early on in an innovations implementation process could help identify context-specific determinants of implementation success. Ultimately, this could lead to the development of tailored national implementation strategies which overcome identified barriers and exploit known facilitators.

Chapter 6: Development and dissemination of a questionnaire to explore the implementation of the consolidated warfarin and NSAIDs care bundles

6.1 Summary of chapter

Background

Piloting of the consolidated warfarin and NSAIDs care bundles commenced in February 2017, with final amendments actioned following implementation within community pharmacy practice. This afforded the opportunity to develop a questionnaire which explored (i) the extent of their successful implementation, (ii) the barriers and facilitators influencing implementation, and (iii) their penetration within pharmacy practice.

Methods

A questionnaire was developed based on a review of the literature, including the results of the systematic review (Chapter 5). The questionnaire underwent validity and pilot testing, and the final questionnaire was disseminated in June 2017 to the 24 participating pharmacies. Reliability testing was conducted for the implementation success scale developed, which was designed to measure the care bundles' implementation success.

Results

Out of the sample of 217 participants, 74 (34.1%) questionnaire responses were received from 17 pharmacies (70.8%). Reliability testing identified that the implementation success scale had a high level of internal consistency (Cronbach's alpha coefficient = 0.947).

Conclusion

A questionnaire has been developed which measures three key aspects regarding the implementation of the consolidated warfarin and NSAIDs care bundles The use of a questionnaire increases the number of potential participants and generalisability of the results than would have been possible with qualitative methods. The results relating to the successful implementation of the care bundles and associated barriers and facilitators is presented in Chapter 7, and the results relating to the care bundles' penetration is presented in Chapter 8.

6.2 Background

In response to identified harm associated with the high risk medicines warfarin and NSAIDs [28-32], consolidated care bundles were developed which focus on the clinical assessment of these medicines and informing patients of their risks (Chapter 4). Piloting of these care bundles began in February 2017 within 24 community pharmacies across Scotland, with a strategic desire to implement them within all community pharmacies in Scotland to effect nation-wide improvements. This afforded the opportunity to evaluate the pilot implementation using a questionnaire to support and inform this national implementation process. Three areas of importance were selected to evaluate the care bundles within this questionnaire: (i) the extent of their successful implementation, (ii) the barriers and facilitators influencing their implementation, and (iii) their penetration within community pharmacy practice.

First and foremost, identifying if the care bundles have been successfully implemented within the pilot community pharmacies is of importance, considering that successful implementation is a pre-requisite for achieving intended clinical outcomes of the bundles [103]. It is considered a necessity for studies to evaluate implementation success [235], with studies which do not encompass an outcome measure for this criticised [72, 81, 236]. Identifying the extent of successful implementation of the care bundles within their pilot phase will allow consideration of the likelihood of successful national implementation, and may indicate the degree of facilitation required for this.

Secondly, identifying barriers and facilitators when implementing specific innovations is also widely advocated in order to develop tailored implementation strategies [57, 58, 237, 238], with some evidence suggesting that tailored implementation strategies increase the likelihood of successful implementation [58]. Barriers, facilitators and hypothetical facilitators[3] to the implementation of national community pharmacy innovations were identified within the systematic review presented in Chapter 5, which offers a useful starting point when considering which barriers and facilitators may be most salient in relation to the consolidated warfarin and NSAIDs care bundles. As a measure of

[3] Hereon will be referred to as barriers and facilitators only

implementation success will also be sought, the relative effect each identified barrier and facilitator exerts upon successful implementation can be quantified [58, 237].

Thirdly, the penetration of the care bundle within community pharmacy practice will also be explored, as an innovation's integration within existing workflows positively influences successful implementation [63, 239, 240]. This is termed 'penetration' and is formally defined by Proctor et al as the 'integration of a practice within a service setting and its subsystems' [87]. The outcome penetration encompasses (i) if and how innovations become incorporated within routine practice, as well as (ii) the number of healthcare providers which deliver an innovation [87]. This latter concept of penetration is what will be explored within this question, with the former aspect of penetration explored using on-site visits which is presented within Chapter 8. Within this context, this aspect of penetration can be considered as the extent to which all community pharmacy staff within the pilot pharmacies deliver the care bundle. This is of particular importance as within the community pharmacy setting the benefit of wider pharmacy support staff involvement with innovations is acknowledged [168, 169]. Therefore, the exploration of penetration within the questionnaire will explore the contribution of the various levels of pharmacy staff within the process.

6.3 Aims and objectives

To explore these important facets of implementation, the aim was to develop a questionnaire to explore the barriers and facilitators influencing implementation success for the warfarin and NSAIDs care bundles and their penetration into routine community pharmacy practice. The specific objectives of this study were to:

1. Develop questionnaire items to identify:
    a. implementation success of the consolidated NSAIDs and warfarin care bundles
    b. barriers and facilitators influencing implementation success
    c. penetration of the care bundles into routine practice
2. Conduct validity and reliability testing for the questionnaire
3. Pilot the questionnaire
4. Disseminate the final questionnaire to the participating pharmacies

6.4 Subjects and settings

The questionnaire is designed for the community pharmacy staff within the 24 pharmacies piloting the consolidated warfarin and NSAIDs care bundles. These include pharmacies within NHS GG&C (n=9), NHS Highland (n=3), NHS Fife (n=7), and NHS Grampian (n=5). The characteristics of these pharmacies are presented previously in Chapter 4, Table 4.1. Previous evaluation activities in 2016 estimated the total number of community pharmacy staff within these pharmacies to be 217 based on pharmacies' self-reported staff numbers [38].

6.5 Methods

6.5.1 Questionnaire content

The questionnaire sections are shown in Figure 6.1. Firstly, respondents' perception of implementation success (Section 1) is explored, followed by Section 2 of the questionnaire which explores self-reported experience of barriers and facilitators in alignment with the CFIR, as presented in Chapter 5. Penetration of the care bundles is then explored by identifying participants' involvement with the care bundles including what resources they use (Section 3). Open-ended questions allow participants to offer further commentary (Section 4), and the concluding section of the questionnaire sought participants' demographics characteristics (Section 5). Questionnaire headings considered more meaningful to a community pharmacy audience were used for the final questionnaire to delineate between these five sections, as shown in Figure 6.1.

The five questionnaire sections	Rephrased heading for questionnaire
1. Implementation success	Implementation of the [warfarin/NSAIDs] care bundle
2. Implementation barriers and facilitators (CFIR domains)	
Characteristics of the Individual*	Your Knowledge and Beliefs
Innovation Characteristics*	About the [warfarin/NSAIDs] care bundle
Outer Setting*	Patients Other Healthcare Professionals Policy
Inner Setting*	In Your Pharmacy In General
Process*	Engagement
3. Penetration	Involvement with the [warfarin/NSAIDs] care bundle
4. Open-ended questions	Your Opinions
5. Demographics	About You

Figure 6.1. The five questionnaire sections

**These are the five domains of the Consolidated Framework for Implementation Research (CFIR), NSAID(s) = non-steroidal anti-inflammatory drug(s)*

6.5.1.1 Development of items to measure implementation success (Section 1)

Limitations of previous studies within the field of implementation science include not identifying a measure of implementation success [72, 81, 236]. A review of instruments measuring implementation outcomes conducted by Lewis et al in 2015 was referred to in order to identify an appropriate measure of implementation success for this study [241]. However, many of the tools identified sought the willingness of organisations to adopt new technology during pre-implementation stages [242-244], or explored in general the translation of "research knowledge" within settings [245-248]. Where the implementation of specific innovations was evaluated in a study, they were designed for single use in a specific setting which were not of contextual relevance to this study and could not be adapted for use [249-253]. This included an arson and tobacco prevention programmes for adolescents [249-251], a Taiwanese learning transfer systems [252], and the adoption of therapeutic models used by therapists with their clients [253]. One questionnaire was identified which could be used to measure implementation success for specific innovations and was adaptable to evaluate different healthcare innovations [254]. However, the questionnaire was awarded a quality assessment of 2/16 by Lewis et al as its reliability and validity was untested, with its usability only considered 'adequate' due to its length (50-100

questionnaire items) [241]. Therefore, on the basis of its poor quality assessment and extensive length this questionnaire was not applied for this study.

Consequently, a new questionnaire was developed to ascertain participants' perception of implementation success for the NSAIDs and warfarin bundles which would undergo validity and reliability testing. A scale was purposefully chosen over a single question indicator to allow for empirical reliability testing to ensure the items within the scale were reliably measuring perceptions of implementation success. To clarify the concept of 'implementation' and facilitate item generation for the scale [255], definitions of 'implementation' were collated from literature identified within the introductory chapter of this thesis and from the Oxford English Dictionary [49, 52, 66, 82, 99, 256, 257]. This led to the development of six questionnaire items, which were conceptually linked yet worded differently, each asking if participants thought the care bundle was implemented within their pharmacy, shown in Figure 6.2. A six-item scale was considered sufficient as self-reported perception of implementation success is a narrow trait and not deemed conceptually rich [258].

The care bundle is fully implemented in my pharmacy
The care bundle is applied to all eligible patients (i.e. "every patient, every time")
The care bundle is fully integrated into the way my pharmacy works
The care bundle is a normal part of what we do in my pharmacy
The care bundle is fully used in my pharmacy
The care bundle is a part of routine practice in my pharmacy

Figure 6.2. The six-item implementation success scale

6.5.1.2 Development of items to explore barriers and facilitators (Section 2)

(i) Selection of CFIR constructs to be explored

As previous studies have been criticised for arbitrarily deciding which barriers and facilitators to focus on during evaluations [81, 99, 259], the results of Chapter 5's systematic review were used to select CFIR constructs of salience within the community pharmacy setting to explore within the questionnaire. The CFIR constructs present the myriad of factors which can influence successful implementation, and the systematic review

identified emergent CFIR constructs applicable to the national implementation of community pharmacy innovation. Of these, CFIR constructs were selected for inclusion within the questionnaire if over 9 of the 39 studies from the systematic review (23.1%) reported it as a barrier, facilitator, or hypothetical facilitator. The corresponding CFIR sub-constructs were included within the questionnaire if they were reported by three or more studies. Therefore, 39 CFIR sub-constructs from 14 CFIR constructs were selected for inclusion (Table 6.1). This selection process was peer reviewed by RN and EDC.

Table 6.1. Consolidated Framework for Implementation Research (CFIR) constructs and sub-constructs included within questionnaire

CFIR domain (n=5)	CFIR constructs (n=14)	CFIR sub-constructs (n=39)
Characteristics of the Individuals	Knowledge & Beliefs about the Innovation	Negative/positive perceptions
		Awareness of the innovation
		Knowledge about the innovation
		Lack of clinical knowledge
	Individual Stage of Change	Reluctance/lack of motivation
		Willingness/enthusiasm
Outer Setting	Patient Factors	Negative/positive patient perceptions
		Patient demand
		Patient awareness and knowledge
		Difficulty recruiting patients
	Cosmopolitanism	Negative perceptions of other healthcare professional (HCP)
		HCP referral/engagement
		HCP communication/collaboration
	External Policy & Incentives	Sufficient funding/remuneration
		Incentives (financial and other)
		Making the innovation compulsory
Inner Setting	Compatibility	Compatibility with roles
		Compatibility with values
		Compatibility with pharmacy processes
		Increase in legal liability
	Organizational Incentives & Rewards	Improved professional recognition/influence/extended role
		Commercial benefits/increased footfall
		Professional satisfaction
	Available Resources	Time
		Increased workload
		Resources
		Access to clinical information
		Suitable space/area
		Staffing
	Access to Knowledge & Information	Training
		Access to information/well informed
Innovation Characteristics	Relative Advantage	Advantages and disadvantages of the innovation
	Complexity	Difficulty of innovation
		Complexity of innovation
	Design Quality & Packaging	Poor design of innovation
		Poor quality of innovation
Process	Engaging (Stakeholders)	Engagement of pharmacies
		Informing/engagement of other HCPs
	Engaging (Innovation Participants)	Informing/education the public/patients

(ii) Review of previously developed questionnaires

Following the identification of which CFIR constructs and sub-constructs to explore, attempts were made to identify a pre-existing questionnaire exploring these barriers and facilitators, as the development of novel 'in house' questionnaires to identify barriers and facilitators is discouraged as they usually have applicability for single use within a specific context and setting [260]. In 2015, a systematic review by Kirk et al identified 26 studies which applied the CFIR within the research design [81]. Of these, three applied a questionnaire derived specifically from the CFIR constructs [261-263]. However, Kirk et al concluded that none of these questionnaires were widely accepted or transferrable to other setting [81].

To identify if a widely accepted or transferrable questionnaire had been developed since this review, Kirk et al's systematic review search strategy [81] was repeated. The citation index databases Web of Science and Scopus were searched on April 21st 2017 from January 2015 onwards for studies citing the CFIR's original publication [99]. Studies were considered relevant if they were:

- within a healthcare setting
- applied a quantitative instrument derived from the CFIR constructs
- published in the English language

Of the 673 studies identified which underwent title/abstract screening, 102 studies were identified of potential relevance and had their full text methods screened, with a final eight studies identified as relevant [236, 259, 264-269]. See Figure 6.3 for this search process.

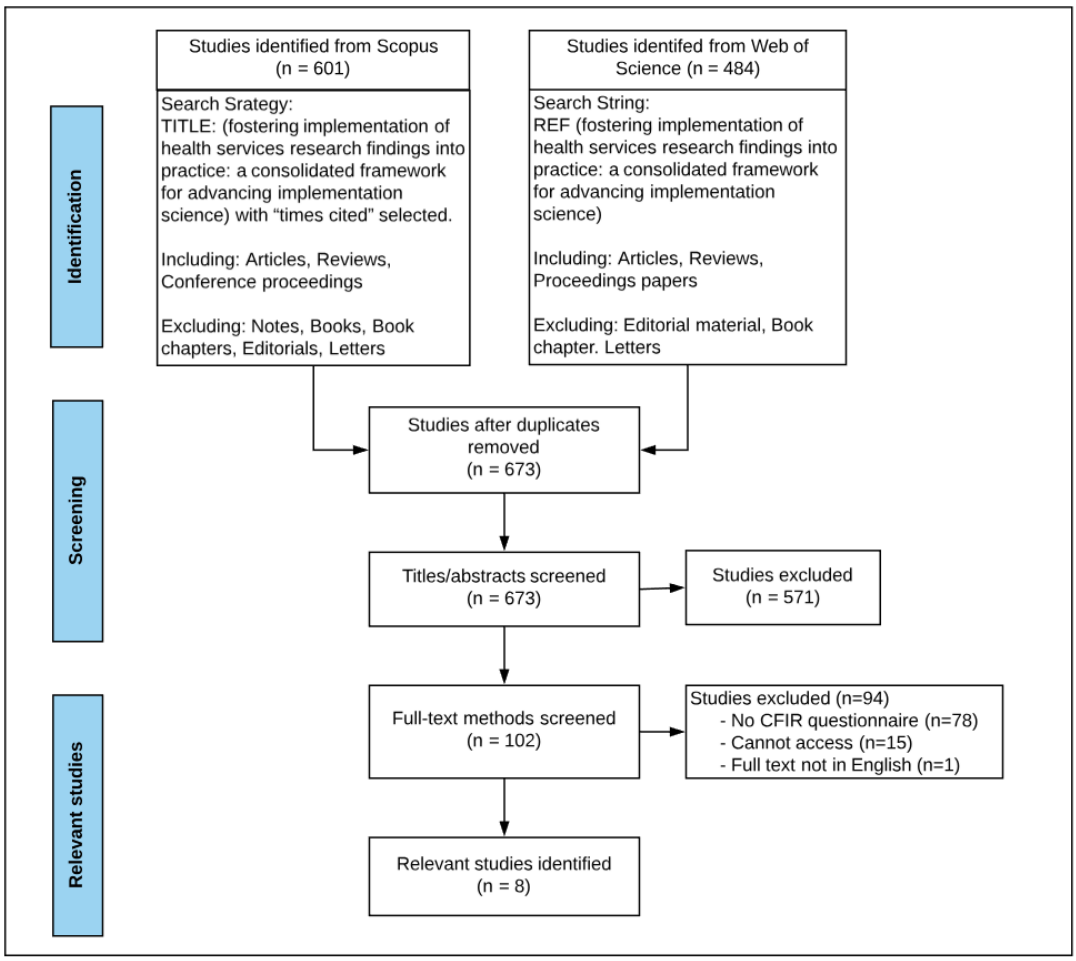


Figure 6.3. Search for studies that developed a questionnaire derived from the Consolidated Framework for Implementation Research (CFIR) (Jan 2015 – Apr 2017)

A review of these eight studies revealed that there was still no accepted quantitative measure for the CFIR domains and constructs: each questionnaire was developed for sole use within one setting and context and none underwent psychometric testing for validity or reliability [236, 259, 264-269]. Of the 11 studies which applied a questionnaire developed from the CFIR - three from Kirk et al's review and eight from the repeated search shown in Figure 6.3 - no study explicitly reported the development process of the questionnaire [236, 259, 261-269]. Each questionnaire covered only some CFIR constructs, and none covered all of those identified of interest in this study [236, 259, 261-269]. Of two questionnaires which did explore some of the constructs of interest identified [262, 263], an attempt was made to see if these could facilitate item generation for this study. However, for one study the questionnaire was developed for pre-implementation assessment in contrast to the current studies post-implementation evaluation [263], and the other was highly contextualised to a specific context - therapists' use of an arm and hand exercise program

with stroke patients - which lacked transferability to the community pharmacy setting [262].

A further search conducted included reviewing two instrument repositories: The Society for Implementation Research Collaborations' Instrument Review Project [270], and the National Cancer Institute Grid-Enables Measures Project [271]. Within both repositories each CFIR construct of interest was searched to identify applicable questionnaires, yet no questionnaire suitable for this study was identified.

(iii) Development of barriers and facilitators questionnaire items

As the search for previously developed questionnaires yielded no tangible results, a new set of questionnaire items were developed to ascertain the presence of barriers and facilitators by moving from the broad CFIR constructs to the more specific sub-constructs [255]. This was conducted by NW by developing a set of forty-three questionnaire items which were based on the CFIR sub-construct identified by the systematic review (see Table 6.1). This development process involved ensuring the questionnaire items accurately reflected the sub-constructs identified, and would be comprehendible by all levels of community pharmacy staff. Of the 39 CFIR sub-constructs identified, 37 were represented by a single questionnaire item. Two CFIR sub-constructs were represented by two questionnaire items as they were considered conceptually broader. These were the sub-constructs 'Disadvantage/ advantage of the innovation' and 'Training'. The sub-construct 'Disadvantage/advantage of the innovation' was split into both patient and pharmacy advantages and disadvantages. The sub-construct 'Training' had a preceding question asking if training had been received (where a dichotomous yes/no response was offered), followed by a question asking if the training received was considered sufficient.

Due to this design, whereby each questionnaire item measured a unique barrier or facilitator, this part of the questionnaire does not represent a psychometric scale to which reliability testing would be appropriate [72, 260, 272]. Developing a scale would have required asking numerous questions per individual CFIR constructs which would have resulted in an extensively long questionnaire. It was considered that this limitation could be overcome by focusing on fewer sub-constructs, but this would have been at the expense of potentially missing important barriers and facilitators and not truly exploring the range of factors which may influence successful implementation of the warfarin and NSAIDs care bundles.

Table 6.2. Barriers and facilitators item generation for each Consolidated Framework of Implementation Research (CFIR) sub-construct

CFIR Domain	CFIR construct	Sub-constructs	Questionnaire item
Characteristics of individuals	Knowledge and Beliefs about the innovation	Negative/Positive perceptions	I think the HRM CB is a good idea
	Knowledge and Beliefs about the innovation	Awareness of the innovation	I am aware of the HRM CB
	Knowledge and Beliefs about the innovation	Knowledge about the innovation	I have working knowledge about the HRM CB
	Knowledge and Beliefs about the innovation	Lack of clinical knowledge	I have sufficient clinical knowledge about the HRM of interest in my pharmacy
	Individual Stage of Change	Reluctance/ lack of Motivation	I am not motivated to be involved with the HRM CB
	Individual Stage of Change	Enthusiasm/willingness	I am enthusiastic about the HRM CB
Outer Setting	Patient Factors	Negative/positive patient perceptions	I think the HRM CB is viewed positively by patients
	Patient Factors	Patient demand	I think there is a lack of patient demand for the HRM CB
	Patient Factors	Patient knowledge	I think patients lack knowledge about what the HRM CB is about
	Patient Factors	Patient awareness	I think patients are aware of the HRM CB
	Patient Factors	Difficulty recruiting patients	I think it is difficult to get patients involved with the HRM CB
	Cosmopolitanism	Negative HCP perceptions	I think the HRM CB is viewed positively by other healthcare professionals (e.g. GPs)
	Cosmopolitanism	HCP referral/engagement	I think other healthcare professionals (e.g. GPs) are engaged with the HRM CB
	Cosmopolitanism	HCP Communication/collaboration	I think a collaborative relationship exists between my pharmacy and other healthcare professionals (e.g. GPs).

CFIR Domain	CFIR construct	Sub-constructs	Questionnaire item
Outer Setting	External Policy and Incentives	Sufficient funding/remuneration	I think there is sufficient funding for the HRM CB
	External Policy and Incentives	Incentives (financial and other)	There are incentives to being involved in the HRM CB
	External Policy and Incentives	Making the innovation compulsory	I think the HRM CB should be compulsory in all pharmacies
Innovation characteristics	Relative advantage	Disadvantage/ Advantage of the innovation	I think the HRM CB benefits patients
	Relative advantage	Disadvantage/ Advantage of the innovation	I think the HRM CB benefits community pharmacy practice
	Complexity	Difficulty of the innovation	I think the HRM CB is difficult
	Complexity	Complexity of the innovation	I think the HRM CB is complex
	Design Quality & Packaging	Poor quality of innovation	I think the HRM CB is of good quality
	Design Quality & Packaging	Poor design of innovation	I think the HRM CB has been designed poorly
Inner Setting	Compatibility	Compatibility with roles	I think the HRM CB is compatible with the roles I have within my pharmacy
	Compatibility	Compatibility with values	I think the HRM CB is aligns with the values I have regarding community pharmacy work
	Compatibility	Compatibility with processes	I think the HRM CB is compatible with the way my pharmacy works
	Compatibility	Fear/Increase in liability	I think involvement in the HRM CB increases the legal responsibility of community pharmacy practice
	Organisation Incentives and Rewards	Improved professional recognition	I think the HRM CB improves the professional recognition of community pharmacy practice

CFIR Domain	CFIR construct	Sub-constructs	Questionnaire item
Inner Setting	Organisation Incentives and Rewards	Increased influence/extended role	I think the HRM CB increases the influence of community pharmacy practice
	Organisation Incentives and Rewards	Commercial benefits/increased footfall	I think the HRM CB has commercial benefits for my pharmacy
	Organisation Incentives and Rewards	Professional satisfaction	I think the HRM CB is professionally satisfying
	Available Resources	Time	I think there is enough time to be involved with the HRM CB
	Available Resources	Increased workload	I think the HRM CB increases my workload
	Available Resources	Physical Resources	I think there are sufficient resources to be involved with the HRM CB
	Available Resources	Access to Clinical information	I think having access to clinical information about patients would help our involvement with the HRM CB
	Available Resources	Suitable space/area	I think there is a suitable area in our pharmacy to deliver the HRM CB to patients
	Available Resources	Staffing	I think we have sufficient staff in our pharmacy to be involved with the HRM CB
	Access to Knowledge and Information	Training	I have been trained on the HRM CB
	Access to Knowledge and Information	Training	The training I received was sufficient for me to be confident in my abilities to be involved with the HRM CB
	Access to Knowledge and Information	Access to information/well informed	There is no information available about the HRM CB
Process	Engaging (stakeholders)	Engagement of pharmacies	The SPSP-PPC Project Team have engaged with my pharmacy team
	Engaging (stakeholders)	Informing/engagement of other HCPs	The SPSP-PPC Project Team have engaged with non-pharmacy healthcare professions (e.g. GPs)

CFIR Domain	CFIR construct	Sub-constructs	Questionnaire item
	Engaging (innovation participants)	Informing/education the public/patients	Patients have been well informed about the HRM CB

HRM CB = High Risk Medicine care bundle, SPSP-PPC = Scottish Patient Safety Programme - Pharmacy in Primary Care, GPs = general practitioners

6.5.1.3 Development of items to explore penetration (Section 3)

The implementation outcome 'Penetration' - which relates to how innovations integrate within routine practice [70] - was explored in relation to the various pharmacy staff members' involvement with the care bundle and their use of the care bundles' resources. Two questionnaire items were developed to explore this. The first questionnaire item asked participants 'What involvement do you have with the care bundle?', where participants were able to select if they: identified eligible patients; clinically assessed patients warfarin/NSAIDs medication; collected and/or used resources for the care bundle; spoke with patients/carers; or documented delivery of the care bundle. These nominal responses were developed based on previous evaluation of the processes involved in delivering the care bundles prior to their consolidation [39]. The second questionnaire item asked participants 'What resources have you used in your pharmacy with the care bundle?'. Coloured images of the resources developed for the care bundles were included within the questionnaire for participants to indicate which resources they had used (as presented in Appendix 1.1). Participants were given the option to offer other areas of involvement with the bundle or other resources used within open-ended questions. Participants also had the option to indicate if they had no involvement with the care bundle or had not used any of the care bundles' resources.

6.5.1.4 Development of open-ended questions (Section 4)

Questionnaires which use entirely closed-ended questions can be criticised as they do not allow participants to freely express opinions or offer any elaboration [272], and the use of open-ended questions can remove the power balance between researchers and participants [273]. Open-ended questions were developed for participants to report on barriers and facilitators not already listed; offer suggestions of what would hypothetically facilitate implementation; elaborate upon barriers and facilitators specified within the questionnaire; and to offer any other comments.

6.5.1.5 Development of demographic questions (Section 5)

Demographic questions were developed as per those captured within previous evaluations of the warfarin and NSAIDs care bundles prior to consolidation [38]. These included: gender, age, length of involvement in the SPSP-PPC collaborative, length of time working in community pharmacy, main role in community pharmacy, length of time working in this main

role, contract type (e.g. part time/full time), and if they have had training on quality improvement methods (e.g. PDSA cycles).

6.5.2 Questionnaire design

6.5.2.1 Language considerations

Various textbooks were referred to when choosing the language of the questionnaire items [255, 272, 274-276], with the main considerations summarised in Figure 6.4.

Language considerations
• Use simple language as this may reduce risk of acquiescence • Make sure the questions are clear and unambiguous • Ensure all respondents will interpret the questions similarly • Ensure all respondents can answer all questions • Keep the questions as short as possible, but use complete sentences • Avoid abbreviations • Do not use double-barrelled questions • Avoid leading questions • Have positive and negatively worded statements throughout to reduce risk of acquiescence

Figure 6.4. Language considerations when developing questionnaire items [255, 272, 274-276]

6.5.2.2 Likert scale considerations

Sections 1 and 2 of the questionnaire, which explore implementation success and the barriers and facilitators, used a Likert-scale to obtain participants' responses to allow participants to demonstrate what degree of attitude they had towards questionnaire items. On reflection of the design considerations in relation to Likert-scales, which are summarised in Figure 6.5, participants were asked to select the extent to which they agreed or disagreed with the statements on implementation success and barriers and facilitators using the following five-point Likert-scale: strongly disagree, disagree, neutral, agree, and strongly agree.

Likert Scale Considerations:

- Likert scales can use the following format:
  - Strongly agree/strongly disagree
  - Very favourable/very unfavourable
  - Excellent/poor
  - Extremely satisfied/extremely dissatisfied
- Ensure Likert scales focus on one concept with equal number of positive and negative categories
- Ensure Likert scales go in one direction (e.g. from negative to positive)
- State both sides of attitude in the question (e.g. "to what extent do you agree or disagree")
- Most Likert scales have 5 response options but anything between 2-9 has the same reliability
- A trichotomous scale is problematic if participants have moderately positive or negative attitudes
- A mid-point "neutral" option prevents coercing participants to provide an opinion, which has implications for the reliability and validity of the questions
- It is not standard practice to include an "I don't know" option unless offered by the respondent

Figure 6.5. Likert-scale considerations [255, 272, 274-277]

6.5.2.3 Design considerations

The final design of the questionnaire considered the order of questions, visual design aspects, and strategies which can increase participants' motivation to respond, which are summarised in Figure 6.6.

Survey order

• Position instructions where they are needed and not all at the beginning
• Commence with questions which will be easily answered, interesting, and obviously related to the questionnaires objectives
• Questions on the same topic should be grouped together
• Options to structure the progression of questions include proceeding from:
  o General to specific questions
  o Easily understood to more complex questions
  o Most salient to least salient questions
• Place objectionable questions or those on sensitive topics towards the end
• Place open-ended questions at the end with sufficient space
• Place demographic questions at the end as they can arouse suspicion when positioned at the beginning

Visual design of questionnaire
• Print questions on only one side, stapled at the top left hand corner, or develop a booklet • Use dark print for questions and light print for answer choices (or the former in bold and the latter in normal typeface) • Avoid capitalising the questions as this can be difficult to read • Minimise the use of matrices • Avoid putting answer choices into columns
Optimising motivation to respond
• Show positive regard by offering reasons as to why the survey is being conducted • Phrase the introduction so it is evident you are asking the respondent for advice • Provide a number for participants to call if they have questions • Make the task appear important by appealing to people on the basis that something important will happen with the results • Avoid subordinate language • Thank participants within the questionnaire • Offer material and financial incentives • A response deadline may influence people to act • Include estimated time of completion

Figure 6.6. Questionnaire design considerations [255, 272, 274-277]

6.5.3 Validity testing

Validity of a questionnaire indicates the degree to which an instrument accurately measures the construct(s) it intends to explore [275]. Face and content validity are examples of theoretical validity whereby there is an assumed correlation between the underlying latent construct and the questionnaire items [275].

6.5.3.1 Face validity testing methods

Face validity is established when an individual subjectively reviews a questionnaire and concludes that at 'face value' it measures what it intends [278]. It can provide insights into

how respondents may interpret the questionnaire [278], and the process can also involve assessment of the questionnaire for grammar, syntax, organization, appropriateness and flow [279]. Those conducting face validity can vary from experts in the area of research or lay people [278].

Researchers within the Improvement Science group at the University of Strathclyde were approached to conduct face validity testing, which included two research associates (RN, EDC), a PhD student in similar area of research (YS), a Professor of Pharmacy Practice (MB), and a Senior Lecturer (AT). An Improvement Advisor at Healthcare Improvement Scotland also reviewed the questionnaire and offered comments on syntax and flow (AM). Any amendments made following the face validity testing were peer-reviewed by MB and EDC, and the final version circulated to the Improvement Science group for approval. Additionally, the SPSP-PPC Steering Group discussed early iterations of the questionnaire at a steering group (1st of June 2017) where comments and suggestions to the questionnaire were offered.

6.5.3.2 Content validity testing methods

Content validity is more thorough than face validity, and involves establishing if each questionnaire item measures the different aspects relevant to the aim of the questionnaire [274]. Content validity of a questionnaire can also be assumed in terms of relevancy if the item generation was informed from reference to the literature [275, 279], as was done for this study. However, other methods of establishing content validity can involve rational analysis [272, 279], whereby relevance and clarity of each question is assessed by a group of experts or those aware of the context in relation to the questionnaire [279, 280]. The quantitative method proposed by Zamanzadeh et al involves each questionnaire item being scored on its clarity and relevancy using a four point Likert scale. This was additionally conducted for this study (as described Figure 6.7); however, as items already has assumed relevancy as they were developed from the results of the systematic review (Chapter 5), items were not removed based on their relevancy score. Instead, this method was used to refine the questionnaire items' language for appropriateness to the community pharmacies piloting the care bundles.

Content validity stages
1. Seven members of the SPSP-PPC steering group assessed the questionnaire for relevance and clarity using the following Likert scales: o not relevant = 1, somewhat relevant = 2, relevant but needs minor revision = 3 , very relevant = 4 o not clear = 1, somewhat clear = 2, clear but needs minor revision = 3, very clear = 4 2. Those assessing the questionnaire were asked to make suggestions to improve questionnaire items where appropriate. 3. The "Item-Level Content Validity" index (I-CVI) for relevancy and clarity was calculated for each questionnaire item. This is the proportion of respondents who scored an item ≥3. 4. Questionnaire items with an I-CVI score of <0.7 were modified based on the reviewer's comments.

Figure 6.7. Calculating Item-Level Content Validity (I-CVI) for questionnaire items [280]

6.5.4 Pilot testing

Following face and content validity testing, the warfarin and NSAIDs questionnaires were piloted by community pharmacy staff in Scotland with experience of the care bundles but were not currently involved in the SPSP-PPC collaborative. Pharmacy staff in two pharmacies were approached: a pharmacy in NHS GG&C who had previously been involved in the warfarin bundle, and a pharmacy in NHS Forth Valley who used a modified NSAIDs care bundle. The pilot questionnaires were disseminated to participants via email, and participants were asked to print and complete these. The pilot questionnaire sought open-ended feedback on any suggestions to improve the questionnaire, general comments, and the time it took to complete the questionnaire which was used as a guide time for the final participants.

6.5.5 Final questionnaire dissemination

Postal dissemination of the final questionnaire (presented later within the results section) with participants' self-administration was selected to reduce social desirability response bias [255, 272, 274-277]. Questionnaires were posted to participating pharmacies on the 26th of June (2017), with a deadline of completion by the 19th of July (2017). Disseminated alongside the questionnaire was a cover letter, a Participant Information Sheet and guidance for completing the questionnaire. The SPSP-PPC Regional Leads disseminated an email to the participating pharmacies so they were expecting it in advance. Pharmacies were sent the

number of questionnaires relative to the approximate pharmacy staff members in each pharmacy which was estimated during previous evaluation activities [38], with pharmacies instructed to request extra if required. Each participant was provided an individual stamped and addressed A5 envelope for returning completed questionnaires to ensure individual responses were kept anonymous from other pharmacy staff members to reduce risk of social desirability bias [281]. Each pharmacy was allocated a unique number which was placed on the back of the questionnaires (which participants were informed of), to ascertain the responses obtained from each sampled pharmacy. Telephone reminders were conducted on the week commencing 17th of July. Due to the non-response of some pharmacies an extended deadline of 28th of July was set. A final telephone reminder was conducted the week beginning 14th of August for those who still hadn't responded, with a final deadline set for the end of August. Ethical approval was not sought for this study as it was deemed service evaluation [282, 283].

6.5.6 Reliability testing of disseminated implementation success scale

Reliability testing of the six-item implementations success scale was conducted to ensure its consistency of measurement of implementation success. Internal consistency reliability, measured by Cronbach's alpha coefficient, measures if items within a scale are measuring the same underlying construct [284]. A Cronbach's alpha coefficient of >0.7 was used to indicate if the scale was of adequate reliability [285]. It is generally accepted that five to ten participants per question are required to ascertain reliability of a scale; thus, 30-60 responses were required to conduct this analysis [260, 272] which was considered attainable given the maximum response rate of 217 and previous response rates achieved by the SPSP-PPC collaborative's evaluation [38].

6.5.7 Questionnaire analysis plan

Implementation success of the care bundles was determined by participants' responses to the implementation success scale, which included a series of questions such as if the care bundle was considered "fully implemented", or delivered to "every patient, every time". Participants mean results were dichotomised to those who consider the bundle to be "Implemented" (mean sore >3) and those which consider it "Not implemented" (mean score ≤3). Implementation success was used as an outcome measure to identify the relative influence of reported barriers and facilitation on this outcome, as is advocated [72, 81, 236].

This involved regression analysis conducted within IBM SPSS Statistics v24.0 to identify the barriers and facilitators (the independent variables) influencing the outcome of successful implementation (the dependent variable). The full details of the statistical analysis conducted is presented in Chapter 7 (Section 7.4.2). The open-ended questions within Section 4 of the questionnaire were analysed in NVivo v11.0, with inductive content analysis conducted and aligned deductively to the CFIR. Where questions were negatively worded the response was reverse coded and the question reworded for consistency of reporting. The presentation of descriptive statistics for the responses to the five questionnaire sections is detailed in Figure 6.8.

Questionnaire sections (n=5)	Presentation of descriptive statistics
1. Implementation success	• If reliability is established (Cronbach's alpha coefficient >0.7), a mean implementation success score for each participant will be calculated from their individual responses to each of the six items [285]. • Participants mean results will be dichotomised to those who consider the bundle to be "Implemented" (mean sore >3) and those which consider it "Not implemented" (mean score ≤3). • Participants who exhibited acquiescence were removed from analysis. Acquiescence was presumed if the response to the negatively-worded question within the scale was at least 2 responses different from the positively worded questions within the implementation success scale.
2. Implementation barriers and facilitators	• Response to individual questionnaire items will be presented as medians with inter-quantile ranges. • For regression analysis, participants responses will be trichotomised to agree/strongly agree, neutral, and disagree/strongly disagree to increase statistical power
3. Penetration	• Response to questionnaire items on participants' involvement with the bundle and resources used will be presented as frequencies and percentages. The results will be stratified to the various staff members to allow for analysis of whole team involvement.
4. Open-ended questions	• Content-analysis of the open ended questions will be summated and presented as frequencies.
5. Demographics	• Response to questionnaire items on demographic characteristics will be presented as frequencies and percentages.

Figure 6.8. Presentation of descriptive statistics to present questionnaire data

6.6 Results

The results presented here relate to the validity and pilot testing of the questionnaire, the final questionnaire developed, the response rate achieved, validation of data entry, and the reliability of the implementation success scale. The findings from the questionnaire in relation to barriers and facilitators and their influence on implementation success are presented in Chapter 7, and results on the penetration of the care bundles are presented in Chapter 8.

6.6.1 Validity testing results

Face validity testing resulted in amendments to nineteen of the questionnaire items, which related to minor rewording and design considerations (Table 6.3).

Table 6.3. Results of face validity testing for questionnaire

Part of Questionnaire	Comments	Output
General suggestions	Instead of one questionnaire, a separate warfarin and NSAID questionnaire should be developed to prevent confusion and explicitly mention throughout as "warfarin HRM CB" and "NSAID HRM CB", instead of just "HRM CB" (RN, YS, AT)	Suggestion accepted.
	Change the term "High Risk Medicine (HRM) Care Bundle (CB)" to "Bundle" as they are commonly referred to as "Warfarin Bundle" and "NSAIDs Bundle" (SPSP-PPC Steering Group, MP)	Suggestion accepted.
	Use of "neutral" within the Likert scale may result in participants preferring to choose this option (RN)	Pilot responses will be analysed to see if tendency to choose "neutral"
	Avoid numbering the closed ended questions to make the questionnaire appear less lengthy (EDC and MB)	Suggestion accepted.
	Re-position some of the negative worded questions which are adjacent to similar positively worded questions which may make people automatically answer the opposite way they answered the negative one (AM)	Suggestion accepted.
	Include more thorough explanation of what the CBs are (i.e. add in the CB questions) (SPSP-PPC Steering Group, ME).	Suggestion accepted.
	Include a question on QI training (SPSP-PPC Steering Group, unknown)	Suggestion accepted and included within the demographics section.

Part of Questionnaire	Comments	Output
	Clarify training question (SPSP-PPC Steering Group, unknown)	Suggestion accepted with wording changed to "Have you had any training on how you can be involved with the Warfarin Bundle?"
Participant Information Leaflet	Attempt to get Participant Information Leaflet and Guidance for Completion sheet to one page each (EDC and MB)	Suggestion accepted - Content retained but reformatted and re-phrased to sit on a single page.
	Instead of the following wording "…refusing to participate or withdrawing participation will not affect any aspects of how you are treated…" amend the wording from "treated" to something less startling (AM)	Suggestion accepted and updated to "Your participation is voluntary and refusing to participate or withdrawing participation will not affect any aspects of your job and you have a right to withdraw without detriment."
	Include that that the questionnaires will be numbered to aid analysis and tracking of responses.(AM)	Suggestion accepted and the following sentence included: "To allow us to track the response from different pharmacies and NHS health boards, and to help us analyse the results, each questionnaire is numbered"
Introduction	Remove "You may not know the answers to the questions asked." as not appropriate, and each question would require a "Don't Know" option if included (RN)	Suggestion accepted.
	When displaying the example circling of responses, include "For example, someone might give the following answers" to emphasise that this is not the "right" answer that they should then give (AT)	Suggestion accepted.
Part 1: Implementation of the High Risk Medicine Care Bundle (HRM CB)		
Q1-6	The questions were commented to be similar and mean the same thing (YS and AT)	No amendments made as this was intentional to allow for reliability testing of the scale.
Part 1: Your knowledge and beliefs		
Q10. I have sufficient clinical knowledge of the high risk medicine we focus on in this pharmacy as part of the HRM CB	Comment to be unclear and awkward, and linking with a specific drug might be clearer (AT, YS). Wording suggestions included "I have sufficient clinical knowledge of warfarin/NSAIDs to apply the HRB CB"	Suggestion accepted.

Part of Questionnaire	Comments	Output
Part 1: About the High Risk Medicine Care Bundle (HRM CB)		
Q15. I think the HRM CB is difficult	May need some additional text to clarify, suggested to have "I think the HRM CB is difficult to do/apply/understand/justify" (AT)	Suggestion accepted and reworded to "I think the HRM CB is difficult to do"
Part 1: Other Healthcare professionals		
Q24-26	Regarding the term "healthcare professionals (e.g. GPs)". YS commented on how to analyse this "Some may answer thinking HCP is consultant others GP – what is important and ask about that group of HCPs"	The results of the systematic review primarily centred on doctors and nurses. However, within the Scottish setting it is possible more healthcare professionals may be influential. It was decided not to specifically ask the series of questions about nurses, GPs, dentists etc. due to the length of the questionnaire, but instead keep it as it is.
Part 1: In your pharmacy		
Q36. I have been trained on the HRM CB	Q37 not applicable if the answer to Q36 is negative (EDC and RN). Suggested to have a non-applicable option or separate out at the end.	Suggestion accepted and Q36 was made a yes or no question (instead of the 5 point agree/disagree Likert scale), with instructions for participants to answer Q37 only if they answered yes to Q36.
Q37. The training I received was sufficient for me to be confident in my abilities to be involved with the HRM CB		
Part 1: Engagement		
Q49. Patients have not been well informed about the HRM CB	It was queried whether to remove the "well", as possibly not needed and a simple question may be better asking if they have been informed (AT)	Suggestion accepted.
Part 2: Involvement with the HRM CB		
Q50. What involvement do you have with the HRM CB?	Move "I have no personal involvement with the HRM CB" to be the last option of this question (RN)	Suggestion accepted.

Part of Questionnaire	Comments	Output
	Make it link more clearly to the process map which was used to develop it (MB)	Suggestion accepted, and changes made peer reviewed by EDC.
Part 3: Your Opinion		
Q51-56	Precede the open ended questions with a closed ended Yes/No question on the challenges, what has helped, and what would be useful. This would allow for some data capture even if people do not offer written comments (EDC).	Suggestion not accepted - MB noted this made the questionnaire longer.
Q53. Has there been anything which has helped your pharmacy to use the warfarin HRM CB?	Emphasise the difference between these questions by underling "which has" and "would have" (unknown)	Suggestion accepted.
Q55. Is there anything which could have been helpful to your pharmacy with the HRM CB?		
Q55. Is there anything which could have been helpful to your pharmacy with the HRM CB?	Commented to be unclear (AT and YS). AT suggested "Can you suggest anything that would have helped you to introduce or implement the HRM CB?"	The suggested could be considered two questions in one (introduce or implement). The following wording was chosen "Can you suggest anything that would have helped you to implement the HRM CB?"
Part 4: About You	Commented that demographics questions generally located at the start of questionnaires (YS)	Previous questionnaires within the programme have had the demographics section at the back, and literature suggests to have it at the back to prevent the arousal of suspicion.
	It was suggested that for demographic Q58 on gender remove the option "Prefer not to say" (RN)	Suggestion accepted.
	Remove some of the demographics questions as they are not crucial and make the questionnaire appear too long (MB and ECD) • Remove part of Q62 which asks if owner or manager works within the dispensary	Suggestion accepted.

Part of Questionnaire	Comments	Output
	• Remove Q65 as community pharmacy type is already known	

From the content validity testing, the Item-Level Content Validity (I-CVI) results and amendments made following content validity testing are presented within Table 6.4. For one questionnaire item with an ICV-I score <0.7 – 'I think the NSAIDs/warfarin Bundle has commercial benefits for my pharmacy' - no reviewers offered suggestions on how to reword this. NW and advisors (EDC and MB) could not propose better wording, and it was retained in its original format on the assumption that any interpretive issues with this questionnaire item would become apparent during piloting.

Table 6.4. Relevance and clarity results of validity testing

Questionnaire Items	Item Content Validity Index	
	Relevance	Clarity
Part 1: The NSAIDs/Warfarin Bundle		
Implementation of the NSAIDs/Warfarin Bundle		
The NSAIDs/Warfarin Bundle is fully implemented in my pharmacy	1.00	1.00
The NSAIDs/Warfarin Bundle is applied to all eligible patients (i.e. "every patient, every time")	1.00	1.00
The NSAIDs/Warfarin Bundle is fully integrated into the way my pharmacy works	1.00	1.00
The NSAIDs/Warfarin Bundle is a part of routine practice in my pharmacy	0.71	1.00
The NSAIDs/Warfarin Bundle is a normal part of what we do in my pharmacy	0.86	1.00
The NSAIDs/Warfarin Bundle is not fully used in my pharmacy	1.00	1.00
Your Knowledge and Beliefs		
I think the NSAIDs/Warfarin Bundle is a good idea	1.00	1.00
I am aware of the NSAIDs/Warfarin Bundle	1.00	1.00
I have working knowledge of the NSAIDs/Warfarin Bundle^	1.00	1.00
I am not motivated to be involved with the NSAIDs/Warfarin Bundle	1.00	1.00
I have sufficient clinical knowledge of NSAIDs/Warfarin to apply the NSAIDs/Warfarin Bundle†	1.00	0.86
I am enthusiastic about the NSAIDs/Warfarin Bundle	1.00	1.00
About the NSAIDs/Warfarin Bundle		
I think the NSAIDs/Warfarin Bundle benefits patients	1.00	1.00
I think the NSAIDs/Warfarin Bundle benefits community pharmacy practice	1.00	0.86
I think the NSAIDs/Warfarin Bundle is difficult to do	1.00	1.00
I think the NSAIDs/Warfarin Bundle is complex	1.00	1.00
I think the NSAIDs/Warfarin Bundle is of good quality^	1.00	0.71
I think the NSAIDs/Warfarin Bundle has been designed poorly^	1.00	1.00
Patients		
I think the NSAIDs/Warfarin Bundle is viewed positively by patients	1.00	1.00

Questionnaire Items	Item Content Validity Index	
	Relevance	Clarity
I think there is a lack of patient demand for the NSAIDs/Warfarin Bundle	0.86	1.00
I think patients are aware of the NSAIDs/Warfarin Bundle	1.00	1.00
I think it is difficult to get patients involved with the NSAIDs/Warfarin Bundle	0.86	1.00
I think patients lack knowledge about what the NSAIDs/Warfarin Bundle is about†	0.57	0.86
Other Healthcare Professionals		
I think the NSAIDs/Warfarin Bundle is viewed positively by other healthcare professionals (e.g. GPs)	0.71	0.86
I think other healthcare professionals (e.g. GPs) are engaged with the NSAIDs/Warfarin Bundle	0.86	1.00
I think a collaborative relationship exists between my pharmacy and other healthcare professionals (e.g. GPs)	1.00	1.00
Policy		
I think there is insufficient funding for the NSAIDs/Warfarin Bundle	0.86	0.86
There are incentives for my pharmacy to be in involved in the NSAIDs/Warfarin Bundle	0.86	0.86
I think the NSAIDs/Warfarin Bundle should be compulsory in all pharmacies^	1.00	1.00
In Your Pharmacy		
Have you had any training on using the NSAIDs/Warfarin Bundle? (Please tick one)^	1.00	0.86
The training I received was sufficient for me to be confident in my abilities to be involved with the NSAIDs/Warfarin Bundle (Please only answer if you ticked YES above)^	1.00	1.00
I think we have enough time to be involved with the NSAIDs/Warfarin Bundle^	1.00	0.86
I think the NSAIDs/Warfarin Bundle increases my workload	1.00	1.00
I think there are sufficient resources for my pharmacy to be involved with the NSAIDs/Warfarin Bundle^	1.00	0.86
I think having access to patients' clinical information would help our involvement with the NSAIDs/Warfarin Bundle	1.00	1.00
I think there is suitable space in our pharmacy to deliver the NSAIDs/Warfarin Bundle to patients	0.71	1.00
I think there are sufficient staff in our pharmacy to be involved with the NSAIDs/Warfarin Bundle	1.00	0.86
There is no information available in my pharmacy about the NSAIDs/Warfarin Bundle	1.00	1.00
I think the NSAIDs/Warfarin Bundle is not compatible with the way my pharmacy works	1.00	1.00
I think the NSAIDs/Warfarin Bundle is compatible with the role(s) I have within my pharmacy	1.00	1.00
I think being involved in the NSAIDs/Warfarin Bundle makes my job more satisfying	1.00	1.00
I think the NSAIDs/Warfarin Bundle has commercial benefits for my pharmacy	0.57	0.57
In General		

Questionnaire Items	Item Content Validity Index	
	Relevance	Clarity
I think the NSAIDs/Warfarin Bundle improves the professional recognition of community pharmacy practice	1.00	1.00
I think the NSAIDs/Warfarin Bundle increases the influence of community pharmacy practice within the NHS	1.00	1.00
I think involvement in the NSAIDs/Warfarin Bundle means pharmacy staff have more legal responsibility for patient care	0.57	1.00
I think the NSAIDs/Warfarin Bundle aligns with the values I have regarding community pharmacy work	1.00	1.00
Engagement		
The SPSP-PPC Team have engaged with my pharmacy team	1.00	1.00
The SPSP-PPC Team have engaged with non-pharmacy healthcare professionals (e.g. GPs)	0.57	0.71
Patients have not been informed about the NSAIDs/Warfarin Bundle^	0.86	0.57
Part 2: Involvement with the NSAIDs/Warfarin Bundle*		
1. What involvement do you have with the NSAIDs Bundle?	1.00	1.00
2. What resources do you use in your pharmacy with the NSAIDs Bundle?	1.00	1.00
1. What involvement do you have with the Warfarin Bundle?	1.00	1.00
2. What resources do you use in your pharmacy with the Warfarin Bundle?	1.00	1.00
Part 3: Your Opinion		
3. Have there been any challenges in your pharmacy with using the NSAIDs/Warfarin Bundle?	1.00	1.00
4. Has there been anything which has helped your pharmacy to use the NSAIDs/Warfarin Bundle?	1.00	1.00
5. Is there anything that would have helped you to implement the NSAIDs/Warfarin Bundle in your pharmacy?	1.00	1.00
6. If you have any other comments, please add them below.	1.00	1.00

** This is the only section where the question differs based on the high risk medicine of focus, thus the Item Content Validity Index was calculate separately for the NSAIDs Bundle Questionnaire and the Warfarin Bundle Questionnaire.*

^ Questions which were reworded based on comments made.

N.B. Not all questions with a clarity score of less than 1 were amended if the expert validators did not comment on how it could be made clearer. The supervisory team discussed possible changes and where rewording could not be suggested it was left for comments to be made during the piloting of the questionnaire.

The changes made to the questionnaire are outlined below in (except for minor grammatical/spelling amendments).

Table 6.5 Revisions made to questionnaire following validity retesting

Original	Revisions made
Revisions made to the Guidance for Completion	
As the staff working in Scottish Patient Safety Programme – Pharmacy in Primary Care (SPSP-PPC) pharmacies come from varied backgrounds and have different levels of experience, there is no correct level of knowledge.	As the pharmacy staff working in Scottish Patient Safety Programme – Pharmacy in Primary Care (SPSP-PPC) pharmacies come from a variety of backgrounds and have different levels of experience, there is no correct level of knowledge.
N/A – addition not revision	Addition of the statement: It is funded through the 2016/17 community pharmacy contract.
N/A – addition not revision	Addition of the definition of Fully Implemented: "The NSAIDs/Warfarin bundle could be described as "fully implemented" if it is considered to be a normal part of your community pharmacy work."
Revisions made to Part 1: NSAIDs/Warfarin Bundle Questions	
I have working knowledge of the NSAIDs/Warfarin Bundle	I have working knowledge of how to be involved with the NSAIDs/Warfarin Bundle
I have sufficient clinical knowledge of NSAIDs/Warfarin to apply the NSAIDs/Warfarin Bundle	I have sufficient knowledge of non-steroidal anti-inflammatory drugs (NSAIDs) to apply the NSAIDs Bundle/ I have sufficient knowledge of the medication warfarin to apply the NSAIDs/Warfarin Bundle
I think the NSAIDs/Warfarin Bundle is of good quality	I think the NSAIDs/Warfarin Bundle is of good quality (i.e. is easy to understand)
I think the NSAIDs/Warfarin Bundle has been designed poorly	I think the NSAIDs/Warfarin Bundle has been poorly designed
I think patients lack knowledge about what the NSAIDs/Warfarin Bundle is about	I think patients lack knowledge of what the NSAIDs/Warfarin Bundle is about
I think the NSAIDs/Warfarin Bundle should be compulsory in all pharmacies	I think all pharmacies in Scotland should deliver the NSAIDs/Warfarin bundle to patients
Have you had any training on using the NSAIDs/Warfarin Bundle?	Have you had any training on using the NSAIDs/Warfarin Bundle? *This could be from the SPSP-PPC team directly or from somebody in your pharmacy.* An open ended part was also added to this question: "*If YES, please provide details below:"*
The training I received was sufficient for me to be confident in my abilities to be involved with the NSAIDs/Warfarin Bundle	The training I received was sufficient for me to be involved with the NSAIDs/Warfarin bundle with confidence
I think we have enough time to be involved with the NSAIDs/Warfarin Bundle	I think we have enough time to deliver the NSAIDs/Warfarin Bundle to patients
I think there are sufficient resources for my pharmacy to be involved with the NSAIDs/Warfarin Bundle	I think the resources which are part of the NSAIDs/Warfarin bundle are sufficient
Patients have not been informed about the NSAIDs/Warfarin Bundle	Patients have not been informed about the NSAIDs/Warfarin Bundle by the SPSP-PPC Team

Revisions made to Part 2: Involvement with the NSAIDs/Warfarin Bundle Questions	
Q1 - Planning appropriate follow-up for patients: who reside in care homes; get their medication delivered; or have a representative collecting the prescription for them (i.e. arranging for NSAIDs/Warfarin Bundle to be delivered to non-attending patients)	Q1 - Planning appropriate delivery of the care bundle to patients who: reside in care homes; get their medication delivered; or have a representative collecting the prescription for them (i.e. arranging for NSAIDs/Warfarin Bundle to be delivered to non-attending patients)
Medicines Sick Day Card	Medicines Sick Day Rules Card
Revisions made to Part 3: Your Opinion	
Q4 - Has there been anything which has helped your pharmacy to use the NSAIDs/Warfarin Bundle?	Q4 - Has there been anything specific which has helped your pharmacy to use the NSAIDs/Warfarin Bundle?
Q5 - Is there anything that would have helped you to implement the NSAIDs/Warfarin Bundle in your pharmacy?	Q5 - Is there anything that was not provided which would have helped you to implement the NSAIDs/Warfarin Bundle in your pharmacy?
Revisions made to Part 4: About You	
N/A – removal not amendment.	Q9 - Remove option "Since the beginning (April 2014)"
Q11 - "Pharmacist branch manager"	Q11 – "Pharmacist manager"
Q11 - "Second pharmacist"	Q11 - "Pharmacist"

6.6.2 Pilot testing results

Seven participants piloted the questionnaire, one of which piloted the warfarin version of the questionnaire, whilst six piloted the NSAIDs version. Pilot participants included pharmacy managers (n=3), a pharmacist (n=1), a pre-registration pharmacist (n=1), an accredited checking technician (n=1), and a dispenser (n=1). There were no suggested amendment to the questionnaire. All participants completed the questionnaire in full and appropriately. There was no apparent overuse of the neutral response therefore the Likert-scale was not changed for one which omits a middle-point. The median, mean and mode time in minutes for completing the questionnaire was 15, 17 and 15 respectively. Thus, 15 minutes was included in the final questionnaire as an estimated time of completion.

6.6.3 Final questionnaire developed

The final questionnaire developed following validity and pilot testing is presented within Figure 6.9, alongside an explanatory cover letter, a Participant Information Sheet and guidance for completing the questionnaire

Dear colleagues,

The SPSP-PPC Steering Group would like to thank you for your ongoing support and enthusiasm with the warfarin bundle, and we appreciate the hard work gone in to testing this within your pharmacy. We are pleased to announce that collectively we are in the process of building a case to support further roll-out of this bundle to more community pharmacies across Scotland. Your feedback has been critical in allowing us to get to this stage, and in order to build a supportive case we wish to gather more of your feedback.

The SPSP-PPC Evaluation Team have developed a questionnaire which aims to determine the factors that have influenced the success of the warfarin bundle. The questionnaire is enclosed within this pack with instructions on how to complete it. The questionnaire is designed to be completed by **all** members of staff within your pharmacy - not just those who may have attended the SPSP-PPC learning events.

Your responses to the questionnaire will give us an idea of the resources used and the different staff members involved with the bundle. The information gathered from this can be used to develop a training package, determine the best way to implement the bundle in pharmacies, and give us an understanding of the support required to deliver the bundle.

We would kindly ask if you could return the completed questionnaires within the enclosed envelopes by the **19th of July.**

If you have any questions or would like to request more questionnaires, please contact Natalie Weir directly at the University of Strathclyde on natalie.m.weir@strath.ac.uk or 0141 548 2367.

Kind Regards,

The SPSP-PPC Steering Group

Warfarin Bundle Questionnaire

PARTICIPANT INFORMATION SHEET

What is the purpose of this questionnaire? This questionnaire explores which factors may influence the success of the Warfarin Bundle. This is a care bundle which is part of the Scottish Patient Safety Programme – Pharmacy in Primary Care (SPSP-PPC) collaborative. We wish to explore which factors may influence the success by asking those working in SPSP-PPC pharmacies about their thoughts and experiences. The most straightforward way to do this is through a postal questionnaire.

Why have I been invited to take part? You have been invited to take part in this questionnaire because you work within an SPSP-PPC pharmacy which has been involved with the Warfarin Bundle.

Do I have to take part? As you work within an SPSP-PPC pharmacy, you are asked to engage with the evaluation which includes completing this questionnaire. However, it is your own decision if you wish to take part. Your participation is voluntary and refusing to participate or withdrawing participation will not affect any aspect of your job and you have a right to withdraw without detriment.

What does taking part involve? The questionnaire involves answering a series of open and closed ended questions and usually takes around 15 minutes in total to complete.

What happens to the information? The information will be used to assess the programme, and the results used to inform the future direction of the SPSP-PPC collaborative. The questionnaire is confidential and you will not be identified. To allow us to track the responses from different pharmacies and NHS health boards, and to help us analyse the results, each questionnaire has been numbered by the research team. No one at your workplace, your NHS Health Board or anyone working at Healthcare Improvement Scotland (HIS) will see your answers to the questionnaire. The results may be written into a report, a PhD thesis, or published in a peer-reviewed journal. All copies of the data will be stored in either a locked cabinet or on a password protected system. Your data will be destroyed at the end of the evaluation period.
The University of Strathclyde is registered with the Information Commissioner's Office who implements the Data Protection Act 1998. All personal data on participants will be processed in accordance with the provisions of the Data Protection Act 1998.

Ethical Approval. The SPSP-PPC Evaluation did not require ethical approval as it is service evaluation.

Who is organising and funding this evaluation? The SPSP-PPC programme is being delivered by HIS, and is being evaluated by teams from NHS Education for Scotland (NES) and the University of Strathclyde. The Health Foundation has funded the evaluation as part of the overall SPSP-PPC programme.

What if I have any questions? Thank you for reading this information. If you have any questions or would like more information and wish to speak to someone, please contact Natalie Weir (PhD student) at the following address:

Strathclyde Institute of Pharmacy & Biomedical Science, 161 Cathedral Street, Glasgow G4 0NR
Email: natalie.m.weir@strath.ac.uk Phone: 0141 548 2367

Warfarin Bundle Questionnaire

GUIDANCE FOR COMPLETION

- This questionnaire explores which factors may influence the success of the Warfarin Bundle. As the pharmacy staff working in Scottish Patient Safety Programme – Pharmacy in Primary Care (SPSP-PPC) pharmacies come from a variety of backgrounds and have different levels of experience, there is no correct level of knowledge.
- If you work in more than one community pharmacy, please answer the questions thinking only of the SPSP-PPC pharmacy you work in.
- A number of terms will be used throughout the questionnaire. Please see the following key for help:

<table>
<tr><td>Warfarin Bundle</td><td>The Warfarin Bundle is a care bundle which would have been introduced in your pharmacy in early 2017. It is funded through the 2016/17 community pharmacy contract. It has six bundle questions for patients prescribed the medication warfarin. These are shown below:
<table>
<tr><th>No.</th><th>Bundle Question</th></tr>
<tr><td>1.</td><td>Has the patient been told of the importance in carrying an up-to-date alert card? Yes/No</td></tr>
<tr><td>2.</td><td>Has the member of staff asked to see the patient's 'up-to-date information' that includes their indication, duration of treatment, therapeutic range and current dose of warfarin?</td></tr>
<tr><td>3.</td><td>Has the patient been informed what to do if they have missed a dose of warfarin?</td></tr>
<tr><td>4.</td><td>Has the patient been told that they should inform the team responsible for their warfarin care of any significant changes that may affect their warfarin?</td></tr>
<tr><td>5.</td><td>Have the common signs and symptoms of over/under-coagulation been discussed with the patient?</td></tr>
<tr><td>6.</td><td>Has the patient been informed that they should have an INR test after starting a course of antibiotics?</td></tr>
</table></td></tr>
<tr><td>Patient</td><td>Refers to patients as well as patients' carers and representatives.</td></tr>
<tr><td>Fully Implemented</td><td>The Warfarin bundle could be described as "fully implemented" if it is considered to be a normal part of your community pharmacy work.</td></tr>
<tr><td>SPSP-PPC Team</td><td>Comprises the local SPSP-PPC Health Board Leads, National Leads and others who may sit on the SPSP-PPC Steering Group including representatives from Healthcare Improvement Scotland (HIS).</td></tr>
</table>

Commercial benefits	Either a financial benefit in your pharmacy or an increase in customer footfall.
Clinical information about patients	Clinical information about patients which is not available in most community pharmacies, such as the information that a GP may have access to (e.g. blood test result, patient diagnoses etc.).

- To complete this questionnaire, you will be asked to circle a score for each statement using a 5 item scale:
  1 = Strongly Disagree
  2 = Disagree
  3 = Neutral
  4 = Agree
  5 = Strongly Agree

- Please indicate the extent to which you agree with each statement from 1 (Strongly Disagree) to 5 (Strongly Agree) by **circling one response per statement**. For example, someone may give the following response:

Thinking about your own experience with the Warfarin Bundle so far, please read each question and circle the number that best represents the extent to which you agree or disagree with the following statements.	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
Implementation of the Warfarin Bundle					
The Warfarin Bundle is fully implemented in my pharmacy	1	2	(3)	4	5
The Warfarin Bundle is applied to all eligible patients (i.e. "every patient, every time")	1	(2)	3	4	5
The Warfarin Bundle is fully integrated into the way my pharmacy works	1	2	3	(4)	5

- Please complete the questionnaire and place it in one of the small envelopes provided. An individual envelope has been provided for each participant to protect your anonymity.
- Each envelope is stamped and addressed for you to post these back to the SPSP-PPC Evaluation Team at the University of Strathclyde, addressed to Emma D. Corcoran.
- We kindly ask for you to post the completed questionnaires to the University of Strathclyde by the 7th of July.

PART 1: WARFARIN BUNDLE QUESTIONS

Thinking about your own experience with the Warfarin Bundle so far, please read each question and circle the number that best represents the extent to which you agree or disagree with the following statements.	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
Implementation of the Warfarin Bundle					
The Warfarin Bundle is fully implemented in my pharmacy	1	2	3	4	5
The Warfarin Bundle is applied to all eligible patients (i.e. "every patient, every time")	1	2	3	4	5
The Warfarin Bundle is fully integrated into the way my pharmacy works	1	2	3	4	5
The Warfarin Bundle is a part of routine practice in my pharmacy	1	2	3	4	5
The Warfarin Bundle is a normal part of what we do in my pharmacy	1	2	3	4	5
The Warfarin Bundle is not fully used in my pharmacy	1	2	3	4	5
Your Knowledge and Beliefs					
I think the Warfarin Bundle is a good idea	1	2	3	4	5
I am aware of the Warfarin Bundle	1	2	3	4	5
I have working knowledge of how to be involved with the Warfarin Bundle	1	2	3	4	5
I am not motivated to be involved with the Warfarin Bundle	1	2	3	4	5
I have sufficient knowledge of the medication warfarin to apply the Warfarin Bundle	1	2	3	4	5
I am enthusiastic about the Warfarin Bundle	1	2	3	4	5
About the Warfarin Bundle					
I think the Warfarin Bundle benefits patients	1	2	3	4	5
I think the Warfarin Bundle benefits community pharmacy practice	1	2	3	4	5
I think the Warfarin Bundle is difficult to do	1	2	3	4	5
I think the Warfarin Bundle is complex	1	2	3	4	5
I think the Warfarin Bundle is of good quality (i.e. it is easy to understand)	1	2	3	4	5
I think the Warfarin Bundle has been poorly designed	1	2	3	4	5
Patients					
I think the Warfarin Bundle is viewed positively by patients	1	2	3	4	5
I think there is a lack of patient demand for the Warfarin Bundle	1	2	3	4	5
I think patients are aware of the Warfarin Bundle	1	2	3	4	5
I think patients lack knowledge of what the Warfarin Bundle is about	1	2	3	4	5
I think it is difficult to get patients involved with the Warfarin Bundle	1	2	3	4	5
Other Healthcare Professionals					
I think the Warfarin Bundle is viewed positively by other healthcare professionals (e.g. GPs)	1	2	3	4	5
I think other healthcare professionals (e.g. GPs) are engaged with the Warfarin Bundle	1	2	3	4	5
I think a collaborative relationship exists between my pharmacy and other healthcare professionals (e.g. GPs)	1	2	3	4	5

PART 1: WARFARIN BUNDLE QUESTIONS

Thinking about your own experience with the Warfarin Bundle so far, please read each question and circle the number that best represents the extent to which you agree or disagree with the following statements.	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
Policy					
I think there is insufficient funding for the Warfarin Bundle	1	2	3	4	5
There are incentives for my pharmacy to be in involved in the Warfarin Bundle	1	2	3	4	5
I think all pharmacies in Scotland should deliver the Warfarin bundle to patients	1	2	3	4	5
In Your Pharmacy					
Have you had any training on using the Warfarin Bundle? *This could be from the SPSP-PPC team directly or from somebody in your pharmacy.*	*Please tick one:* ☐ Yes ☐ No *If YES, please answer the question below about training, if not please leave blank.*				
If YES, please provide details below:					
The training I received was sufficient for me to be involved with the Warfarin bundle with confidence *(Please only answer if you ticked YES above)*	1	2	3	4	5
I think we have enough time to deliver the Warfarin Bundle to patients	1	2	3	4	5
I think the Warfarin Bundle increases my workload	1	2	3	4	5
I think the resources which are part of the Warfarin bundle are sufficient	1	2	3	4	5
I think having access to patients' clinical information would help our involvement with the Warfarin Bundle	1	2	3	4	5
I think there is suitable space in our pharmacy to deliver the Warfarin Bundle to patients	1	2	3	4	5
I think there are sufficient staff in our pharmacy to be involved with the Warfarin Bundle	1	2	3	4	5
There is no information available in my pharmacy about the Warfarin Bundle	1	2	3	4	5
I think the Warfarin Bundle is not compatible with the way my pharmacy works	1	2	3	4	5
I think the Warfarin Bundle is compatible with the role(s) I have within my pharmacy	1	2	3	4	5
I think being involved in the Warfarin Bundle makes my job more satisfying	1	2	3	4	5
I think the Warfarin Bundle has commercial benefits for my pharmacy	1	2	3	4	5
In General					
I think the Warfarin Bundle improves the professional recognition of community pharmacy practice	1	2	3	4	5
I think the Warfarin Bundle increases the influence of community pharmacy practice within the NHS	1	2	3	4	5
I think involvement in the Warfarin Bundle means pharmacy staff have more legal responsibility for patient care	1	2	3	4	5
I think the Warfarin Bundle aligns with the values I have regarding community pharmacy work	1	2	3	4	5

Thinking about your own experience with the Warfarin Bundle so far, please read each question and circle the number that best represents the extent to which you agree or disagree with the following statements.	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
Engagement					
The SPSP-PPC Team have engaged with my pharmacy team	1	2	3	4	5
The SPSP-PPC Team have engaged with non-pharmacy healthcare professionals (e.g. GPs)	1	2	3	4	5
Patients have not been informed about the Warfarin Bundle by the SPSP-PPC Team	1	2	3	4	5

PART 2: INVOLVEMENT WITH THE WARFARIN BUNDLE

1. What involvement do you have with the Warfarin Bundle?

When we say "involvement", we are asking if you have you undertaken any of these processes, even if not very often. Please tick where appropriate. You may tick more than one option. If you are not personally involved then please tick "I have no personal involvement with the Warfarin Bundle".

In my pharmacy, I am involved in:

☐ Identifying patients who are suitable to receive the Warfarin Bundle (i.e. they are on warfarin)

☐ Clinically assessing patients' warfarin medication

☐ Preparing the prescription ready to be collected with a prompt that the Warfarin Bundle is to be delivered (e.g. putting alert stickers on prescription bags)

☐ Delivering the Warfarin Bundle (i.e. speaking to the patient/carer)

☐ Planning appropriate delivery of the care bundle to patients who reside in care homes, or to patients who get their medication delivered.

☐ Planning appropriate delivery of the care bundle to patients who have a representative collecting the prescription for them

☐ Documenting that the Warfarin Bundle has been delivered (e.g. updating the patient record or writing it down etc.)

☐ Documenting the fortnightly compliance data (which is sent back to the SPSP-PPC Health Board Leads)

☐ Other involvement with the Warfarin Bundle *(please specify below)*

_____

_____

_____

_____

_____

_____

☐ I have no personal involvement with the Warfarin Bundle

PART 2: INVOLVEMENT WITH THE WARFARIN BUNDLE

2. What resources have you used in your pharmacy with the Warfarin Bundle? *Images of resources you may or may not use have been included to help you answer this question.*

☐ Warfarin flyers *(shown below)*

☐ Warfarin teach back counselling tool *(shown below)*

☐ Warfarin Patient Information video, accessible via YouTube *(shown below)*

☐ High Risk Medicine Intervention sticker *(shown below)*

☐ Other resources *(please specify)*_____

_____

_____

_____

☐ We have not used any resources with the Warfarin Bundle

PART 3: YOUR OPINION

Thinking about the Warfarin Bundle in your pharmacy:

3. Have there been any challenges in your pharmacy with using the Warfarin Bundle?
If YES please comment below.

4. Has there been anything specific which has helped your pharmacy to use the Warfarin Bundle?
If YES please comment below.

5. Is there anything that was not provided which would have helped you to implement the Warfarin Bundle in your pharmacy? *If YES please comment below.*

6. If you have any other comments, please add them below.

PART 4: ABOUT YOU

7. Are you: *(Tick one box only)*

- ☐ Male
- ☐ Female
- ☐ Other

8. How old are you? *(Tick one box only)*

- ☐ 16 – 24 years old
- ☐ 25 – 34 years old
- ☐ 35 – 44 years old
- ☐ 45 – 54 years old
- ☐ 55 – 64 years old
- ☐ 65 years or older

9. How long have you been involved in the SPSP-PPC collaborative? *(Tick one box only)*

- ☐ Less than 1 year
- ☐ 1-2 years
- ☐ 2-3 years

10. How long have you worked in community pharmacy? *(Tick one box only)*
Consider when you started your first job in community pharmacy. This may not be your current position or where you currently work.

- ☐ Less than 1 year
- ☐ 1 – 5 years
- ☐ 6 – 10 years
- ☐ 11 – 15 years
- ☐ 16 - 20 years
- ☐ More than 20 years

NOTE: If you regularly work in more than one pharmacy, please answer the final questions regarding your role in the site that is involved in the SPSP-PPC project.

11. Which of the following categories best describes your MAIN role in this community pharmacy? *(Tick one box only)*

- ☐ Pharmacist proprietor/owner
- ☐ Pharmacist manager
- ☐ Pharmacist
- ☐ Accredited Checking Technician
- ☐ Locum pharmacist (i.e. self-employed)
- ☐ Registered Pharmacy Technician
- ☐ Relief pharmacist (i.e. employee)
- ☐ Dispenser/Dispensing Assistant (trainee)
- ☐ Pre-registration pharmacy graduate
- ☐ Medicines counter assistant
- ☐ Other *(please state)*:_____

PART 4: ABOUT YOU

12. How long have you worked in the role you identified in Question 11? *(Tick one box only)*

- ☐ Less than 1 year
- ☐ 1 – 5 years
- ☐ 6 – 10 years
- ☐ 11 – 15 years
- ☐ 16 – 20 years
- ☐ More than 20 years

13. What kind of contract do you currently have? *(Tick one box only)*

- ☐ Owner
- ☐ Fixed term/temporary
- ☐ Permanent full-time (35 hours or more per week)
- ☐ Permanent part-time (less than 35 hours per week)
- ☐ Locum/sessional
- ☐ Other *(please state)*_____

14. Have you previously undergone any training (including face-to-face or online training) on Quality Improvement methods?

This may include Plan-Do-Study-Act (PDSA) cycles, the Model for Improvement, run charts etc. This may be any training, not only that associated with the SPSP-PPC collaborative.

- ☐ Yes
- ☐ No

If YES, please provide details below:

Thank you for completing this questionnaire.

Figure 6.9. Final questionnaire developed with explanatory letter and participant information sheet

6.6.4 Final sample participants

A total of 74 questionnaire responses were received out of the sample of 217 participants (34.1%), from 17 of the 24 pharmacies (70.8%).[4] Respondents were mostly pharmacy support staff (n=54, 72.9%) rather than pharmacists (n=18, 24%), including dispensers (n=28, 37.8%), medicine counter assistants (n=13, 17.6%), pharmacy technicians (n=10, 13.5%), and students (n=3, 4.1%). The response rate in relation to varying demographic characteristics is shown in Table 6.6.

Table 6.6. Questionnaire response rate according to demographic variables at participant and pharmacy level

Demographic variables	PARTICIPANT LEVEL n response/n sample (%)	PHARMACY LEVEL n response/n sample (%)
Total response	74/217 (34.1)	17/24 (70.8)
Care bundle involvement		
NSAIDs care bundle	47/126 (37.3)	10/12 (83.3)
Warfarin care bundle	27/91 (29.7)	7/12 (58.3)
Health Board		
Fife	30/65 (46.2)	7/7 (100)
Grampian	17/61 (27.9)	3/5 (60.0)
GG&C	27/76 (35.5)	7/9 (77.8)
Highland	0/15 (0.0)	0/3 (0.0)
Rurality		
Urban	68/198 (34.3)	16/21 (76.2)
Rural	6/19 (31.6)	1/3 (33.3)
Pharmacy Type		
Single, independent pharmacy	25/66 (37.9)	4/7 (57.1)
Small chain (2-4 pharmacies)	7/9 (77.8)	1/1 (100.0)
Medium chain (5-30 pharmacies)	13/34 (38.2)	3/4 (75.0)
Large chain (>30 pharmacies)	29/108 (26.9)	9/12 (75.0)

NSAID(s) = non-steroidal anti-inflammatory drug(s), GG&C = Greater Glasgow and Clyde

[4] Eight (11%) randomly selected questionnaire responses were independently entered within a separate data set by a research technician (LK) to validate the accuracy of NW's data entry. 100% of the sample data entered by NW was accurate and analysis pursued.

6.6.5 Reliability of implementation success scale

As the response rate exceeded the 30-60 required to conduct reliability testing, Cronbach's alpha coefficient was applied for the implementation success scale, which identified a high level of internal consistency at 0.947. Removal of any of the items did not increase Cronbach's alpha coefficient and the Corrected Item-Total correlations were all >0.7, as shown in Table 6.7. Therefore, no questionnaire item warranted removal. When subdividing the data for the high risk medicines of interest (i.e. NSAIDs and warfarin), Cronbach's alpha coefficients for the implementation success scale remained acceptable at 0.945 and 0.940, respectively. Participants were removed from the analysis if they did not complete all six items (n=2), or if they exhibited acquiescence in the implementation success scale (n=3). Acquiescence was presumed if a participants' response to the negatively-worded question was at least 2 scores different from their responses to the positively-worded questions within the implementation success scale.

Table 6.7. Reliability results of the six-item implementation success scale

Implementation Success Scale (n=69)	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
The bundle is fully implemented in my pharmacy	0.810	0.940
The bundle is applied to all eligible patients (i.e. "every patient, every time")	0.868	0.933
The bundle is fully integrated into the way my pharmacy works	0.847	0.936
The bundle is part of routine practice in my pharmacy	0.910	0.930
The bundle is a normal part of what we do in my pharmacy	0.825	0.939
The bundle is fully used in my pharmacy	0.825	0.943

NB. Participants were excluded if they did not complete all six items (n=2) or if they appeared to exhibit acquiescence (n=3).

6.7 Discussion

A questionnaire was developed which measures three key aspects regarding the implementation of the consolidated warfarin and NSAIDs care bundles: their successful implementation, the causative barriers and facilitators influencing successful implementation, and their penetration into routine community pharmacy practice.

Exploration of these areas can offer a more holistic view of their implementation, and the use of a questionnaire to capture this increases the number of potential participants and generalisability of the results than would have been possible with qualitative methods.

6.7.1 Future application of questionnaire

The results of the systematic review (Chapter 5), when compared with other similar reviews [142, 143], suggest that the barriers and facilitators emergent in small-scale stages are the same as those emerging within national cohorts, albeit with differing strength of influence. Therefore, it would be a logical approach to apply the questionnaire Sections 1 and 2 during the pilot stages of the warfarin and NSAIDs care bundles in order to predict which barriers and facilitators may influence their national implementation through regression analysis (presented in Chapter 7). Section 3 of the questionnaire further explores the implementation of the care bundles by understanding their penetration within routine practice, which was outwith the scope of the systematic review. The results obtained from this part of the questionnaire will be presented in conjunction with data obtained from on-site visits in eight pharmacies (Chapter 8), and will be used to develop process maps which depict each of the care bundles' operationalisation within the community pharmacies. Overall, exploration of these key areas will allow strategists to understand the success factors of the care bundles and to visualise the processes in practice, which could ultimately help inform tailored implementation and improve the likelihood of successful national implementation [58].

6.7.2 Strengths and limitations

The questionnaire can be considered an advancement within the field of implementation science as there is scope for identified barriers and facilitators to be linked to implementation success, with their relative influence quantified through regression analysis. Furthermore, the results of the systematic review were used to justify the inclusion of specific CFIR constructs, which overcomes limitations of previous studies which have been criticised for arbitrarily deciding which barriers and facilitators to explore [81, 99, 259]. The barriers and facilitators covered are reflective of those experienced for a wide variety of innovations within community pharmacy, which means the questionnaire has applicability in wider contexts where the wording can be modified to evaluate other pharmacy innovations. This will ultimately allow for cross comparison of results [81, 260].

To the author's knowledge, this study presents the first reliable and valid scale which measures successful implementation to specific healthcare innovations (Section 1). It is promising that the reliability of the scale was ascertained with a Cronbach's alpha coefficient of >0.7. As it is of >0.90 this may suggest there are redundancies within the scale and indicate that the scale could be shortened with the removal of some of its questionnaire items; however, the questionnaire should be tested in further diverse settings before omitting any questions.

The use of a questionnaire to explore the barriers and facilitators allowed for a greater representation of the views of the community pharmacy staff than would have been possible with a qualitative approach. However, a qualitative approach could have sought more in-depth exploration of the barriers and facilitators experienced in practice than is possible with a questionnaire, albeit with a lesser sample size. On reflection, qualitative exploration during the development of the questionnaire could have facilitated the development of questionnaire items. This could have been valuable to ensuring its relevance to the context, as well as ensuring the terminology used was amendable to all levels of community pharmacy staff. Despite this not being conducted, the results of the validity and pilot testing of the questionnaire evidenced the questionnaires relevance to the context and it's usability within the community pharmacy setting

It should be appreciated that only face and content validity were assessed, with no evidence of empirical validity. It was intended to establish criterion-related empirical validity of the implementation success scale using run chart data routinely collected by the pilot pharmacies as a secondary implementation success measure; however, these data were incomplete and could not be used with confidence. Thus, in the absence of empirical validity the questionnaire scale can only be considered as measuring *perceptions* of implementation success.

The reliability of Sections 2 and 3 of the questionnaire, which explores barriers and facilitators and the penetration of the bundles into routine practice, could not be ascertained as the Cronbach's alpha coefficient is only applicable if a scale has been developed which measures the same underlying phenomenon. Sections 2 and 3 of the questionnaire are unlike this, as each item was designed to measure either a unique CFIR sub-construct or a specific process in practice. The test-retest method is the only method which can measure the reliability of questionnaire items which do not represent a scale [255], which involves re-

administering the questionnaire to the same participants after 2-4 weeks [255]. Consistency in participants' responses indicates reliability [255]; however, for this context this method was not appropriate as the implementation of an innovation is not a static phenomenon, and the processes in practice and the presence of barriers and facilitators may change over time. This method also requires the same participants to conduct the re-test of the questionnaire which would have required collecting identifiable information of participants, and the method is generally criticised as participants may remember their previous responses and answer accordingly [255].

Although it was logically presumed that Sections 2 and 3 of the questionnaire comprised items which measured either a unique CFIR sub-construct or a specific process in practice, an alternative analytical approach could have been to conduct an exploratory factor analysis [286]. This analysis could have identified if any of these questionnaire items grouped together and represented underling constructs, such as those defined by the CFIR [286]. Although there is no apparent consensus on the minimum sample size required to conduct exploratory factor analysis [287], Ferguson suggests a minimum of 100 respondents [288], while other researchers suggest that at least five respondents per item is required [289]. As neither of these suggested minimum sample sizes were obtained in this current study, exploratory factor analysis could not be conducted with any assurance that the results would be valid or reliable.

The relatively low response rate obtained (n=74, 34.1%) with no responses from any of the NHS Highland pharmacies limits the potential generalisability of the results. However, there was representation from the array of different pharmacy and staff types sampled (Section 6.6.4), and the response rate was sufficient to allow for reliability testing of the implementation success scale. The poor response rate could be attributed to the questionnaire's length as it spanned 10 pages due to its coverage of 14 CFIR constructs. Those applying the questionnaire in the future could select a sub-set of CFIR constructs of salience within their setting to explore, which would reduce the questionnaire's length and may improve the response rate.

The provision of individual envelopes to each respondent may have reduced the risk of desirability bias [281], as the ability of participants to conceal their responses from colleagues may have increased the likelihood of honest responses. However, the possibility of selection bias cannot be ruled out [281], whereby the pharmacy managers within sampled pharmacies

may have chosen which staff they wanted to complete the questionnaire either due to their involvement with the care bundles or their adoption of similar views as the pharmacy manager.

6.8 Conclusion

This study has produced a questionnaire to measure implementation success of the warfarin and NSAIDs care bundles, the barriers and facilitators which influence this, and their penetration into routine community pharmacy practice. Exploration of these three areas of implementation will offer a holistic overview of the care bundles' implementation to help inform a national rollout programme for the care bundles. The questionnaire is an advancement within the field of implementation science as the analysis will seek to link barriers and facilitators to implementation success, made possible through the development of a reliable and valid scale measuring implementation success. Adaptability of the questionnaire items exploring implementation success and barriers and facilitators ensures it is applicable to evaluate other community pharmacy innovations, which can allow for future cross comparison of results and eventual theory generation.

Chapter 7: Barriers and facilitators influencing successful implementation of the consolidated warfarin and NSAIDs care bundles

7.1 Summary of chapter

Background

The existence of barriers and facilitators complicates national implementation of innovations. Identifying context specific barriers and facilitators can allow tailored implementation strategies to be developed. This study aimed to identify the barriers and facilitators influencing successful implementation of the warfarin and NSAIDs care bundles.

Methods

A questionnaire was disseminated in June 2017 which explored the community pharmacy staff perceptions of implementation success of the care bundles, and the barriers and facilitators influencing this. Multiple linear regression analyses were conducted to identify which barriers and facilitators significantly influenced perceptions of implementation success. Open-ended questions underwent content analysis.

Results

Seventeen (70.8%) of the 24 pharmacies sampled responded, with a total of 74 participants (34.1%). For the NSAIDs bundle, four predictors of implementation success were identified: pharmacy staff having sufficient knowledge of NSAIDs; incentives to delivering the bundle; workload of the bundle; and funding. For the warfarin bundle, compatibility of the bundle within the pharmacies and patient perceptions were the identified success factors.

Conclusion

The difference in emergent success factors between the care bundles indicates the necessity to develop distinct implementation strategies for each. In response to these, recommendations have been developed for the national implementation strategy of the care bundles. This includes reinforcing the evidence on the risk associated with NSAIDs to facilitate implementation of the NSAIDs care bundle, and adopting patient engagement strategies to facilitate implementation of the warfarin care bundle.

7.2 Background

National implementation of the care bundles developed in Chapter 4 is required in order to achieve wide-scale reductions in the harm associated with the high risk medicines warfarin and NSAIDs [28-32]. However, national implementation is complicated by the existence of barriers and facilitators once innovations are scaled-up throughout different contexts (16).

The systematic review, presented in Chapter 5, identified three key thematic areas which influence the implementation of national community pharmacy innovations: operationalisation of innovations (e.g. the sufficiency of resources); pharmacy staff engagement (e.g. their perceptions and knowledge); and external engagement (e.g. the perceptions of patients and other healthcare professionals). However, to what extent this represents the challenges which may be faced when implementing the warfarin and NSAIDs care bundles was unknown.

Although the systematic review identified pharmacy staff reported barriers and facilitators, the causative influence of these reported barriers and facilitators on successful implementation has not been established, so it is unknown whether these reported barriers and facilitators are *perceived* or *actual* [72, 81, 236]. Therefore, implementation success[5], and the barriers and facilitators which influence this, requires exploration from the perspectives of the front-line community pharmacy staff involved in the NSAIDs and warfarin care bundles. Furthermore, by examining the relationship between barriers and facilitators and successful implementation, tailored implementation strategies for the care bundles can be developed accordingly to increase the likelihood of their successful national implementation [58, 72, 81, 236].

7.3 Aims and objectives

The aim of this study was to identify the barriers and facilitators influencing implementation of the consolidated warfarin and NSAIDs care bundles. The specific objectives of this study were to:

1. Identify pharmacy staff perspectives of implementation success
2. Identify barriers and facilitators influencing implementation success

[5] See Chapter 6, Section 6.5.1.1 for more discussion on the implementation success scale developed

3. Develop recommendations to inform the national implementation of the warfarin and NSAIDs care bundles

7.4 Methods

7.4.1 Data collection

A questionnaire was used to ascertain participants' perceptions of implementation success and the barriers and facilitators influencing this. This questionnaire included a six-item implementation success scale which was of adequate reliability (Cronbach's alpha coefficient = 0.947), and a series of questionnaire items explored the barriers and facilitators to implementation which were developed from the results of the systematic review. Responses to the questions utilised a 5-point Likert scale from strongly agree to strongly disagree, with a series of open ended questions for participants to elaborate. The development and testing of this questionnaire has been described in detail in Chapter 6, Section 6.5.1. The questionnaire was disseminated within the post on the 26th of June 2017, with postal responses accepted until the end of August 2017.

7.4.2 Questionnaire analysis

7.4.2.1 Descriptive statistics

To present the data regarding implementation success, a mean implementation success score for each participant was calculated from their responses to each of the six items [285].[6] Participants' mean results were dichotomised to those who considered the bundle to be 'Implemented' (mean sore >3) and those which considered it "Not implemented" (mean score ≤3). To present participants' responses to individual questionnaire items on implementation barriers and facilitators, medians with inter-quantile ranges were calculated.

7.4.2.2 Regression analysis: identifying causative barriers and facilitators influencing implementation success

Regression analyses were conducted to identify which barriers and facilitators (the independent variables) significantly influenced implementation success (the dependent

[6] Reliability of the implementation success scale has been established (Cronbach's alpha coefficient >0.7)

variable). These regression analyses modelled the data in a way that the dependent variable (i.e. implementation success) was predicted by the independent variables (i.e. barriers and facilitators) by taking into account the relationship between the independent variables and the effect on the model if variables are removed [290].

A univariate linear regression analysis between each of the barriers and facilitators with the dependent variable (implementation success) was the basis for shortlisting items for multiple linear regression analysis [291], with significance set at $p<0.05$. Inter-item correlations were assessed for the short-listed variables before conducting the multiple linear regression analysis. For items with a correlation coefficient >0.8, only the item with the highest r-squared value in univariate regression analysis was retained and inputted within the multiple linear regression analysis [292].

For the multiple linear regression analysis, the dependent variable (implementation success) was kept in its mean, interval form and the independent variables (the response to the barriers and facilitators questions) were trichotomised to agree/strongly agree, neutral, and disagree/strongly disagree. This was to increase the statistical power by having less ordinal groups. For the multiple regression model produced, multicollinearity was assessed using variance inflation factor (VIF) scores and tolerance levels. A VIF score >10 and a tolerance level <0.2 was indicative of problematic multicollinearity [292]. Normality was assessed using P-P plots and homoscedasticity was assessed using a scatter plot of standardised residuals and standardised predicted variables, where visual analysis aims to identify a wide distribution [293]. Backwards and forwards selection method for the multiple linear regression analysis were used, which is discussed in more detail in the Sections 7.6.4. The analysis plan developed for this study was peer-reviewed by the Statistics & Mathematics Advice, Research & Training (SMART) consultancy unit[7] [294].

7.4.2.3 Analysis of open-ended questions

The open-ended questions were exported into NVivo v11.0. Inductive content analysis was conducted to summate findings, which was then aligned deductively to the CFIR with reporting frequencies presented.

[7] The SMART consultancy unit is based at the University of Strathclyde and offers guidance on statistical analysis

7.5 Results

7.5.1 Demographics

7.5.1.1 Pharmacy-level demographics

Staff from seventeen (70.8%) of the 24 pharmacies sampled responded to the questionnaire. Of these, ten of the pharmacies participated in the NSAIDs care bundle and seven in the warfarin bundle. No questionnaire responses were obtained from pharmacies within NHS Highland. Seven pharmacies responded from NHS Fife, three from NHS Grampian, and seven from NHS GG&C. Nine (52.9%) of the pharmacies were classified as large chain (>30 pharmacies), three (17.6%) were medium chain (5-30 pharmacies), one (5.9%) was a small chain, and four (24%) were single, independent pharmacies. One (5.9%) of the pharmacies resided in a rural location, with the rest located within urban settings. Full details in relation to participant and pharmacy characteristics is presented in Chapter 6, Section 6.6.4.

7.5.1.2 Participant demographics

Seventy-four responses (34.1%) were received out of the approximated maximum of 217 pharmacy staff. Forty-seven participants were involved in the NSAIDs bundle (63.5%), and 27 were involved with the warfarin bundle (36.4%). Most of the participants were female (n=64, 86.5%). Respondents were mostly pharmacy support staff (n=54, 72.9%) rather than pharmacists (n=18, 24.3%). Most participants held permanent employment contracts (n=67, 90.5%), including full time (n=37, 50.0%) and part time positions (n=30, 40.5%). Participants' age, years worked within community pharmacy, main role, and length of involvement in the SPSP-PPC collaborative is shown in Table 7.1 stratified according to their involvement in either the warfarin or NSAIDs care bundle.

Table 7.1. Demographics of participants responding to the questionnaire (n=74)

Demographic variables	Warfarin bundle (n=27) n (%)	NSAIDs bundle (n=47) n (%)
Age (years)		
16-24	5 (18.5)	6 (12.7)
25-34	7 (25.9)	8 (17.0)
35-44	6 (22.2)	10 (21.3)
45-54	6 (22.2)	13 (27.7)
55-64	3 (11.1)	9 (19.1)
65+	0 (0.0)	1 (2.1)
Years worked in a community pharmacy		
<1	0 (0.0)	2 (4.3)
1-5	7 (25.9)	14 (29.8)
6-10	7 (25.9)	14 (29.8)
11-15	6 (22.2)	2 (4.3)
16-20	3 (11.1)	7 (14.8)
20+	4 (14.8)	8 (17.0)
Main role in community pharmacy		
Pharmacist Proprietor/Owner	2 (7.4)	1 (2.1)
Pharmacist	7 (25.9)	8 (17.0)
Accredited Checking Technician	1 (3.7)	3 (6.4)
Registered Pharmacy Technician	0 (0.0)	6 (12.7)
Dispenser/Dispensing Assistant (trainee)	15 (56)	13 (27.7)
Pre-registration pharmacist/student	0 (0.0)	3 (6.4)
Medicines Counter Assistant	1 (3.7)	12 (25.5)
Missing data	1 (3.7)	1 (2.1)
Length of involvement in collaborative (years)		
<1	12 (44.4)	14 (29.8)
1-2	4 (14.8)	10 (21.3)
2-3	6 (22.2)	18 (38.3)

NSAIDs = non-steroidal anti-inflammatory drugs

Eighteen participants (24.3%) stated they had had previous quality improvement training (n=7 for the warfarin bundle, and n=11 for the NSAIDs bundle). Sixteen of these participants provided more details which included training as part of the SPSP programme (n=11), Health Board training (n=3), online training (n=3), training delivered by the pharmacy company (n=2), NHS Education for Scotland training (n=1) and head office training (n=1).

7.5.2 Implementation success

Participants' mean score for the 6 item implementation success scale for the warfarin bundle ranged from 2.0 to 5.0, and for the NSAIDs bundle from 2.3 to 5.0. When participants' mean implementation success scores were dichotomised (>3 indicating the bundle was considered implemented and ≤3 indicating it was not considered implemented), 73.1% (n=19) of

participants involved with the warfarin bundle considered it implemented, and 72.1% (n=31) of participants involved with the NSAIDs bundle considered it implemented.

7.5.3 Barriers and facilitators

Participants' median responses to the questionnaire items on the barriers and facilitators, which were derived from the CFIR constructs, are shown below in Table 7.2 for the warfarin and NSAIDs bundles. The median response to the questionnaire statements were mostly neutral or positive (median ≥3), except for two instances where participants disagreed with questionnaire statements. For the NSAIDs bundle participants disagreed (median = 2, IQR 2-3) with the statement 'I think patients have knowledge of what the bundle is about', and for the warfarin bundle participants disagreed with the statement 'I think the bundle does not increase my workload' (median = 2, IQR 2-3). Fifty-three participants (74.6%) stated they had training on using the bundles, with eighteen participants responding that they had no training on using the bundle. Of these, 12 were involved in the warfarin bundle (44.4%) and six were involved with the NSAIDs bundle (12.7%).

Table 7.2. Descriptive statistics of barriers and facilitators questionnaire items

CFIR Domains (n=5)	Questionnaire Items (n=NSAIDs, n=warfarin)	Median (IQR)	
		NSAIDs bundle	Warfarin bundle
Characterist-ics of the Individual	I think the bundle is a good idea (n=44, 27)	4 (4-5)	4 (4-5)
	I am aware of the bundle (n=44, 27)	4 (4-5)	4 (4-5)
	I have working knowledge of how to be invovled with the bundle (n=44, 27)	4 (4-5)	4 (3-5)
	I am motivated to be invovled with the bundle (n=44, 27)	4 (3-5)	4 (3-5)
	I have sufficient knowledge of the medication to apply the bundle (n=44, 27)	4 (4-5)	4 (2-5)
	I am enthusiastic about the bundle (n=n=44, 26)	4 (3-4.75)	3 (3-4)
Innovation Characterist-ics	I think the bundle benefits patients (n=44, 27)	4 (4-5)	4 (4-5)
	I think the bundle benefits community pharmacy practice (n=44, 27)	4 (4-5)	4 (4-4)
	I think the bundle is not difficult to do (n=44, 27)	4 (3.25-4)	4 (3-4)
	I think the bundle is not complex (n=42, 26)	4 (3-4)	4 (3-4)
	I think the bundle is of good quality (i.e. it is easy to understand) (n=44, 27)	4 (3-4)	4 (3-4)
	I think the bundle has been well designed (n=44, 27)	4 (4-5)	4 (4-4)
Outer Setting	I think the bundle is viewed positively by patients (n=44, 27)	4 (3-4)	3 (3-4)
	I think there is patient demand for the bundle (n=44, 27)	3.5 (3-4)	3 (3-4)
	I think patients are aware of the bundle (n=44, 27)	3 (2-4)	3 (2-4)
	I think patients have knowledge of what the bundle is about (n=44, 27)	2 (2-3)	3 (3-4)
	I think it is easy to get patients involved with the bundle (n=44, 27)	3 (3-4)	4 (3-4)
	I think the bundle is viewed positively by other HCPs (e.g. GPs) (n=44, 27)	3.5 (3-4)	4 (3-4)
	I think other HCPs (e.g. GPs) are engaged with the bundle (n=44, 27)	3 (3-3.75)	3 (3-4)
	I think a collaborative relationship exists between my pharmacy and other HCPs (e.g. GPs) (n=44, 27)	4 (3-4)	4 (3-4)
	I think there is sufficient funding for the bundle (n=44, 26)	3 (3-3)	3 (3-3)
	There are incentives for my pharmacy to be invovled in the bundle (n=43, 26)	3 (3-3)	3 (2-3)
	I think all pharmacies in Scotland should deliver the bundle to patients (n=44, 26)	4 (4-4)	4 (3-4)

CFIR Domains (n=5)	Questionnaire Items (n=NSAIDs, n=warfarin)	Median (IQR)	
		NSAIDs bundle	Warfarin bundle
Inner Setting	The training I recieved was sufficient for me to be invovled with the bundle with confidence (n=37, 15)	4 (4-5)	4 (4-4)
	I think we have enough time to deliver the bundle to patients (n=41, 24)	3 (3-4)	3 (2-3)
	I think the bundle does not increase my workload (n=42, 24)	3 (2-3.25)	2 (2-3)
	I think the resources which are part of the bundle are sufficient (n=41, 24)	4 (3-4)	4 (3-4)
	I think having access to patients' clinical information would help our invovlement with the bundle (n=40, 24)	4 (3-4)	4 (3.25-4)
	I think there is suitable space in our pharmacy to deliver the bundle to patients (n=42, 24)	4 (3-4.25)	4 (3-4)
	I think there are sufficient staff in our pharmacy to be invovled with the bundle (n=42, 24)	4 (2-4)	3 (2-3.75)
	There is information available in my pharmacy about the bundle (n=42, 24)	4 (4-5)	4 (4-5)
	I think the bundle is compatible with the way my pharmacy works (n=42, 24)	4 (3.75-5)	4 (3.25-5)
	I think the bundle is compatible with the role(s) I have within my pharmacy (n=42, 24)	4 (3.75-4)	4 (3-4)
	I think being invovled in the bundle makes my job more satisfying (n=42, 24)	3.5 (3-4)	3 (3-4)
	I think the bundle has commercial benefits for my pharmacy (n=42, 24)	3 (3-3)	3 (3-3)
	I think the bundle improves the professional recognition of community pharmacy practice (n=43, 26)	4 (3-4)	4 (3-4)
	I think the bundle increases the influence of community pharmacy practice within the NHS (n=43, 26)	4 (3-4)	3 (3-4)
	I think invovlement in the bundle means pharmacy staff have more legal responsibility for patient care (n=42, 26)	3.5 (3-4)	3 (2-4)
	I think the bundle aligns with the values I have regarding community pharmacy work (n=43, 26)	4 (3-4)	4 (3-4)
Process	The SPSP-PPC team have engaged with my pharmacy team (n=37, 25)	4 (3-4)	3 (3-4)
	The SPSP-PPC team have engaged with non-pharmacy HCPs (e.g. GPs) (n=37, 24)	3 (3-3)	3 (3-3)
	Patients were informed about the bundle by the SPSP-PPC team (n=37, 24)	3 (2.5-3)	3 (3-3)

CFIR = Consolidated Framework for Implementation Research, HCPs = Healthcare professionals, IQR = Interquartile range, SPSP-PPC = Scottish Patient Safety Programme – Pharmacy in Primary Care collaborative, NHS = National Health Service.

Median response 1 = Strongly disagree, 2 = Disagree, 3 = Neutral, 4 = Agree, 5 = Strongly agree. Participant were removed if they exhibited acquiescence in implementation success scale (n=3), i.e. if the response to the negatively-worded question was at least 2 scores different from the positively worded questions within the scale.

7.5.4 Barriers and facilitators influencing implementation success (regression analysis)

Initially, the regression analysis was conducted for the NSAIDs care bundle's data to allow for the model produced from this to have its predictive capability assessed by subsequently applying it to the warfarin care bundle data. The NSAIDs analysis was conducted first due to the greater number of participants.

7.5.4.1 NSAIDs care bundle regression analysis

Eleven barriers and facilitators from the 43 questionnaire items were selected for inclusion in multivariate analysis due to significance ($p<0.05$) in univariate regression analysis, following removal of two items due to inter-item collinearity [292]. Table 7.3 presents the items selected for inclusion and those removed due to inter-item collinearity. For the NSAIDs care bundle regression analysis, items removed due to inter-item collinearity were *"I think the bundle is difficult to do"*, and *"The training I received was sufficient for me to be involved with the bundle with confidence"*.

Table 7.3. Questionnaire items selected for inclusion in NSAIDs care bundle multivariate analysis and those removed due to inter-item collinearity

CFIR Domain	Questionnaire item selected for inclusion in multivariate analysis	P value
Characteristics of the Individual (Knowledge and Beliefs)	I have working knowledge of how to be involved with the bundle	0.01
	I have sufficient knowledge of the medication to apply the bundle	0.001
	I am enthusiastic about the bundle	0.001
Innovation Characteristics (About the Bundle)	I think the bundle benefits community pharmacy practice	0.032
	I think the bundle is of good quality (i.e. it is easy to understand)	0.001
Outer Setting (Patients)	I think it is not difficult to get patients involved with the bundle	0.018
Outer Setting (Policy)	I think there is sufficient funding for the bundle	0.042
	There are incentives for my pharmacy to be involved in the bundle	0.014
Inner Setting (In your Pharmacy)	I think we have enough time to deliver the bundle to patients	<0.001
	I think the bundle does not increase my workload	<0.001
	I think there are sufficient staff in our pharmacy to be involved with the bundle	0.018

CFIR = Consolidated Framework for Implementation Research, VIF = Variance Inflation Factor.

Forced entry of variables within the regression analysis was purposefully not conducted based on the results of the systematic review as none of the included studies focused specifically on high risk medicine care bundles. As there is no agreed best selection method for regression analysis [294], the stepwise, forward and backward selection methods were all applied and the selection method which produced the most parsimonious model was chosen. For the NSAIDs bundle regression analysis, the backwards elimination model produced the most parsimonious model. The final model, shown in Table 7.4, contained four barriers/facilitators which significantly predicted successful implementation: $F(4,34)=14.682$, $p<0.001$, $R^2=0.633$, adjusted $R^2=0.590$. This shows that better perceptions of implementation success were apparent for participants who were more positive when responding to the questionnaire items on: having sufficient knoweldge of NSAIDs medication; considering the funding to be sufficient; that there are incentives to being invovled with the bundle; and that the bundle did not increase workload.

Table 7.4. Success factors which significantly predict successful implementation of the NSAIDs bundle

CFIR Constructs	Questionnaire Item	Standardized Beta Coefficient	P value	Tolerance	VIF
Knowledge and beliefs about the innovation	I have sufficient knowledge of the medication to apply the bundle	0.513	<0.001	0.935	1.069
External Policy and Incentives	I think there is sufficient funding for the bundle	0.195	0.095	0.831	1.203
	There are incentives for my pharmacy to be involved in the bundle	0.290	0.015	0.838	1.193
Available Resources	I think the bundle does not increase my workload	0.356	0.003	0.869	1.151

CFIR = Consolidated Framework for Implementation Research, VIF = Variance Inflation Factor
VIF and Tolerance scores indicated there was no problematic multi-collinearity within the model, and visual inspection of P-P plots and the scatter plot of standardised residuals and standardised predicted variables confirmed that assumptions of normality and homoscedasticity were met.

Regression analysis was conducted for the NSAIDs bundle initially. The model generated from this was then used to test the predictive capability of this model for the warfarin bundle data. Despite an adjusted R^2 value of 0.590 for the NSAIDs care bundle data, the predicative capability of this was poor for the warfarin care bundle data as could only explain 18.1% of the variance in the dependent variable (adjusted $R^2=0.181$). This suggests that the barriers

and facilitators influencing the implementation of the warfarin and NSAIDs bundle differ. Resultantly, separate regression analyses were conducted for the NSAIDs and warfarin bundles.

7.5.4.2 Warfarin regression analysis

Fourteen barriers and facilitators from the 43 questionnaire items were selected for inclusion in multivariate regression analysis due to significance ($p<0.05$) in univariate regression analysis, following removal of three items due to inter-item collinearity (correlation co-efficient >0.8), as presented in Table 7.5. For the warfarin bundle regression analysis, items removed due to inter-item collinearity were *"I have working knowledge of how to be involved with the bundle"*, *"I think the bundle is complex"*, and *"The training I received was sufficient for me to be involved with the bundle with confidence"*.

Table 7.5. Success factors which significantly predict successful implementation of the warfarin bundle

CFIR Domain	Questionnaire item selected for inclusion in multivariate analysis	P value
Characteristics of the Individual (Knowledge and Beliefs)	I have sufficient knowledge of the medication to apply the bundle	0.038
	I am enthusiastic about the bundle	0.001
Innovation Characteristics (About the Bundle)	I think the bundle benefits patients	0.016
	I think the bundle is difficult to do	0.015
Outer Setting (Patients)	I think the bundle is viewed positively by patients	<0.01
	I think patients lack knowledge of what the bundle is about	0.005
	I think it is difficult to get patients involved with the bundle	0.018
Outer Setting (Other HCPs perceptions)	I think the bundle is viewed positively by other healthcare professionals (e.g. GPs)	0.009
Outer Setting (Policy)	I think all pharmacies in Scotland should deliver the bundle to patients	0.033
Inner Setting (In your pharmacy)	I think there is suitable space in our pharmacy to deliver the bundle to patients	0.003
	There is no information available in my pharmacy about the bundle	<0.001
	I think the bundle is not compatible with the way my pharmacy works	<0.001
	I think the bundle is compatible with the role(s) I have within my pharmacy	0.004
Inner Setting (General)	I think the bundle improves the professional recognition of community pharmacy practice	0.009

CFIR = Consolidated Framework for Implementation Research, VIF = Variance Inflation Factor

Stepwise, forward and backward selection methods were all applied. The model produced by backwards linear regression analysis failed assumption of normality of residuals through visual analysis of P-P Plots and histogram. The forward selection method produced the most parsimonious model, and two barriers/facilitators statistically significantly predicted successful implementation: $F(1,21)=30.963$, $p<0.001$, $R^2=0.752$, adjusted $R^2=0.727$, presented in Table 7.6. This shows that better perceptions of implementation success were apparent for participants who were more positive when responding to these questionnaire items on compatibilty and patient views.

Table 7.6. Success factors which significantly predict successful implementation of the warfarin bundle

CFIR Domain	Questionnaire Item	Standardized Beta Coefficient	P value	Tolerance	VIF
Compatibilty	I think the bundle is compatible with the way my pharmacy works	0.658	<0.001	0.924	1.083
Patient Factors	I think the bundle is viewed positively by patients	0.411	0.002	0.924	1.083

CFIR = Consolidated Framework for Implementation Research, VIF = Variance Inflation Factor
VIF and Tolerance scores indicated there was no problematic multi-collinearity within the model, and visual inspection of P-P plots and the scatter plot of standardised residuals and standardised predicted variables confirmed that assumptions of normality and homoscedasticity were met.

7.5.5 Responses to open-ended questions

Thirty-five participants (47.3%) responded to the open-ended questions. These allowed participants to report on barriers and facilitators not already listed; offer suggestions of what hypothetically would facilitate implementation; elaborate upon barriers and facilitators specified within the questionnaire; and to offer any other comments. Once the comments were aligned to the CFIR constructs, it was evident that the majority of the barriers and facilitators stated would have been captured within the questionnaire items, as shown in Table 7.7. Three barriers/facilitators which would not have been encompassed within the questionnaire items were: forgetting to document (n=2), previous involvement with warfarin bundle (n=1), and being organised (n=1). Of these, none were identified within the systematic review.

Table 7.7. Content analysis of open-ended questions aligned to constructs of the Consolidated Framework for Implementation Research (CFIR)

	NSAIDs Bundle	Warfarin Bundle
Barriers (n=26)	Available Resources – Time/Workload Barriers Time (n=9) Time to train staff (n=2) Workload (n=2) Time to submit data (n=1) Available Resources – Staff Barriers Low staff/staff shortage (n=3) Staff changes (n=1) Staff sickness (n=1) Different pharmacists covering (n=1) Available Resources – Access to clinical information Lack of access to patient notes (n=1) Patient Factors Patients disengaged (n=2) Patients lacking understanding (n=1) Patients not having time (n=1) Cosmopolitanism Communicating with GPs (n=2) Access to Knowledge and Information Unsure at start before it was explained (n=1) Knowledge & Beliefs about the Innovation Lack of knowledge (n=1) Complexity - Difficulty of the innovation Difficulty identifying patients (n=1) Other Forgetting to document (n=2)	Available Resources – Time/Workload Barriers Time (n=3) Available Resources – Staff Barriers Staff issues/understaffed (n=3) Staff confidence (n=1) Patient Factors Patients disengaged (n=1) Cosmopolitanism Communicating with warfarin clinic (n=1) Anticoagulant nurse has issue with supply of warfarin alert cards (n=1)
Facilitators (n=21)	Available Resources – Physical Resources Information Cards (n=8) Stickers (n=7) Bundle questions (n=1) Available Resources – Staff Facilitators Staff awareness (n=1) Staff huddles (n=1) Access to Knowledge and Information Training (n=3) Pharmacist is part of SPSP team (n=1) Engaging (Stakeholders) SPSP leads were motivating (n=1) Other Previous involvement with warfarin bundle (n=1)	Available Resources – Physical Resources (n=7) Stickers (n=2) Teach back counselling tool (n=1) Patient leaflets (n=1) Bundle questionnaire developed in pharmacy (n=1) Alert sheets (n=1) Aid memoires (n=1) Available Resources – Staff Facilitators Pre-reg pharmacist (n=1) Engaging (Innovation Participants) Wishing to supply patient care (n=1) Other Being organised (n=1)
Hypothetical Facilitators (n=5)	Access to Knowledge and Information More information on NSAIDs (n=3) More staff at training events (n=1) Available Resources – Staff More staff (n=1) Available Resources – Time/Workload Time (n=1) Shorter amount of questions to ask (n=1)	Access to Knowledge and Information Training for staff (n=1)
Other comments (n=2)	*"I like it and think it is a good idea which we try to implement as much as possible. But certainly not "every patient every time" as would be the ideal scenario."*	Nil

7.6 Discussion

Generally, the community pharmacy staff held positive perceptions of the care bundles' implementation. For the NSAIDs care bundle, four predictors of implementation success were identified: pharmacy staff having sufficient knowledge of NSAIDs; incentives to delivering the bundle; workload of the bundle; and funding. For the warfarin bundle, compatibility of the bundle within the pharmacies and positive patient perceptions were the two identified determinants of implementation success. The difference in emergent success factors between the bundles suggests the necessity to develop distinct implementation strategies for each.

7.6.1 NSAIDs care bundle success factors

Pharmacy staff having sufficient knowledge of NSAIDs medication was a predictor for successful implementation of the NSAIDs care bundle. However, for the studies evaluating clinical pharmacy innovations identified within the systematic review (n=21), lack of clinical knowledge relating to innovations was relatively rarely reported (n=3 studies) [164, 168, 190]. This could be explained by the greater representation of community pharmacy support staff relative to pharmacists within this study, whilst the studies evaluating clinical pharmacy innovations as identified by the systematic review often sampled only pharmacists (n=13 studies) [60, 134, 179, 182-190, 192]. Ensuring development and distribution of information on NSAIDs medication to the community pharmacy staff may facilitate it's successful national implementation [295].

The workload associated with the NSAIDs bundle was also a risk to its successful implementation, potentially explained by the greater number of eligible patients in comparison to the warfarin bundle. This was a commonly reported barrier identified within the systematic review [167, 169, 170, 174, 181]. The positive influence of monetary incentives associated with innovations was also a key finding from the systematic review [168-170, 173, 179, 191, 200], and for the NSAIDs care bundle funding and incentives were identified success factors based on the regression analysis. Although economic analysis was outwith the scope of this thesis, this suggests that for the national roll-out adequate funding arrangements may be necessary to compensate for the increase in workload. Formal arrangements with money allocation (i.e. via a contractual framework) could be required for successful national implementation [295], as opposed to more passive diffusion mechanisms.

Further strategies to incentivise pharmacy staff to deliver the care bundle to patients could include relaying clinical data to the pharmacy staff [295] - such as reinforcing the NSAIDS bundle's rationale and the evidence on the risk associated with NSAIDs use, and the application of quality improvement run-charts within pharmacies to self-incentivise local improvements [295].

7.6.2 Warfarin care bundle success factors

For the warfarin bundle, patients' perceptions influenced successful implementation. The influence of such external engagement was identified within the systematic review and was particularly salient for clinical pharmacy services; despite reports of positive patient engagement for the clinical innovations [167, 168, 170, 172, 182, 183], lack of patient demand [60, 134, 168, 169, 182-184, 191] was just as common. Engaging patients is a known facilitator to implementation [295], and was a common suggestion of the studies included within the systematic review findings [134, 167-169, 173-175, 177, 190, 193, 198, 200], with potential strategies including banners and displays [170], patient education programmes [175, 177, 191, 200] and local publicity and media campaigns [167-169, 173]. Obtaining patient-reported perceptions of the warfarin care bundles would help identify the most appropriate patient engagement strategy within this context.

The compatibility of the warfarin care bundle with the way the pharmacies worked was a success factor, which exemplifies the necessity to understand how innovations penetrate within routine practice to support successful implementation [39]. As all pharmacies within Scotland have been delivering warfarin services to a percentage of their patients as part of previous contractual arrangements (see Chapter 1, Section 1.2), it may have been assumed that this care bundle would have been compatible within all pharmacies. Exploring the penetration of the warfarin care bundle into practice will help to develop strategic recommendations; however, at pharmacy level the local use of PDSA cycles to iteratively test different workflow strategies may be beneficial for the national implementation of this care bundle [295].

7.6.3 Comparison of NSAIDs and warfarin care bundle success factors

The emergent barriers and facilitators between the warfarin and NSAID bundle with relation to the three thematic areas identified from the systematic review are presented in Table 7.8. For the NSAIDs bundle, success factors were identified in relation to pharmacy staff

engagement and operationalisation of the innovation. For the warfarin bundle, the success factors identified related to operationalisation of the innovation and external engagement. The differences in the emergent success factors exemplifies the necessity to develop tailored implementation strategies for specific innovations, and suggests that in this Scottish community pharmacy context strategists must veer away from using a 'one size fit's all' implementation strategy.

Table 7.8. Comparison of the emergent success factors between the warfarin and NSAIDs bundle

Thematic areas identified from systematic review with description	NSAIDs bundle	Warfarin bundle
Operationalisation of the innovation Operationalisation of innovations encompasses its attributes (such as design and complexity), but also surround factors including resources, compatibility with pharmacy systems, and pharmacy staff access to knowledge and information about the innovation.	- Workload	- Compatibility within pharmacy
Pharmacy staff engagement Pharmacy staff engagement encompasses their knowledge and beliefs relating to an innovation, its compatibility with their roles and values, whether it poses advantages or not, and the incentives and strategies which engage community pharmacy staff.	- Knowledge about NSAIDs medication - Incentives - Sufficient funding	
External engagement External engagement is encompassed by the relationship with patients and other healthcare professionals, their perceptions, and strategies to engage these stakeholders.		- Patient perceptions

NSAIDs = non-steroidal anti-inflammatory drugs

The differences may be explained by the contextual differences of the innovations themselves, such as the different high risk medicines of focus. For example, it could be theorised that as NSAIDs are prescribed in higher quantitates and more readily available compared to warfarin it is plausible that workload would influence its success compared to the warfarin bundle. Furthermore, the necessity for sufficient funding and incentives for the NSAIDs bundle may be related to this associated increase in workload, which may explain why this was not a predictor of success for the warfarin bundle. Without further exploration,

it is currently unknown why compatibility and patient perceptions were influential for the warfarin bundle and not for the NSAIDs bundle.

7.6.4 Strengths and limitations

The strengths and limitations in relation to the questionnaire design and method used for this study has been discussed in Chapter 6, Section 6.7.2. Further to this, some of the results presented may also exemplify the validity of the questionnaire items on barriers and facilitators in terms of completeness, as analysis of the open-ended questions did not identify the common emergence of barriers or facilitators which were not captured by the CFIR constructs identified from the systematic review.

The use of psychometric testing to identify the barriers and facilitators of salience is exemplified when considering the questionnaire items which had negative responses, which at face value would indicate the presence of a barrier. There were two questionnaire items that most participants disagreed with (Section 7.5.3): 'I think patients have knowledge of what the NSAIDs bundle is about', and 'I think the warfarin bundle does not increase my workload'. At face value this suggests these factors would be a barrier to implementation as it indicates lack of patient knowledge of the NSAIDs bundle, and increased workload associated with the warfarin bundle. However, neither of which were identified as success factors from the regression analysis. This suggests that although these barriers existed, they did not actually influence the pharmacies' implementation of the care bundle as perceived by the pharmacy staff. For example, although the warfarin bundle may have increased workload, this did not appear to influence whether or not the warfarin bundle was delivered. Had the regression analysis not been conducted, these two factors may have been the focus of the national implementation strategies which may have offered little facilitation as the regression analysis did not identify them to truly impact perceptions of successful implementation.

For this study, the barriers and facilitators were explored following the pilot implementation of the care bundles. Alternatively, the barriers and facilitators could have been explored at the pre-implementation stage prior to their introduction within the community pharmacies, where the results could have been used to refine the care bundles prior to their piloting. However, a limitation of this approach is that the barriers and facilitators identified during pre-implementation phases would have been hypothetical in nature and may not accurately

reflect those which are experienced once pharmacy staff begin to operationalise the care bundles. Additionally, the implementations success scale (the dependent variable in this study) would not have been relevant at a pre-implementation stage and could not have been applied. Thus, the regression analysis could not have been conducted and the relative influence of the barriers and facilitators not determined.

7.6.5 Future directions and recommendations

The difference in the emergent success factors between the care bundles demonstrates the necessity of identifying context-sensitive barriers and facilitators to develop innovation-specific tailored implementation strategies. In response to the wider success factors identified, strategic recommendations have been developed for the national implementation of the care bundles, as shown in Table 7.9. Individual implementation interventions have been categorised as per a taxonomy developed by the Expert Recommendations for Implementing Change (ERIC) project for the purpose of ensuring consistency of reporting within the implementation science literature [295]. This taxonomy developed has been previously described in Chapter 2 (Section 2.3.3), with the full taxonomy presented in Appendix 2.2.

Table 7.9. Recommendation for the national implementation of the care bundles in response to success factors identified

Success factor identified	Proposed ERIC implementation interventions	Contextualised recommendation
NSAIDs care bundle		
Knowledge about NSAIDs medication	Develop and distribute educational materials	Disseminate information to all community pharmacy staff on NSAIDs medication to ensure each have the minimum level of knowledge required to deliver the bundle
Sufficient funding and workload	Fund and contract the clinical innovation	Incorporate within community pharmacy contract to ensure an appropriate funding model aligns with the workload demands
Incentives	Facilitate relay of clinical data to providers	Reinforce the evidence on the risk associated with NSAIDs use and the rationale behind the care bundle to incentivise pharmacy staff involvement
	Develop and implement tools for quality monitoring	Promote use of quality improvement run-charts to incentivise local improvements in care bundle delivery
Warfarin care bundle		
Patients' perceptions	Involve patient/consumers and family members	Adopt patient engagement strategies, such as better signposting or campaigns
Compatibility within pharmacy	Conduct cyclical small tests of change	Promote the use of 'PDSA' cycles so pharmacies can use a trial and error approach to integrate the bundle within their pharmacies work processes

NSAIDs = Non-steroidal anti-inflammatory drugs, ERIC = Expert Recommendations for Implementing Change, PDSA = Plan-Do-Study-Act

7.7 Conclusion

This study has identified key success factors for both the warfarin and NSAIDs care bundles which have been used to develop key recommendations for their national implementation. For the NSAIDs bundle, recommendations include: (i) incorporating it within the national community pharmacy contract to secure appropriate funding; (ii) disseminating information to all community pharmacy staff on NSAIDs to facilitate whole team engagement; (iii) reinforcing the risks of NSAIDs; and (iv) promoting the use of run charts[8] to incentivise involvement. For the warfarin bundle, recommendations include: (i) adopting patient engagement strategies, and (ii) promoting the use of PDSA cycles for pharmacies to iteratively test how to best integrate the bundle within their pharmacy. Further evaluation is required to further develop these recommendations, which will explore fidelity and penetration of the bundles into community pharmacy practice (Chapter 8) and patient-reported experience and outcomes of the care bundles (Chapter 9).

[8] See Section 1.3.3 for more information on run charts

Chapter 8: Exploration of the fidelity and penetration of the consolidated warfarin and NSAIDs care bundles

8.1 Summary of Chapter

Background

Achieving intended outcomes of innovations requires their successful implementation within practice. This study aimed to explore the fidelity of the NSAIDs and warfarin care bundles (i.e. if they are delivered as intended), and their penetration in relation to their incorporation within community pharmacies and extent of pharmacy team involvement.

Methods

A mixed methods study was conducted; a questionnaire was disseminated to the 24 pilot community pharmacies which explored penetration (Jun - Aug 2017), and on-site visits were conducted in eight pharmacies exploring both penetration and fidelity (Oct - Nov 2017).

Results

The care bundles' core components were not always delivered as intended: not all care bundle questions were delivered, and repeated delivery of the care bundle was often condensed. The same approach for incorporating both care bundles within the dispensing process was identified, with scope for whole team involvement. However, there was a tendency for the responsibility of delivering the care bundles to lie with the pharmacists.

Conclusion

The fidelity findings indicate that modifications are required to ensure the care bundles' core components are appropriate, including permitting condensed versions of the care bundle to be repeatedly delivered to patients. The positive penetration findings suggests the care bundles could be successfully integrated within the national community pharmacy context. Recommendations have been made to facilitate national implementation of the care bundles, including disseminating a process map detailing the care bundles' process.

8.2 Background

Successful implementation of novel innovations within healthcare settings underpins the achievement of their intended clinical outcomes [63, 151]. Previous studies have been criticised for not exploring if innovations are successfully integrated within practice or delivered as intended, which complicates the assessment of an innovation's intended outcomes. For example, if an innovation does not achieve intended outcomes, without exploring its implementation, researchers are unable to attribute this to its suboptimal implementation or inadequacies in its design [103, 235]. Although implementation scientists advocate exploring how innovations become implemented and institutionalised within routine practice [70], it is considered an under researched area within the field of health service evaluation [296].

Weir et al (2017) identified that earlier iterations of the warfarin and NSAIDs care bundles successfully integrated within the community pharmacy dispensing process (Appendix 8.1) [39]. However, prior to their consolidation, the care bundles' variation in content meant that equitable outcomes might not have been achievable if they were scaled up in their pre-consolidated state [38]. Consolidated care bundles were developed and implemented within 24 pharmacies in February 2017, as detailed in Chapter 4 of this thesis; however, the ability of these consolidated care bundles to be successfully implemented within community pharmacies is unknown. As this is a precursor for achieving intended clinical outcomes, exploring this could support - or discourage - the argument for implementing them throughout the national community pharmacy context. A taxonomy of outcomes developed by Proctor et al (2010) includes eight discrete yet inter-related implementation outcomes: adoption, feasibility, acceptability, appropriateness, penetration, fidelity, cost and sustainability [70]. Two of these are of interest when exploring if and how innovations are delivered as intended: 'fidelity' and 'penetration' [70]. Each of these will now be discussed in turn, as will the necessity for exploring both in tandem.

Implementation fidelity is defined as the 'the degree to which an intervention was implemented as intended' [86]. If national improvements in NSAIDs and warfarin safety-related outcomes are to be realised, the care bundles must be delivered as intended when introduced within real-world community pharmacy settings [103]. The warfarin and NSAIDs care bundles were developed with core components that relate to the care bundles'

questions and patient eligibility which are to be delivered to every patient, every time as presented in Chapter 4. However, challenges to implementation fidelity exists; over time innovations are commonly only partially delivered as intended [296], and it has been identified that less than 50% of clinicians deliver innovations as intended in routine practice [297]. Therefore, identifying whether the care bundles' core components are adhered to will offer insight into whether implementation fidelity could be achieved if the bundles are nationally introduced throughout Scotland's community pharmacies.

Penetration of an innovation - defined as its 'integration within a service setting' - is an additional outcome measure of implementation [87]. The implementation outcome penetration encompasses (i) if and how innovations become incorporated within routine practice, as well as (ii) the number of healthcare providers which deliver an innovation [87]. Within the community pharmacy setting, the incorporation of innovations within routine practice is challenged by the autonomous nature of community pharmacies [92, 96] and their ability to adopt unique work processes (10, 11). Further to this, evidence suggests that successful penetration of community pharmacy innovations is facilitated by whole-pharmacy team involvement [168, 169, 210, 211], with task delegation considered essential for successful implementation of clinical pharmacy services [212, 298]. However, known barriers to this exist such as concerns over accountability [299, 300]. Therefore, exploration of the care bundles' penetration focused on their incorporation within routine community pharmacy practice and the extent of whole team involvement with them.

Previous work indicates that fidelity and penetration are not discrete implementation outcomes and instead they are considered coherently linked. An innovation's penetration within healthcare settings is known to influence its implementation fidelity [63, 239, 240]. Furthermore, Chambers et al (2013) argue that the most important determinant of an innovation's sustained delivery is its ability to penetrate in practice [301], a viewpoint which was corroborated in a systematic review by Wiltsey Stirman (2012) which identified that the "fit" of an innovation was a common determinant of its fidelity and sustainability [302]. Therefore, concurrent exploration of both fidelity and penetration were considered a necessity to best understand the implementation of the care bundles into routine practice.

8.3 Aims and objectives

The aim of this study was to explore the penetration and fidelity of the consolidated warfarin and NSAIDs care bundles with the following objectives:

1. Conduct a fidelity assessment of the care bundles' core components
2. Examine penetration of the care bundles in relation to their incorporation within routine community pharmacy practice and the resources used
3. Examine penetration in relation to the extent of pharmacy staff involvement with the care bundles

8.4 Methods

8.4.1 Study design

A mixed methods approach was adopted for this study. Firstly, a questionnaire was disseminated (previously described in Chapter 6) which sampled all pilot community pharmacies (n=24) and obtained data specifically on penetration of the care bundles. On-site visits were then conducted in a selected cohort of eight community pharmacies to conduct a 'walk-through' of the care bundle process to explore more in-depth the fidelity and penetration of the care bundles. An overview of what the different data collection methods explored is presented in Figure 8.1. Ethical approval was not sought for this study as it was deemed service evaluation [282, 283].

Areas explored	Questionnaire (Jun - Aug 2017)	On-site visits (Oct – Nov 2017)
Fidelity	✗	✔
Penetration		
Integration within existing pharmacy work systems	✗	✔
Resources used to deliver the care bundle	✔	✔
Extent of whole team involvement	✔	✔

Figure 8.1. Coverage of fidelity and penetration explored by the on-site visits and questionnaire

8.4.2 Questionnaire method

A questionnaire was used to explore certain aspects of penetration of the care bundles. The development and testing of this has been described in detail in Chapter 6, Section 6.5. The

questionnaire was disseminated by post to all pilot community pharmacies (n=24) on the 26th of June 2017, with postal responses accepted until the end of August 2017.

8.4.3 On-site visits method

8.4.3.1 Study sample

Pharmacies were purposefully selected for on-site visits to ensure a range of pharmacy characteristics with respect to the number of pharmacy staff employed and the varying pharmacy chain sizes and independents pharmacies. This information was already known from previous evaluation activities [38]. To ensure equal representation of pharmacies within each NHS region, a third of pharmacies were selected from each NHS Health Board and resultantly eight pharmacies were selected (GG&C n=3, Fife n=2, Grampian n=2, Highland n=1). Pharmacies were purposefully selected to ensure that four pharmacies were involved in the warfarin care bundle (those located in Highland and GG&C), and the other four were involved in the NSAIDs care bundle (those located in Fife and Grampian).

8.4.3.2 Recruitment of pharmacies

The pharmacy staff of selected pharmacies were contacted via telephone to ascertain if they were willing to have a researcher visit the pharmacy. At this point, the scope of the research project and what would be expected of the pharmacies was explained. The pharmacies were then phoned at a later date to agree suitable times. The pharmacist within each pharmacy was asked to conduct the walk-through as they were assumed to have best insight into how the pharmacy works at a system level due to their managerial role. Additionally, the pharmacist was considered likely to be involved in task delegation and therefore would have awareness of the involvement of different pharmacy staff. During the on-site visit, the pharmacist was given the opportunity to nominate another pharmacy member to conduct the walk-though if they thought they were more appropriate.

8.4.3.3 Data collection

A walk-through of the care bundles was conducted during the on-site visits. The walk-through method is a task-analysis technique, and is the exploration of what an individual or a team is required to do in terms of actions and/or cognitive processes to achieve a system goal [303]. The technique allows for an understanding of the processes involved when performing a

specific task - which in this context was delivering the care bundles, and can provide a blueprint of human involvement and the use of resources [303]. A pharmacy staff member was asked to conduct the walk-through by simulating the task of delivering the care bundle within their community pharmacy with concurrent explanations of the steps involved.

A walk-through guide of prompts was developed to ensure all aspects of the process were considered and to ensure transparency and replicability of the method between pharmacies (Appendix 8.2). The development of this walk-through guide was informed by Weir et al's study (Appendix 8.1) [39], and was peer reviewed by MB and RN. Fidelity was explored by asking participants their process for delivering the care bundles' core components as well as asking if there was ever a time where they deviated from their stated process. The care bundles' core components include the patients considered eligible to receive the care bundle and the delivery of the care bundles' questions, as presented in Figure 8.2. To explore penetration, the walk-through guide included questions on the care bundle process and any resources used, how this was positioned within the dispensing process, and the involvement of different community pharmacy staff members.

The walk-through did not occur in real-time, which afforded the researcher the opportunity to ask for further elaboration or clarification where required. Resources used within the pharmacy environment also acted as material probes to prompt discussion [304]. During the walk-through, a process map was drafted which depicted the details of the steps involved in delivering the care bundle, how this integrated within the pharmacy dispensing process, the resources used, and the involvement of pharmacy staff members [303]. After the walk-through, the process map drafted was presented to the participant and discussed to ensure all steps were covered, to validate the accuracy of the process map, and to ensure the researcher had correctly interpreted the process.

Care bundle	Care bundle questions	Eligible patients
NSAIDs care bundle	**Communication bundle**	
	1. Informing patient to take NSAID with or after food	All OTC, eMAS and Rx supplies of an NSAID. The care bundle should be repeatedly delivered to patients.
	2. Informing patient to report of potential adverse drug reactions	
	3. Informing patient to stop NSAID medication during dehydrating illness	
	Safer care bundle	
	4. Assessing use/need of NSAID	All Rx supplies of an NSAID. The care bundle should be repeatedly delivered to patients.
	5. Identifying if patient is in high risk group	
	6. Identifying triple whammy interactions	
Warfarin care bundle	1. Informing patient of importance of carrying alert card	All Rx supplies of warfarin. The care bundle should be repeatedly delivered to patients.
	2. Reviewing patients' information on indication, duration of treatment, therapeutic range and current dose of warfarin	
	3. Informing patient of what to do if missed a dose of warfarin	
	4. Informing patient to report any significant changes which may affect their warfarin	
	5. Discussing common signs and symptoms of over/under-coagulation	
	6. Informing patient that the need INR test if starting antibiotics	

Figure 8.2. Core components of the consolidated warfarin and NSAIDs care bundles

OTC = over the counter, eMAS = minor ailments service, Rx = prescription, NSAIDs = non-steroidal anti-inflammatory drugs, INR = international normalised ratio

The walk-through was audio-recorded and transcribed verbatim to aid analysis. A participant information sheet was provided at the time of the on-site visits, and participants were asked to complete a consent form and a demographics form. Demographic details sought of the walk-though participants were their age, gender, length of involvement in SPSP-PPC collaborative, how long they had worked in a community pharmacy, their job role within the pharmacy, length of time worked within this job role, and their contract type. Details sought of the pharmacy included on average how many care bundles were delivered a week to patients in their pharmacy. Pharmacy characteristics such as size of pharmacy chain and rurality were already known from previous evaluation activities [38]. The on-site visits were conducted between October 2017 and November 2017.

8.4.4 Data analysis

8.4.4.1 Analysis of fidelity data

Data on fidelity was derived from the on-site visits only. A conceptual framework of implementation fidelity, developed by Carroll et al, was used to develop the criteria to assess the fidelity of the care bundles' core components [103]. The criteria are presented in Figure 8.3, and relate to the care bundles' content and coverage (i.e. are all care bundle questions being delivered), and their frequency (i.e. are all eligible patients being repeatedly delivered the care bundle) [103]. Each of the pharmacies' self-reported delivery of the care bundle was assessed against this criteria.

Fidelity assessment	NSAIDs care bundle	Warfarin care bundle
Content and coverage	• Is the Communication Bundle (Q1-3) delivered with all OTC, eMAS and Rx supplies? • Is the Safer Care Bundle (Q4-6) delivered with all Rx supplies?	• Is the warfarin bundle delivered with all Rx supplies?
Frequency	• Are the care bundles delivered to every patient, every time?	• Is the care bundle delivered to every patient, every time?

Figure 8.3. Criteria for assessing the fidelity of the consolidated warfarin and NSAIDs care bundles

NSAIDs = non-steroidal anti-inflammatory drugs, OTC = over the counter, eMAS = minor ailments service, Rx = prescription

Initial analysis identified that lapses of implementation fidelity could be persistent or transient which was used to stratify the results. Persistent lapses for the purpose of this study were defined as an instance where a care bundles' core component was *never* adhered to. Transient lapses of implementation fidelity were defined as an instance where a care bundle's core component was *sometimes* not adhered to. Although this stratification is novel to this study, it was considered necessary to delineate between persistent and transient lapses in implementation fidelity for two reasons. Firstly, it is conceptually plausible that persistent lapses in fidelity may have greater impact on an innovation's intended outcomes than transient lapses. Secondly, there may be different reasons explaining why community pharmacy staff may persistently do not adhere to a core component of the care bundle rather than transiently not adhere to a care bundle's core component. An inductive thematic

analysis of the transcribed audio-recorded data from the on-site visits was conducted in NVivo v11.0 to identify emergent themes explaining if and why there were lapses in implementation fidelity.

8.4.4.2 Analysis of penetration of the care bundles' incorporation within routine community pharmacy practice

The process maps drawn during the on-site visits were developed electronically using the process mapping software LucidChart [305]. The pharmacies' process maps were compared and through visual analysis commonalities were identified. Common processes which occurred within each of the pharmacies were termed 'key process steps', i.e. integral to care bundle delivery.

Both the on-site visits and the questionnaire explored the resources used when delivering the care bundles. For the on-site visit data, summative content analysis was conducted to present this data. For the questionnaire data, the results of participants reported use of resources are presented as frequencies and percentages. Response to the open-ended question which asked if any other resources underwent summative content analysis. As both the questionnaire and on-site visits explored the resources used, this data is presented together [306].

8.4.4.3 Analysis of penetration in relation to extent of pharmacy staff involvement with the care bundles

Both the on-site visits and questionnaire data explored the extent of whole team involvement. For the on-site visits data, the pharmacies' process maps, which depicted the different pharmacy staff involvement with the care bundle, were cross-examined to identify which steps necessitated a pharmacist's involvement as reported by the pharmacist during the walk through. For the questionnaire data, questionnaire items on participants' involvement with the bundle and its resources are presented as frequencies and percentages, with the results being stratified to the various staff members to allow for analysis of whole team involvement. As both the questionnaire and on-site visits explored the involvement of different staff members, this data is present together [306].

8.5 Results

8.5.1 Demographics

8.5.1.1 On-site visits demographics

The pharmacies visited included five large chain pharmacies (n=5, 62.5%), a small chain pharmacy (n=1, 12.5%), and two single independent pharmacies (n=2, 12.5%). When pharmacies were telephoned it became apparent that no pharmacies in NHS Highland continued to deliver the warfarin care bundle, therefore a retrospective walk-through was conducted (Pharmacy 6). For the pharmacies visited which participated with the NSAIDs bundle, the weekly number of patients who received the bundle ranged from 1 to 20 patients per week. For the warfarin bundle, this ranged from 2 to 5 per week. The full demographics of the eight pharmacies that participated in the on-site visits are shown in Table 8.1. All participants who conducted the walk-through were pharmacists (n=8, 100%), including one pharmacy owner (n=1, 12.5%). Most were involved in the SPSP-PPC collaborative for two to three years (n=5, 62.5%), with only one participant involved with the collaborative for less than one year (n=1, 12.5%).

Table 8.1. Characteristics of pharmacies visited (Oct - Nov 2017) (n=8)

Pharmacy characteristics	NSAIDs care bundle pharmacies				Warfarin care bundle pharmacies			
Pharmacy ID number	1	2	5	8	3	4	6	7
NHS Region	Grampian	Grampian	Fife	Fife	GG&C	GG&C	Highland	GG&C
Responded to questionnaire	✔	✘	✔	✔	✔	✔	✘	✔
Weekly number of care bundles delivered	15	1-2	10-20	10	4	4	2	5
Pharmacy chain type*	Small	Large	Single	Large	Large	Large	Single	Large
No of pharmacy staff	9	11	17	14	7	19	6	5
Delivery service	✔	✔	✔	✘	✔	✔	✘	✔
Care home service	✘	✔	✘	✘	✘	✔	✔	✔
Automated dispensing technology	✔	✘	✘	✘	✘	✘	✘	✘
Spoke and hub dispensing model^	✘	✘	✘	✔	✘	✘	✘	✘

**Large chain = >30 pharmacies, small chain = 2-4 pharmacies, independent pharmacy = one, single pharmacy; ^Spoke and hub dispensing is when repeat prescriptions are dispensed off-site at a central 'hub' which are then sent back to the 'spoke' pharmacy for the patient to collect*
NSAIDS = non-steroidal anti-inflammatory drugs, GG&C = Greater Glasgow and Clyde

8.5.1.2 Questionnaire demographics

See Chapter 7, Section 7.5.1 for the demographics of participants who responded to the questionnaire.

8.5.2 Implementation fidelity of the care bundles' core components

8.5.2.1 Persistent lapses in implementation fidelity with the NSAIDs care bundle

Persistent lapses in implementation fidelity were identified for the NSAIDs bundle. Although all pharmacies adhered to parts of the NSAIDs care bundle, only one pharmacy adhered to all elements of the care bundle's core components (Pharmacy 5). The remaining pharmacies

either did not repeatedly deliver the care bundle to patients (Pharmacy 1), repeated only a condensed version of the care bundle (Pharmacies 2, 5 and 8), or did not deliver all of the care bundle questions (Pharmacy 2 and 8). Table 8.2 presents the assessment of implementation fidelity for the NSAIDs care bundle's core components.

Table 8.2. Assessment of implementation fidelity of the NSAIDs care bundle's core components

Fidelity assessment	N (%) of pharmacies	Details of persistent lapses in fidelity
Content and coverage		
Is the Communication Bundle (Q1-3) delivered with all OTC, eMAS and Rx supplies?	2 (50.0)	Pharmacy 8 did not deliver Q3 for any supplies of NSAIDs, and Pharmacy 2 did not deliver Q3 if short-term OTC NSAID. Both pharmacies justified this as they provided the NSAIDs Safety Information Card which had this information: *"we wouldn't ask them, but they would still be given that [NSAIDs information card]" (Pharmacy 2)*
Is the Safer Care Bundle (Q4-6) delivered with all Rx supplies?	3 (75.0)	Pharmacy 8 did not deliver the Safer Care bundle to patients who hadn't presented in the pharmacy before due to lack of information on them: *"I would go through the first three questions, but I probably wouldn't go through 4, 5 and 6 if I didn't have any other information for them" (Pharmacy 8)*
Frequency		
Are the care bundles delivered to every patient, every time?	1 (25.0)	Pharmacy 1 did not repeatedly deliver the NSAIDs bundle to patients. Pharmacy 2 and Pharmacy 8 would repeat a condensed version of the care bundle and not the full bundle: *"I would generally still put on the [prescription information form][9] to take with or after food and attach one of these [NSAIDs information card]" (Pharmacy 8)*

OTC = over the counter, NSAIDs – non-steroidal anti-inflammatory drugs, eMAS = minor ailments service, Rx = prescription

[9] The prescription information form is used in this pharmacy to prompt and indicate what counselling is to be offered to the patient when the prescription is handed out.

8.5.2.2 Persistent lapses in implementation fidelity with the warfarin care bundle

The assessment of the persistent lapses in implementation fidelity for the warfarin bundle identified that all pharmacies adhered to parts of the warfarin care bundle. However, only one pharmacy adhered to all of the care bundle's core components (Pharmacy 1). The remaining pharmacies either did not deliver the care bundle to all eligible patients (Pharmacy 4), or did not repeatedly deliver the full care bundle to patients (Pharmacies 4,6 and 7). See Table 8.3 for the fidelity assessment of the warfarin care bundle. For Pharmacy 6 which no longer delivered the care bundle, the data is reported based on their retrospective account of what they did when they delivered the care bundle.

Table 8.3. Assessment of implementation fidelity of the warfarin care bundle's core components

Fidelity assessment	N (%) of pharmacies	Details of persistent lapses in fidelity
Content and coverage		
Is the warfarin bundle delivered with all Rx supplies?	3 (75.0)	Pharmacy 4 did not deliver the warfarin care bundle to their patients who reside in care homes due to the presence of medical staff within this setting: *"cause there's a doctor which goes in to the nursing homes, so we don't really take much to do with any sort of counselling in there, unless they phone us" (Pharmacy 4)*
Frequency		
Is the care bundle delivered to every patient, every time?	1 (25.0)	*Pharmacies 4,6 and 7* would repeat a condensed version of the care bundle and not the full bundle: *"we'd probably go through it all with them most times for the first two or three times then after that it's just about you know when's your next blood check, what is your INR, what's your dose" (Pharmacy 7)*

Rx = prescription

For Pharmacy 6, which no longer delivered the care bundle, this was reportedly due to lack of patient engagement: *"I found that a lot of the customers were quite sort of 'och, I don't need that, I know what I'm doing', they weren't really engaging … they were like 'oh my nurse deals with that'"* (Pharmacy 6). Pharmacy 6 also reported that they had noticeably fewer patients on warfarin due to a prescribing shift to the newer oral-anticoagulant rivaroxaban.

8.5.2.3 Transient lapses in implementation fidelity for both care bundles

A thematic analysis of the NSAIDs and warfarin care bundles' walk-through transcripts identified that transient lapses in implementation fidelity were due to three key factors:

patients' preferences regarding receiving the bundle; the pharmacy staff's judgment of the necessity of delivering all care bundle questions to certain patients; and time pressures within the pharmacy. This is presented in Table 8.4 alongside illustrative quotes.

Table 8.4. Factors influencing transient lapses in fidelity with illustrative quotes

Factors	Illustrative quotes	
Patients' preferences	*"Some patients tend to get a wee bit pestered and they'll avoid it at all costs and they just want to come in and out and get on with things"* *- Pharmacy 1 (NSAIDs bundle)*	*"you can tell whether they want to hang about for the information or not, if not then it's just quickly just to remind you to take it with or after food, it stops any stomach issues"* *- Pharmacy 5 (NSAIDs bundle)*
Pharmacists' judgment	*"On every prescription, if it's a new item, then an 'N' is annotated by the dispenser who is labelling that prescription to annotate that that's a new item. So they are really the priority in terms of counselling or the ones who have additional meds"* *- Pharmacy 5 (NSAIDs bundle)*	*"we establish if they're using it for occasional use, and in that case sometimes the [NSAIDs information] card's not always appropriate if they're using it now and again for acute sort of pain."* *- Pharmacy 1 (NSAIDs bundle)*
Time pressures	*"we might just miss the chance to speak to certain people just because again just busy periods"* *- Pharmacy 3 (warfarin bundle)*	*"Obviously we have different time pressures and sometimes we might miss out a couple steps particularly if a person that you know very well"* *- Pharmacy 7 (warfarin bundle)*

*NSAIDs = non-steroidal anti-inflammatory drugs*8.5.3 Penetration of the care bundles in relation to their incorporation within routine community pharmacy practice and the resources used

8.5.3.1 Key process steps of the care bundles

The walk-through task analysis technique resulted in detailed process maps for each of the pharmacies visited. Pharmacy 1's process map is presented as an example in Figure 8.4

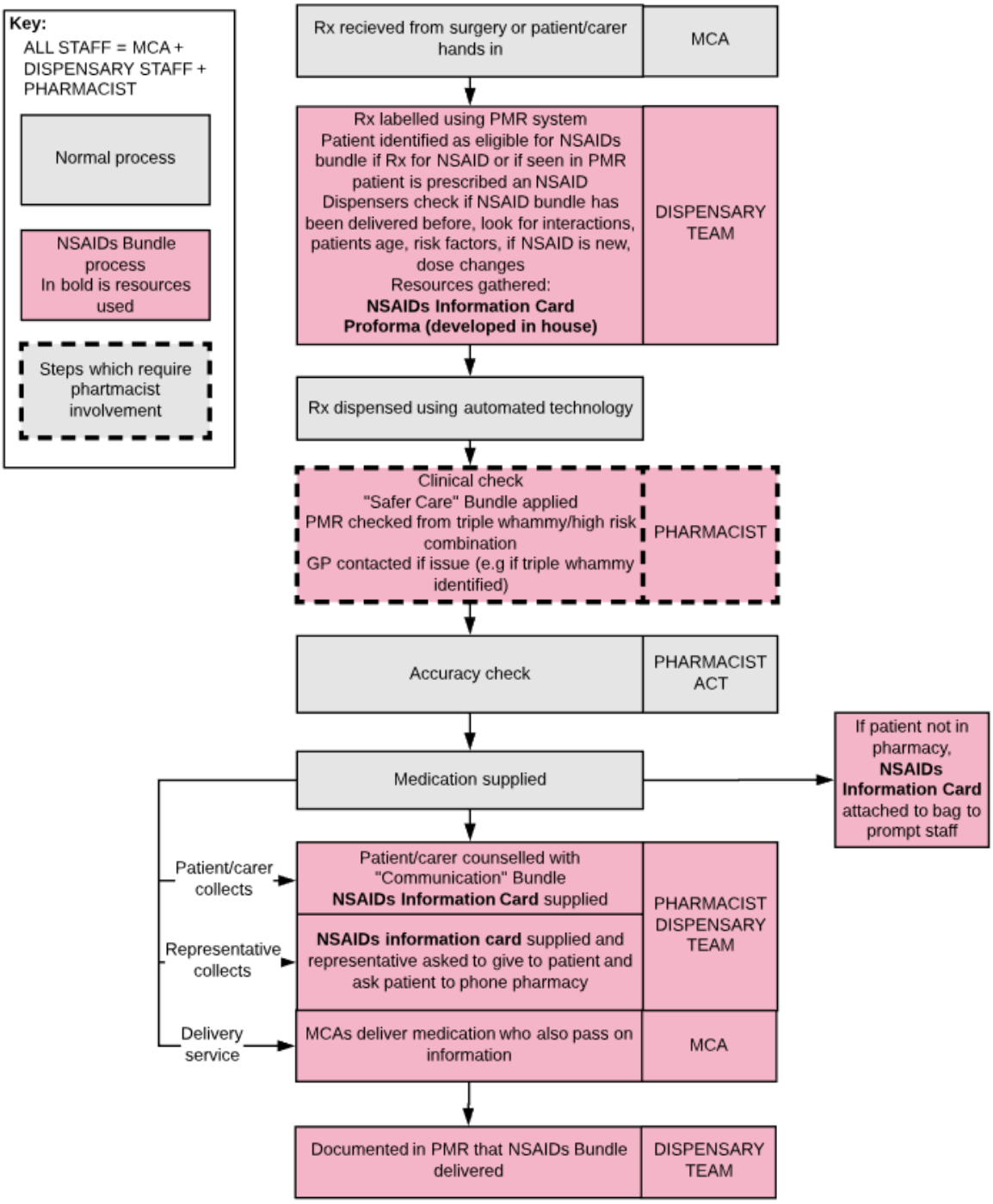


Figure 8.4. Detailed process map for Pharmacy 1

MCA = medicine counter assistant, NSAID(s) = non-steroidal anti-inflammatory drug(s), PMR = patient medication record, GP = general practitioner, ACT = accuracy checking technician

Visual analysis of the process maps developed for each pharmacy (n=8) from the on-site visits identified four key process steps for both the warfarin and NSAIDs care bundle. These four key process steps were undertaken every time when delivering the care bundles to patients. These included: patient identification, clinical assessment, care bundle prompt, and care bundle delivery, which happened in this sequential order. A description of these key process steps based on the visual analysis of the process maps is presented in Table 8.5 for the NSAIDs and warfarin care bundles.

Table 8.5. Description of key process steps for the NSAIDs and warfarin care bundles

Key process steps	NSAIDs care bundle	Warfarin care bundle
1. Patient identification	Identifying if patient is eligible to receive the care bundle.	Identifying if patient is eligible to receive the care bundle.
2. Clinical assessment	Application of the "Safer Care" Bundle by pharmacist during clinical check of the prescription. The patient medication record (PMR) may be reviewed, the GP contacted, or the patient spoken with. The dispensary staff may also have reviewed patient's PMR for information and communicated this to pharmacist. For the NSAIDs bundle, GP referral occurred if interactions were identified or to discuss the appropriateness of an NSAID for particular patients.	This may include reviewing the patients' warfarin yellow book, speaking to the patient, or assessing the PMR for interactions or changes in the patients' medication. GP referral occurred if the pharmacy had to query something with the prescription, such as if an antibiotic was concomitantly prescribed for a patient on warfarin.
3. Care bundle prompt	Eligible patients are flagged that they are to be delivered the NSAIDs care bundle using resources assembled with the prescription bag (e.g. alert stickers).	Eligible patients are flagged that they are to be delivered the warfarin care bundle using resources assembled with the prescription bag (e.g. alert stickers).
4. Care bundle delivery	If the patient/carer is in pharmacy: • The NSAIDs Communication Care Bundle questions are asked to the patient/carer.	If the patient/carer is in pharmacy: • The warfarin care bundle questions are asked to the patient/carer.
	If representative is in pharmacy: • The representative may be asked to have patient phone the pharmacy or to inform the patient/carer that the pharmacy would like to speak to them. • A label may be attached to the prescription bag asking the patient/carer to phone the pharmacy.	If representative is in pharmacy: • The warfarin bundle questions may be asked to the representative • Alternative, the patient may be spoken to on the phone, or spoken to when they come in.
	If a care home patient: • The NSAIDs Communication Care Bundle questions are asked to the patients' carer over the phone.	If a care home patient: • The warfarin care bundle questions are asked to the patients' carer in person or over the phone,
	If delivery patient: • The NSAIDs Communication Care Bundle questions will be asked in person by the pharmacy staff member who delivers the medication to the patient, or over the phone.	If delivery patient: • The warfarin bundle questions are asked to the patient/carer over the phone before the medication is delivered.
	Patient resources may also be supplied.	Patient resources may also be supplied.

NSAIDs = non-steroidal anti-inflammatory drugs, GP = general practitioner

8.5.3.2 Integration of key process steps within dispensing process

The integration of the four key process steps within the pharmacy dispensing process is presented in Figure 8.5, which identified that this is the same for both the NSAIDs and warfarin care bundles. For Pharmacy 8 which adopted the spoke-and-hub dispensing model, the dispensing phase for repeat GP prescriptions occurred off-site at a dispensing support pharmacy, which did not appear to impact the care bundle's process.

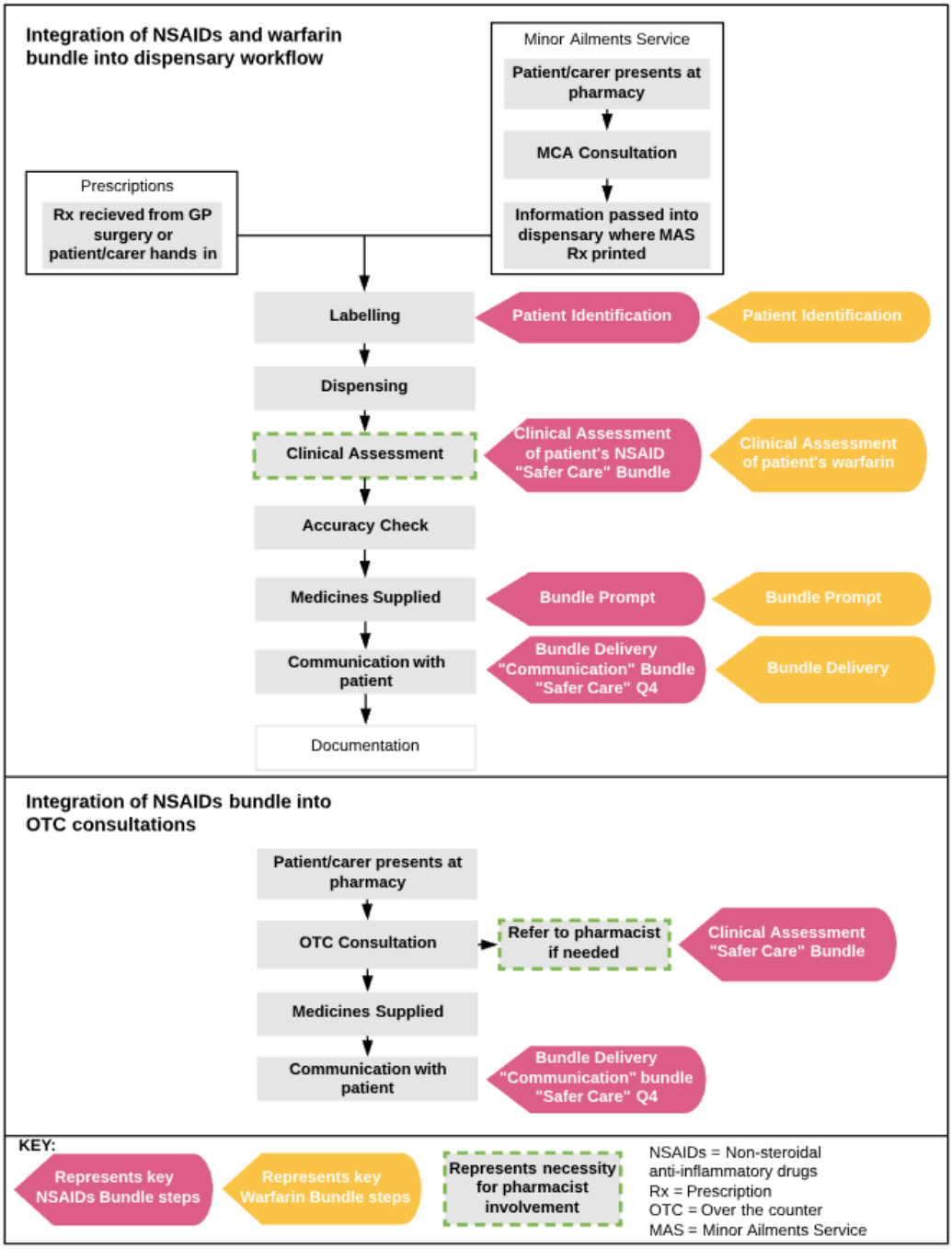


Figure 8.5. Process map of the care bundle's penetration in routine practice

NSAIDs = non-steroidal anti-inflammatory drugs, GP = general practitioner

8.5.3.3 Resources used when delivering the care bundles

The resources used when delivering the warfarin and NSAIDs care bundles are presented in Table 8.6, including resources purposefully developed for the care bundles and those which were either developed in house or obtained elsewhere. The most common resources used were the NSAIDs Safety Information card and the Warfarin flyers. The questionnaire data identified that some pharmacies used the NSAIDs alert stickers (70%) and the warfarin alert stickers developed (42.9%). However, all of the NSAIDs on-site visit pharmacies (n=4, 100%) used alternative alert tools, and all of the warfarin on-site visit pharmacies used alternative alert tools (n=4, 100%) with only one (25%) also using the warfarin alert sticker developed.

Table 8.6. Resources used when delivering the care bundles (data from questionnaire and on-site visits)

Resources used	**Questionnaire data (Jun – Aug 2017)** % (n pharmacies)	**On-site visits data (Oct – Nov 2017)** % (n pharmacies)
NSAIDs care bundle		
NSAIDs Safety Information card	100.0 (n=10)	100.0 (n=4)
Medicines Sick Day Rules card	100.0 (n=10)	0.0 (n=0)
Alert tools		
NSAIDs alert sticker	70.0 (n=7)	0.0 (n=0)
Speak/refer to pharmacist stickers	0.0 (n=0)	75.0 (n=3)
NSAIDs Safety Information card	0.0 (n=0)	25.0 (n=1)
Other resources		
NHS information leaflet on AKI	0.0 (n=0)	25.0 (n=1)
NSAIDs care bundle "proforma"	0.0 (n=0)	50.0 (n=2)
Warfarin care bundle		
Warfarin flyers	100.0 (n=7)	75.0 (n=3)
Warfarin counselling tool	85.7 (n=6)	0.0 (n=0)
Warfarin YouTube video	28.6 (n=2)	0.0 (n=0)
Alert tools		
Warfarin alert sticker	42.9 (n=3)	25.0 (n=1)
"Alert sheet"	14.3 (n=1)	0.0 (n=0)
Stickers developed for pharmacy chain	14.3 (n=1)	0.0 (n=0)
High Risk Medicine Intervention stickers	0.0 (n=0)	25.0 (n=1)
SPSP sticker	0.0 (n=0)	25.0 (n=1)
Refer to pharmacist sticker	0.0 (n=0)	25.0 (n=1)
Warfarin laminate	0.0 (n=0)	25.0 (n=1)

NSAIDs = non-steroidal anti-inflammatory drugs, NHS = National Health Service, AKI = acute kidney injury, SPSP = Scottish Patient Safety Programme

8.5.4 Penetration in relation to extent of pharmacy staff involvement with the care bundles

For both the warfarin and NSAIDs care bundles, the data from the questionnaire revealed that there was evidence of both pharmacists and support staff being involved with all parts of the care bundle, as presented in Tables 8.7 and 8.8. The on-site visits confirmed that the only step which necessitated a pharmacist's involvement was the clinical assessment step, as is presented in Figure 8.5. Seven community pharmacy support staff participants (9.5%) responded that they had no involvement with the warfarin care bundle.

Table 8.7. Involvement of pharmacy staff with the NSAIDs care bundle key process steps (n=45)

NSAIDs care bundle key process steps	Pharmacists (n=9)	Technicians (n=9)	Dispensers (n=12)	Medicines counter assistants (n=12)	Pre-registration pharmacists/ students (n=3)
Key process step 1: Patient identification	✔	66%	67%	50%	✔
Key process step 2: Clinical assessment	✔	22%	17%	✖	33%
Key process step 3: Care bundle prompt	88%	66%	58%	17%	✔
Key process step 4: Care bundle delivery					
Delivering the NSAIDs care bundle to patients who are prescribed an NSAIDS	✔	44%	42%	50%	66%
Delivering the NSAIDs care bundle to patients who buy an NSAID over-the-counter	88%	55%	67%	92%	50%
Delivering the NSAIDs care bundle to patients who are supplied an NSAID on the Minor Ailments Service	✔	55%	58%	50%	50%
Planning appropriate delivery of the bundle to patients who reside in care homes or get their medication delivered	66%	✖	25%	8%	33%
Planning appropriate delivery of the bundle to patients who have a representative collecting the prescription for them	88%	22%	33%	✖	66%

A green tick (✔) indicates where all participants of this job role stated they had involvement with a process. An amber percentage indicates that some participants of this job role (i.e. at least one but not all) stated they had involvement with a process. A red cross (✖) indicates that no participants of this job role stated they had involvement with a process. Participants who were not included in this analysis included a dispenser/dispensing assistant who did not respond to this part of the questionnaire, and one participant who did not disclose job role.
NSAIDs = non-steroidal anti-inflammatory drugs

Table 8.8. Involvement of pharmacy staff with the warfarin bundle key process steps (n=25)

Warfarin care bundle key process steps	Pharmacist (n=9)	Technicians (n=1)	Dispensers (n=13)	Medicines counter assistants (n=1)
Key process step 1: Patient identification	✔	✔	69%	×
Key process step 2: Clinical assessment	88%	×	9%	×
Key process step 3: Care bundle prompt	88%	✔	62%	×
Key process step 4: Care bundle delivery				
Delivering the warfarin care bundle to patients	88%	×	54%	×
Planning appropriate delivery of the care bundle to patients who reside in care homes or get their medication delivered.	66%	×	15%	×
Planning appropriate delivery of the care bundle to patients who have a representative collecting the prescription for them	88%	×	38%	×

A green tick (✔) indicates where all participants of this job role stated they had involvement with a process. An amber percentage indicates that some participants of this job role (i.e. at least one but not all) stated they had involvement with a process. A red cross (×) indicates that no participants of this job role stated they had involvement with a process. Participants who were not included in this analysis included a dispenser/dispensing assistant did not respond to this part of the questionnaire, and one participant who did not disclose job role.

As presented in Tables 8.7 and 8.8, there was evidence of other pharmacy support staff being involved in clinically assessing patients NSAIDs and warfarin medication (key process step 2), this did not replace the pharmacist's clinical assessment and was additional. During the on-sites visits, this was corroborated for the NSAIDs care bundle:

> *"all approved dispensers and technicians are trained, they can identify all the different types of NSAIDs, so they have that knowledge already, so when they're dispensing a prescription they're also quite good, going to be looking for other drugs that might interfere, patients age, they're looking for all the different risk factors"*
>
> *– Pharmacy 1 (NSAIDs)*

The questionnaire responses provided evidence of whole team involvement when delivering the warfarin and NSAIDs care bundles and speaking with patients (key process step 4). The on-site visits also corroborated that there was whole team involvement with this step, however it was identified that for some pharmacies there was a tendency for pharmacists to do this step. In some instances this was just the "way it worked out" (Pharmacy 2, NSAIDs),

however other pharmacies did this purposefully. One reason was to ensure the best advice was being offered to patients:

> *"often it would be [the pharmacist] because we tend to try and have the pharmacist at the front, you know so that the patients feel that they're getting the best advice" (Pharmacy 8, NSAIDs).*

Another reason reported by Pharmacy 4 for preferring the pharmacist delivering the care bundle was to prevent support staff leaving the pharmacist themselves within the dispensary: *"if I pulled [the support staff] away that means I'm labelling and dispensing and checking"* (Pharmacy 4, warfarin).

8.6 Discussion

This study explored the implementation of the NSAIDs and warfarin care bundles with respect to their fidelity and penetration when introduced within routine community pharmacy practice. On-site visits and a postal questionnaire were conducted to explore the fidelity of the care bundles, if and how they penetration within community pharmacy practice, and the extent of pharmacy team involvement. This study identified instances where the care bundles were not delivered as intended, such as not all care bundle questions being delivered to patients. Transient lapses in fidelity were also identified, and were based on pharmacists' judgment, patients' preferences, and time pressures. A critical finding of this study was that the same approach for incorporating both the NSAIDs and warfarin care bundles within the dispensing process was identified, with scope for whole team involvement evidenced as only one step in the process necessitated a pharmacist's involvement - the clinical assessment step. However, there was a tendency within some pharmacies for the responsibility of delivering the care bundle and speaking with patients to lie with the pharmacist.

8.6.1 Fidelity

Persistent lapses in implementation fidelity were assessed during the on-site visits by exploring adherence to the bundles' core components. Instances where the care bundle questions were not all delivered were identified, yet the pharmacists justified the deviations from their intended design. For example, one pharmacy chose not to deliver the warfarin bundle to their care home patients due to medical staff input within the care home. For the

pharmacies involved in the NSAIDs bundle, some pharmacies did not verbally deliver the NSAIDs care bundle question which related to stopping an NSAID during a dehydrating illness, yet acknowledged that this information was available within the NSAIDs Safety Information Card supplied. More commonly, lapses in fidelity occurred in relation to the repeated delivery of the care bundle. Only two of the eight pharmacies visited reported that they repeatedly delivered the full care bundle to patients, and five pharmacies reported that they would deliver a condensed version when repeating the care bundle to patients. One pharmacy involved in the NSAIDs care bundle did not repeatedly deliver the NSAIDs care bundle at all, which could negatively impact intended outcomes as evidence suggests that repeated delivery of instructions to patients may translate to better health related outcomes [307].

For both the care bundles, transient lapses in care bundle delivery were also identified, and were due to the pharmacists' judgement, the patients' preferences, and time constraints. These three determinants' of fidelity have all be previously recognised [308], and have been identified for other primary care innovations [309]. Evaluating the implementation of brief cognitive behavioural therapy in medical centres identified that adaptations occurred due to the providers' judgement, patient-emergent issues, and resource constraints [309].

In light of the identified persistent and transient lapses in fidelity of the care bundles' core components, it would be considered that these would compromise the potential impact of the care bundles as they are not being delivered to every patient, every time in the way intended [301]. As of yet, the impact these deviations have on intended outcomes is unknown. However, the pharmacists could justify reasons for these deviations, and modifying the care bundle's delivery based on patient preference or pharmacist judgement may be beneficial as a tailored service deemed most suitable to specific patients is being offered. Chambers et al (2013) also argues that modifying innovations could actually *improve* clinical outcomes as it facilitates their institutionalisation and sustainment in practice [301]. In essence, it is better to have a modified innovation sustained, rather than the innovation not existing in practice at all. In conclusion, although instances of the pharmacies deviating from intended care bundle design were identified, this may not necessarily have compromised the bundles' intended outcomes. Overall, this suggests that the core components of the care bundles require further refinement to be appropriate in community pharmacy practice. In response to the findings of this study, modifications that could be made to the core components of the care bundles are:

- Permitting delivery of a condensed version of the warfarin and NSAIDs care bundle information when repeating it to patients
- Delivering the NSAIDs Communication Care bundle question which advises patients to stop taking their NSAID during periods of dehydrating illness only to patients taking an NSAID regularly
- Considering whether delivery of the warfarin care bundle is necessary for patients who reside in care homes which have medical staff input daily

8.6.2 Penetration

Two facets of penetration were explored in this study: the integration of the care bundles within the pharmacy setting including the resources used, and the extent of whole team involvement. With regards to the integration of the care bundles, it was identified from the on-site visits that both care bundles had the same four key process steps that integrated within the dispensing process similarly (Figure 8.5). This was despite heterogeneity of the sites as the pharmacies sampled included an independent pharmacy, single chain pharmacies and multiples, and some pharmacies also used more innovative approaches to the dispensing process (i.e. automated technology and spoke and hub dispensing). This evidences that the bundles can integrate within these newer community pharmacy workflow models. Furthermore, as the care bundles integrated within the dispensing process at various different points, as opposed to being added on at the end [296], this may suggest they have truly institutionalised within these pharmacies and may be more likely to be sustained [296].

As a process map of the NSAIDs and warfarin care bundles' integration could be developed, this suggests adaptability of the process to varying clinical content. Therefore, it is plausible that if the care bundles become nationally implemented, the content of the care bundle can be adapted in light of emerging safety concerns without affecting their compatibility with the pharmacy dispensing process. This could offer a promising platform for seamless translation of evidence into practice. For example, the care bundle questions could be modified or changed entirely to focus on a different high risk medicine of interest.

Within the pharmacies, there was on-going and almost universal use of only two of the supportive resources designed for the care bundles: the NSAIDs Information Card and the warfarin flyers, as identified by the on-site visits and questionnaires (see Table 8.6). All

pharmacies used an alert sticker of some form to prompt care bundle delivery, yet not all used the NSAIDs or warfarin stickers purposefully developed for the care bundles. It should be noted that some of the alternative alert stickers used by the pharmacies specified for a referral to a pharmacist (i.e. 'refer to pharmacist' stickers). The use of alert stickers like this may hinder whole team involvement when delivering the bundle to patients, and the NSAIDs and warfarin alert sticker may be preferable as they do not state that a pharmacist's input is needed. Therefore, when considering the scale up of the bundles, the resources that could be of most value to the national community pharmacy cohort include the NSAIDs Information Card and the NSAIDs sticker for the NSAIDs bundle, and the warfarin flyers and the warfarin sticker for the warfarin care bundle.

The second facet of penetration explored was the involvement of the various community pharmacy staff. We found evidence of community pharmacy support staff being involved in all aspects of the care bundles' delivery, however there appeared to be greater whole team involvement with the NSAIDs bundle than with the warfarin bundle (Tables 8.7 and 8.8). This may be explained by the accessibility of NSAIDs over the counter and via minor ailments supplies, thus community pharmacy support staff may have greater opportunity to be involved with the NSAIDs care bundle and be more familiar with this medicine.

An unexpected finding of this study was the evidence of pharmacy support staff being involved in assessing the high risk medicines clinically (key process step 2), which included identifying risk factors for patients taking an NSAID (see Table 8.5). Although this did not replace the pharmacist's clinical assessment, this suggests that within the Scottish community pharmacy context the roles of support staff are more evolved than in other countries. Gernant et al (2017) reviewed the international literature published up until August 2016 on the involvement of pharmacy technicians in clinical innovations [310]. This review found evidence of technicians only being involved with clinically reviewing medication and offering education to patients within specialised centres, such as pre-operation wards and poison control centres [310].

Within this study, it was identified that there was a tendency for the pharmacist rather than support staff to be involved in delivering the care bundles to patients (i.e. speaking with patients). Therefore, although we found promising evidence of task delegation, there may be scope for improvement. In this study, some pharmacists justified the preference for a pharmacist to do this key process step. One reported that the pharmacist was able to offer

better advice compared with pharmacy support staff, and another stated that having support staff leave the dispensary and speak to patients would leave the pharmacist having to label and dispense prescriptions. This is not wholly consistent with the wider literature, as previously identified barriers to task delegation in pharmacies include mixed views over the reconfiguration of the skill mix and concerns over accountably [299, 300, 311], which was not identified in this study.

When evaluating clinical community pharmacy services in the US, Chui et al identified that to support whole team involvement pharmacies must actively consider how support staff can be involved [298], and suggests that pharmacies should match the skillset of individual staff to specific tasks [296]. Therefore, to support whole team involvement if the bundles are nationally implemented in Scotland, the implementation strategy may benefit from actively encouraging the community pharmacists to consider how whole team involvement could be realised within their specific pharmacy. As Chui et al found that technicians' adoption of new skills and responsibilities improves their job satisfaction [296], the benefits of this may transcend further than improved implementation of the warfarin and NSAIDs care bundles.

8.6.3 Strengths and limitations

A strength of this study was the use of mixed methods. The amalgamation of both qualitative and quantitative methods, as captured from the on-site visits and the questionnaire, allowed for explanation of some of the data emergent from the questionnaire. For example, the questionnaire identified non-pharmacists to be involved in the clinical assessment of the high risk medicines - an unexpected finding - which was corroborated and explored in more detail during the on-site visits.

The use of on-site visits and the walk-through task-analysis technique to explore fidelity and penetration offered an advantage over traditional qualitative interviews as it facilitated better understanding of how the care bundles are operationalised, and allowed for the resources used in the pharmacy to act as material probes [304]. Ideally, participation of the whole pharmacy team with the walk-through would have been desirable, but previous evaluation activities indicated this to be difficult within a community pharmacy setting due to the necessity for the service to operate [39]. An alternative task analysis technique which could have been applied is the think aloud protocol which involves a participant undergoing concurrent verbalisation of whatever crosses their mind whilst performing a specific task.

However, this was purposefully not used as it focuses on the cognitive process of specific individuals and therefore would not offer useful understanding of the pharmacies process at a system level. The think aloud protocol also requires real time analysis whilst the task is happening in practice, which means the researcher would be required to wait in a pharmacy until an eligible patient presents which could be disruptive.

The use of a questionnaire to explore penetration allowed for greater generalisability of data pertaining to whole team involvement and the use of resources than possible if only on-site visits occurred. The strengths and limitations specific to this questionnaire are discussed in more detail in Chapter 6, Section 6.7.2, and its key limitation is that only 17 of the 24 (70.8%) pharmacies responded to the questionnaire. This is particularly an issue for the pharmacies within NHS Highland as no questionnaire responses were obtained from this region. The questionnaire also explored only two facets of penetration – whole team involvement and the resources used, which was purposeful to keep the questionnaire to a manageable length. The author of this thesis was also sceptical if fidelity and integration into practice could appropriately be explored using a questionnaire, and no previous studies were identified as doing so.

A strength of this study is that lapses in implementation fidelity have been transparently described, which overcomes identified limitations of other studies which offer no description of what adaptations have been made [311]. Deciphering between persistent and transient lapses in fidelity is novel to this study. Future studies may benefit from adopting this categorisation approach, especially if assessments are to be made on the impact of lapses in fidelity on intended outcomes, as persistent and transient lapses in fidelity may impact intended outcomes to differing degrees. However, it is unknown how valid the implementation fidelity data obtained in this study is, particularly considering the limitations of self-reported data and the inherent risk of social desirability bias.

There are two important aspects that were out with the scope of this study. Firstly, an aspect of fidelity which was not explored was duration, i.e. the continued delivery of the care bundles [103]. As the on-site visits and the questionnaire each occurred at only one time point we cannot comment on how implementation fidelity or penetration may have changed over time, a notable limitation as ongoing change is expected within healthcare settings [301]. Secondly, and most importantly, it is unknown what impact the identified lapses in

fidelity of the care bundles may have on the intended clinical outcomes, which is consistent with the limitations of similar studies [296].

8.6.4 Future directions and recommendations

In the absence of attributable outcome data, it is difficult to ascertain what impact deviations in intended delivery of the care bundles will have. Patients' preferences, patients' needs, and pharmacists' judgments were used to adapt and tailor care bundle delivery, therefore mandating that the care bundle always be delivered in the same way may de-personalise the innovation and impact patients' satisfaction with it. Rather, modification of the core components of the care bundles may be necessary to ensure their appropriateness in community pharmacy practice. Exploration of patients' experience and perceptions of the care bundles may help shape recommendations in relation to this. This is of particular interest considering that the pharmacy in NHS Highland did not continue to deliver the care bundle due to perceived lack of patient demand.

This study highlights that the consolidated warfarin and NSAID care bundles penetrated into routine community pharmacy which supports the argument for scaling them up throughout Scotland. The scope for whole team involvement was a positive finding and promoting this within the wider Scottish community pharmacy context could involve encouraging pharmacies to consider within their specific pharmacy how task delegation could take place, particularly by matching the skillset of individuals to the care bundles' key process steps [296].

There are two potential uses of the process map developed of the care bundles' penetration into community pharmacy practice (Figure 8.5). Firstly, it will allow strategists to better understand the front-line processes and thus could facilitate strategic decision making when considering the scale up of the care bundles. Secondly, it could be disseminated to pharmacies as a tool to facilitate the care bundles' implementation, as the use of process maps in community pharmacy has been suggested to improve efficiency, identify support staff roles, and ensure higher skilled staff perform tasks only themselves can do [39, 210]. The process map could also offer an evidence based guide of how the bundles could penetrate within different pharmacies which may facilitate whole team engagement as it distinctly presents where there is and isn't a need for a pharmacist's input.

In response to this study, recommendations have been developed for the national implementation of the care bundles building upon the recommendations posed following the success factors identified (see Chapter 7, Section 7.6.5). These are presented in Table 8.9 where individual implementation interventions have been categorised as per the ERIC taxonomy [295]. This taxonomy developed has been previously described in Chapter 2 (Section 2.3.3) with the full taxonomy presented in Appendix 2.2.

Table 8.9. Recommendations for the national implementation of the care bundles in response to the fidelity and penetration evaluation

Identified issue	Proposed ERIC implementation interventions	Contextualised recommendation
Recommendations based on penetration analysis:		
Scope for improved whole team involvement	Capture and share local knowledge	Disseminate the process map developed to pharmacies
	Facilitation	Promote pharmacy teams' in house interactive problem solving to consider how the skillset of pharmacy staff can be matched to the care bundles' key process steps.
Recommendations based on fidelity analysis:		
Scope for improvement in implementation fidelity	Promote adaptability	The care bundles' core components require refinement to be appropriate in community pharmacy practice. Modifications that could be made to the care bundles are: • Delivering the NSAIDs care bundle question which advised patients to stop taking their NSAID during periods of dehydrating illness only to patients taking an NSAID regularly • Permitting a delivery of a condensed version of the warfarin and NSAIDs care bundle information when repeating it to patients • Considering whether delivery of the warfarin care bundle is necessary for patients who reside in care homes which have medical staff input daily

ERIC = Expert Recommendations for Implementing Change, NSAID(s) = non-steroidal anti-inflammatory drug(s)

8.7 Conclusion

This study identified that the care bundles can be integrated within routine practice, yet they are not always delivered as intended due to patients' preferences, pharmacists' judgement,

and time pressures. Suggested modification of the care bundle delivery have been posed, including permitting condensed versions of the care bundle to be repeatedly delivered to patients as opposed to the full care bundle. A positive finding of this study was the similarity in the way the NSAIDs and warfarin care bundles were incorporated into practice despite heterogeneous characteristics of the pharmacies and their adoption of novel workflow solutions (e.g. automated dispensing technology). This suggests they could successfully penetrate within the national community pharmacy context and be adapted in the future in light of new emerging safety concerns. Whole team involvement with the process was evidenced as only one step in the process necessitated a pharmacist's involvement, yet there is scope for improvement as there was a tendency for the pharmacists to deliver the care bundle questions to patients. Exploring fidelity and penetration has allowed the development of key recommendation for scale up, including disseminating the process map to pharmacies and providing examples of whole team involvement from the pilot pharmacies. Exploring patient perceptions may also help shape recommendations regarding the delivery of the care bundle to patients, which will be explored in Chapter 9.

Chapter 9: Patient perceptions of the consolidated warfarin and NSAIDs care bundles

9.1 Summary of chapter

Background

Exploring patient perceptions of healthcare offers insight into the quality and benefit of care received. The aim of this study is to explore patient perceptions of the consolidated warfarin and NSAIDs care bundles during their pilot phase.

Methods

During April - June 2018, nine pharmacies recruited patients who received the warfarin or NSAIDs care bundle. Telephone interviews were conducted involving a semi-structured interview schedule and a closed-ended questionnaire. The interview data was structured using the framework method and interpreted by content or thematic analysis. The questionnaire data were described using medians, inter-quartile ranges and percentages.

Results

Nineteen participants were included in the study: eight warfarin care bundle participants, and 11 NSAIDs care bundle participants. The NSAIDs care bundle was reportedly delivered in greater depth than the warfarin care bundle. Participants were satisfied with the NSAIDs care bundle, yet the necessity of a warfarin care bundle was queried. There was evidence of positive impact of the NSAIDs care bundle, however a minority reported unintended consequences such as reluctance to take their NSAID. An emergent theme was the role of pharmacy within the wider healthcare system, as was the role of media and family members as sources of information about patients' medication.

Conclusion

The value associated with the NSAIDs care bundle supports its intended national implementation, yet the same cannot be assured for the warfarin care bundle and further exploratory work is necessary. During scale up, ongoing monitoring of patient perceptions is advocated to monitor impact, particularly any unintended consequences.

9.2 Background

The evaluation of the consolidated NSAIDs and warfarin care bundle has thus far focused on their implementation from the perspectives of the community pharmacy staff. This has largely been informed by a taxonomy of implementation outcomes developed by Proctor et al (2011) [70], where penetration and fidelity have been explored. This taxonomy also acknowledges the importance of exploring 'client outcomes' in order to explore the potential impact of innovations, such as symptomology and satisfaction [70]. Exploring these outcomes of healthcare innovations offers insight into the quality and benefit of care received [312, 313], and is strongly advocated by the Scottish Government [9] and internationally [314]. Additionally, the community pharmacy setting is an area where it is increasingly important to explore client outcomes due to their adoption of novel, patient-facing innovations [315], such as the NSAIDs and warfarin care bundles.

Within this study, client outcomes were to be explored via patient-reported perceptions of the care they have received. Within the pharmacy context, two important facets of patient perceptions of innovations exist: patient-reported satisfaction and patient-reported impact [312, 316]. Studies exploring patient perceptions of community pharmacy innovations tend to focus on satisfaction [317], with patient-reported impact of community pharmacy innovations less emergent within the literature [318]. There is a positive association between patient satisfaction with healthcare innovations and attainment of positive outcomes [319, 320]; however, the magnitude of this association is not strong enough to suggest that only one of these facets need explored [320]. Instead, it is advocated that both patient satisfaction and impact are explored for best insight of the quality and benefit of healthcare [320].

In relation to patient satisfaction, patients tend to report being satisfied with community pharmacy innovations [207, 221, 318, 321]. However, studies exploring patient satisfaction within the pharmacy context have been criticised for poorly understanding and defining the concept of patient satisfaction [221]. In response to this criticism, van der Berg (2014) conceptualised patient satisfaction with UK community pharmacy medication reviews through observations and patient interviews [322]. Following on from this empirical work, Hindi et al in 2017 developed a validated questionnaire of this, and through exploratory factor analysis identified two unique patient satisfaction concepts for community pharmacy medication reviews: 'experiencing the service' and 'judging the service' [323]. As medication reviews can be considered conceptually similar to the high risk medicine care bundles, this

conceptualisation of patient satisfaction could be extended to explore patient satisfaction with the warfarin and NSAIDs care bundles.

In relation to patient-reported impact of community pharmacy innovations, although there are many studies exploring clinical outcomes of community pharmacy innovations using objective measures, such as improvements in blood pressure or cholesterol levels [324], there are notably less exploring impact as reported by patients themselves [324]. A review of patient perceptions to UK community pharmacy innovations published in 2018 confirmed that exploring patient-reported impact is an under-researched area within the UK community pharmacy setting [318]. Where patient-reported impact of community pharmacy innovations have been identified within the literature, this has included patients reporting improved awareness, knowledge and understanding of medicines [325, 326]; behaviour changes due to following the pharmacy's advice [327]; or pharmacy innovations resulting in a diagnosis of a healthcare condition following referral [328]. These findings suggest that community pharmacy innovations have potential to exert positive outcomes on patients. However, no studies have been identified which explored patient-reported impact of community pharmacy innovations which were similar to the warfarin and NSAIDs care bundles [318]. Due to the lack of research within this area, further exploratory work is needed to identify what impact the warfarin and NSAIDs care bundle have, if any, on patient-reported impact.

9.3 Aim and objectives

The aim of this study was to elicit patient perceptions of the warfarin and NSAIDs care bundles with the following objectives:

1. Seek patients' self-reported experience of receiving the care bundles
2. Explore patient satisfaction with the care bundles
3. Identify patient-reported impact of the care bundles.

9.4 Methods

9.4.1 Study design

A mixed method approach was selected for this study using a semi-structured interview schedule and a questionnaire. The questionnaire elicited patient satisfaction with the care bundles, building upon the work of Hindi et al [323]. The semi-structured interviews

complemented the questionnaire by seeking elaboration of the patient satisfaction constructs covered within the questionnaire and exploring further constructs of interest such as patient-reported experience of the care bundle and its impact [329, 330]. Telephone calls were conducted for the semi-structured interview and the questionnaire, where the questionnaire items were verbally administered. Ethical approval was granted for this study by the Strathclyde Institute of Pharmacy and Biomedical Science Ethics Committee in March 2018.

9.4.2 Development of data collection tools

9.4.2.1 Questionnaire

A validated questionnaire developed by Hindi et al in 2016 was adapted for use in this study [323]. Hindi et al's questionnaire was designed to measure patient satisfaction with community pharmacy Medicine Use Reviews (MURs) within NHS England by exploring patients' experience of the service and their judgment of it [323]. MURs involve a pharmacist addressing patient concerns and questions, and were considered conceptually similar to the NSAIDs and warfarin care bundles. Thus, it was deemed that Hindi et al's questionnaire items could be applicable to evaluate the care bundles. Furthermore, the principal investigator of Hindi et al's study was contacted who stated that they believed the questionnaire would be valid for other community pharmacy innovations, and that their research team were in the process of adapting it to evaluate other NHS England services [331].

For this study, the specific wording of Hindi et al's questionnaire was adapted to ensure its applicability for the warfarin and NSAIDs care bundles, as detailed in Figure 9.1. These were minimal and were discussed with the principal investigator of Hindi et al's study, who stated they felt these adaptions would not impact the validity of the questionnaire [331]. Therefore, further validation of the questionnaire for this study was not conducted.

Original questionnaire items	**Adapted questionnaire items for this study**
I am satisfied with the pharmacist's explanation of the aims of the MUR service to me	I am satisfied with the pharmacy staff member's explanation of the aims of the warfarin/NSAIDs service to me
I am satisfied with the privacy and comfort of the consultation room	I am satisfied with the privacy of where the discussion took place
I am satisfied with the time the pharmacist spent listening to me	I am satisfied with the time the pharmacy staff member spent listening to me

I am satisfied with the pharmacist's personal approach towards me	I am satisfied with the pharmacy staff member's personal approach towards me
I am satisfied with the opportunity I had to raise questions or concerns	I am satisfied with the opportunity I had to raise queries
I am satisfied with the pharmacist's advice and recommendations	I am satisfied with the pharmacy staff member's advice
I wanted to have an MUR consultation	I wanted to have a discussion about my warfarin/NSAIDs medication
The pharmacist answered my questions or concerns	The pharmacy staff member answered my queries
I now feel more confident about managing my condition	I now feel more confident about managing my warfarin/NSAIDs medication
I would use the MUR service again in the future	I would be happy to have a discussion about my warfarin/NSAIDs medication again in the future
I would recommend the MUR service to others	I would recommend the warfarin/NSAIDs service to others
I was satisfied with the MUR service I took part in	I was satisfied with the warfarin/NSAIDs service I took part in

Figure 9.1. Adaptation of Hindi et al's patient satisfaction questionnaire for this study

The final questionnaire items applied in this study are presented in Figure 9.2. The questionnaire comprised twelve positively worded statements with a 5-point Likert scale of strongly agree, agree, neither agree or disagree, disagree, or strongly disagree, as per the original questionnaire design. Other community pharmacy patient satisfaction questionnaires identified within the literature were purposefully not used as they hadn't undergone validity testing [332-335], they evaluated patient perceptions of an innovation dissimilar to the care bundles [336], or were developed in contextually different healthcare settings such as the US [337, 338].

Questionnaire items
Experience of the service
I am satisfied with the pharmacy staff member's explanation of the aims of the warfarin/NSAIDs service to me
I am satisfied with the privacy of where the discussion took place
I am satisfied with the time the pharmacy staff member spent listening to me
I am satisfied with the pharmacy staff member's personal approach towards me
I am satisfied with the opportunity I had to raise queries
I am satisfied with the pharmacy staff member's advice
The pharmacy staff member answered my queries
Judgement of the service
I wanted to have a discussion about my warfarin/NSAID medication
I now feel more confident about managing my warfarin/NSAID medication
I would be happy to have a discussion about my warfarin/NSAID medication again in the future
I would recommend the warfarin/NSAIDs service to others
I was satisfied with the NSAIDs service I took part in

Figure 9.2. Patient satisfaction questionnaire as adapted from Hindi et al's study [323].

NSAIDs – non-steroidal anti-inflammatory drugs

9.4.2.2 Semi-structured interviews

The semi-structured interview schedule was developed to act complementary to the patient satisfaction questionnaire by seeking elaboration of the experience and judgment constructs covered within the questionnaire. The semi-structured interview schedule also extended the range of inquiry by exploring further constructs of interest identified within the literature, including patient-reported impact [207, 318]. Participants were also asked to describe what happened when the pharmacy staff member spoke to them about their NSAIDs or warfarin medication. An overview of the constructs covered within the semi-structured interview is provided in Figure 9.3 below.

- Judgment of the care bundle (e.g. willingness to be involved, expectations, opinions, positive and negative aspects)
- Patient-reported experience of the care bundle (e.g. what did pharmacy staff do, were any resources provided, how long it took)
- Patient-reported impact (e.g. new information acquired, change to confidence or concerns, changes in medication taking behaviour)
- Awareness of the care bundle
- Suggestions to improve the care bundles

Figure 9.3. Overview of areas covered within the semi-structured interview schedule

The interview schedule for participants who had experienced the NSAIDs and warfarin care bundle interviews included the same areas yet the prompts differed slightly. During early data collection stages, two participants could not recall receiving a care bundle so a further question was included within the interview schedule which asked if participants had received the care bundle.[10] If interview participants did not recall receiving the care bundle they were asked the questions hypothetically to elicit their opinions. The full interview schedule is presented in Appendix 9.1.

9.4.2.3 Piloting of data collection tools

Both data collection tools were piloted with a patient who had received the NSAIDs care bundle. The pilot participant suggested no changes to the interview schedule or questionnaire. It took 25 minutes to administer the interview schedule and questionnaire, which was used as a guide time to inform participants of approximately how long the study would take.

9.4.3 Study setting

Nine pharmacies were selected to recruit participants for the study. Initially, eight pharmacies were recruited based on their previous engagement with evaluation activities; these were the pharmacies that participated with the on-site task-analysis techniques (see

[10] This amendment was approved by the Strathclyde Institute of Pharmacy and Biomedical Science Ethics Committee in May 2018.

Table 8.1 of Chapter 8). Four of these pharmacies were involved in the NSAIDs bundle, and four were involved in the warfarin bundle. Following an initial low response rate, the pharmacy from which the pilot participant was recruited was approached and asked to recruit more participants. This pharmacy was involved in the NSAIDs care bundle and was located within NHS Grampian (small chain pharmacy, urban locality).

9.4.4 Recruitment strategy

The selected pharmacies were contacted by telephone and asked to recruit participants for this study. Following agreement via telephone communication, the pharmacies were sent an information sheet explaining what was expected of them. Eligible participants were patients who had received the warfarin or NSAIDs care bundle from their pharmacy as identified by the pharmacy staff. To maximise response rate, a three-tiered recruitment strategy was adopted as shown in Figure 9.4. Pharmacies were called twice weekly to monitor their progress. There were no offers of payments, expenses or other incentives for pharmacies to recruit participants or for patients to participate.

Plan A	Pharmacies were sent 10 Participant Information Sheets to give to eligible patients. If willing to participate, the participants were instructed to provide NW with their first name and contact telephone number directly by post, telephone communication, or email. A telephone interview with the participant was then scheduled.
Plan B	Pharmacies were sent a further 10 Participant Information Sheets to give to eligible patients. If willing to participate, the participants were asked to provide the pharmacy team with their first name and contact telephone number. The pharmacy team were asked to communicate this to NW, for NW to phone the participant to schedule the telephone interview.
Plan C	A sub-set of the selected pharmacies were visited depending on their locality and ease of travel for NW. Pharmacy staff identified eligible patients when they presented at the pharmacy and asked if they would participate in an interview with NW. Willing participants were provided with the Participant Information Sheet, a consent form, and the study verbally explained. A face-to-face interview was conducted in the pharmacy or participants' contact details were collected and a telephone interview scheduled.

Figure 9.4. Three tiered patient recruitment strategy (Apr – Jun 2018)

9.4.5 Data collection

Data collection occurred between April and June 2018. The telephone calls conducted with participants were audio-recorded for analysis purposes. For the telephone interviews (Plan

A and Plan B), a Verbal Consent Script was read to participants and audio recorded. For face-to-face interviews (Plan C) participants were asked to sign a consent form. At the end of the interviews, debriefing included thanking the participant for their involvement, explaining again why the study was being conducted, and asking participants if they had any questions.

9.4.6 Analysis plan

The point of integration of the qualitative and quantitative components of this study was at the interpretation and reporting level. The results of the questionnaire are presented in their entirety. However, where results of the questionnaire and the interview data were conceptually linked, the 'weaving approach' was adopted whereby the results were written as an integrative account on a theme-by-theme basis [306].

9.4.6.1 Questionnaire

To analyse the questionnaire data the Likert scale was assigned a numerical code: strongly agree = 5, agree = 4; neither agree or disagree = 3; disagree = 2; strongly disagree = 1. The questionnaire results were analysed by calculating a median and interquartile range for participants' responses to each of the questionnaire items. The percentage of participants in agreement (i.e. responded that they agreed or strongly agreed) with each questionnaire item was calculated.

9.4.6.2 Semi-structured interviews

The semi-structured interview data were structured using the framework method, whereby a matrix of summarised data is formed of codes and participants. The seven stage framework method for managing qualitative data has been previously described by Gale et al [339], and the application of this method for this study is described in Figure 9.5. The framework method is increasingly used within healthcare research, and was selected as it enables analysis of large data sets using a transparent, replicable method [339].

During the interpretive stage (Stage 7), it was evident that the interview data pertaining to participants' reported experience of receiving the care bundle and their reported impact of the care bundle would be most appropriately analysed using summative content analysis [158]. The remaining data was conceptually rich and a thematic analysis was conducted, whereby themes were developed by reviewing the data and making connections between

the participants and codes [339]. Following this, the quantitative data collected using the questionnaire were reviewed to identify if it aligned to any of the themes identified [306].

Stage	Description
Stage 1: Transcription	The audio-recordings of each interview were transcribed using the intelligent verbatim approach, which allowed the author of this thesis to become 'immersed' in the data. Four transcripts were selected at random and validated by TM and EDC to ensure accuracy of transcription.
Stage 2: Familiarisation	To become familiar with the data, NW listened to the audio-recordings and read the interview transcripts. Reflexive notes and early impressions of the data were noted during this familiarisation stage.
Stage 3: Initial coding	Four interview transcripts considered the most conceptually rich were initially coded; two NSAIDs transcripts and two warfarin transcripts were selected. Coding was done inductively and involved assigning a paraphrase or label which accurately represented a unit of data. This was done by NW and AJ independently.
Stage 4: Developing a framework	NW and AJ compared their initial coding and came to a consensus on a framework to apply to all subsequent transcripts. EDC acted as a mediator during this in cases of disagreement. Where appropriate, codes of similar concepts were grouped within categories.
Stage 5: Applying the framework	The framework was applied to the other transcripts. Where changes were made to the framework, EDC and AJ were consulted to validate the appropriateness of these. The final framework can be found in Appendix 9.2.
Stage 6: Charting data into the framework matrix	A spreadsheet was used to present the framework matrix in NVivo v11.0, where the data was presented by each code and participant.
Stage 7: Interpreting the data	Substantive data identified underwent summative content analysis. The data considered conceptually rich underwent thematic analysis. The thematic analysis was influenced by the original research questions and by themes identified inductively from the data. To develop the themes, NW reviewed the framework matrix to make connections within and between codes and participants. Analytical memos were developed to facilitate this, which is a written investigation of a concept emergent within the data

Figure 9.5. Overview of the framework method adopted for this study, as informed by Gale et al [339]

NSAIDs = Non-steroidal anti-inflammatory drugs

9.5 Results

9.5.1 Recruitment

All nine pharmacies approached agreed to recruit participants for this study. One pharmacy in NHS GG&C agreed only to recruitment Plan A due to time pressures, whilst the remainder recruited participants using both Plan A and Plan B strategies. Two pharmacies (one in NHS Grampian and one in NHS GG&C) participated in recruitment Plan C. In total, 21 participants were recruited and interviewed: three from recruitment Plan A, 18 from recruitment Plan B, and none from recruitment Plan C. As the pilot participant did not suggest changes to the interview or questionnaire the participant was included within the analysis with their permission. The second and third participants interviewed were excluded from the analysis as they could not recall receiving the care bundle, and the interview schedule was only amended after these interviews to allow participants to hypothetically offer their opinion, as described earlier in Section 9.4.2.2.

Of the 19 participants included within the analysis, eight were recruited from two pharmacies delivering the warfarin care bundle, and 11 were recruited from four pharmacies delivering the NSAIDs care bundle. The participants recruited in relation to the NSAIDs care bundle all received their NSAID via a prescription. The three pharmacies which did not manage to recruit participants stated this was because of time pressures within the pharmacy making recruitment challenging (n=1 pharmacy), or due to lack of eligible patients presenting within the pharmacy (n=2 pharmacies).

9.5.2 Participants

The demographics of the 19 participants included within the analysis are presented in Table 9.1. The age range of participants was 43-86 years old, and most participants were female (n=11, 57.9%). In general, the participants interviewed regarding the warfarin care bundle were older in age (median age = 74, IQR = 71-82) than those interviewed regarding the NSAIDs care bundle (median age = 60, IQR = 52-69). Due to this noticeable difference in age ranges, post hoc analysis was conducted to identify if the differences in the median ages of the warfarin and NSAIDs care bundle participants were significantly different. The independent-samples median test conducted within IBM SPSS Statistics v24.0 identified the median ages between the warfarin participants and the NSAIDs participants were

significantly different (p=0.001), with the median age of the warfarin participants being significantly greater than the NSAIDs participants.

Table 9.1. Demographic characteristics of interview participants included within analysis (n=19)

Demographic characteristics	NSAIDs participants (n,%)	Warfarin participants (n,%)	All participants (n,%)
Gender			
Female	7 (63.6)	4 (50.0)	11 (57.9)
Male	4 (36.4)	4 (50.0)	8 (42.1)
Age (years)			
40-50	2 (18.2)	0 (0.0)	2 (10.5)
51-60	5 (45.5)	0 (0.0)	5 (26.3)
61-70	3 (27.3)	1 (12.5)	4 (21.1)
71-80	1 (9.1)	4 (50.0)	5 (26.3)
81-90	0 (0.0)	3 (37.5)	3 (15.8)

NSAIDs – non-steroidal anti-inflammatory drugs

9.5.3 Participants' reported delivery of the care bundles

During the interviews, participants were asked to report what happened when the pharmacy delivered the care bundle to them. The content analysis of this data is presented here.

9.5.3.1 Participants' NSAIDs care bundle experience

Of the 11 participants who received the NSAIDs care bundle, six (54.5%) reported being delivered all three of the NSAIDs Communication Care Bundle questions, which relate to taking the NSAID with food, adverse drug reactions, and to stop taking their NSAID during a dehydrating illness (Table 9.2). The remaining five participants (45.5%) reported being delivered the first NSAIDs Communication Care Bundle question (n=1, 9.1%), or the first two (n=4, 36.4%). For the NSAIDs Safer Care Bundle, four participants (36.4%) reported their use/need being reviewed, whilst two (18.2%) were identified as high risk. Seven participants (63.6%) were given the NSAIDs Safety Information Card. Of these, four (36.4%) also reported being given an information sheet. Five participants (45.5%) reported being delivered other care relating to their NSAIDs which was outwith the care bundle. Participants' experience of the NSAIDs care bundle questions and other NSAIDs related care delivered is presented in Table 9.2.

Table 9.2. Patient-reported delivery of the NSAIDs care bundle questions and other NSAIDs-related care received (n=11)

NSAIDs care bundle	Delivery of care bundle question to patients, n (%)	Illustrative quotes
Communication bundle		
1. Informing patient to take NSAID with or after food	11 (100.0)	"he made sure that I knew when to take it and what to take it with, you know, to take it with food" (P18)
2. Informing patient to report of potential adverse drug reactions	10 (90.0)	"they basically explain obviously people can have problems with their intestines and things like that, stomach problems and taking things on a regular basis, and have I noticed any such problems, and if so they advise me to see the doctor" (P19)
3. Informing patient to stop NSAID medication during dehydrating illness	6 (54.5)	"well she explained if that [vomiting and diarrhoea] happened to stop taking them and get in contact with the local health centre" (P8)
NSAIDs Safer Care bundle		
4. Assessing use/need of NSAID	4 (26.4)	"as he was giving me the medication he was just advising me of the usage" (P17)
5. Identifying if patient is in high risk group	2 (18.2)	"he was noticing that I was at risk of having a problem because I was taking these tablets and the doctors hadn't prescribed alongside it something to protect my stomach" (P12)
6. Identifying triple whammy interactions	0 (0.0)	N/A
Other care provided by pharmacy relating to NSAIDs		
Discussing use of NSAIDs if have a respiratory condition	2 (18.2)	"I have seasonal asthma, I was told that they may upset that" (P1)
Informing patient of what NSAID was indicated for	2 (18.2)	"so he took me to one side, sort of away from everybody and said just to see that you know that this is an anti-inflammatory" (P18)
Informing patient to take tablet with water	1 (9.1)	"just take it with a sip of water, just wash it down with water" (P9)
Informing patient to read information provided about NSAIDs	1 (9.1)	"just to read everything and just understand what's on the boxes" (P10)

NSAIDs = non-steroidal anti-inflammatory drugs

9.5.3.2 Participants' warfarin care bundle experience

For the warfarin care bundle, seven (87.5%) of the eight participants reported being delivered the second care bundle question (Table 9.3). This relates to the pharmacy reviewing patients' information on their warfarin indication, duration of treatment, therapeutic range and current dose of warfarin. No other questions were reported to be delivered, and the remaining one (12.5%) participant reported than none of the care bundle questions were delivered to them. Three participants (37.5%) reported being delivered other care relating to their warfarin which was outwith the care bundle, which related to checking for interactions with other medication. No participants reported being given any warfarin related resources from their pharmacy. A summation of participants' reported experience of the warfarin care bundle questions and other warfarin care received is presented in Table 9.3.

Table 9.3. Patient-reported delivery of the warfarin care bundle questions and other warfarin-related care received (n=8)

Warfarin care bundle	Delivery of care bundle question to patients, n (%)	Illustrative quotes
1. Informing patient of importance of carrying alert card	0 (0.0)	N/A
2. Reviewing patient's information on indication, duration of treatment, therapeutic range and current dose of warfarin	7 (87.5)	"yes they do, most of the time, most times when I go down to collect my warfarin they always ask me if I've been to get my bloods checked, which I usually have, I always have my little book with me anyway ... sometimes they look at it, but other times they just take my word for it" (P21)
3. Informing patient of what to do if missed a dose of warfarin	0 (0.0)	N/A
4. Informing patient to report any significant changes which may affect their warfarin	0 (0.0)	N/A
5. Discussing common signs and symptoms of over/under-coagulation	0 (0.0)	N/A
6. Informing patient that the need INR test if starting antibiotics	0 (0.0)	N/A
Other care provided by pharmacy relating to warfarin		
Check other medicines are okay with warfarin	3 (37.5)	"they'll always ask me if I'm taking any other medication, and obviously when I'll tell them what I'm taking they'll tell me whether I can take it in conjunction with the any other medication" (P13)

INR = International normalised ratio

9.5.4 Participants' satisfaction with the care bundles

Participants' satisfaction with the care bundles was explored through the use of a questionnaire, which stratified satisfaction into two domains: experience of the service, and judgement of the service. All of the recruited participants who experienced the NSAIDs care bundle responded to this questionnaire within the telephone interview (n=11). However, the patient satisfaction questionnaire was not applicable for the patient cohort interviewed regarding the warfarin care bundle, as participants did not report enough experience of the warfarin care bundle for it to be relevant. Therefore, the data here presents only patients' satisfaction with the NSAIDs care bundle, as shown in Table 9.4.

In relation to the experience of the care bundle, all participants (n=11, 100%) were satisfied with the pharmacy staff member's explanation of the NSAIDs service, their personal approach, and their advice. Two participants (18.1%) did not agree that they were satisfied with the privacy of where the discussion took place. In relation to the time the pharmacy staff member spent listening, the opportunity there was to raise queries, and if the staff member answered queries, one participant to each of these questions responded neutrally (9.1%), with the rest of participants agreeing with these statements (90.9%).

In relation to the judgement of the care bundle, four participants (36.4%) did not agree that they wanted to have a discussion about their NSAIDs medication, yet all participants (n=11, 100%) reported that they were satisfied with the care bundle received and would recommend it to others. In relation to participants' confidence in managing their medication and if they would be happy to discuss their NSAIDs medication again, one participant to each of these questions responded neutrally (9.1%), with the rest in agreement with these statements (90.9%).

Table 9.4. Results of the patient satisfaction questionnaire for the NSAIDs care bundle (n=11)

Questionnaire items	Median* (IQR)	% of participants in agreement
Experience of the service		
I am satisfied with the pharmacy staff member's explanation of the aims of the NSAIDs service to me	5 (4-5)	100.0
I am satisfied with the privacy of where the discussion took place	4 (4-5)	81.8
I am satisfied with the time the pharmacy staff member spent listening to me	5 (4-5)	90.9
I am satisfied with the pharmacy staff member's personal approach towards me	5 (4-5)	100.0
I am satisfied with the opportunity I had to raise queries	5 (4-5)	90.9
I am satisfied with the pharmacy staff member's advice	5 (4-5)	100.0
The pharmacy staff member answered my queries^	5 (4-5)	90.0
Judgement of the service		
I wanted to have a discussion about my NSAID medication	4 (3-5)	63.6
I now feel more confident about managing my NSAID medication	4 (4-5)	90.9
I would be happy to have a discussion about my NSAID medication again in the future	4 (4-5)	90.9
I would recommend the NSAIDs service to others	5 (4-5)	100.0
I was satisfied with the NSAIDs service I took part in	5 (4-5)	100.0

** strongly agree = 5, agree = 4; neither agree or disagree = 3; disagree = 2; strongly disagree = 1*
^ One participant stated this item was not applicable as they had no queries and were excluded
NSAID(s) – non-steroidal anti-inflammatory drug(s)

9.5.5 Thematic analysis

The thematic analysis of the interview data from participants recruited from both the warfarin and NSAIDs pharmacies identified two dominant themes:

- Theme 1: Value of the care bundles
- Theme 2: Pharmacy's position in medication safety

These themes and their associate sub-themes are summarised in Table 9.5. The summative content analysis of the impact of the care bundles and some of the questionnaire data on patient satisfaction were conceptually linked to Theme 1 and are presented there.

Table 9.5. Summary of themes and sub-themes identified from thematic analysis

Theme	Sub-themes	Summary of sub-theme
Value of the care bundles	Perceptions of the NSAIDs care bundle	Patients were satisfied with the NSAIDs care bundle and had positive perceptions of the manner with which it was delivered to them.
	Impact of the NSAIDs care bundle	The NSAIDs care bundle had a positive influence upon patients' knowledge, their attitudes and behaviours, and high risk scenarios were identified leading to medication changes. However, some unintended consequences were identified.
	Necessity of the warfarin care bundle	Most warfarin participants were sceptical over the necessity of a community pharmacy warfarin service, however some participants did not appear to be knowledgeable about their warfarin medication.
Pharmacy's position in medication safety	The role of pharmacy in managing medicines	Receiving the NSAIDs care bundle made patients more aware of the role of pharmacy in the safer use of their medicines. However, there was mixed opinions about pharmacies adopting a more informative role regarding warfarin, and their capacity to do so was questioned.
	Pharmacy's position amongst wider influences: GPs, nurses, peers and the media	The pharmacy's role in the provision of the NSAIDs care bundle was perceived as complementary to the role of other healthcare professionals, yet conflicting for the warfarin bundle. It was also evident that the participants received information about their medication from other sources, including the media and family members.

NSAIDs = non-steroidal anti-inflammatory drugs, GPs = general practitioners

9.5.6 Theme 1: Value of the care bundles

9.5.6.1 Perceptions of the NSAIDs care bundle

The NSAIDs care bundle was supported by patients; it was considered "*a very good idea*" (P1) and a source of valuable information which patients appreciated: "*I'm really glad that [the pharmacy] drew my attention to it*" (P18). This interaction was also considered an opportunity for pharmacy staff to *"check in"* (P1) with patients. For participants who stated they already knew the information encompassed within the NSAIDs care bundle, they positively advocated being reminded about it and considered the NSAIDs care bundle would be useful for patients with less knowledge of their NSAIDs medication:

"it was good to have that sort of information again, just a reminder if you like … there will be some people that haven't a clue what they're doing" (P17)

The provision of the NSAIDs Safety Information Card was also valued, and it was commented that it could be referred to later if needed or be read by others: *"I left it sitting on top of the tablets so that if I did have a query I went and looked at it, and my husband also knew about it, he read it as well"* (P8).

The manner with which the pharmacy staff conducted themselves when delivering the NSAIDs care bundle was also positively commented on. The professionalism of the pharmacy staff was commended, as was the ability of the safety-related information to be delivered in a way that was *"relaxed"* (P17). In an instance where a pharmacist discussed the risks of the concomitant use of naproxen alongside another gastro-irritant, the participant appreciated the pharmacist's ability to deliver this information in a way that did not cause them undue worry: *"it wasn't done in a way that made you feel scared or terrified or think 'oh my god I can't take this tablet anymore', it was done very well"* (P12).

As identified from the patient satisfaction questionnaire, participants were satisfied with the experience and positively judged their experience (see Table 9.4). All participants who experienced the NSAIDs care bundle (n=11, 100.0%) agreed or strongly agreed that they were satisfied with: the pharmacy staff member's explanation of the NSAIDs care bundle; the pharmacy staff member's personal approach; the pharmacy staff member's advice; and the NSAIDs care bundle itself. All participants (n=11, 100.0%) agreed that they would recommend the NSAIDs care bundle to others, and the majority (n=10, 90.9%) would be happy to discuss their NSAIDs medication again in the future.

9.5.6.2 Impact of the NSAIDs care bundle

The patient-reported impact of the NSAIDs care bundle indicated its influence on patients' knowledge, their attitudes, their behaviour, and their prescribed medication. A summation of participants' self-reported impact is presented in Table 9.6.

Table 9.6. Summation of participants self-reported impact of the NSAIDs care bundle (n=11)

Area of impact	Description	N participants (%)
Knowledge and attitudes	Greater awareness of NSAID and its risks	8 (72.7)
	Gained new knowledge of NSAID	6 (54.5)
	Increased confidence with taking NSAID	2 (18.2)
	Learnt about role of pharmacy	2 (18.2)
	Less concerned	1 (9.1)
	More concerned	1 (9.1)
Behaviour	More likely to take NSAID with food	6 (54.5)
	Read more information on NSAIDs	6 (54.5)
	Will use pharmacy for advice in the future	2 (18.2)
	Reluctance to take NSAID	1 (9.1)
	Desire to stop taking NSAID	1 (9.1)
	More likely to take NSAID	1 (9.1)
Medication	Lower dose of NSAID prescribed	1 (9.1)
	Omeprazole prescribed	1 (9.1)

NSAID(s) = non-steroidal anti-inflammatory drug(s)

As a consequence of receiving the NSAIDs care bundle, participants become more aware of their NSAIDs medication and its risks, with some reporting that they gained new knowledge about their NSAIDs medication during the interaction with the pharmacy: *"I didn't actually know what the more serious side effects would be, you know, bleeding from the stomach"* (P17). However, some participants struggled to recall all the information provided to them by their pharmacy: *"I really couldn't tell you off hand now what all the side effects are, I can't remember all that"* (P5). Some participants noted they were more likely to take their NSAID with or after food in response to receiving the bundle: *"I now make sure I take it with food, so it's kind of highlighted that"* (P9). Others read information which was given to them by the pharmacy about their NSAID, and for some participants receiving the care bundle prompted them to read the information leaflet of their other prescribed medication:

"Participant 8: Well, apart for making me aware that the things that that can cause with your stomach and your other various ailments it can cause, it has made me think more about all the things that you take, like my inhalers and everything else, it's made me aware that I should read the leaflets and pay attention

Interviewer: Yeah, so is that something you're going to do then, read all the leaflets, or?

Participant 8: I already have" (P8)

In two instances, the NSAIDs care bundle identified high risk patients which instigated changes to their medication following GP referral. One participant who was experiencing gastro-irritation was subsequently prescribed omeprazole following the pharmacist's advice which relieved their symptoms*: "I did notice a big difference when I started taking the omeprazole that I wasn't getting the burning sensation in my stomach"* (P12). Another participant's NSAID dose was lowered as they were concomitantly prescribed another gastro-irritant:

> *"when I phoned [the GP] and explained the problem he looked into it and he actually phoned me back and offered me the 'half measure', but without the pharmacy having the chat with me I wouldn't have had any idea"* (P18)

Although the impact was mostly positive in nature, there was emergence of some unintended consequences. For one participant, receiving the care bundle increased their desire to stop taking their NSAID eventually: *"I think it prompted me to think a bit more about it, and think I have to get off this"* (P5). For another participant newly prescribed their NSAID, receiving the information about their NSAIDs medication made them more reluctant to take it:

> *"It made me reluctant to take it, even when the doctor reduced it from 500mg down to 250mg, it made me think about, you know, what else does this medicine do? Do I really need this medication? Is it actually going to help with the pain that I've got?"* (p18)

Another participant stated that receiving the information made them more concerned, which prompted them to take their NSAID with food: *"Yes, I am more concerned about my medication, because I do take a few of them, but I will also remember, even if it's just to remind myself to have a biscuit with the morning coffee when I take my meds"* (P1).

9.5.6.3 Necessity of the warfarin care bundle

As the participants could not recall receiving a warfarin care bundle, they were asked hypothetically what they would think of such a service. Participants felt there was no valuable information that could be offered by the pharmacy:

"I don't have any pressing need for more information at the moment" (P20)

"I think it would waste a lot of their time, you know, I've not had any problems you know from that angle taking the warfarin, you know, I've never had a problem" (P14)

Often, participants justified this viewpoint by re-iterating that they hadn't experienced any problems with their warfarin medication: *"I don't have any side effects with it anyway, as far as it goes, and I've been on it a few years so I've not had any ups or downs with it to be honest with you (P16)".* Only one of the warfarin participants (P13) did not comment on a lack of need of the warfarin care bundle. However, some participants appeared to lack knowledge about their warfarin medication which may have been covered within the warfarin care bundle: *"Well I don't know about certain foods, I do know that I'm not supposed to take any medication over the counter without advice"* (P21)*, "I don't think you have any side effects at all, you don't seem to have any bother with it"* (P14).

When asked to suggest what would be useful information to receive from the pharmacy regarding their warfarin medication, none of the participants' suggestions centred on any of the information which was covered within the care bundle. Participants most commonly stated they would like to be informed if an alternative medicine to warfarin became available:

"Well, nothing I can think of at the moment, most of the literature I've got relates to the warfarin and also my other medication, but unless something new comes on the market and they were to advise me" (P15)

9.5.7 Theme 2: Pharmacy's position in medication safety

The thematic analysis in this study was conducted inductively so that unexpected aspects of participants' perceptions could be identified [339]. An unexpected theme emergent from the data was how the participants viewed community pharmacy's position in medication safety.

9.5.7.1 The role of pharmacy in managing medicines

Most participants (n=18, 94.7%) reported that they were aware of community pharmacy's role in the provision of advice to patients, and it was reported that some participants had sought the counsel of pharmacy staff before: *"that's the first place I would go to get advice"*

(P11). However, for the NSAIDs care bundle, only two participants (P18, P7) expected the pharmacy to discuss their NSAIDs medication with them: *"if you are on any kind of a drug or prescription that can cause side effects I would have presumed that the pharmacist would have a word"* (P7).

The interaction with the pharmacy staff about their NSAIDs medication meant participants began to appreciate the wider role of pharmacy with their medication: *"It's made me realise that the pharmacy play a much bigger job than you perhaps initially realise"* (P18). One participant stated that *"it makes you feel that somebody was watching out for you"* (P12), whilst another commented that *"it's showing they're not just giving sweeties over the counter"* (P19).

For the participants on warfarin, some were not resistant to the pharmacy adopting a more informative role about their warfarin: *"probably wouldn't do me any harm to be honest"* (P13), *"well, there might not be a demand, but I would think that any information about things like that it's always good to hear about it"* (P16). However, others did not feel this was within their role; *"I just don't know whether it's their place"* (P4), and some participants queried the capacity of the pharmacy to adopt this role:

> *"the chemist is so busy and people are coming and going, and they're waiting on prescriptions, I wouldn't think they would have even a place that you could sit and they could talk to you because they just seem to be going back and forward and people in for their prescription, I wouldn't think they would have much time to discuss your warfarin"* (P16)

For the participants who experienced the NSAIDs care bundle, although the capacity of pharmacy to deliver the NSAIDs care bundle was not queried, the business of the pharmacy was also acknowledged: *"I also know pharmacy staff are really very, very busy*" (P1), with a participant exclaiming that *"they're never stopped"* (P10).

9.5.7.2 Pharmacy's position amongst wider influences: GPs, nurses, peers and the media

Other healthcare professionals were involved in patients' warfarin and NSAIDs treatment. For the patients taking an NSAID, GPs were involved in initially prescribing them the NSAIDs medication. Often the relationship between the GP and the pharmacy was seen as complementary: *"it's good to know that there's somebody checking up on what the doctors*

are doing" (P12), and for some participants it was evident that the pharmacy offered further information than provided by their doctor:

> *"the doctor prescribed something, but when I picked it up [the pharmacy] told me to take it in the morning along with the pill I was prescribed to line the stomach, cause they cause a lot of heartburn, upset stomachs, and that sort of stuff"* (P6)

For the patients taking warfarin, the medication was prescribed by their GP and patients also attended nurse-led warfarin clinics where they got their INR tested. Many participants felt that pharmacies adopting a more informative role about their warfarin may conflict with the role of other healthcare professionals involved in their warfarin management: *"I think that's between the doctor and the warfarin clinic"* (P11), *"if I'm going to see anybody it's going to be a nurse or a doctor, it wouldn't be a pharmacist"* (P15).

Furthermore, it was also evident that the participants used other sources of information about their medication, including the media, the internet, and family members. One participant reported that their primary source of information about their warfarin was their sister:

> *"P21: Oh my sister keeps me up on warfarin, [laughter] my sister's been on warfarin for about 30 years, and I mean although she's my young sister I am always getting lectured "and you do not drink and you don't do this and you do that"* (21)

A participant reported that after receiving the NSAIDs care bundle they *"googled the anti-inflammatory as well after"* (P18), whilst another reported how newspapers informed them of warfarin, and stated that *"if the papers can do it, maybe the chemist can do it"* (P14). For another participant taking warfarin, they reported that a popular TV presenter reminds his audience at 6 o'clock to take their warfarin: *"Paul O'Grady reminds you when he's on [laughter], and he'll say at six o'clock very quietly 'right everyone, get the warfarin'"* (P4).

9.6 Discussion

This study sought patient perceptions of the NSAIDs and warfarin care bundles in order to inform their wider roll out within Scottish community pharmacies. The study was necessary

given that previous evaluation activities focused only on the implementation process as reported by the community pharmacy staff. The major finding of this study was the difference in the participants reported delivery of the care bundles, with the NSAIDs care bundle reportedly covered in greater depth that the warfarin care bundle. Additionally, there were notable differences in how patients perceived each. Whilst participants were satisfied with the NSAIDs care bundle with evidence of its positive impact, the warfarin patients could not recall receiving the care bundle and did not perceive a need for it. This was partly due to the involvement of other healthcare professionals with their warfarin medication, and participants also queried the capacity of community pharmacy to provide this service. An unexpected finding of the study was the emergence of potentially unintended consequences of the NSAIDs care bundle, albeit reported by a minority of participants, such as reluctance of patients to take their NSAID medication or a desire to stop it in the future.

As reported by patients, not all elements of the warfarin and NSAIDs care bundle appeared to be delivered to them. The third question of the NSAIDs Communication care bundle, which advises patients to stop taking an NSAID if dehydrated, was not delivered to five participants. This was unsurprising given that it was identified during the on-site visits (Chapter 8) that not all these pharmacies delivered this care bundle question. The pharmacies justified this as the NSAIDs Safety Information Card was supplied to patients which informed participants to stop their NSAID if suffering a dehydrating illness, but not all participants in this study reported receiving this information card. The NSAIDs Safer Care Bundle was rarely reported upon, which again is unsurprising as this typically involves pharmacy staff identifying interactions and assessing NSAID use within the patient's medication record, and participants would likely be unaware of this unless any issues were identified.

In general, the NSAIDs care bundle was reportedly delivered in greater depth than the warfarin care bundle, as patients only reported being asked one of the six warfarin care bundle questions. Variation in the delivery of care to patients has previously been identified within UK community pharmacies [340]; variable delivery of the WWHAM[11] questions have been identified when exploring pharmacy staff compliance to over-the-counter consultation protocols [340]. Alongside the results of the current study, this may suggest that adherence

[11] The WWHAM acronym stands for Who is the patient, What are the symptoms, How long have the symptoms been present, Action taken, and Medication taken.

to guidelines and standards within the UK community pharmacy setting in general is variable, and is an area which may benefit from further research.

As identified from the patient satisfaction questionnaire, only 63.6% agreed that they wanted to have a discussion about their NSAID, yet all patients (100%) who experienced elements of the NSAIDs care bundle reported that they were satisfied with it. This mirrors the findings of Hindi et al where the same questionnaire was used to evaluate satisfaction with MURs [323]. Similarly, only 65% of participants agreed that they wanted to have a MUR, yet 97% were satisfied with the MUR once received [323]. Our findings therefore corroborate Hindi et al's argument that initial reluctance of patients to receive community pharmacy services cannot act as an indicator of potential patient satisfaction with a service [323].

There were three areas of patient impact as a result of receiving the NSAIDs care bundle: impact on knowledge and attitudes, impact on behaviour, and impact on patients' medication. An unexpected result was the emergence of unintended consequences of the NSAIDs care bundle. Although reported by a minority of participants, increased concerns and/or reluctance to take NSAIDs medication were identified. Monitoring for unintended consequences is strongly advocated for all quality improvement initiatives [341]; however, to the authors knowledge this is the first instance where patient-reported unintended consequences of community pharmacy innovations have been identified.

The range of positive impact of the NSAIDs care bundle identified was also wider than has previously been identified with community pharmacy innovations. As identified from previous reviews [207, 318, 321], patient-reported impact of community pharmacy innovations include improved awareness and knowledge of medicines [325, 326], and behaviour changes due to following pharmacy's advice [327, 328]. In this study, additional behaviour changes were identified - such as participants reporting to be more likely to read information on their NSAIDs, as well as changes being instigated to patients' medication – such as omeprazole being prescribed and patient's NSAID dose reduced. Considering that patient-reported impact of community pharmacy innovations appear to be rarely collected [318], and that these examples of positive and negative impacts are unlikely to be detectable within routinely collected data, the true extent of impact of community pharmacy innovations may be largely unknown.

Interestingly, the role of pharmacy and its position within the wider primary healthcare setting was perceived differently between the warfarin and NSAIDs patients. The

involvement of the pharmacy with patients' NSAIDs medication was seen as complementary to the role of GPs, which corroborates previously identified attitudes of the Scottish general public who generally view community pharmacy as being supportive to GP services [342]. However, this was not considered to be the case for the warfarin bundle, where participants thought it may conflict with or duplicate the role of the nurses and GPs who were involved with their warfarin care. This has been previously reported by participants in the UK with type 2 diabetes, where pharmacy innovations were not seen as integrated within the wider healthcare setting and in instances duplicated care received elsewhere [343]. A potential explanation for the different viewpoints between the warfarin and NSAIDs participants could be that the warfarin participants were older in age, as elderly populations in Scotland have been identified to be more likely to hold negative views of pharmacists and prefer GP-led services [342].

Another interesting finding of this study was participants' use of the media, the internet, and family members as sources of information, despite the fact that almost all participants considered the pharmacy as a place for advice. The use of media as a source of healthcare information [344, 345] and the influence of friends and family on health behaviours [346] has been previously identified. Crilly et al (2018) conducted a survey with the general public in London (n=820) which found that community pharmacies were the third preferred source of healthcare advice, with GPs in first place and digital and tele-mediums in second place [347]. Likewise to this study, this was despite the fact that most of the respondents were aware that community pharmacies offered advice [347]. The publics increasing use of digital and tele-mediums as healthcare information sources is thought to be due to their perceived reliability, convenience, and ease of use of these mediums [347]. Within the current study, patients reported that community pharmacies may lack capacity in terms of how busy they are to deliver an informative warfarin care bundle. Thus, it could also be postulated that patients use the media and peers due to their perception of the availability of pharmacy staff to offer advice. This argument is further supported by a UK study which identified public scepticism of pharmacy's ability to deliver additional services due to their high workload [318]. Wider exploration of the factors which influence a person's decision to use media and peers as a source of information, instead of seeking the advice of qualified healthcare professionals such as community pharmacists, would be an interesting area for future research.

9.6.1 Strengths and limitations

Overall, an adequate sample size was obtained for the qualitative arm of this study (n=19). However, as many of the results were stratified to the specific high risk medicine of interest, the sample size for each of the care bundles was relatively low. Only eight participants were interviewed regarding the warfarin care bundle and 11 patients were interviewed regarding the NSAIDs care bundle. Ideally, more participants would have been recruited; however, resource and time constraints meant that the three-month data collection period (Apr-Jun 2018) could not have been extended. The sample size obtained limits the generalizability of the quantitative arm, particularly as the questionnaire was only applicable for the 11 participants who experienced the NSAIDs care bundle. Additionally, all participants interviewed regarding the NSAIDs care bundle received their NSAID on prescription. Therefore, it remains unknown what patients' experience and perception is of the care bundle when their NSAID is supplied via the minor ailments service or bought over-the-counter.

Although participants were recruited from a variety of localities within NHS Scotland from a range of different pharmacies to enhance generalisability (see Table 8.1 of Chapter 8), three of the pharmacies did not manage to recruit participants and none were recruited from NHS Highland. Furthermore, all the warfarin participants recruited reported receiving just one of the warfarin care bundle questions, thus the data reports their hypothetical perceptions. Because of this, the questionnaire was not applicable for this specific cohort of patients, and the use of mixed methods was only possible for the NSAIDs participants.

For the NSAIDs participants, the qualitative data were able to expand upon constructs encompassed within this questionnaire and explore further constructs of interest (i.e. patient-reported impact). Additionally, the interview data obtained from the NSAIDs participants corroborated much of the data obtained from the questionnaire. This further indicates the validity of the questions to identify patient-reported satisfaction with the care bundles. Consequently, the questionnaire used in this study (Figure 9.2) could be a valid tool able to evaluate satisfaction with the care bundles if scaled up throughout Scotland to obtain large-scale generalizable data of this nature. As the questionnaire was initially developed to evaluate MURs in NHS England and was successfully used in this study, this evidences the applicability of this questionnaire to evaluate different community pharmacy innovations. This means the questionnaire could be applied to evaluate other community pharmacy

innovations to offer useful cross comparison of patient satisfaction. Scope also lies for the patient-reported impact identified for the NSAIDs care bundle to be developed into a questionnaire which could be disseminated to wider cohorts if this care bundle is scaled up throughout Scotland. This could act as a valuable tool to identify quantitative patient-reported outcome measures (PROMs) on a wider scale to obtain more generalisable data on the impact of the NSAIDs care bundle.

A notable limitation of this study is the risk of recall bias, which was evident as participants in this study self-reported that they could not remember the entirety of the NSAIDs care bundle delivered to them. This could be due to two reasons. Firstly, participants may have forgotten information within the time lag between receiving the care bundle and being interviewed. This limitation would have been mitigated had participants been interviewed immediately after receiving the care bundle as would have happened in recruitment Plan C, however this strategy was the most labour and time intensive and it was not pragmatic for this to be the sole recruitment strategy. Additionally, interviewing participants immediately after receiving the care bundle may have meant behaviour changes (e.g. reading information about NSAIDs) and medication changes (e.g. omeprazole being concomitantly prescribed) may not have been actioned yet and thus not captured within the data. The second reason for potential recall bias particularly for the warfarin patients is the age of participants, as increasing age has been negatively associated with patients' knowledge of their warfarin medication [348]. In light of this, this data should not be considered a valid measure of implementation fidelity of the warfarin and NSAIDs care bundles.

A further limitation of the study is the risk of selection bias, whereby pharmacy staff had the freedom to select which patients to be recruited within this study. Thus, it is possible they may have selected patients who they believed would offer a more favourable opinion of their pharmacy's practice. This could have been mitigated if the researcher directly recruited patients, yet this raised ethical issues regarding confidentiality and consent. Additionally, the Hawthorne effect [349] cannot be ruled out given that the pharmacy staff were aware of this study's intent, and it is possible they may have altered their delivery of the care bundles to patients who they intended to recruit. To mitigate this bias, simulated NSAIDs patients with concealed microphones could have been used for the over-the-counter sales of NSAIDs using 'mystery shopper' methods [350]. However, this would not have been possible for the

prescribed warfarin and NSAIDs supplies as this would require obtaining a legitimate prescription for these medicines.

9.6.2 Future directions and recommendations

Patient satisfaction with the NSAIDs care bundle, alongside evidence of its positive impact, supports the intentions for its national implementation throughout Scotland. The identification of unintended consequences was unexpected, and developing a PROMs tool from the participants' self-reported impact in this study could be a useful mechanism through which positive impact and unintended consequences could be monitored during scale up. The degree of impact the NSAIDs care bundle had on participants despite lack of delivery of the third NSAIDs care bundle question to all patients may indicate that this question is not a core component required to achieve positive outcomes. This is consistent with the findings of Chapter 8, and supports the recommendation that this care bundle question may not be applicable for all patients.

For the warfarin care bundle, the lack of participants reporting having received the warfarin care bundle limits the development of recommendations for its national implementation. Furthermore, it is unknown if the participants had received the warfarin care bundle yet could not recall it, or if they hadn't actually received it from their community pharmacy. Participants in general did not consider a warfarin care bundle necessary, yet conducting a wider needs assessment with more patients on warfarin may be beneficial to confirm this in light of this studies questionable generalisability. Considering that the role of pharmacy within wider primary care setting was an emergent theme from this study, a needs assessment could also explore the views of other primary care clinicians involved in patients warfarin care. This may indicate if there is a place for community pharmacy to support the safer use of warfarin via a care bundle. Overall, further exploratory work is required to identify the necessity of the warfarin care bundle and to explore its potential impact and/or unintended consequences.

A summation of the recommendations for the care bundles based on the results of this study are presented in Table 9.7. These strategic recommendations have been categorised as per the ERIC taxonomy [295]. This taxonomy developed has been previously described in Chapter 1 (Section 2.3.3), with the full taxonomy presented in Appendix 2.2. These recommendations are additional to those posed in Chapter 7 where the success factors were identified (Section

7.6.5), and in Chapter 8 where the fidelity and penetration of the care bundles was explored (Section 8.6.4).

Table 9.7. Recommendations for the national implementation of the care bundles in response to patient perceptions

Care bundle	Identified issue	Proposed ERIC implementation interventions	Contextualised recommendation
NSAIDs care bundle	Identification of unintended consequences	Develop and implement tools for quality monitoring	Develop a PROMs tool from the reported impact to allow positive impact and unintended consequences to be monitored during scale up.
Warfarin care bundle	Perceived lack of need	Conduct local needs assessment	Conduct a wider study with patients on warfarin as well as healthcare professionals involved to identify the necessity of a warfarin care bundle

ERIC = Expert Recommendations for Implementing Change, NSAIDs = non-steroidal anti-inflammatory drugs, PROMs = patient-reported outcome measures

9.7 Conclusion

This study has identified patient perceptions of the warfarin and NSAIDs care bundles for the purpose of informing their wider implementation throughout Scotland. Stark contrast in the reported experience and perceived value between the warfarin and NSAIDs care bundle was identified. Whilst the positive findings in relation to the NSAIDs care bundle supports the argument for its national implementation throughout Scotland, the same cannot be said about the warfarin care bundle. Participants did not perceive the warfarin care bundle necessary or within the role or capacity of community pharmacy; therefore, a wider needs assessment should be conducted prior to its scale up. The identification of unintended consequences of the NSAIDs care bundle was unexpected, including increased patient concerns and reluctance to take NSAIDs, which should require further monitoring using a PROMs tool during this care bundle's scale up.

Chapter 10: Discussion

Preventable adverse effects and hospital admissions are associated with the medicines warfarin and NSAIDs [28-35], and high risk prescribing practices relating to these medicines have been identified in Scottish GP practices [36]. Considering the evolving role of the community pharmacy profession into one which provides public health benefits through patient-facing services [6], the SPSP-PPC collaborative was established in 2014. This aimed to utilise the skillset of community pharmacy staff to reduce the associated risks of warfarin and NSAIDs. This was realised through the development of NSAIDs and warfarin care bundles in November 2014 as part of the SPSP-PPC collaborative, which were piloted in 27 community pharmacies throughout Scotland [38]. Building upon the initial evaluation of these care bundles [38], this thesis focused on the progression of these care bundles to ensure their appropriateness for national implementation throughout Scotland and to inform this process. The aims of this thesis were to design consolidated warfarin and NSAIDs care bundles (Stage 1), evaluate their pilot implementation within Scottish community pharmacies (Stage 2), and inform their national scale up through the development of key recommendations (Stage 3). Stage 3 is presented in this chapter in Section 10.3, where final recommendations for the national implementation of the care bundles are compiled.

10.1 Overview of key findings (Stages 1 and 2)

Stage 1 of this thesis centred on the consolidation of the care bundles based on the previous evaluation's conclusion that having four warfarin and NSAIDs care bundles could compromise equality of patient care if scaled up throughout Scotland [38]. A consolidated NSAIDs care bundle and a consolidated warfarin care bundle were therefore developed with core components and adaptable peripheries (Chapter 4). Through a consensus approach, a multi-speciality group agreed on these core components, and the care bundle questions and eligible patient cohort were developed and later refined in community pharmacy practice. Both of the care bundles hosted six questions which were to be repeatedly delivered to eligible patients, although the NSAIDs care bundle was stratified into two parts depending on how the NSAID was supplied to patients. The core components of the consolidated warfarin and NSAIDs care bundles developed are shown in Figure 10.1. The adaptable peripheries of the care bundles were which pharmacy staff member(s) delivered the care bundle; the communication method with patients (i.e. in person or over the phone); and the use of resources. These consolidated care bundles were then implemented within 24

community pharmacies in February 2017 across NHS Grampian (n=7), NHS Fife (n=5), NHS GG&C (n=9), and NHS Highland (n=3).

Care bundle	Care bundle questions	Eligible patients
NSAIDs care bundle	**Communication Care Bundle**	
	1. Informing patient to take NSAID with or after food	All OTC, eMAS and Rx supplies of an NSAID.
	2. Informing patient to report of potential adverse drug reactions	
	3. Informing patient to stop NSAID medication during dehydrating illness	
	Safer Care Bundle	
	4. Assessing use/need of NSAID	All Rx supplies of an NSAID.
	5. Identifying if patient is in high risk group	
	6. Identifying triple whammy interactions	
Warfarin care bundle	1. Informing patient of importance of carrying alert card	All Rx supplies of warfarin.
	2. Reviewing patients' information on indication, duration of treatment, therapeutic range and current dose of warfarin	
	3. Informing patient of what to do if missed a dose of warfarin	
	4. Informing patient to report any significant changes which may affect their warfarin	
	5. Discussing common signs and symptoms of over/under-coagulation	
	6. Informing patient that the need INR test if starting antibiotics	

Figure 10.1. Core components of the consolidated warfarin and NSAIDs care bundles

OTC = over the counter, eMAS = minor ailments service, Rx = prescription, NSAID(s) = non-steroidal anti-inflammatory drug(s), INR = international normalised ratio

Stage 2 of this thesis involved the evaluation of the care bundles within the 24 pilot pharmacies. A summary of the evaluation findings is presented in Table 10.1. The determinants of implementation success, identified through the use of a questionnaire with the pharmacy staff, differed between the care bundles (See Table 7.6, Chapter 7). For the NSAIDs care bundle the success factors were the pharmacy staff having sufficient knowledge of NSAIDs, perceiving the funding and incentives to be sufficient, and not perceiving the bundle to negatively impact workload. Whereas, for the warfarin care bundle, patient perceptions and the compatibility of the care bundle were success factors. On-site visits in a cohort of pharmacies (n=8) identified that both care bundles penetrated well within community pharmacy practice and shared the same four key process steps: patient identification, clinical assessment, care bundle prompt, and care bundle delivery (see Table

8.5, Chapter 8). However, an assessment of their fidelity identified that the care bundles were not always delivered as intended (see Section 8.6.1).

When patients were interviewed about their perceptions of receiving the care bundle (Chapter 9), none of the warfarin patients recalled receiving a care bundle and its necessity was queried. Conversely, the NSAIDs participants were satisfied with their experience of the NSAIDs care bundle, and it mostly had a positive impact on patients' knowledge, their attitudes, their behaviour, and in some instances instigated changes in prescribed medication (see Table 9.6, Chapter 9). However, a minority of patients reported emergence of unintended consequences, including increased concerns and reluctance to take their NSAID.

Table 10.1. Summary of Stage 2 evaluation findings

Evaluation participants	Evaluation component	NSAIDs care bundle	Warfarin care bundle
Community pharmacy staff	**Determinants of implementation success* (Chapter 7)**	Success factors reported by the pharmacy staff were the pharmacy staff having sufficient knowledge of NSAIDs, perceiving the funding and incentives to be sufficient for the care bundle, and not perceiving it to negatively impact workload.	Success factors reported by the pharmacy staff were compatibility of the care bundle, and how the pharmacy staff perceived patients' perceptions of the care bundle.
	Fidelity^ (Chapter 8)	Not all core components of the NSAIDs care bundle were delivered to all patients as reported by the community pharmacy staff, which was corroborated with patient-reported experience of the care bundle (Chapter 9).	Not all core components of the care bundle were delivered as intended as reported by the community pharmacy staff, and patients when interviewed could not recall delivery of the warfarin care bundle (Chapter 9).
	Penetration^ (Chapter 8)	The NSAIDs care bundle penetrated well within community pharmacy practice, with evidence of whole pharmacy team involvement. However, there was a tendency for pharmacists to deliver the care bundle (i.e. speak with patients). Most common resources were the NSAIDs Safety Information Card and alert stickers.	The warfarin care bundle penetrated well within community pharmacy practice, yet whole team involvement was realised to a lesser extent when compared with the NSAIDs care bundle. Resources most commonly used included the warfarin flyers and alert stickers.
Patients	**Patient perceptions^ (Chapter 9)**	Patients were satisfied with the NSAIDs care bundle, and it had positive impact on patients' awareness and knowledge, their behaviour, and instigated changes to patients' medication. A minority reported unintended consequences, such as increased concerns about their medication.	The necessity of a warfarin care bundle was queried given the involvement of other healthcare professionals with patients' warfarin, and the capacity of community pharmacy to offer this role was questioned.

** This evaluation component was informed by the Consolidated Framework of Implementation Research (CFIR); ^ This evaluation component was informed by Proctor's taxonomy of implementation outcomes*

NSAIDs – non-steroidal anti-inflammatory drugs

10.2 Key discussion points from Stages 1 and 2 which informed recommendations for scale up (Stage 3)

10.2.1 Determinants of implementation success

In Chapter 5 of this thesis, the systematic review conducted identified that barriers and facilitators influencing perceived successful implementation of community pharmacy innovations can be stratified to three thematic areas: operationalization of the innovation, pharmacy staff engagement, and external engagement (see Table 5.4 in Chapter 5). These findings were used to develop a questionnaire to explore the determinants of implementations success of the warfarin and NSAIDs care bundles (Chapter 6). This identified that the success factors differed between the care bundles, as presented in Table 10.2. The evaluation results in relation to these thematic areas for the consolidated and warfarin care bundle will now be discussed in turn.

Table 10.2. Comparison of the emergent success factors between the warfarin and NSAIDs bundle as reported by pharmacy staff

Thematic areas identified from systematic review	NSAIDs bundle	Warfarin bundle
Operationalisation of the innovation Operationalisation of innovations encompasses its attributes (such as design and complexity), but also surround factors including resources, compatibility with pharmacy systems, and pharmacy staff access to knowledge and information about the innovation.	- Workload	- Compatibility within pharmacy
Pharmacy staff engagement Pharmacy staff engagement encompasses their knowledge and beliefs relating to an innovation, its compatibility with their roles and values, whether it poses advantages or not, and the incentives and strategies which engage community pharmacy staff.	- Knowledge about NSAIDs medication - Incentives - Sufficient funding	
External engagement External engagement is encompassed by the relationship with patients and other healthcare professionals, their perceptions, and strategies to engage these stakeholders.		- Patient perceptions

NSAIDs = non-steroidal anti-inflammatory drugs

Firstly, in relation to operationalization of community pharmacy innovations, the systematic review identified that the most commonly reported barrier was lack of available resources -

such as time constraints and workload, with less commonly reported barriers including insufficient training, poor design, complexity, and lack of compatibility of the innovation. For the NSAIDs care bundle, the workload of the care bundle was a determinant of implementation success; those who did not perceive increased workload to be a barrier to its implementation were more likely to report successful implementation within their pharmacy. This is understandable considering that NSAIDs - in comparison to warfarin - are prescribed in greater quantities and are more readily available; therefore, it is understandable that the perceived ability of pharmacy staff to cope with this workload would influence successful implementation.

For the warfarin care bundle, within the theme operationalization, compatibly with the pharmacy was a determinant of implementation success. As on-site visit data evidenced the ability of both care bundles to penetrate into community pharmacy practice, why compatibility was a success factor for the warfarin care bundle and not the NSAIDs care bundle is not clear. It could be postulated that this may be due to the warfarin care bundle challenging the traditional role of the community pharmacy support staff, as it was evidenced there was less whole team involvement with this care bundle in comparison to the NSAIDs care bundle.

The second thematic area identified from the systematic review was pharmacy staff engagement, and pharmacy staff's positive and negative perceptions of community pharmacy innovations were commonly reported. Interestingly, for both the NSAIDs and warfarin care bundle, the positive or negative perceptions of the community pharmacy staff of the care bundles were not identified as determinants of implementations success. However, for the NSAIDs care bundle, pharmacy staff perceiving the incentives and funding for this care bundle to be sufficient were more likely to report higher levels of implementation. Pharmacy staff knowledge of NSAIDs was also a determinant of successful implementation, which is interesting considering that the systematic review found this to be relatively rarely reported (n=3 studies) [164, 168, 190]. The importance of pharmacy staff knowledge in this study could be secondary to the involvement of both pharmacists and support staff (who may have less background knowledge of NSAIDs), particularly considering that 13 of the 21 studies evaluating clinical pharmacy innovations as identified by the systematic review sampled only pharmacists [60, 134, 179, 182-190, 192].

The third theme identified from the systematic review was external engagement, which centred on the perceptions of both healthcare professionals and patients. Whilst the negative perceptions of other healthcare professionals was a commonly reported barrier reported from studies included within the systematic review, this was not an identified determinant of implementation success of either the warfarin or NSAIDs care bundle. In relation to patient perceptions, this was an identified determinant of implementation success for the warfarin care bundle, which was explained following the perceptions sought of warfarin patients. Patients reported lack of perceived need of the warfarin care bundle, particularly considering the active role other healthcare professionals had with patients' warfarin (as discussed in upcoming section 10.2.4), which understandably may influence the delivery of the care bundle by the pharmacy staff.

Overall, the difference in the determinants of implementation success between the care bundles indicate that within the Scottish community pharmacy setting innovations require tailored implementation strategies, and that a one size fits all implementation approach will not be suffice. Additionally, the difference in the reported determinants of implementation success compared to those most commonly identified within the international literature, as identified from the systematic review, suggests the Scottish community pharmacy context may differ from other countries.

10.2.2 Fidelity

Implementation scientists have long debated the use of top down and bottom up approaches. In this thesis, the development of consolidated care bundles with core components alongside adaptable peripheries was considered a meet-in-the-middle approach. The core components were to be delivered to every patient, every time to ensure equality of care delivered to patients and to achieve improvements in patient safety. However, in practice, the community pharmacy staff involved in both the warfarin and NSAIDs care bundles did not always deliver the core components of the care bundles as intended due to patient preferences, clinical judgment, and time pressures. Whilst the latter of these is regrettable, constraints regarding time pressures are perhaps unavoidable within such healthcare settings. In relation to the instances where the care bundles were not delivered as intended due to patient preference and clinical judgment, these lapses in fidelity were appropriately justified. For example, in relation to patient preferences, pharmacy staff did not always repeat the delivery of the care bundle if there was patient reluctance towards

this. In relation to clinical judgement, patients were not always informed to stop taking their NSAID during a dehydrating illness if taking it short term, or were not delivered the warfarin care bundle if they resided in a care home with medical staff input daily. As these lapses in fidelity were justifiable, this suggests that the core components of the care bundles require further refinement to be appropriate within community pharmacy practice. Although the every patient, every time approach promotes equality of patient care, what may actually be best - as observed in this thesis - is the community pharmacy delivering an equity-based service, whereby tailored care bundles based on patient preferences and/or patient needs are delivered. In response to this, modifications that could be made to the care bundles drawn from this thesis are:

- Delivering the care bundle question which advises patients to stop taking their NSAID during periods of dehydrating illness to regular NSAID users only
- Condensing the warfarin and NSAIDs care bundle information when repeating it to patients
- Considering whether delivery of the warfarin care bundle is necessary for patients who reside in care homes which have medical staff input daily

10.2.3 Penetration

Through on-site visits, it was evidenced that both the consolidated NSAIDs and warfarin care bundles penetrated into the dispensing process similarly with the same four key process steps, which led to the development of a process map (Figure 8.5). This was observed even when innovative work solutions were adopted - such as the hub and spoke dispensing model and automatic dispensing technology, which is a positive finding considering the strategic drive for future wide scale adoption of such technology to free up pharmacy staff time to deliver more patient-facing services [12].

The similarity in the way both care bundles penetrated within community pharmacy practice also suggests adaptability of the care bundle process to differing clinical contexts. Therefore, it is plausible that if either of the care bundles progress onto national implementation, the high risk medicine of focus or target patient cohort could be amended in light of emerging safety concerns, which would allow for seamless translation of evidence into practice. However, considering that the determinants of implementation success associated with the

care bundles differed, any changes in the focus of the care bundles should happen alongside a tailored implementation strategy to maximise likelihood of successful implementation.

Throughout the timeline of the SPSP-PPC collaborative the community pharmacy staff were encouraged to foster whole team involvement with the care bundles. Whole team involvement was evidenced for both the care bundles, and there were examples of pharmacy support staff being involved in the clinical assessment of NSAIDs, where they contributed to identifying high risk patients. This suggests that the role of Scottish community support staff may be more evolved than in other countries when compared to a review on this topic [310]. However, the on-site visits identified that the onus for delivering the care bundle to patients (i.e. communicating the care bundle questions) was often on the pharmacist. This indicates scope for improvements in whole team involvement with the care bundle, and generally there was greater whole team involvement with the NSAIDs care bundle than for the warfarin care bundle.

The most commonly used supportive resources for the care bundles were the NSAIDs Safety Information Card, the warfarin flyers, as well as a variety of alert stickers used to prompt and remind staff about the care bundle. The use of specific NSAIDs and warfarin alert stickers developed may be beneficial for scale up considering these do not state that referral to a pharmacist is necessary - unlike other alert stickers commonly used in Scottish community pharmacies, which may help foster whole team involvement.

10.2.4 Patient perceptions

For the NSAIDs care bundle, the participants interviewed regarding the NSAIDs care bundle were satisfied with it and considered it valuable. The extent of positive impact identified was greater than has been previously observed within the literature [207, 318, 321], and included impact on knowledge and attitudes, impact on behaviour, and impact on patients' medication. However, a minority of participants reported unintended consequences, which was unexpected given that this does not appear to have been reported within prior literature. Considering that patient-reported impact of community pharmacy innovations appear to be rarely collected, and that the examples of positive and negative impact identified within this thesis are unlikely to be detectable within routinely collected data, the true extent of the impact of community pharmacy innovations may be largely unknown.

When patients were interviewed about the care bundles, there was notable contrast between the perceptions of the warfarin care bundle and the NSAIDs care bundle. Of the patients interviewed about the warfarin care bundle, they could only recall receiving up to one of the care bundle question. Therefore, the potential impact of the warfarin care bundle remains unknown. Additionally, the necessity of such a service was queried considering the involvement of nurses and GPs with patients' warfarin. This finding also relates to an unexpected theme emergent from the patient interviews: participants' perception of community pharmacy's role and how it positions within the wider health care setting. Although locally and internationally community pharmacy is becoming an increasingly patient-facing profession [4, 5, 12], very few participants expected the pharmacy staff to talk to them about their warfarin or NSAID medication. This suggests that further engagement with the public may be necessary for wider realisation of the evolving role of community pharmacy.

10.3 Recommendations for scale up (Stage 3)

The author of this thesis proposes first and foremost that scale up efforts should centre on the NSAIDs care bundle, and that future scale up of the warfarin care bundle should not commence unless further exploratory work indicates its value through a wider needs assessment. This is particularly important considering this thesis identified that high risk medicine care bundles within community pharmacy can have potentially unintended consequences as realised through the evaluation of the NSAIDs care bundle. Therefore, without identifying potential unintended consequences for the warfarin bundle, and to what extent they may co-exist amongst any positive impact, it cannot be assumed that the warfarin care bundle if scaled-up would be beneficial for patient care. Therefore, this section will focus on the recommendations for scale up of the NSAIDs care bundle only.

Key findings of this thesis supports national implementation of the NSAIDs care bundle: it penetrated well within community pharmacy practice, patients were satisfied with the experience of the care bundle, and it mostly had a positive impact on patients. The recommendations for the national implementation of the NSAIDs care bundle developed throughout this thesis have been categorised as per a taxonomy of implementation interventions developed - the Expert Recommendations for Implementing Change (ERIC)

taxonomy [295]. As introduced in Section 2.3.3, this ERIC taxonomy stratifies 73 discreet implementation interventions into nine classifications.

Of these 73 discreet implementation interventions, seven were proposed to inform the national implementation of the NSAIDs care bundle. This led to the developed of eight recommendations, presented in Table 10.3, which were contextualised to the community pharmacy setting. These recommendations were derived from the determinants of implementations success identified (Chapter 7), the fidelity and penetration analysis (Chapter 8), and from patient perceptions (Chapter 9). If, and how, these implementation interventions were actioned for the national implementation of the NSAIDs care bundle is presented in the upcoming Section 10.3.1.

Table 10.3. Compilation of the eight recommendations for the national implementation of the NSAIDs care bundle

Key finding	Proposed ERIC implementation interventions	Contextualised recommendation
Recommendations based on the determinants of implementation success (Chapter 7):		
Knowledge about NSAIDs medication is a determinant of implementation success	Develop and distribute educational materials	1. Disseminate information to all community pharmacy staff on NSAIDs medication to ensure each have the minimum level of knowledge required to deliver the bundle
Sufficient funding and workload is a determinant of implementation success	Fund and contract the clinical innovation	2. Incorporate within community pharmacy contract to ensure an appropriate funding model aligns with the workload demands
Incentives are a determinant of implementation success	Facilitate relay of clinical data to providers	3. Reinforce the evidence on the risk associated with NSAIDs use and the rationale behind the care bundle to incentivise pharmacy staff involvement
	Develop and implement tools for quality monitoring	4. Promote use of quality improvement run-charts to incentivise local improvements in care bundle delivery
Recommendations based on penetration analysis (Chapter 8):		
Scope for improved whole team involvement	Capture and share local knowledge	5. Disseminate the process map developed to pharmacies
	Facilitation	6. Promote pharmacy teams' in house interactive problem solving to consider how the skillset of pharmacy staff can be matched to the care bundles' key process steps
Recommendations based on fidelity analysis (Chapter 8):		
Scope for improvement in implementation fidelity	Promote adaptability	7. The care bundles core components require refinement to be appropriate in community pharmacy practice. Suggested refinements are: • Delivering the NSAIDs care bundle question which advises patients to stop their NSAID during a dehydrating illness only to patients taking an NSAID regularly • Permitting delivery of a condensed version of the NSAIDs care bundle when repeating it to patients
Recommendations based on patient perceptions (Chapter 9):		
Identification of unintended consequences	Develop and implement tools for quality monitoring	8. Develop a PROMs tool from the reported impact to allow positive impact and unintended consequences to be monitored during scale up

ERIC = Expert Recommendations for Implementing Change, NSAIDs = non-steroidal anti-inflammatory drugs, PROMs = patient reported outcome measures

Interestingly, the recommendations posed represent seven of the nine classifications of implementation interventions, as shown in Figure 10.2. This indicates the multifaceted nature of the recommendations posed. The two classifications not represented are 'Engage consumers', and 'Change infrastructure', which is understandable considering the evaluation findings. Consumers - which are the NSAIDs patients in this context - were supportive of the care bundle, therefore tactics to engage consumers were not a necessity. Secondly, the NSAIDs care bundle aligned with the current healthcare strategy and penetrated well within community pharmacy practice, indicating that infrastructural changes may not be required.

Nine classifications of implementation interventions	**Proposed ERIC implementation interventions for the national implementation of the NSAIDs care bundle**
1. Use evaluative and iterative strategies	• Develop and implement tools for quality monitoring
2. Provide interactive assistance	• Facilitation
3. Adapt and tailor to context	• Promote adaptability
4. Develop stakeholder interrelationships	• Capture and share local knowledge
5. Train and educate stakeholders	• Develop and distribute educational materials
6. Support clinicians	• Facilitate relay of clinical data to providers
7. Engage consumers	• Nil
8. Utilise financial strategies	• Fund and contract the clinical innovation
9. Change infrastructure	• Nil

Figure 10.2. Representation of the nine classifications of implementation interventions for the national implementation recommendations for the NSAIDs care bundle [80]

ERIC = Expert Recommendations for Implementing Change, NSAIDs = non-steroidal anti-inflammatory drugs

10.3.1 National implementation of the NSAIDs Communication Care bundle

In November 2017, it was announced that national implementation of the NSAIDs care bundle would be realised through its incorporation within the community pharmacy contractual framework in May 2018 [351], as was advocated by the recommendations borne from this thesis. Information on the full NSAIDs care bundle was communicated to pharmacies [352], yet funding was specifically allocated for delivery of the NSAIDs Communication Care Bundle. A single payment of £1,600 was paid in December 2017 to community pharmacy contractors to undertake the NSAIDs Communication Care Bundle from May 2018 to September 2018, and to also undertake the safety climate survey (SafeQuest-CP) for a second time by the 30th of September 2018 [353].

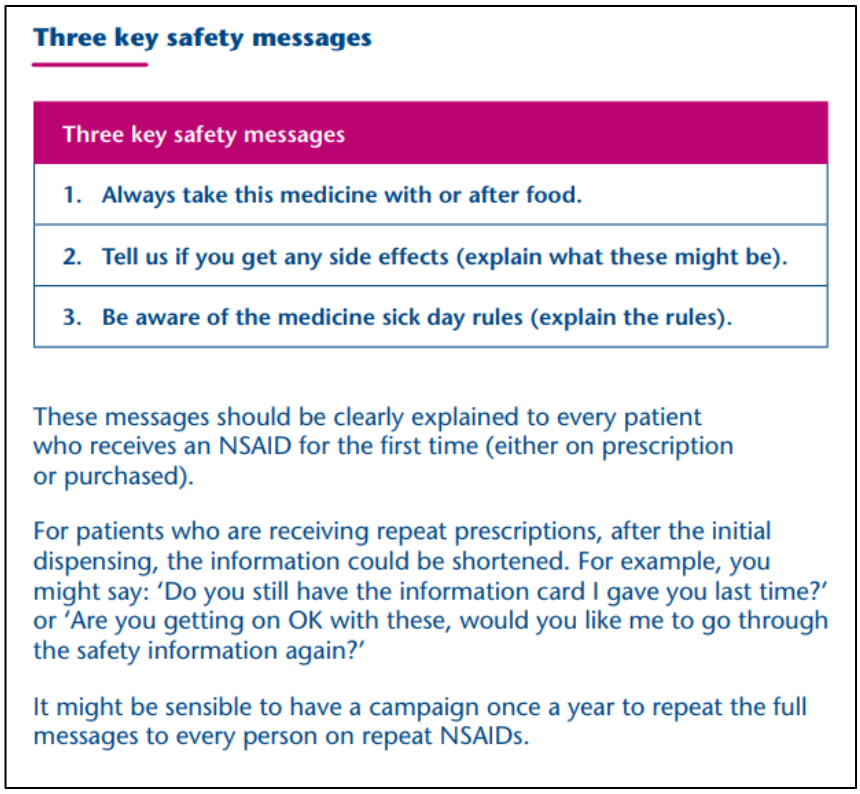
To support this national implementation of the NSAIDs Communication Care Bundle, the recommendations posed in Table 10.3 were communicated to the strategists involved in devising the national implementation strategy during a teleconference call on the 16th of January 2018. Due to the timing of this, the patient interviews had not yet been conducted. Therefore, the recommendations were based on the results of the determinants of implementation success of the NSAIDs care bundle (Chapter 7), and the penetration and fidelity analysis (Chapter 8). If, and how, these recommendations were actioned by the strategists is presented in Table 10.4. Additionally, a webinar for community pharmacy staff was hosted on the 9th of March 2018, where NW presented some of the key findings of this thesis and how they were used to shape recommendations (Appendix 10.1).

Table 10.4. Recommendations posed for the national implementation of the NSAIDs Communication Care Bundle and how they were actioned (Jan 2018)

Contextualised recommendations	Actioned	How recommendation were actioned
Recommendations based on the determinants of implementation success (Chapter 7):		
1. Disseminate information to all community pharmacy staff on NSAIDs medication to ensure each have the minimum level of knowledge required to deliver the bundle	✔	• An A5 flyer for support staff was developed with information on NSAIDs and the rationale for the care bundle questions (Appendix 10.2). • Webinars developed were made available to all pharmacy staff [352].
2. Incorporate within community pharmacy contract to ensure an appropriate funding model aligns with the workload demands	✔	• The communication care bundle was incorporated within the 2018 community pharmacy contract [41].
3. Reinforce the evidence on the risk associated with NSAIDs use and the rationale behind the care bundle to incentivise pharmacy staff involvement	✔	• The rationale for selecting NSAIDs was detailed within information disseminated in a toolkit to pharmacies, including NSAIDs' association with hospital admissions. • Anticipated outcomes of reduced gastro-intestinal side effects and acute kidney injuries were stated within this information [352].
4. Promote use of quality improvement run-charts to incentivise local improvements in care bundle delivery	✔	• Laminated data collection sheets and run charts were disseminated to pharmacies [352].
Recommendations based on penetration analysis (Chapter 8):		
5. Disseminate the process map developed to pharmacies	✘	• This recommendation was viewed as over prescriptive by strategists. Instead, the process map was an optional resource for regional face to face NES training sessions.
6. Promote pharmacy teams' in house interactive problem solving to consider how the skillset of pharmacy staff can be matched to the care bundles' key process steps.	✔	• A webinar was developed which referred to the necessity of harnessing whole team engagement, to establish roles and responsibilities for staff members, and to plan staff training [352].
Recommendations based on fidelity analysis (Chapter 8):		
7. The care bundles core components require refinement to be appropriate in community pharmacy practice.	✔	• The NSAIDs care bundle question which informs patients to stop taking their NSAID if dehydrated is only to be delivered to patients taking an NSAID regularly (33). • Full delivery of the NSAIDs Communication Care Bundle was advocated for the first encounter with a patient with a tailored condensed version repeated to patients (33).

A green tick (✔) indicates where a recommendation was taken forward. A red cross (✘) indicates where a recommendation was not taken forward.
NSAID(s) = non-steroidal anti-inflammatory drug(s), NES = NHS Education for Scotland

Overall, the national implementation strategy was largely influenced from the findings of this thesis. As presented in Table 10.4, modifications were made to the NSAIDs Communication Care Bundle's core components for its national roll out, which aligned with the recommendations of this thesis. Pharmacy staff were advised that the NSAIDs care bundle question which informed patients to stop taking their NSAID during a dehydrating illness was only relevant for patients taking an NSAID regularly [352]. In relation to repetition of the care bundle to patients, full delivery of the NSAIDs Communication Care Bundle was advocated for the first encounter with a patient, yet it was suggested that pharmacy staff shorten the care bundle when repeating it, as shown in Figure 10.3 [352].



Three key safety messages

Three key safety messages
1. Always take this medicine with or after food.
2. Tell us if you get any side effects (explain what these might be).
3. Be aware of the medicine sick day rules (explain the rules).

These messages should be clearly explained to every patient who receives an NSAID for the first time (either on prescription or purchased).

For patients who are receiving repeat prescriptions, after the initial dispensing, the information could be shortened. For example, you might say: 'Do you still have the information card I gave you last time?' or 'Are you getting on OK with these, would you like me to go through the safety information again?'

It might be sensible to have a campaign once a year to repeat the full messages to every person on repeat NSAIDs.

Figure 10.3. Information disseminated to pharmacies on the three safety messages of the NSAIDs Communication Care Bundle with guidance on repeated delivery

NSAID(s) = non-steroidal anti-inflammatory drugs

In relation to the resources disseminated to support the care bundle, the NSAIDs Safety Information Card and the NSAIDs alert stickers were disseminated to all community pharmacy staff as recommended. Additional resources were also disseminated relating to the risk of NSAIDs' induced acute kidney injury (AKI), comprising an information card for

patients, an information sheet for patients, and an information sheet for healthcare professionals [352].

To promote whole team engagement with the NSAIDs care bundle, a one hour webinar hosted on the 9th of March 2018 referred to the importance of whole team engagement and assigning specific roles and responsibilities to pharmacy staff. This webinar also included information on the NSAIDs care bundle and quality improvement techniques. To ensure all pharmacy staff have sufficient knowledge of NSAIDs and the care bundle, an A5 flyer was developed with this information (Appendix 10.2) and a two minute "How to" webinar was developed specifically for pharmacy support staff to foster their engagement. To incentivise pharmacy staff involvement, information on the risks of NSAIDs and potential benefits of the care bundle were disseminated to pharmacies, as shown in Figure 10.4.

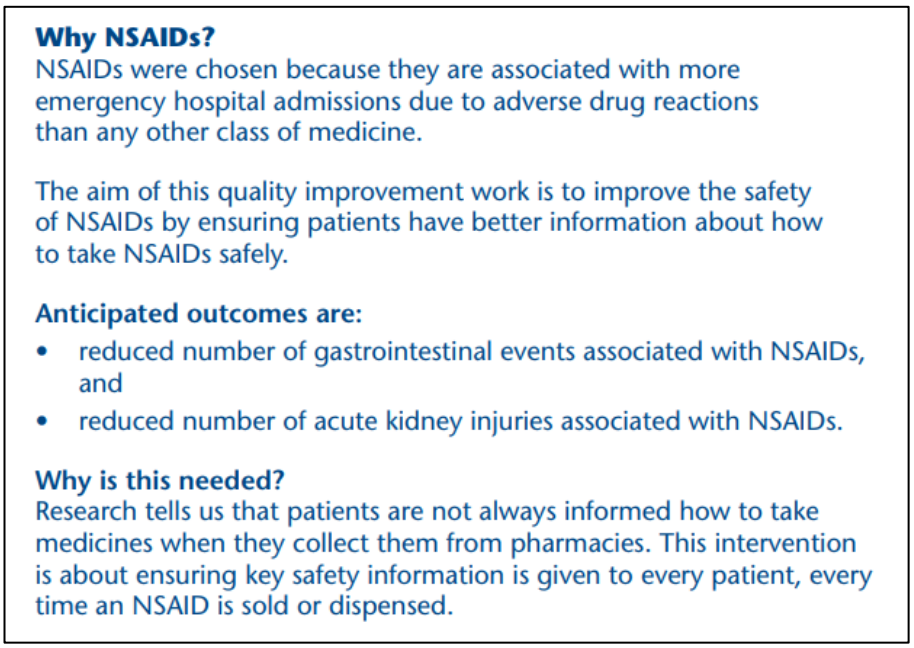


Figure 10.4. Information disseminated to pharmacies on NSAIDs' risks and anticipated outcomes of the NSAIDs Communication Care Bundle

NSAID(s) = non-steroidal anti-inflammatory drugs

A recommendation not taken forward, however, was the dissemination of the process map for the NSAIDs Communication Care Bundle to the national cohort of pharmacies. This was considered over-prescriptive, and alternatively the process map was used as an optional resource during regional face-to-face training sessions hosted by NES. The implications of this recommendation not being actioned may be lessened by the fact that only the NSAIDs Communication Care Bundle was to be implemented. This part of the NSAIDs care bundle

does not require any input from a pharmacist (Figure 8.5), thus there may be greater opportunity for support staff involvement.

10.3.2 National implementation of the NSAIDs Safer Care Bundle

The NSAIDs Safer Care Bundle involves pharmacy staff assessing patients use and/or need of their NSAID, identifying high risk patients, and identifying triple whammy interactions. Therefore, as this has not been nationally implemented, the patient reported impact identified in this thesis relating to impact on medicines (e.g. initiation of the gastro-protective agent omeprazole) is unlikely to be realised (Table 9.6, Chapter 9), and reductions in high risk prescribing is unlikely. Considering that high risk prescribing in relation to NSAIDs has been identified within Scottish GP practices [36], future national implementation of the NSAIDs Safer Care Bundle is required to achieve maximal improvements in the safety of this high risk medicine.

Within this thesis, both the NSAIDs Communication Care Bundle and the NSAIDs Safer Care Bundle were evaluated together, thus the recommendations posed in Table 10.3 are also applicable for the implementation of NSAIDs Safer Care Bundle. Therefore, the national implementation of the NSAIDs Communication Care Bundle may have created a supportive environment for the implementation of the NSAIDs Safer Care Bundle. However, how strategists may action these recommendations may differ when contextualised specifically to the NSAIDs Safer Care Bundle. Similarly to when the NSAIDs Communication Care Bundle was implemented, the author of this thesis will seek to actively pose these recommendations to the strategists involved in designing the national implementation strategy for the NSAIDs Safer Care Bundle to facilitate the development of a context-sensitive implementation strategy.

10.4 Future research

Unanswered questions remain regarding the warfarin care bundle; the patients interviewed could not recall receiving a warfarin care bundle from their pharmacy, which meant that exploring patient perceptions of the care bundle was not possible. Furthermore, the patients interviewed queried the necessity of a warfarin care bundle. Therefore, prior to any scale up of this care bundle a wider needs assessment should be conducted with a larger cohort of patients and healthcare professionals involved with warfarin management. This would identify if there is a need for community pharmacy to support the safer use of this medicine.

In general, however, further exploration of this may not be the most valuable use of resources considering the declining use of warfarin due to the emergence of newer oral-anticoagulants on the market [354]. Instead, it may be more valuable for future research to focus on the national evaluation of the NSAIDs Communication Care Bundle and the NSAIDs Safer Care Bundle (if implemented), with an emphasis on outcomes. An overview of the outcomes which should be prioritised are presented in Table 10.5 as per Proctor et al's stratification [70].

Table 10.5. Outcome measures to prioritise following national implementation of the NSAIDs care bundles

Outcome measures	Methodological approach	Communication Care Bundle	Safer Care Bundle
Implementation outcome measures			
Fidelity	Communication Care Bundle: Simulated patient study Safer Care Bundle: Electronic SBAR reports	✔	✔
Service outcome measures			
Changes in prescribing patterns of NSAIDs: - reduced NSAIDs prescribing - lower doses of NSAIDs prescribed	Drug utilisation study		✔
Reduced high risk prescribing: - age ≥75 and concomitantly prescribed an NSAID and any of the following: anti-coagulant, aspirin, corticosteroid, SSRI, venlafaxine, duloxetine - age ≥75 years and prescribed an NSAID without gastroprotection - age ≥75 and concomitantly prescribed an NSAID in patient with excessive use of alcohol or smoking	Drug utilisation study		✔
Reduced triple whammy interactions: - concomitant prescribing of an NSAID, an ACEi/ARB, and a diuretic	Drug utilisation study		✔
Increased concomitant prescribing of an NSAID alongside gastro-protective agent (e.g. a PPI)	Drug utilisation study		✔
Client outcome measures			
Reduced NSAIDs induced gastro-irritation	Case series (longitudinal study)		✔
Reduced NSAIDs induced AKI	Case series (longitudinal study)		✔
PROMs	Patient questionnaire	✔	✔
Patient satisfaction	Patient questionnaire	✔	✔

NSAIDs = non-steroidal anti-inflammatory drugs; SBAR = situation, background, assessment, recommendation; SSRI = selective serotonin reuptake inhibitor; ACEi = angiotensin converting enzyme inhibitor; ARB = angiotensin receptor blocker; AKI = acute kidney injury; PPI = proton pump inhibitor; PROMs = patient reported outcome measures,

The fidelity of both of the NSAIDs care bundles should be explored following scale up if there are intentions to explore associated service and client outcomes. Studies have been criticised for not exploring if innovations are delivered as intended before assessing an innovation's intended outcomes. For example, if the NSAIDs care bundles do not achieve intended service or clinical outcomes, exploring their fidelity allows researchers to attribute this to their suboptimal implementation or inadequacies in their design [103, 235]. The national implementation strategy did not mandate formal submission of documentation regarding the delivery of the NSAIDs Communication Care Bundle, which would have allowed for national fidelity data on whether the NSAIDs Communication Care Bundle is being delivered in practice. As the entirety of the NSAIDs Communication Care Bundle is applicable for delivery for over-the-counter NSAID supplies, this permits the opportunity to use simulated patients (i.e. 'mystery shoppers') to assess the delivery of NSAIDs Communication Care Bundle [350], which may offer greater validity than the self-reported fidelity as was conducted in this thesis.

For potential implementation of the NSAIDs Safer Care Bundle, strategists may wish to mandate that pharmacy staff document the care bundle's delivery in order to obtain robust data on its fidelity and ensure it is being delivered in practice. An option is to stipulate that Situation-Background-Assessment-Recommendation (SBAR) reports are developed and submitted when an issue relating to a patient's NSAID is identified. An SBAR report is an electronic report generated via the online Pharmacy Care System which is a function already introduced within all Scottish community pharmacies. The SBAR reports are intended to facilitate the commutation of issues between community pharmacies and GP practices; therefore, collation of this data at national level would allow for an exploration of both the incidence and nature of NSAID issues identified.

As presented in Table 10.5 the NSAIDs Communication Care Bundle is unlikely to result in any of the service outcome measures detailed. Thus, it is less likely to have an impact on client outcome measures relating to reduced NSAIDs induced gastro-irritation and AKI when compared with the NSAIDs Safer Care Bundle. Therefore, exploration of these service and client outcome measures should not be prioritised for the Communication Care bundle.

Contrary, the NSAIDs Safer Care Bundle is designed intentionally to influence these service outcome measures presented in Table 10.5, thus drug utilisation studies could explore changes in the prescribing patterns of NSAIDs and the incidence of high risk prescribing. The

Prescribing Information System (PIS) within NHS Scotland makes this possible; it provides information on reimbursed medicines and affords the opportunity to conduct pharmaco-epidemiological studies at a national level within Scotland [122]. The scope to link PIS data to other health records, such as hospital activity statistics and the Scottish morbidity record [355], also affords the opportunity to explore potential impact this may have on client outcome measures such as NSAIDs induced gastro-irritation and AKI. This is simplified by the presence of specific ICD-10 codes for some of these outcomes, including: 'NSAID adverse effects in therapeutic use' (ICD10 code: Y45.3), and 'analgesic nephropathy' (ICD10 code: N14.0) [356]. Additionally, National Therapeutic Indicators - which are used to indicate the quality of prescribing within Scotland - exist for some of the outcomes of interest [357]. This means data pertaining to the safe used of NSAIDs are routinely analysed and disseminated. This includes the incidence of the triple whammy interaction; the incidence of high risk patients prescribed an NSAID without gastro-protection; and the prescribing incidence of NSAIDs and proton pump inhibitors (e.g. omeprazole) [357, 358].

For both the NSAIDs Communication Care Bundle and the NSAIDs Safer Care Bundle, scope also lies to explore patient-reported measures of each. The patient-reported impact identified for the NSAIDs care bundle within this thesis (see Table 9.6, Chapter 9) allows for the development of a PROMs tool which could be applied at scale to evaluate the care bundles' impact. This would also allow for ongoing monitoring of the unintended consequences which were reported by a minority of the patients interviewed. As the PROMs tool is likely to be in the form of a questionnaire, the patient satisfaction questionnaire applied in this thesis could concomitantly be administered (Figure 9.2, Chapter 9). An example of what this might look like is presented in Figure 10.5.[12] Exploring both PROMs and patient satisfaction would align with recommendations posed by the *Healthcare Quality Strategy for NHS Scotland,* which advocates the routine collection of both patient-reported outcomes and experience of NHS services [9].

[12] This draft questionnaire presented is in its preliminary development stage and has not undergone any form of validy or pilot testing. It therefore should not be used without consulting the author of this thesis.

Thinking about your own experience of the NSAIDs service, please read each question and circle the number that best represents the extent to which you agree or disagree with the following statements	Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly Agree
Experience of the service					
I am satisfied with the pharmacy staff member's explanation of the aims of the NSAIDs service to me	1	2	3	4	5
I am satisfied with the privacy of where the discussion took place	1	2	3	4	5
I am satisfied with the time the pharmacy staff member spent listening to me	1	2	3	4	5
I am satisfied with the pharmacy staff member's personal approach towards me	1	2	3	4	5
I am satisfied with the opportunity I had to raise queries	1	2	3	4	5
I am satisfied with the pharmacy staff member's advice	1	2	3	4	5
The pharmacy staff member answered my queries	1	2	3	4	5
Judgement of the service					
I wanted to have a discussion about my NSAIDs medication	1	2	3	4	5
I now feel more confident about managing my NSAIDs medication	1	2	3	4	5
I would be happy to have a discussion about my NSAIDs medication again in the future	1	2	3	4	5
I would recommend the NSAIDs service to others	1	2	3	4	5
I was satisfied with the NSAIDs service I took part in	1	2	3	4	5
Outcome of the service					
I have improved awareness of NSAID and its risks	1	2	3	4	5
I have gained new knowledge of NSAID	1	2	3	4	5
I have increased confidence with taking my NSAID	1	2	3	4	5
I have learnt about the role of pharmacy	1	2	3	4	5
I am more concerned about taking my NSAID medication	1	2	3	4	5
I am more likely to take my NSAID medication with food	1	2	3	4	5
I am more likely to use the pharmacy for advice in the future	1	2	3	4	5
I am reluctant to take my NSAID medication	1	2	3	4	5
I want to stop taking my NSAID medication	1	2	3	4	5
I am more likely to take my NSAID medication	1	2	3	4	5

For the following questions, please tick yes or no. Please offer details if you have selected yes.

1. Because of the NSAIDs service , I read more information about my NSAID medication YES ◯ NO ◯

   If yes, please offer details:_____
   _____
   _____

2. Because of the NSAIDs service, a lower dose of NSAID was prescribed YES ◯ NO ◯

   If yes, please offer details:_____
   _____
   _____

3. Because of the NSAIDs service, my medication was changed YES ◯ NO ◯

   If yes, please offer details:_____
   _____
   _____

Figure 10.5. Draft questionnaire to explore patient reported outcome measures (PROMs) and satisfaction of the NSAIDs care bundle(s)

10.5 Strengths and limitations

A strength of this thesis was that the development and evaluation of the care bundles sought involvement of a variety of key stakeholders. For the design of the care bundles, collaborative input from national strategists, regional leads, a patient representative, and front-line community pharmacy staff ensured the care bundles were amenable to all and aligned with both national strategy and local service delivery. The evaluation of the care bundles sought input from community pharmacy staff and patient perceptions, which enabled understanding of both providers' and users' perspectives. However, also exploring the perceptions of the wider primary care team may have offered further valuable insight, considering the involvement of nurses with patients' warfarin and that sometimes the care bundles required GP referral. Additionally, an unexpected emergent theme from the patient interviews was the perceived role of pharmacy, and interviewing other primary care clinicians would have helped to conceptualise this.

The use of mixed methods in this thesis was considered a strength, as it helped foster a more enriched understanding of the implementation of the care bundles within their pilot phase. In some instances the qualitative data helped explain quantitative findings and offered explanations to the data, and the different data sources allowed findings to be crosschecked for validity. However, the collection and analysis of qualitative data can be influenced by the subjective bias of the researcher(s) involved. This bias could have been mitigated had all qualitative data interpretation been conducted independently by another researcher to validate its analysis, yet resource constraints made this not possible.

A further strength of this thesis was the purposeful selection of implementations guides applied, which circumvents the criticisms of previous studies which have arbitrarily decided which implementation guides to apply [79]. The selection of implementation guides within this thesis was influenced by their plausibility, their development process, and how commonly they were applied - which was considered important for the cross-comparison of findings with other studies.

Following its application in this thesis, the CFIR was deemed sufficiently broad in depth to cover the myriad of different factors identified by the systematic review (Chapter 5) [63], with only minimal suggestions posed to improve the CFIR, as is described in Section 5.6.1. Furthermore, the CFIR's ability to facilitate cross comparison was evidenced when the

systematic review results were compared to a similar review by Shoemaker et al who also applied the CFIR (Table 5.5) [143]. It should also be acknowledged that a systematic review was conducted to identify the CFIR constructs of interest to explore in relation to the care bundles. This represents a robust process for selecting CFIR constructs of interest - which in this thesis informed the development of a questionnaire (Chapter 6). However, studies in other contexts may not have sufficient time and resources to conduct a similar systematic review for this purpose. In these instances, the selection of which CFIR constructs to explore may be challenging, given that it is unlikely that a study could explore all 39 constructs of the CFIR.

Proctor et al's taxonomy of outcomes helped identify which outcomes should be explored within this thesis [70], and the stratification of outcomes to implementation outcomes, service outcomes, and client outcomes was useful to understand what was, and was not, within the scope of this thesis (see Section 2.3.2). The prior evaluation of the pre-consolidated care bundles was referred to in order to select the outcomes of interest, as an exploration of all of them would not have been possible given resource constraints. Therefore, similar to the CFIR, in research contexts where there has been no preliminary evaluation, selection of which outcomes to explore may be challenging.

The ERIC taxonomy was applied in this thesis to identify implementation interventions for the national roll out of the care bundles. Therefore, the selection of implementation interventions was based on this extensive list of 73 different implementation interventions and not developed based on ideas formulated only by the researcher (NW), which could have been influenced by the subjective bias of the researcher. Additionally, as these 73 different implementation interventions are stratified to 9 classifications, this meant that the implementation strategy developed for the NSAIDs Communication Care Bundle could be judged against this. This was useful to consider if it was sufficiently multifaceted or focused heavily on a single classification of implementation interventions. Furthermore, as the selection of ERIC implementation interventions was dependent on outputs derived from the application of the CFIR and Proctor et al's taxonomy of outcomes, this exemplifies that applying more than one implementation guide can be beneficial when evaluation innovations for the purpose of informing their scale up.

During the evaluation timeline of this thesis when recommendations for the national implementation of the care bundles were being developed and communicated to the

national strategists, there was no established method of selecting implementation interventions in response to evaluation findings [359]. Therefore, the transparent and logical process applied when developing an implementation strategy in response to the evaluation findings represents a strengths of this thesis. Subsequently, in May 2018 Lewis et al proposed a more collaborative approach whereby a variety of stakeholders' views are sought when matching implementation interventions to identified barriers and facilitators [359]. This thesis can therefore be criticised for lacking this collaborative process. However, a study conducted by Hutink et al found that implementation strategies generated by different stakeholders (e.g. researchers, healthcare professionals, patients, quality improvement advisers) were of little difference [360], which may suggest that wider stakeholder contribution in this process is not necessary. Nevertheless, wider stakeholder engagement was sought later in the process when communicating the proposed recommendations to national strategists involved with the NSAIDs care bundle implementation, as was discussed in Section 10.3.

Although the application of implementation guides within this thesis was considered a strength, it has been suggested that the application of implementation guides may cause researchers to ignore problems which do not fit within an implementation guide's predefined domains or constructs [43]. However, all three implementation guides applied within this thesis are notably broad in their coverage and are designed to be applicable to a myriad of settings [63, 70, 80]. Additionally, as alluded to earlier, the selection of specific CFIR constructs to explore was informed by a context-specific systematic review conducted (Chapter 5), and the subsequent questionnaire developed from this enclosed open-ended questions which confirmed completeness of data capture (Chapter 6). Also, the selection of specific outcomes of interest, as defined by Proctor et al, was informed by prior evaluation conducted as part of the SPSP-PPC collaborative [38]. On reflection, as the selection of CFIR constructs and the selection of Proctor et al's taxonomy of outcomes was informed from preliminary exploration, this highlights that these implementation guides are not prescriptive in nature and are not intended to govern implementation evaluations. Instead, as evidenced in this thesis, they allow researchers to frame an evaluation, ensure the use of terminology which is consistent with that of the wider literature, and allow researchers to understand how their work positions within the field of implementation science.

There are key limitations of this thesis which need addressed. This thesis aimed to design and evaluate the warfarin and NSAIDs care bundles in order to inform their national implementation; however, only 24 community pharmacies piloted the care bundles. Additionally, not all of the 24 community pharmacies sampled responded to the questionnaire disseminated (Chapter 7), only eight were selected for on-site visits (Chapter 8), and only six recruited patients to be interviewed (Chapter 9). Furthermore, engagement of the three pharmacies in NHS Highland involved in the warfarin care bundle was low. None of these pharmacies responded to the questionnaire, the pharmacy selected for an on-site visit in NHS Highland no longer delivered the warfarin care bundle (thus a retrospective walk through was conducted), and no patients were recruited to be interviewed from this region. This has negative implications for the generalisability of the findings, yet it should be acknowledged that the pharmacies involved with the care bundles and those who responded to the evaluation represented heterogeneous characteristics in terms of NHS region, ownership, rurality and pharmacy staff numbers.

An additional implementation outcome measure was intended to be collected by the community pharmacies. As described in Section 4.9, the pharmacies which implemented the consolidated warfarin and NSAIDs care bundles were expected to routinely submit their quality improvement run charts to their respective SPSP-PPC Regional Leads. This was intended to be used as an additional measure of fidelity which would have offered longitudinal data on the care bundles' fidelity, and could have been used to validate the implementation success scale developed (Figure 6.2, Chapter 6). However, this run-chart data was not routinely submitted by the pharmacies and could not be used.

Although the impact of the care bundles was explored, this was via patient-reported perceptions, and quantifiable client outcome measures could have offered a more definitive evaluation of the value of the care bundles. Examples of such include improvements in warfarin INR control; reduced incidences of NSAID-included gastro-irritation and/or AKI; and reduced incidence of the triple whammy combination. However, in such small-scale and short-term pilot stages, achieving the statistical power to explore these meaningfully was unlikely. Being unable to quantify the clinical impact of the care bundles has wider implications for the evaluation; an analysis of how lapses in fidelity may have influenced intended outcomes of the bundle was not possible. This is regrettable as would have allowed

for definitive identification of the core components of the care bundles required to achieve intended outcomes.

Ideally, a test of scale up of the care bundles in a larger setting prior to anticipated national implementation would have offered more generalisable findings [21, 361], and may have offered the statistical power to explore quantifiable improvements in service outcome measures. Nevertheless, scalability of the NSAIDs Communication Care Bundle was indicated through its implementation as a local enhanced service in NHS Highland [362]. By December 2017, all 81 community pharmacies within this region implemented it [362]. Although an evaluation of this was outwith the scope of this thesis, this suggests the appropriateness of this care bundle's within Scottish community pharmacies.

10.6 Final conclusions

The successful implementation of healthcare innovations is a known challenge internationally, and the field of implementation science has developed a plethora of implementation guides to facilitate this. Within this thesis, purposeful selection of implementation guides allowed for the systematic exploration and progression of the warfarin and NSAIDs care bundles within Scottish community pharmacies. The evaluation conducted indicated that scale up efforts should focus on the NSAIDs care bundle considering its successful penetration in practice and positive patient perceptions, contrasted with a lack of perceived need of the warfarin care bundle. In 2018, national implementation of part of the NSAIDs care bundle - the NSAIDs Communication Care Bundle - was realised through its inclusion within the Scottish community pharmacy contractual framework. Key evaluation findings successfully informed the national implementation strategy for this, which included supporting whole team involvement; ensuring pharmacy staff sufficiency in knowledge; and incentivising engagement. Future efforts should focus on securing the national implementation of the NSAIDs Safer Care Bundle to achieve maximal improvements in the safer use of NSAIDs. Additionally, the intended service and client outcomes of the care bundles should be explored utilising routinely collected national data available within Scotland, alongside continued monitoring of patient-reported outcome measures and unintended consequences.

Afterword by the author

The aims of this thesis were purposefully formulated to act complementary to the wider SPSP-PPC collaborative to ensure research outputs could inform the progression of the warfarin and NSAIDs care bundles. Whilst successful completion of this thesis was intrinsically dependent on the engagement of those involved in the SPSP-PPC collaborative, the entirety of the thesis is the sole work of the author, Natalie Weir. The aims formulated, the methods adopted, the analysis applied, the presentation of the results, the conclusions drawn, and the recommendations made solely represent the academic input and research skills of the author.

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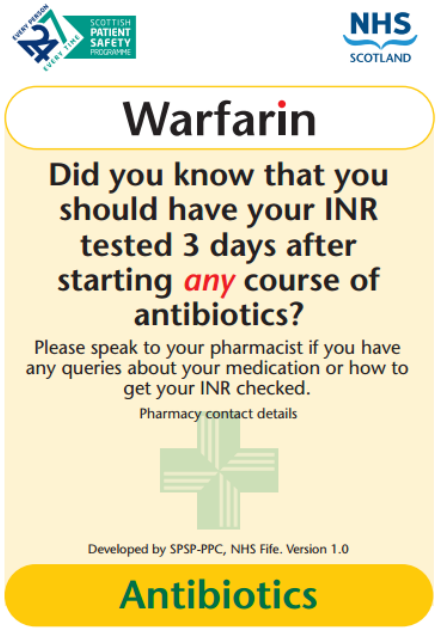
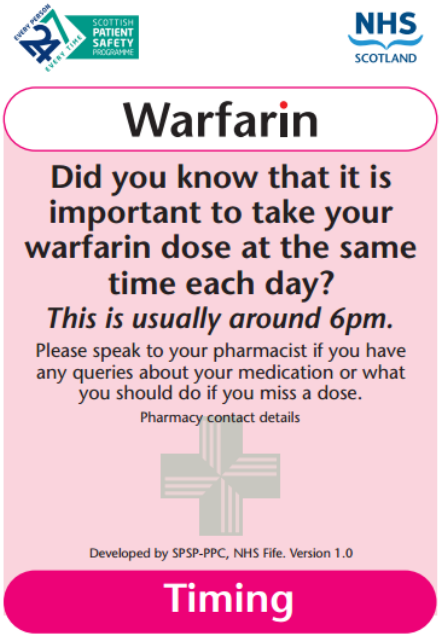
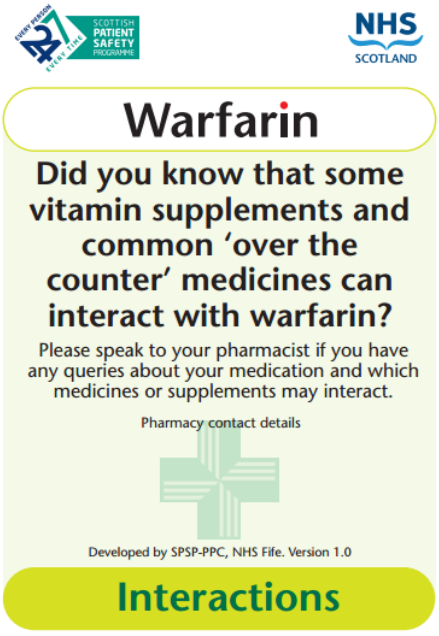
Appendices

Appendix 1.1: Resources developed for the warfarin and NSAIDs care bundles

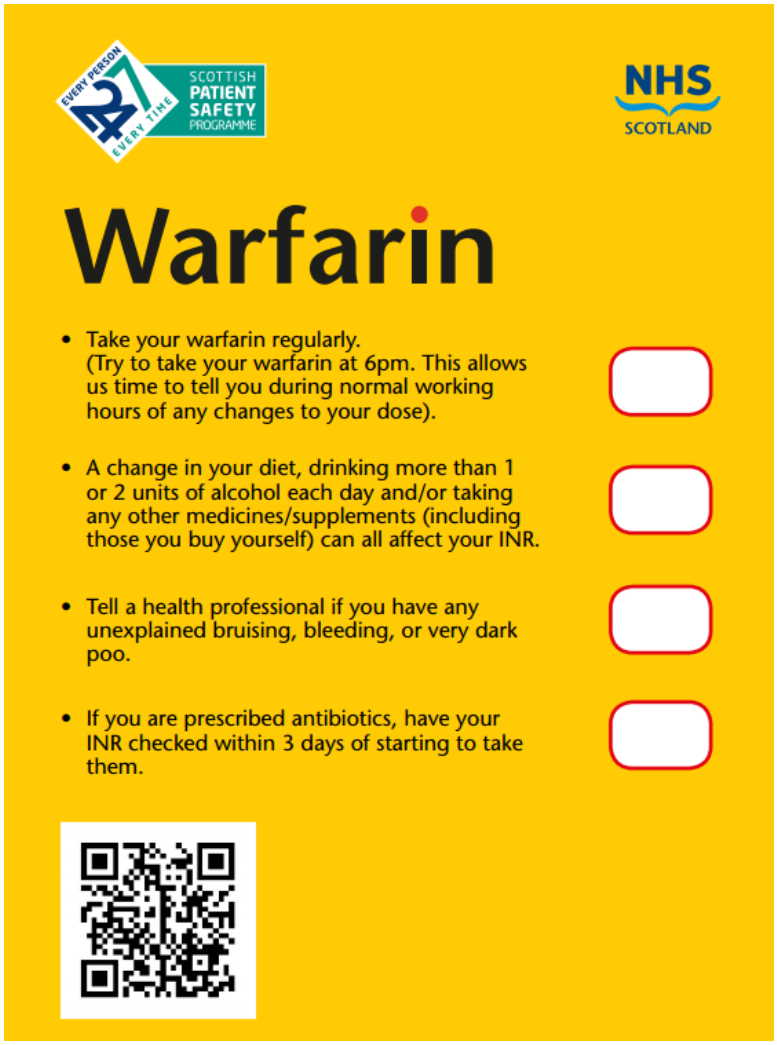
Warfarin flyers







Warfarin Teach Back counselling tool



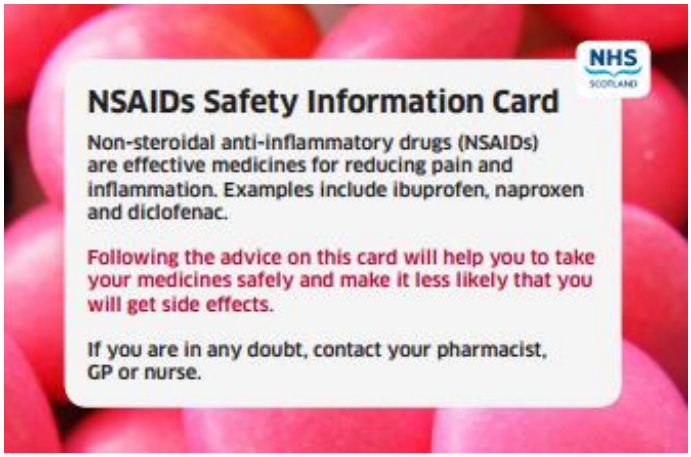
The QR code when scanned links to the warfarin patient information video.

High Risk Medicine Intervention sticker

Warfarin Patient Information Video

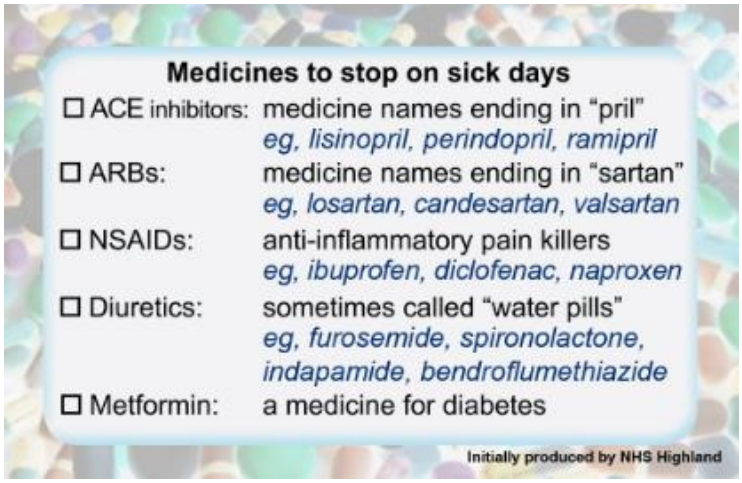
Available from: https://www.youtube.com/watch?v=kbD37FfXMco

NSAIDs Safety Information card



Non-steroidal Anti-inflammatory Drug (NSAID) sticker

Medicines Sick Day Card



Appendix 2.1: Full definitions of the Consolidated Framework for Implementation Research (CFIR) constructs

	CONSTRUCT	DEFINITION
I. INNOVATION CHARACTERISTICS		
A	Intervention Source	Perception of key stakeholders about whether the intervention is externally or internally developed.
B	Evidence Strength & Quality	Stakeholders' perceptions of the quality and validity of evidence supporting the belief that the intervention will have desired outcomes.
C	Relative Advantage	Stakeholders' perception of the advantage of implementing the intervention versus an alternative solution.
D	Adaptability	The degree to which an intervention can be adapted, tailored, refined, or reinvented to meet local needs.
E	Trialability	The ability to test the intervention on a small scale in the organization, and to be able to reverse course (undo implementation) if warranted.
F	Complexity	Perceived difficulty of implementation, reflected by duration, scope, radicalness, disruptiveness, centrality, and intricacy and number of steps required to implement.
G	Design Quality & Packaging	Perceived excellence in how the intervention is bundled, presented, and assembled.
H	Cost	Costs of the intervention and costs associated with implementing the intervention including investment, supply, and opportunity costs.
II. OUTER SETTING		
A	Patient Needs & Resources	The extent to which patient needs, as well as barriers and facilitators to meet those needs, are accurately known and prioritized by the organization.
B	Cosmopolitanism	The degree to which an organization is networked with other external organizations.
C	Peer Pressure	Mimetic or competitive pressure to implement an intervention; typically because most or other key peer or competing organizations have already implemented or are in a bid for a competitive edge.
D	External Policy & Incentives	A broad construct that includes external strategies to spread interventions, including policy and regulations (governmental or other central entity), external mandates, recommendations and guidelines, pay-for-performance, collaboratives, and public or benchmark reporting.
III. INNER SETTING		

A	Structural Characteristics	The social architecture, age, maturity, and size of an organization.
B	Networks & Communications	The nature and quality of webs of social networks and the nature and quality of formal and informal communications within an organization.
C	Culture	Norms, values, and basic assumptions of a given organization.
D	Implementation Climate	The absorptive capacity for change, shared receptivity of involved individuals to an intervention, and the extent to which use of that intervention will be rewarded, supported, and expected within their organization.
	1. Tension for Change	The degree to which stakeholders perceive the current situation as intolerable or needing change.
	2. Compatibility	The degree of tangible fit between meaning and values attached to the intervention by involved individuals, how those align with individuals' own norms, values, and perceived risks and needs, and how the intervention fits with existing workflows and systems.
	3. Relative Priority	Individuals' shared perception of the importance of the implementation within the organization.
	4. Organizational Incentives & Rewards	Extrinsic incentives such as goal-sharing awards, performance reviews, promotions, and raises in salary, and less tangible incentives such as increased stature or respect.
	5. Goals and Feedback	The degree to which goals are clearly communicated, acted upon, and fed back to staff, and alignment of that feedback with goals.
	6. Learning Climate	A climate in which: a) leaders express their own fallibility and need for team members' assistance and input; b) team members feel that they are essential, valued, and knowledgeable partners in the change process; c) individuals feel psychologically safe to try new methods; and d) there is sufficient time and space for reflective thinking and evaluation.
E	Readiness for Implementation	Tangible and immediate indicators of organizational commitment to its decision to implement an intervention.
	1. Leadership Engagement	Commitment, involvement, and accountability of leaders and managers with the implementation.
	2. Available Resources	The level of resources dedicated for implementation and on-going operations, including money, training, education, physical space, and time.
	3. Access to Knowledge & Information	Ease of access to digestible information and knowledge about the intervention and how to incorporate it into work tasks.
IV. CHARACTERISTICS OF INDIVIDUALS		

A	Knowledge & Beliefs about the Intervention	Individuals' attitudes toward and value placed on the intervention as well as familiarity with facts, truths, and principles related to the intervention.
B	Self-efficacy	Individual belief in their own capabilities to execute courses of action to achieve implementation goals.
C	Individual Stage of Change	Characterization of the phase an individual is in, as he or she progresses toward skilled, enthusiastic, and sustained use of the intervention.
D	Individual Identification with Organization	A broad construct related to how individuals perceive the organization, and their relationship and degree of commitment with that organization.
E	Other Personal Attributes	A broad construct to include other personal traits such as tolerance of ambiguity, intellectual ability, motivation, values, competence, capacity, and learning style.
V. PROCESS		
A	Planning	The degree to which a scheme or method of behaviour and tasks for implementing an intervention are developed in advance, and the quality of those schemes or methods.
B	Engaging	Attracting and involving appropriate individuals in the implementation and use of the intervention through a combined strategy of social marketing, education, role modelling, training, and other similar activities.
	1. Opinion Leaders	Individuals in an organization who have formal or informal influence on the attitudes and beliefs of their colleagues with respect to implementing the intervention.
	2. Formally Appointed Internal Implementation Leaders	Individuals from within the organization who have been formally appointed with responsibility for implementing an intervention as coordinator, project manager, team leader, or other similar role.
	3. Champions	"Individuals who dedicate themselves to supporting, marketing, and 'driving through' an [implementation]", overcoming indifference or resistance that the intervention may provoke in an organization.
	4. External Change Agents	Individuals who are affiliated with an outside entity who formally influence or facilitate intervention decisions in a desirable direction.
C	Executing	Carrying out or accomplishing the implementation according to plan.
D	Reflecting & Evaluating	Quantitative and qualitative feedback about the progress and quality of implementation accompanied with regular personal and team debriefing about progress and experience.

Appendix 2.2: Compilation of implementation interventions as categorised by the Expert Recommendations for Implementing Change (ERIC) taxonomy

1. Use evaluative and iterative strategies
Assess for readiness and identify barriers and facilitators
Audit and provide feedback
Purposefully re-examine the implementation
Develop and implement tools for quality monitoring
Develop and organize quality monitoring systems
Develop a formal implementation blueprint
Conduct local need assessment
Stage implementation scale up
Obtain and use patients/consumers and family feedback
Conduct cyclical small tests of change
2. Provide interactive assistance
Facilitation
Provide local technical assistance
Provide clinical supervision
Centralize technical assistance
3. Adapt and tailor to context
Tailor strategies
Promote adaptability
Use data experts
Use data warehousing techniques
4. Develop stakeholder interrelationships
Identify and prepare champions
Organize clinician implementation team meetings
Recruit, designate, and train for leadership
Inform local opinion leaders
Build a coalition
Obtain formal commitments
Identify early adopters
Conduct local consensus discussions
Capture and share local knowledge
Use advisory boards and workgroups
Use an implementation advisor
Model and simulate change
Visit other sites
Involve executive boards
Develop an implementation glossary
Develop academic partnerships
Promote network weaving

5. Train and educate stakeholders
Conduct ongoing training
Provide ongoing consultation
Develop educational materials
Make training dynamic
Distribute educational materials
Use train-the-trainer strategies
Conduct educational meetings
Conduct educational outreach visits
Create a learning collaborative
Shadow other experts
Work with educational institutions
6. Support clinicians
Facilitate relay of clinical data to providers
Remind clinicians
Develop resource sharing agreements
Revise professional roles
Create new clinical teams
7. Engage consumers
Involve patients/consumers and family members
Intervene with patients/consumers to enhance uptake and adherence
Prepare patients/consumers to be active participants
Increase demand
Use mass media
8. Utilize financial strategies
Fund and contract for the clinical innovation
Access new funding
Place innovation on fee for service lists/formularies
Alter incentive/allowance structures
Make billing easier
Alter patient/consumer fees
Use other payment schemes
Develop disincentives
Use capitated payments
9. Change infrastructure
Mandate change
Change record systems
Change physical structure and equipment
Create or change credentialing and/or licensure standards
Change service sites
Change accreditation or membership requirements
Start a dissemination organization
Change liability laws

Appendix 4.1: Review of consensus methods

A number of consensus methods exist which were reviewed for applicability for agreeing specific core elements of the care bundles. These will be discussed in turn, and the reason for selecting the NGT over other methods will be detailed.

(i) The Classic Delphi method

The Classic Delphi method originated from the RAND Corporation in the mid-20th century, with the objective 'to obtain the most reliable consensus of opinion of a group of experts' [363]. It was theorised that in the absence of exact knowledge 'two heads were better than one' [364]. The Classic Delphi method involves anonymous participation in rounds of questionnaires with controlled iterative feedback, and concludes with final aggregation of opinions which is presented back to the participants. The Classic Delphi method was not deemed suitable for developing the consolidated care bundles as it does not incorporate group interaction and discussion, which was considered essential for the four participating NHS Health Boards in order to learn from, and reflect on, the initial testing phases of the care bundles.

(ii) The Decision Delphi

The Decision Delphi is an adaptation of the Classic Delphi first described in 1979 by Raunch [365]. It has comparable methodology to classic applications, albeit with a specific emphasis on decision making [365]. The process is more interactive than classical methods – 'panellists will be required to consider a broad area and to elaborate their own ideas (standpoint) concerning it' [365]. However, no recent applications of the method within healthcare was identified within the literature; the method lacks formal attainment of consensus; and the intended panellists are 'decision makers' [112]. Thus, the method may not lend itself to participation from patient representatives and/or lay members which would be desirable for this study.

(v) The Nominal Group Technique

The Nominal Group Technique (NGT) is a method used for decision-making and consensus generating which was first described in the 1960s [91, 111, 112]. Potter et al has previously summarised the five common NGT stages into: introduction and explanation; silent

generation of ideas; sharing of ideas; group discussion; voting and ranking. As a technique, it overcomes some of the limitations of the previously described methods [113]. It has similarities to the Classic Delphi as there is structured consensus generating, but additionally there is group interaction and discussion akin to a focus group setting. However, unlike the focus group, the NGT allows for everybody's input– preventing dominant individuals overpowering the process. The NGT involves a formal ranking procedure that is not weighted – meaning all participants (strategists, patient representatives etc.) have equitable influence. Unlike the Classic Delphi method and the Focus Group, the results can be instantaneously generated and presented back to the participants allowing for immediate gratification of their input [111]. It allows for a large amount of work to be completed relatively quickly, and there is minimal preparatory requirements. This means that it is ideally suited for the current study where participants include healthcare professional and national strategists with potentially limited time to commit [114].

The NGT is a well-documented, extensively used, and modifiable consensus method [113], and is said to be 'building traction within the pharmacy setting' [366]. Examples of use include guideline development in the absence of a robust evidence base [367], identifying high priority areas to focus implementation efforts, or to elicit the views of a select group in relation to service development [106, 126].

The NGT is led by moderators who are not formal participants [114]. To begin, the moderators pose the nominal question [114]. More than one question can be posed [368], either during the meeting where it could be posed verbally or presented on paper, or prior to the meeting via email or survey [369]. For example, McMillian et al asked participants to *'imagine their local pharmacy several years into the future: what services could they offer to help them to meet their individual health goals, or to best support them in their role as a carer?'* [126]. After the question is posed, participants then independently and privately write down ideas and/or opinions relating to the question posed. Five to twenty minutes is usually allocated for this stage [113]. Instead of elucidating various ideas, the technique can also be used to reduce a list of previously identified ideas to a smaller number of more favourable items [367].

Following this, in a round-robin fashion, participants verbalise their ideas and/or opinions, going round the group until all ideas are written down on a flipchart or projected onto a screen [368]. Typically, fifteen to thirty minutes are dedicated to this stage [113]. This is

followed by a group discussion of the ideas and/or opinions presented [114]. Each participant then ranks the items [106]. Examples of ranking methods includes selecting and/or ranking participants' top 5 items, ranking in terms of importance, or 'priority ranking' [113]. The moderators then collate and tally the ranking scores, which are then immediately presented back to the nominal group [114].

This is then followed by determining whether or not the nominal group agree with the top ranked items by identifying if consensus has been achieved. Researchers have argued that the term consensus could mean a plethora of different things: a view that is acceptable to all members; the same view shared by all members; or the majority view [370]. Typically, the latter definition is chosen, with a percentage of agreement of >70% commonly used to signify consensus [371]. A clear definition of consensus prior to conducting the NGT is advocated to prevent it being arbitrarily determined afterwards [372].

Appendix 4.2: Nominal Group Technique (NGT) workbook example

SPSP-PPC Consensus Workshop

Nominal Group Technique 1 Workbook

What should the consolidated NSAID care bundle questions be?

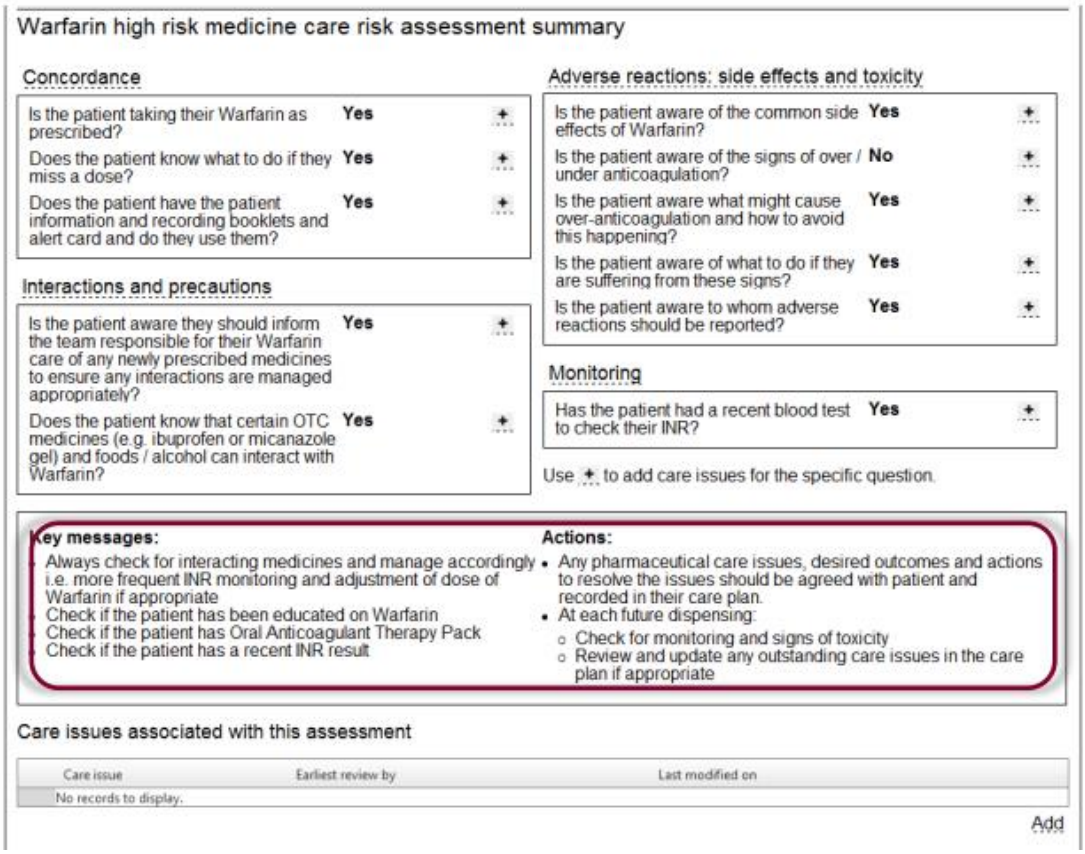
NSAID Care Bundle Questions

1	Have you checked that the patient is concordant with taking their NSAID
2	Has the patient been informed to take it with or after food?
3	Has gastro-protection been prescribed for high risk patients?
	a) Is the patient in a high risk group requiring gastroprotection? (Yes/No) b) If yes, has gastroprotection been prescribed? (Yes/No)
4	Have you checked if the patient is experiencing adverse drug reactions or side effects?
5	Has the patient been informed to report any GI side effects to their pharmacist or GP?
6	Is the patient aware of the Medicine Sick Day Rules? (Yes or No or Not applicable)
7*	For patients identified as taking other high risk drugs, has this risk been highlighted to the prescriber?
8*	a) Is the patient prescribed the triple whammy combination? (Yes or No) b) If yes, has the triple whammy combination been highlighted to the prescriber? (Yes or No)
9	a) If the prescriber was contacted, was the resulting review communicated back to the pharmacy? b) Has this change been discussed by the pharmacist with the patient/carer?
10	Have all measures been met?

Opinions/Thoughts

General Comments

Appendix 4.3: Screenshot of the warfarin assessment within the Pharmacy Care Record system



Warfarin high risk medicine care risk assessment summary

Concordance

Is the patient taking their Warfarin as prescribed?	**Yes**
Does the patient know what to do if they miss a dose?	**Yes**
Does the patient have the patient information and recording booklets and alert card and do they use them?	**Yes**

Interactions and precautions

Is the patient aware they should inform the team responsible for their Warfarin care of any newly prescribed medicines to ensure any interactions are managed appropriately?	**Yes**
Does the patient know that certain OTC medicines (e.g. ibuprofen or micanazole gel) and foods / alcohol can interact with Warfarin?	**Yes**

Adverse reactions: side effects and toxicity

Is the patient aware of the common side effects of Warfarin?	**Yes**
Is the patient aware of the signs of over / under anticoagulation?	**No**
Is the patient aware what might cause over-anticoagulation and how to avoid this happening?	**Yes**
Is the patient aware of what to do if they are suffering from these signs?	**Yes**
Is the patient aware to whom adverse reactions should be reported?	**Yes**

Monitoring

Has the patient had a recent blood test to check their INR?	**Yes**

Use + to add care issues for the specific question.

Key messages:

- Always check for interacting medicines and manage accordingly i.e. more frequent INR monitoring and adjustment of dose of Warfarin if appropriate
- Check if the patient has been educated on Warfarin
- Check if the patient has Oral Anticoagulant Therapy Pack
- Check if the patient has a recent INR result

Actions:

- Any pharmaceutical care issues, desired outcomes and actions to resolve the issues should be agreed with patient and recorded in their care plan.
- At each future dispensing:
  - Check for monitoring and signs of toxicity
  - Review and update any outstanding care issues in the care plan if appropriate

Care issues associated with this assessment

Care issue	Earliest review by	Last modified on
No records to display.		

Add

Appendix 4.4: Consolidated care bundles developed following validation within community pharmacies

SPSP Pharmacy in Primary Care

Warfarin Bundle

Patient Cohort & General Advice:

- All regular and non-regular (that is 'once-off'/'walk-in') patients prescribed warfarin are to be included in the patient cohort.
- For testing phase: Please test the bundle questions each time a prescription containing warfarin is handed out to the patient (or carer if appropriate). Observing current practice may be necessary and this may be 'as observed by another member of staff' or as a 'self-reflective checklist' [specifically for lone workers] after the patient has been handed their prescription and counselled on their medication.
- It will be good practice to check if the patient has had a HRMI previously so as to inform the tone and approach of your engagement/counselling. It may also be good practice to record when the bundle questions have been carried out (e.g. quickly on the patient's patient medication record (PMR) which would be appropriate to consider if the patient collects different strengths at different times.

No.	Bundle Question	Guidance	Rationale
1.	Has the patient been told of the importance in carrying an up-to-date alert card? Yes/No	-The importance of carrying the card at all times should be explained to the patient and/or carer.	The alert card is important in an emergency and also for when the patient has an interaction with the healthcare system.

No.	Bundle Question	Guidance	Rationale
2.	Has the member of staff asked to see the patient's 'up-to-date information' that includes their indication, duration of treatment, therapeutic range and current dose of warfarin? Yes/No	-An appropriately trained member of staff should ask to see this information to confirm it is complete. If the consultation is over the phone they should have asked questions to ensure they can verify that the patient has up-to-date information. -"Up-to-date information" may be recorded in a patients yellow record book/other form. The importance of the information needs to be explained and the importance of presenting it at each clinical encounter. - If the information is not up to date or presented then a care issue may be recorded (e.g. in the appropriate section of the HRMI in the patients PCR) and acted on to resolve the shortcomings.	-The patient should take the information with their indication, duration of treatment, therapeutic range and current dose to each clinical meeting. -Emergency contact details and routine monitoring/"results" should be documented also. This can be used as a prompt/aide memoire but also allows the healthcare professional to assess the appropriateness of dose, length of treatment and action to be taken should international normalised ratio (INR) show variance. - The indication, duration of treatment, therapeutic range and current dose of warfarin may be needed to facilitate safe clinical decision making.
3.	Has the patient been informed what to do if they have missed a dose of warfarin? Yes/No	-Has an appropriately trained member of staff verbally assessed the patient's knowledge on this question? -If assessed as lacking a care issue may be recorded (e.g. in the appropriate section of the HRMI in the patients PCR) and action taken to resolve the shortcomings. -The patient's knowledge should be re-assessed after an agreed time interval.	-Missed doses should be taken immediately within a few hours (consult local guidance and/or patient information leaflet) or omitted if not remembered until the next day. -Patients should record missed doses and discuss this with the anti-coagulation clinic at their next appointment. -A dose should **never** be doubled.

No.	Bundle Question	Guidance	Rationale
4.	Has the patient been told that they should inform the team responsible for their warfarin care of any significant changes that may affect their warfarin? Yes/No	- It should be mentioned (or the patient reminded) to discuss such things as newly prescribed/purchased medicines or 'remedies' [herbal or other] / major change in diet/alcohol consumption with the team that is responsible for their care - An appropriately trained member of staff should verbally assess the patient's knowledge on this question. -If assessed as lacking a care issue may be recorded (e.g. in the appropriate section of the HRMI in the patients PCR) and action taken to resolve the shortcomings. -The patient's knowledge should be re-assessed after an agreed time interval.	-Patients should know to alert the healthcare team responsible for the prescribing/dispensing of warfarin and the testing of INR (GP, pharmacist, nurse, anticoagulant clinician) to any changes that may affect their therapy. -Many medicines/foods/major dietary changes can affect warfarin therapy. If **any** new interacting medicines are commenced, titrated or discontinued during warfarin therapy then an INR should be requested at an appropriate interval. **Note:** Addition of newly prescribed antibiotics should always instigate an INR test. There are also a number of over-the-counter products that should be avoided during warfarin therapy (for example, those containing an azole [miconazole/clotrimazole/ fluconazole, etc.], non-steroidal anti-inflammatory drugs (NSAIDs) and proton pump inhibitors (PPIs).
5.	Have the common signs and symptoms of over/under-coagulation been discussed with the patient? Yes/No	Has an appropriately trained member of staff verbally assessed the patient's knowledge on this question? -If the patient's knowledge is assessed as insufficient a care issue may be recorded (e.g. in the appropriate section of the HRMI in the patients PCR) and action taken to resolve the shortcomings. -The patient's knowledge should be re-assessed after an agreed time interval.	Symptoms of over-coagulation (for example, excessive bruising, epistaxis [lasting longer than 10mins], bleeding gums, severe headache, haematuria, haemoptysis, melaena, excessive menstrual bleeding, etc) or under-coagulation (bluish toes/fingers, chest/severe back pain, blurred vision or symptoms of deep vein thrombosis (DVT), etc) may signal a life-threatening situation. Refer a patient with any presenting symptom(s) to their GP/anticoagulation clinic/ directly to A&E [when out-of-hours (OOH)/emergency]; especially bleeding or unexplained bruising. **Note:** This list is not exhaustive.

No.	Bundle Question	Guidance	Rationale
6.	Has the patient been informed that they should have an INR test after starting a course of antibiotics? Yes/No	-Has an appropriately trained member of staff verbally assessed the patient's knowledge on this question? -This can be done through natural conversation and the patient reminded of this fact in conjunction with Q4 for the bundle (i.e. informing of other/change in medicines).	-Analysis of the causes of patients being admitted to hospital with high INR levels found that co-prescribed antibiotics were a feature in a number of cases. -Checking INR levels after starting a course of antibiotics allows for the pharmacodynamic/kinetic effects of warfarin and clotting factors to be taken into account, as well as warfarin doses to be adjusted if necessary. -This question was deemed currently to be important enough to be a stand-alone question within the bundle.

SPSP Pharmacy in Primary Care
Non-steroidal anti-inflammatory drugs (NSAIDs) Bundle

Patient Cohort for Q1-3:

- Any patient who receives a supply of a NSAID medication from the community pharmacy is eligible for inclusion, regardless of the nature of request. This will include patients who purchase NSAIDs over-the-counter (OTC) or are prescribed a NSAID from an external prescriber or via the Minor Ailment Service.

Patient Cohort for Q4-6:

- Any patient who is prescribed a supply of a NSAID medication is eligible for inclusion. This will include patients who are prescribed a NSAID from an external prescriber or via the Minor Ailment Service.

Part of the Process:

Questions 1-3 The “Communication Bundle” is to be applied to all patients who are supplied a NSAID. The bundle questions are to be answered by an appropriately trained member of staff who randomly observes the interaction between the patient receiving the NSAID medication and the member of staff supplying the NSAID medication.

Questions 4-6 The “Safer Care Bundle” is to be applied to patients who have been prescribed a NSAID.(i.e. during the dispensing process). Prescriptions for NSAIDs include those from an external prescriber or via the Minor Ailment Service.

No.	Bundle Question	Guidance	Rationale
Communication Bundle			
1.	Has the patient been informed to take the NSAID with or after food? Yes/No	Has the patient been given this advice verbally? Advice may be backed up with reference to a patient information leaflet or SPSP-NSAID card.	Taking NSAIDs with or after food may reduce local gastrointestinal side effects (reference: British National Formulary (BNF).

No.	Bundle Question	Guidance	Rationale
2. #	Has the patient been informed to report any potential adverse drug reactions to the pharmacist and/or prescriber? Yes/No	Potential adverse drug reactions of NSAIDs include: - experiencing dyspepsia/indigestion? - experiencing gastrointestinal pain? - experiencing change in bowel habit/change in appearance of stool? - experiencing shortness of breath? - experiencing reduced urine output? - experiencing nausea/vomiting? - experiencing confusion? The member of staff supplying the NSAID medicine should mention at least one of the above whilst discussing the importance to report any side effects.	Reduction in gastrointestinal (GI) bleeds and acute kidney injury.
3.	Has the patient been informed to stop the NSAID medication during periods of dehydrating illness (e.g. sickness and diarrhoea)? Yes/No	The patient should be informed to stop their NSAID medication during periods of prolonged sickness and/or diarrhoea and only restart 48 hours after recovery, and when eating and drinking normally. Has the patient got a Medicine Sick Day Rules card or an NSAIDs card? Has the card been explained to the patient? Does the patient understand when to stop the NSAID and when to re-start it?	Taking an NSAID when dehydrated can provoke acute kidney injury. (Reference: NHS Scotland polypharmacy guideline http://www.sign.ac.uk/pdf/polypharmacy_guidance.pdf, CKS)

No.	Bundle Question	Guidance	Rationale
Safer Care Bundle			
4.	Has the patient's use and/or need of their NSAID been assessed?	During the dispensing process the patients medication record (PMR) should checked to ensure that the quantities and strengths prescribed are appropriate to relieve the patients pain whilst care is also taken to monitor whether prescribed NSAIDs may be over used. - Is the patient re-ordering repeats too frequently? -Is the patient taking the NSAID as prescribed? Are they taking more or less? -Would a topical NSAID be more appropriate for the patients level of use? - Does the patient feel they still require a NSAID? - Can the NSAID be taken intermittently? - If prescribed 'when required', does the patient know how to take it? -Depending on the scenario the Pharmacist must use their professional judgement and act appropriately. - Action via GP communication tool if patient not compliant, NSAID not required, dose/frequency/quantity can be reduced, etc.	Reference: NHS Scotland polypharmacy guideline http://www.sign.ac.uk/pdf/polypharmacy_guidance.pdf, CKS)

No.	Bundle Question	Guidance	Rationale
5.	a) Is the patient in a high risk group? Yes/No b) If yes, has action been taken to reduce this risk? Yes/No	Is the patient in one of the high risk groups listed under rationale (right) for whom gastroprotection would be appropriate? If gastroprotection is not prescribed, consider what the best option is: stopping the NSAID or starting gastroprotection? Remember that gastroprotection is not without risks. It should be limited to these high risk groups and may not be appropriate for some patients in these groups.	People at increased risk of GI adverse events from NSAIDs: age over 75 years, concomitant use of medicines known to increase risk of GI bleeds (such as anticoagulants, aspirin, corticosteroids, selective serotonin reuptake inhibitors (SSRIs), venlafaxine, duloxetine), history of GI ulcer/bleeding, excessive alcohol/smoking. (reference: National Institute for Health and Care Excellence (NICE) Clinical Knowledge Summaries (CKS), BNF and local formularies if available) Proton pump inhibitors (PPIs) are linked with increased risk of *Clostridium difficile* infection and their use should be limited to patients at high risk of GI adverse events. Consider other risks for *Clostridium difficile* infections, such as frequent use of antibiotics, before prescribing PPIs.

No.	Bundle Question	Guidance	Rationale
6.	a) Is the patient prescribed the triple whammy combination? Yes/No (b) If yes, has the triple whammy combination been highlighted to the prescriber? Yes/No	Is there evidence (for example, copy of a communication tool) that the prescriber has been contacted?	Concomitant use of the triple whammy combination of NSAID, angiotensin converting enzyme (ACE) inhibitor (or angiotensin receptor blocker (ARB)) and diuretic should be avoided. Reference: NHS Scotland polypharmacy guideline http://www.sign.ac.uk/pdf/polypharmacy_guidance.pdf, BMJ 2013;346:e8525).

Appendix 5.1: Medline systematic review search strategy

#	Searches	Results	Search Type
1	*Pharmacies/	2839	Advanced
2	*Community Pharmacy Services/	2478	Advanced
3	*Pharmacists/	7827	Advanced
4	*Pharmacists' Aides/	381	Advanced
5	*Students, Pharmacy/	1264	Advanced
6	community pharmac*.mp.	4751	Advanced
7	drug store*.mp.	241	Advanced
8	retail pharmac*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	367	Advanced
9	druggist.mp.	41	Advanced
10	chemist.mp.	1134	Advanced
11	apothecary.mp.	278	Advanced
12	dispensar*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	4230	Advanced
13	pharmacy technician*.mp.	433	Advanced
14	checking technician*.mp.	2	Advanced
15	student pharmacist*.mp.	156	Advanced
16	pre-registration pharmacist*.mp.	4	Advanced
17	trainee pharmacist*.mp.	2	Advanced
18	medicine counter assistant*.mp.	4	Advanced
19	over the counter assistant*.mp.	0	Advanced
20	medication assistant*.mp.	7	Advanced
21	dispenser*.mp.	1411	Advanced
22	dispensing assistant*.mp.	0	Advanced
23	pharmacy team*.mp.	59	Advanced
24	pharmacy staff*.mp.	504	Advanced
25	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24	22237	Advanced
26	*Health Plan Implementation/	1890	Advanced
27	*Information Dissemination/	6130	Advanced
28	*Health Care Reform/	20992	Advanced
29	*"Diffusion of Innovation"/	7439	Advanced
30	*Health Planning Technical Assistance/	124	Advanced
31	*Regional Health Planning/	3095	Advanced
32	*Education, Pharmacy/	3342	Advanced
33	*Quality Improvement/	5280	Advanced
34	Community Health Planning/	4662	Advanced

35	*Health Systems Plans/	76	Advanced
36	*Program Development/	6517	Advanced
37	*Technology, Pharmaceutical/	7020	Advanced
38	*National Health Programs/	18072	Advanced
39	*Patient Care/	4282	Advanced
40	*Patient Care Bundles/	87	Advanced
41	*Patient Education as Topic/	33301	Advanced
42	*Patient Education Handout/	0	Advanced
43	*Health Education/	31094	Advanced
44	*Evidence-Based Practice/	2707	Advanced
45	*Practice Guidelines as Topic/	30743	Advanced
46	*Clinical Protocols/	4839	Advanced
47	*Patient Selection/	14363	Advanced
48	*Teach-Back Communication/	6	Advanced
49	*Consumer Health Information/	1624	Advanced
50	*Health Promotion/	38211	Advanced
51	*Patient Safety/	4427	Advanced
52	intervention*.mp.	610588	Advanced
53	disseminat*.mp.	102472	Advanced
54	implement*.mp.	253333	Advanced
55	adopt*.mp.	149241	Advanced
56	roll* out.mp.	1040	Advanced
57	scale* up.mp.	6947	Advanced
58	knowledge transfer.mp.	749	Advanced
59	uptake*.mp.	285736	Advanced
60	26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58 or 59	1502435	Advanced
61	*Health Services Research/	13393	Advanced
62	*Quality Assurance, Health Care/	29565	Advanced
63	*"Process Assessment (Health Care)"/	1640	Advanced
64	*Program Evaluation/	8067	Advanced
65	*Intervention Studies/	324	Advanced
66	*Data Collection/	12120	Advanced
67	*Evaluation Studies as Topic/	6256	Advanced
68	*Evaluation Studies/	0	Advanced
69	*Feasibility Studies/	127	Advanced
70	*Multicenter Studies as Topic/	1776	Advanced
71	*Pilot Projects/	373	Advanced
72	*Sampling Studies/	815	Advanced
73	*"Attitude of Health Personnel"/	50003	Advanced
74	*Clinical Competence/	34208	Advanced

75	*Professional Competence/	9984	Advanced
76	*Health Knowledge, Attitudes, Practice/	43019	Advanced
77	implementation evaluat*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	218	Advanced
78	program* evaluat*.mp.	53623	Advanced
79	barrier*.mp.	175678	Advanced
80	enabler*.mp.	885	Advanced
81	facilitator*.mp.	13629	Advanced
82	obstacle*.mp.	29102	Advanced
83	challenge*.mp.	369073	Advanced
84	61 or 62 or 63 or 64 or 65 or 66 or 67 or 68 or 69 or 70 or 71 or 72 or 73 or 74 or 75 or 76 or 77 or 78 or 79 or 80 or 81 or 82 or 83	786381	Advanced
85	**25 and 60 and 84**	**1472**	**Advanced**
86	**limit to English language**	**1417**	**Advanced**

Appendix 5.2: Full quality assessment tools used in systematic review

The Critical Appraisal Skills Programme (CASP) tool [150]:

IS THERE A CLEAR STATEMENT OF THE AIMS OF THE RESEARCH?

- *What the goal of the research was?*
- *Why it was thought to be important?*
- *Its relevance?*

IS A QUALITATIVE METHODOLOGY APPROPRIATE?

- *Does the research seek to interpret or illuminate the actions and/or subjective experiences of research participants?*

WAS THE RESEARCH DESIGN APPROPRIATE TO ADDRESS THE AIMS OF THE RESEARCH?

- *Has the researcher justified the research design? (i.e. have they discussed how they decided which method to use?*

WAS THE RECRUITMENT STRATEGY APPROPRIATE TO THE AIMS OF THE RESEARCH?

- *Is it explained how the individual participants were selected?*
- *Is it explained why the participants selected were most appropriate to provide access to the type of knowledge sought by the study?*
- *Was there are any discussions around recruitment (e.g. why some people chose not to take part)*

WAS THE DATA COLLECTED IN A WAY THAT ADDRESSED THE RESEARCH ISSUE?

- *Was the setting for data collection justified?*
- *Is it clear how data was collected (e.g. focus group, semi-structured interview etc.)?*
- *Did the researcher justify the methods chosen?*
- *Did the researcher make the methods explicit (e.g. for interview method, is there an indication of how interviews were conducted, or did they use a topic guide)?*
- *If methods were modified during the study, has the researcher explained how and why?*
- *Is the form of data clear (e.g. tape recordings, video material, notes etc)?*
- *Did the researcher discuss saturation of data?*

HAS THE RELATIONSHIP BETWEEN RESEARCHER AND PARTICIPANTS BEEN ADEQUATELY CONSIDERED?

- *Did the researcher critically examined their own role, potential bias and influence during:*
    - *a) Formulation of research question*
    - *b) Data collection, including sample recruitment and choice of location*
- *How the researcher responded to events during the study and whether they considered the implications of any changes in the research design?*

HAVE ETHICAL ISSUES BEEN TAKEN INTO CONSIDERATION?

- *Is there sufficient details of how the research was explained to participants for the reader to assess whether ethical standards were maintained?*
- *Did the researcher discusses issues raised by the study (e.g. issues around informed consent or confidentiality or how they have handled the effects of the study on the participants during and after the study)*
- *Was approval sought from the ethics committee?*

WAS THE DATA ANALYSIS SUFFICIENTLY RIGOROUS?

- *Was there an in-depth description of the analysis process?*

- *If thematic analysis was used, is it clear how the categories/themes were derived from the data?*
- *Did the researcher explain how the data presented were selected from the original sample to demonstrate the analysis process?*
- *Was sufficient data presented to support the findings?*
- *Was contradictory data taken into account?*
- *Did the researcher critically examine their own role, potential bias and influence during analysis and selection of data for presentation?*

IS THERE A CLEAR STATEMENT OF FINDINGS?

- *Are the findings explicit?*
- *Is there adequate discussion of the evidence both for and against the researchers' arguments?*
- *Did the researcher discuss the credibility ? (e.g. triangulation, respondent validation, more than one analyst.)*
- *Are the findings discussed in relation to the original research question?*

HOW VALUABLE IS THE RESEARCH?

- *Did the researcher discusses the contribution the study makes to existing knowledge or understanding e.g. do they consider the findings in relation to current practice or policy, or relevant research-based literature?*
- *Did they identify new areas where research is necessary?*
- *Did the researchers discuss whether or how the findings can be transferred to other populations or considered other ways the research may be used?*

The Boynton and Greenhalgh Quality Checklist (BGQC) tool [151]:

APPROPRIATE RESEARCH QUESTION AND DESIGN?
• *Was there a clear research question?* • *Was this important and sensible?* • *Was a questionnaire the most appropriate research design for this question?* • *Was the sampling frame sufficiently large?*
APPROPRIATE SAMPLING?
• *Was the sampling frame sufficiently representative?* • *Did all participants in the sample understand what was required of them?* • *Did all participants in the sample attribute the same meaning to the terms in the questionnaire?*
APPROPRIATE INSTRUMENT?
• *Are there any claims for reliability?* • *Are claims for reliability justified?* • *Are there any claims for validity?* • *Are claims for validity justified?* • *Did the questions cover all relevant aspects of the problem?* • *Were questions presented in a non-threatening and non-directive way?* • *Were open-ended (qualitative) used appropriately?* • *Were closed ended (quantitative) questions used appropriately?* • *Was a pilot version administer to participants' representative of those in the sampling frame?* • *Following piloting, was the instrument modified accordingly if required if required?*
APPROPRIATE RESPONSE?
• *Was a satisfactory response rate achieved?* • *Have non-responders been accounted for?*
APPROPRIATE CODING AND ANALYSIS?
• *Was the analysis appropriate (e.g. statistical analysis for quantitative answers, qualitative analysis for open-ended questions)?* • *Were the correct techniques used?* • *Were adequate measures in place to maintain accuracy of data?*
APPROPRIATE PRESENTATION OF RESULTS?
• *Have all relevant results ("significant" and "non-significant") been reported?* • *Was data dredging avoided (i.e. analyses that were not 'hypothesis driven')?*

The initial screening questions within the Mixed Methods Appraisal Tool (MMAT) [153]:

GENERAL SCREENING QUESTIONS
• *Are there clear qualitative and quantitative research questions (or objectives), or a clear mixed methods question (or objective)?* • *Do the collected data address the research question (objective)? E.g., consider whether the follow-up period is long enough for the outcome to occur (for longitudinal studies or study components).*
MIXED METHODS METHODOLOGICAL QUALITY CRITERIA
• *Is the mixed methods research design relevant to address the qualitative and quantitative research questions (or objectives), or the qualitative and quantitative aspects of the mixed methods question (or objective)? (E.g., the rationale for integrating qualitative and quantitative methods to answer the research question is explained.)* • *Is the integration of qualitative and quantitative data (or results) relevant to address the research question (objective)? (E.g., there is evidence that data gathered by both research methods was brought together to form a complete picture, and answer the research question; authors explain when integration occurred (during the data collection-analysis or/and during the interpretation of qualitative and quantitative results); they explain how integration occurred and who participated in this integration.)* • *Is appropriate consideration given to the limitations associated with this integration, e.g., the divergence of qualitative and quantitative data (or results)?*

Appendix 5.3: Full presentation of Consolidated Framework for Implementation Research (CFIR) constructs from systematic review

CFIR Constructs	Sub-constructs					
	Barriers	N	Facilitators	N	Hypothetical Facilitators	N
Intervention Characteristics						
A. Intervention Source	Nil	-	Nil	-	Nil	-
B. Evidence Strength & Quality	Lack of evidence base [178]	1	Nil	-	Nil	--
C. Relative Advantage	Disadvantages of the innovation [165, 176, 191, 192, 199, 200]	6	Advantages of the innovation [166, 167, 169, 170, 174, 175, 183, 186, 191, 198-200]	12	Nil	-
	Lack of observability [179]	1				
D. Adaptability	Lack of adaptability (i.e. over restrictive/rigid) [60, 171, 176, 178, 183, 186, 191]	7	Adaptability of innovation [60]	1	Suggested adaptations to innovation [176, 182]	2
E. Trialability	Nil	-	Nil	-	Nil	-
F. Complexity	Difficulty of innovation [60, 165, 168, 174, 179, 182]	6	Ease of innovation [168, 199]	2	Simplify innovation or make easier [194, 197, 198]	3
	Complexity of innovation [60, 134, 179, 182, 194, 196-198]	8				
	Difficulty of implementation innovation [181]	1				
G. Design Quality & Packaging	Poor design of innovation [177, 182, 188, 191, 192, 197]	6	Convenience of intervention [168, 200]	2	Suggested improvements to design/ quality [177, 180, 184, 188, 192, 194-198, 200]	11
	Poor quality of innovation [60, 169, 188, 191, 195, 199]	6				

CFIR Constructs	Sub-constructs					
	Barriers	N	Facilitators	N	Hypothetical Facilitators	N
H. Cost	Increased cost, financial loss or commercial risk relating to innovation [165, 167, 169, 174, 191, 192]	6	Nil	-	Nil	-
Outer Setting						
A. Patient Needs & Resources	Patient reluctance or negative views [165, 173, 174, 178, 179, 183]	6	Patient acceptance or positive views [166-168, 170, 172, 175, 182, 183]	8	Nil	-
	Lack of patient demand [60, 134, 168, 176, 177, 179, 180, 183, 184]	9	Patient demand [168, 192]	2		
	Lack of patient awareness or knowledge [60, 165, 167-169, 172, 183, 200]	8	Patient awareness [168]	1		
	Difficulties recruiting patients or patients' non-attendance [60, 169, 182, 183, 187, 191]	6	Good relationship between pharmacy and patient [192]	1		
	Cost to patients [178-180]	3				
	Patients' misuse of service [191]	1				
	Little or no feedback from patients [168]	1				
	Difficulty providing innovation to non-regular patients [177]	1				
B. Cosmopolitanism	Negative views of other healthcare professionals [60, 134, 173, 174, 179, 183, 185]	7	Referral from other healthcare professionals [176]	1	Better engagement or collaboration [134, 173, 193, 195, 200]	5
	Lack of healthcare professionals referral or engagement [167, 183, 188, 192]	4	Having relationship with other healthcare professionals [167, 183]	2		

CFIR Constructs	Sub-constructs					
	Barriers	N	Facilitators	N	Hypothetical Facilitators	N
	Lack of HCP communication/collaboration [60, 179, 183, 186, 189, 191, 196]	7	Support from external stakeholders [173]	1		
	Other healthcare professionals lack of knowledge [200]	1				
	Poor relationship with other organisations [196]	1				
C. Peer Pressure	Nil	-	Nil	-	Seeing colleagues doing it [194]	1
D. External Policy & Incentives	Lack of, or insufficient funding or remuneration [134, 170, 174, 190, 191]	5	Financial incentives [134, 192]	2	Financial compensation and incentives [173, 174, 177, 184, 190, 194, 196-198]	9
	Innovation not being policy [177]	1			Making the innovation compulsory [194-198]	5
					Increasing scope of the innovation [134, 173, 177]	3
					Apply penalties to non-compliant physicians [174]	1
Inner Setting						
A. Structural Characteristics	Nil	-	Small pharmacy with few staff [176]	1	Nil	-
			Rurality of pharmacy meaning have previous acquaintances with patients [168]	1		
			Well organised workflow systems [60]	1		

CFIR Constructs	Sub-constructs					
	Barriers	N	Facilitators	N	Hypothetical Facilitators	N
B. Networks & Communication	Lack of communication within pharmacy [168, 176]	2	Teamwork and communication within pharmacy [168]	1	Nil	-
			Alignment of innovation with the values of pharmacy team [164]	1		
C. Culture	Nil	-	Nil	-	Nil	-
D. Implementation Climate						
i. Tension for change	Organisational culture accepting change [60]	1	Nil	-		-
ii. Compatibility	Fear of, or increased, legal liability [174, 194, 196-198]	5	Compatibility of innovation with roles or values [60, 169, 179, 182, 186, 193, 194, 196-198]	10	Suggested workflow changes [177]	1
	Incompatibility of innovation with pharmacy setting or processes [168, 177]	2	Compatibility of innovation with working systems [60, 168, 189]	3		
	Incompatibility of innovation with wider healthcare service [60, 186]	2				
	Innovation outwith pharmacy remit [168]	1				
iii. Relative Priority	Competing priorities [168, 171, 196]	3	Nil	-	Nil	-
iv. Organisation Incentives & Rewards	Target setting relating to innovation perceived as income focused and not based on patient needs [186]	1	Improved professional recognition, influence, or extended professional role [169, 174, 179, 180, 182-184, 191]	8		

CFIR Constructs	Sub-constructs					
	Barriers	N	Facilitators	N	Hypothetical Facilitators	N
			Commercial benefits or increased footfall in pharmacy [168-170, 173, 179, 191, 200]	7		
			Professional satisfaction [60, 172, 173, 182, 190]	5		
v. Goals and Feedback	Lack of feedback in pharmacy [189]	1	Receiving feedback [164, 191]	2	Receiving feedback [171, 194-198]	6
	Lack of feedback from external organisations [195]	1				
vi. Learning Climate	Nil	-	Nil	-	Nil	-
E. Readiness for Implementation						
i. Leadership engagement	Lack of leadership engagement [189, 196]	2	Leadership engagement [164, 168]	2	Nil	-
	Lack of leadership skills [189]	1	Pharmacists leadership [168]	1		
	Reliance on pharmacist leadership [168]	1				
ii. Available Resources	Time constraints or increased workload [134, 166-171, 173, 174, 177, 181, 184-187, 189-191, 193-199]	25	Valued resources [60, 168, 169, 176, 189, 200]	6	Suggested resources [134, 177, 181, 184, 186, 191, 192, 194, 199]	9
	Lack of resources [171, 177, 191, 194-198]	8	Suitable spaces to counsel patients [185, 189]	2	Better support [172, 181]	2
	Lack of access to clinical information about patients [178, 179, 184, 188, 191]	5	Having two pharmacists on duty [60]	1		
	Staffing issues [169, 179, 184, 185, 190]	5	Support from professional body [179]	1		

CFIR Constructs	Sub-constructs					
	Barriers	N	Facilitators	N	Hypothetical Facilitators	N
	Lack of space or suitable area [168, 179, 184, 190]	4				
	Lack of support [167]	1				
Iii. Access to Knowledge and Information	Lack of appropriate training about innovation [168, 180, 186, 189, 192]	5	Access to information or being well informed about innovation [168, 176, 179, 189]	4	Better training or access to information about innovation [60, 168, 174-177, 181, 183, 189, 190, 192-198]	17
	Lack of information about innovation [60, 168, 191]	3	Good training [168, 169]	2		

Characteristics of Individuals						
A. Knowledge and Beliefs about the intervention	Negative pharmacy staff views about the innovation [60, 164, 168, 173, 175, 176, 178-180, 184-186, 192, 194-198]	18	Positive pharmacy staff views about the innovation [134, 166, 168, 169, 173, 174, 176, 179-182, 184, 185, 188, 192-198]	21	Nil	-
-	Lack of pharmacy staff awareness or knowledge [168, 176, 181, 190, 193-198]	10	Pharmacy staff awareness or knowledge about the innovation [173, 176, 193, 198]	4		
	Lack of pharmacy staff's clinical knowledge [171, 194, 195, 197, 198]	5				
B. Self-Efficacy	Lack of pharmacy staff's confidence [171, 172, 186]	3	Confidence of pharmacy staff [172, 175, 179-181]	5	Nil	-
	Belief that skills cannot be developed [164]	1	Belief that success of programme influenced by own approach [164]	1		
C. Individual Stage of Change	Reluctance or lack of motivation regarding innovation [174, 176, 177, 194, 197, 198]	6	Willingness or enthusiasm regarding innovation [164, 167, 168, 170, 172, 173, 175, 176, 189]	9	Nil	-
D. Individual Identification with Organisation	Nil	-	Nil	-	Nil	-
E. Other Personal Attributes	Innovation not aligning with personal gains [194, 197, 198]	3	Pharmacy staff having self-resilience when experience negative feedback [168]	1	Nil	-
	Pharmacy staff having a dispensing-focused role [168]	1	Good communication skills of pharmacy staff [168]	1		
			Pharmacy staff working >21 hours a week [184]	1		

			The pharmacist being store based and not a locum pharmacist [184]	1		
			Having higher socio-economic clientele in pharmacy [176]	1		
			Pharmacy staff having altruistic personality [173]	1		
			Being a younger pharmacist [191]	1		
			Pharmacy staff being based at front counter [168]	1		
			Pharmacy staff having previous experience [168]	1		
Process						
A. Planning	No piloting and evaluation of innovation before national implementation [60]	1	Nil	-	Better piloting and planning of innovation [60]	1
					More methodical implementation plan for innovation [196]	1
					Development of clear aims and objectives [168]	1
B. Engaging Stakeholders	Lack of undergraduate exposure to innovation [197]	1	Nil	-	Better promotions or engagement with pharmacies [60, 167, 189, 192-194, 196-198]	9
					Informing/engaging other HCPs [60, 174, 183, 193, 200]	5

C. Engaging Intervention Participants	Lack of advertising or promotion of innovation[60, 191, 197]	3	Customer awareness of innovation though use of banners and displays [170]	1	Better informing or educating the public about innovation [134, 167-169, 173-175, 177, 191, 193, 198, 200]	12
D. Executing	Nil	-	Nil	-	Nil	-
E. Reflecting and Evaluating	Nil	-	Nil	-	Ongoing review by commissioners once innovation implemented [60]	1

Appendix 8.1: Weir et al (2017) journal article

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Application of process mapping to understand integration of high risk medicine care bundles within community pharmacy practice

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ABSTRACT

Objective: The Scottish Patient Safety Programme – Pharmacy in Primary Care collaborative is a quality improvement initiative adopting the Institute of Healthcare Improvement Breakthrough Series collaborative approach. The programme developed and piloted High Risk Medicine (HRM) Care Bundles (CB), focused on warfarin and non-steroidal anti-inflammatories (NSAIDs), within 27 community pharmacies over 4 NHS Regions. Each CB involves clinical assessment and patient education, although the CB content varies between regions. To support national implementation, this study aims to understand how the pilot pharmacies integrated the HRM CBs into routine practice to inform the development of a generic HRM CB process map.

Methods: Regional process maps were developed in 4 pharmacies through simulation of the CB process, staff interviews and documentation of resources. Commonalities were collated to develop a process map for each HRM, which were used to explore variation at a national event. A single, generic process map was developed which underwent validation by case study testing.

Results: The findings allowed development of a generic process map applicable to warfarin and NSAID CB implementation. Five steps were identified as required for successful CB delivery: patient identification; clinical assessment; pharmacy CB prompt; CB delivery; and documentation. The generic HRM CB process map encompasses the staff and patients' journey and the CB's integration into routine community pharmacy practice. Pharmacist involvement was required only for clinical assessment, indicating suitability for whole-team involvement.

Conclusions: Understanding CB integration into routine practice has positive implications for successful implementation. The generic process map can be used to develop targeted resources, and/or be disseminated to facilitate CB delivery and foster whole team involvement. Similar methods could be utilised within other settings, to allow those developing novel services to distil the key processes and consider their integration within routine workflows to effect maximal, efficient implementation and benefit to patient care.

1. Introduction

Studies within the United Kingdom (UK) show 6.5% of hospital admissions are attributed to adverse effects of High Risk Medicines (HRM) - including Warfarin and Non-steroidal anti-inflammatory drugs (NSAIDs).[1] This figure is not dissimilar to international prospective studies and similar causative medicines have been identified as high risk.[2,3] The pharmacist's potential contribution to patient safety within primary care has been highlighted,[4] and internationally community pharmacists' roles are expanding to be increasingly integrated within primary care.[5–7]

Within the UK, this transition has resulted in the introduction of new services including community pharmacy minor ailment schemes, with positive feedback from pharmacists and patients.[8–10] The drive for community pharmacy to provide enhanced patient safety services aligns with the Scottish Government's vision and action plan,

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Prescription for Excellence.[6] Within Scotland, a national patient safety programme has since launched within community pharmacy in 2014, called The Scottish Patient Safety Programme - Pharmacy in Primary Care (SPSP-PPC) collaborative.[11]

The SPSP-PPC collaborative is a multi-site quality improvement initiative adopting the Institute of Healthcare Improvement Breakthrough Series collaborative approach - a structured learning model consisting of Learning Sessions to share progress and discuss practice changes and Action Periods where those changes are tested in the health care setting.[12] Participating pharmacy teams were trained in the Model for Improvement which was the guiding quality improvement framework operationalized at pharmacy site level through the application of 'Plan-Do-Study-Act' (PDSA) cycles, as a means to facilitate rapid testing of small-scale changes.[13]

The programme aims to improve patient safety by implementing safety interventions using a team-based approach. An ambition of the programme is to make community pharmacy processes safer while strengthening their contribution within primary care. A core component was to reduce the risk associated with the HRMs Warfarin and NSAIDs through the development of Care Bundles (CBs), defined as a "structured way of improving the processes of care and patient outcomes: a small, straightforward set of evidence-based practices".[14] Box 1 provides an overview of the programme structure and the HRM CBs developed.

An anticipated challenge to the adoption of new services within pharmacy practice is the potential variation of processes, as it is well established that integration within existing workflow can influence successful implementation of health service innovations.[16–18] Variation in pharmacy practice has been identified within other health services,[19–21] although to our knowledge there has been no research into the extent of process variation within the Scottish community pharmacy setting. Consequently, an understanding of this variation may support national implementation of the HRM CB by allowing consideration of how this novel service could successfully integrate into routine pharmacy practice.

This study aims to understand how the pilot pharmacies integrated the novel HRM CBs into routine practice in order to inform the development of a generic process map that could be used to facilitate national implementation.

2. Methods

A qualitative case-study method was employed.[22] Process mapping was applied throughout the study. This involves exploration of the tasks occurring within a process, with the findings used to develop sequential flow charts of the actions and decisions performed, with arrows depicting the sequence of activities.[23] Due to the complexity of the programme design – with a focus on 2 different HRMs and 4 different care bundles operationalized in different regions – a four-phased approach was used. An overview of the methods is shown in Fig. 1.

2.1. Phase 1: development of regional process maps

Pharmacies were selected for case study on-site evaluations based on March 2015 activity data reporting on number of patients delivered the CB, CB compliance and reliability. The top 3 performing pharmacies within each NHS Region were identified, and final selection agreed in discussion with the Regional Leads taking account of feasibility of on-site visits. One pharmacy from each participating NHS Region was chosen and contacted to arrange suitable dates.

During June and July 2015 case studies were conducted. Data were collected in 3 ways: (1) observation of a simulation of the CB process with pharmacy staff, (2) documentation of resources used and (3) staff interviews. Demographic details of participants collected included gender, job role and duration worked in community pharmacy.

The simulation exercise involved pharmacy staff providing a "talk and walkthrough" of the CB process as it would normally be delivered to a patient.[24] This allowed for resources used within the pharmacy

Box 1
Overview of the Programme Structure and the High Risk Medicine Care Bundles

Programme Structure and Leadership:

- Four NHS Regions were recruited, involving 27 pharmacy sites in total
  - Region 1 (n = 5) ∘ Region 2 (n = 7)
  - Region 3 (n = 5) ∘ Region 4 (n = 10)
- National Leads (n = 2), Regional Leads (n = 8), Programme Officers, Data Analysts, Improvement Advisors and the Evaluation Team comprise the SPSP-PPC Steering Group.

Programme Support:

- Two National Learning Events (NLE) and 2 Local Learning Events (LLE) were attended by teams from each pharmacy site, typically comprising a pharmacist and a member of support staff (the "Away Team"). Concepts of patient safety, safety culture and Quality Improvement methods were taught and the HRM CBs introduced.
- Regional Leads provided local support, and pharmacy resources developed included an SPSP Launch Folder and the SPSP-PPC Knowledge Network website.[15]

HRM CBs:

- Region-specific CBs comprising of 4–6 questions relating to a measure of care were developed by the Regional Leads and pharmacy Away Teams using driver diagrams.
- The NSAID CB measures focused on concordance, assessment of side effects, gastro-protection and co-prescribing of other high-risk medications.
- The Warfarin CB measures focused on patients' knowledge of interactions and side effects, and patients' use of the warfarin record book and alert card.
- Pharmacy staff compliance with CB measures were documented on run charts, to allow visual representation of pharmacy sites' improvement and the impact of PDSA cycles.

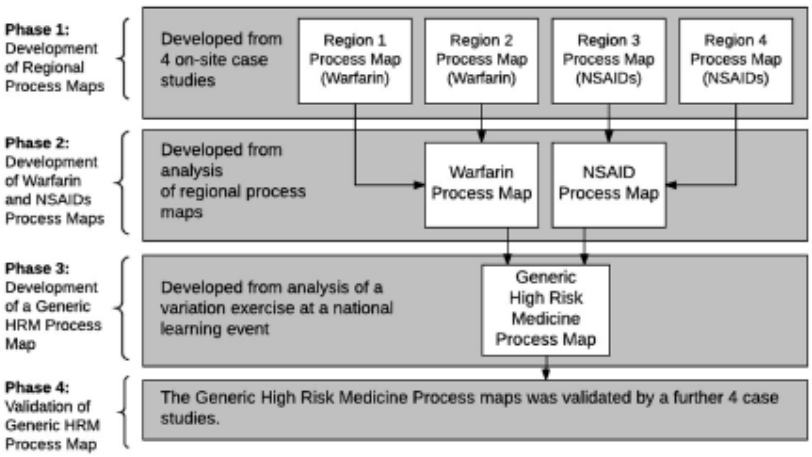

Fig. 1. Staged process map development.

environment to act as material probes to prompt discussion, and was thought to allow for better understanding of the workflow than with traditional interviews.[25] Photographs of relevant pharmacy resources were taken with permission, and identifiable information anonymised. Semi-structured interviews with pharmacy staff were guided by a pre-designed interview schedule (Appendix 1). The Away Team participants were interviewed, followed by a convenience sample of the remainder of the pharmacy staff. Both the simulation exercise and interviews were audio-recorded. The interviews were transcribed using an intelligent verbatim approach and were anonymised to protect participant identity. The resultant data were used to develop a process map for each of the 4 NHS Regions.

2.2. Phase 2: development of warfarin and NSAID process maps

A process map for each HRM (warfarin and NSAIDs) was developed using Lucidchart software.[26] This involved visually inspecting the regional process maps to distil commonalities and differences between the sites. This was supported by re-visiting the original audio recordings and documented resources.

2.3. Phase 3: development of a generic HRM process map

To develop a single HRM generic process map, pharmacy staff who attended the National Learning Event (NLE) in November 2015 completed an exercise to assimilate variation in processes between sites. Each Pharmacy Team received a copy of the NSAID or Warfarin Process Map depending on their NHS Region. Steps that were not commonalities were included within each HRM process map to allow participants to comment on. A paper-based variation exercise (Appendix 2) was provided and participants were instructed to provide written comments on the differences between the process maps presented and the processes within their pharmacies.

All responses were transcribed using an intelligent verbatim approach, and were coded using NVivo v.10. Initially, inductive content analysis was employed, followed by a deductive process of aligning the codes to the process steps identified within the HRM process maps.[27] To allow for comparative analysis of variation, responses were classified according to NHS Region and HRM. Examination of the commonalities between processes was used to create a generic HRM process map detailing the core steps fundamental to successful delivery of the CBs.

2.4. Phase 4: validation

The generic HRM process map was validated against regional process maps developed from a further 4 case studies conducted during October 2015. These involved either on-site or telephone data collection (for Region 1 and 3 due to rural location). To maximise variability, the selection process identified the lower performing pharmacies based on March 2015 reliability data and the final decision informed primarily by discussion with the NHS Regional Leads on feasibility of on-site visits.

The same simulation exercise method was applied as before, however for the telephone interviews a verbal explanation of the CB process was recorded and participants were asked to email photographs of any resources used.[28]

The regional process maps developed were compared with the generic HRM process map. Three aspects were considered during the validation: if each site had a process for the core steps, if there were other steps identified, and what order the steps occurred.

Informed consent was gained throughout. Under UK research governance arrangements, ethical approval was not necessary as this was a service evaluation of a quality improvement programme.[29]

3. Results

3.1. Participants

Of the 27 community pharmacies participating in the SPSP-PPC pilot, 8 pharmacies participated in case studies, representing 30% of all sites. Pharmacy site demographics are shown in Table 1.

Nineteen staff members participated in the Phase One case studies (4–5 from each site). Of which, 84% were female (n = 16), 37% were pharmacists (n = 7) and the remainder were support staff. Most (74%, n = 14) had 10 years or less experience in community pharmacy. For the validation case studies, it was the on-site pharmacist who participated in the simulation exercise.

At the time of the NLE variation exercise (Phase 3), one of the pharmacies involved in the phase one case studies withdrew participation. Of the remaining 26 pharmacy sites, all had Away Team representatives who participated in the variation exercise. Forty-one people participated in the variation exercise, participants were mostly female (n = 28, 68%), pharmacists or pre-registration pharmacists (n = 29, 71%), and most had over 10 years' experience in community pharmacy (n = 21, 52%). Full demographics of pharmacy staff participants are shown in Supplementary File 1.

3.2. Pharmacy workflow and CB core steps

From Phase One it was apparent that each pharmacy had similar

Table 1
Pharmacy site demographics.

Pharmacy site demographics	All sites (n = 27)	Phase 1 case studies (n = 4)	Validation case studies (n = 4)
Pharmacy type[a]	N, (%)	N, (%)	N, (%)
Single, independent pharmacy	7 (26%)	1 (25%)	1 (25%)
Small chain	2 (8%)	1 (25%)	0 (0%)
Medium chain	5 (19%)	2 (50%)	1 (25%)
Large chain	13 (48%)	0 (0%)	2 (50%)
Location	N, (%)	N, (%)	N, (%)
Urban	21 (78%)	3 (75%)	3 (75%)
Rural	6 (22%)	1 (25%)	1 (25%)
Range of pharmacy staff numbers[b]	3–18	5–18	4–11

[a] Small chain defined as 2–4 pharmacies, Medium chain defined as 5–30 pharmacies, Large chain defined as > 30 pharmacies.
[b] Pharmacy staff numbers were determined retrospectively by telephoning participating pharmacies and asking them to provide a best estimate of number of pharmacy staff.

dispensary workflow comprising: (1) prescription received by a member of pharmacy staff; (2) prescription details inputted into the Patient Medication Record system; (3) medicines assembled including generating labels; (4) clinical and accuracy check; (5) medicines prepared for collection; (6) medicine supplied to patient; and (7) patient counselling, if appropriate.

To synthesise the regional process maps to a single Warfarin and single NSAID process map (Phase 2), three areas of importance were identified: work processes, staff involvement and resources. This is shown in Supplementary File 2. Responses to the variation exercise (Phase 3) where the Warfarin and NSAID process maps were presented to participants, revealed that despite differing local practices (i.e. variable resources used), there were 5 core steps surrounding CB delivery which integrated within each pharmacies local dispensing process, described in Table 2.

During the variation exercise, some participants offered their opinion of the NSAID and warfarin process maps as a resource. The presentation was commented to be a "clear and logical" representation of the process, and that "all information was contained in one place". Participants mentioned its ease of use, "it is easy to follow workflow chart", and that it could prompt staff of the required steps. However, 3 participating pharmacies felt the process map was too complex. Also unprompted, 4 participants said that provision of a process map could facilitate staff involvement.

> "Process map - Biggest advantage will be to get other people involved. Even on your days off everybody can carry on with the care bundle." (Pharmacy site 4, NSAID CB, large chain pharmacy)

3.3. Integration of the CB

The commonalities between the NSAID and Warfarin CB processes and how it integrated into practice were sufficient to allow a generic process map to be developed, where it is evident that pharmacist involvement is required only for the clinical assessment stage. The HRM CB generic process map developed is shown in Fig. 2.

3.4. Validation of the generic HRM process map

The generic HRM process map validation (Phase 4) revealed that all sites had a process for each of the 5 core steps, no additional steps were identified, and the order of the steps was comparable. Within one pharmacy there was a two-step patient identification process involving both the support staff and pharmacist. A member of support staff would see an electronic prompt indicating eligibility during the dispensing process (i.e. that the patient was prescribed a HRM) and would gather appropriate resources. This prompt did not indicate if the CB had previously been delivered to the patient. The pharmacist subsequently checked if the patient had previously been delivered the CB; if yes, it would not be repeated. As this two-step process was not reflective of the majority of sites process the generic process map was not altered.

4. Discussion

The study details how the SPSP-PPC pharmacies integrated the CBs into their working practice. Through the exploration of variation, this study identified 5 core steps fundamental to the delivery of the CBs and suitability for a whole team approach - depicted through a generic process map. The sites followed a similar sequential process, encompassing the core steps, adopted individually to fit within their working systems. Despite the heterogeneity of the participating pharmacies, sufficient commonalities enabled development of a generic HRM process map to assist national implementation.

4.1. Strengths and limitations

The phased development of the generic process map allowed all participating pharmacies to contribute. We believe this method reduced the effects of any bias within the data gathered, however, as with any simulation exercise the Hawthorn effect is an unavoidable bias which may have influenced the data gathered via the "talk and walkthrough" simulation method.[30] Additionally, during the on-site simulation exercise there was a tendency for the pharmacist to lead this discussion, although the NLE variation exercise sought input from both pharmacists and support staff participants.

The commonalities with the 5 core stages observed between the pharmacies suggest that our conclusions have validity and are generalisabile. The heterogeneity of the current sample adds confidence regarding the relevance of the process map nationally. However, the authors appreciate that transferability of findings to all community pharmacies (n = 1253) in Scotland cannot be assumed, in part due to the heterogeneity of pharmacy characteristics within the UK, such as ownership and size diversity.[31] Therefore, the generic process map was intentionally designed to be sufficiently high-level to act as a service blueprint,[32] which avoids being over-prescriptive and could accommodate local system adoption on a larger scale. This would allow people to adopt a two-step patient identification process, as observed within one of the latter case studies, if they wished.

Unlike traditional methods of process mapping which focus on identifying system faults, this study applied process mapping as a

Table 2
Description of Core Steps involved in CB Delivery.

(1) Patient Identification	Identification of patients on an HRM (either Warfarin or an NSAID) and eligible to be delivered the CB, either via the presentation of an HRM prescription or via the electronic Patient Medication Record system.
(2) Clinical Assessment	Clinical assessment of the HRM performed by the pharmacist (e.g. medication suitability, interactions, and contraindications).
(3) Pharmacy CB Prompt	Highlighting during the dispensing process that a patient is to be delivered the CB (i.e. by using alert stickers) to alert the pharmacy team and act as a prompt to deliver the CB.
(4) CB Delivery	Delivering the CB to the patient, for example when they present to the pharmacy to collect their prescription or by a telephone consultation.
(5) Documentation	Documentation that the CB was delivered, although variable systems were adopted within the pharmacy sites.

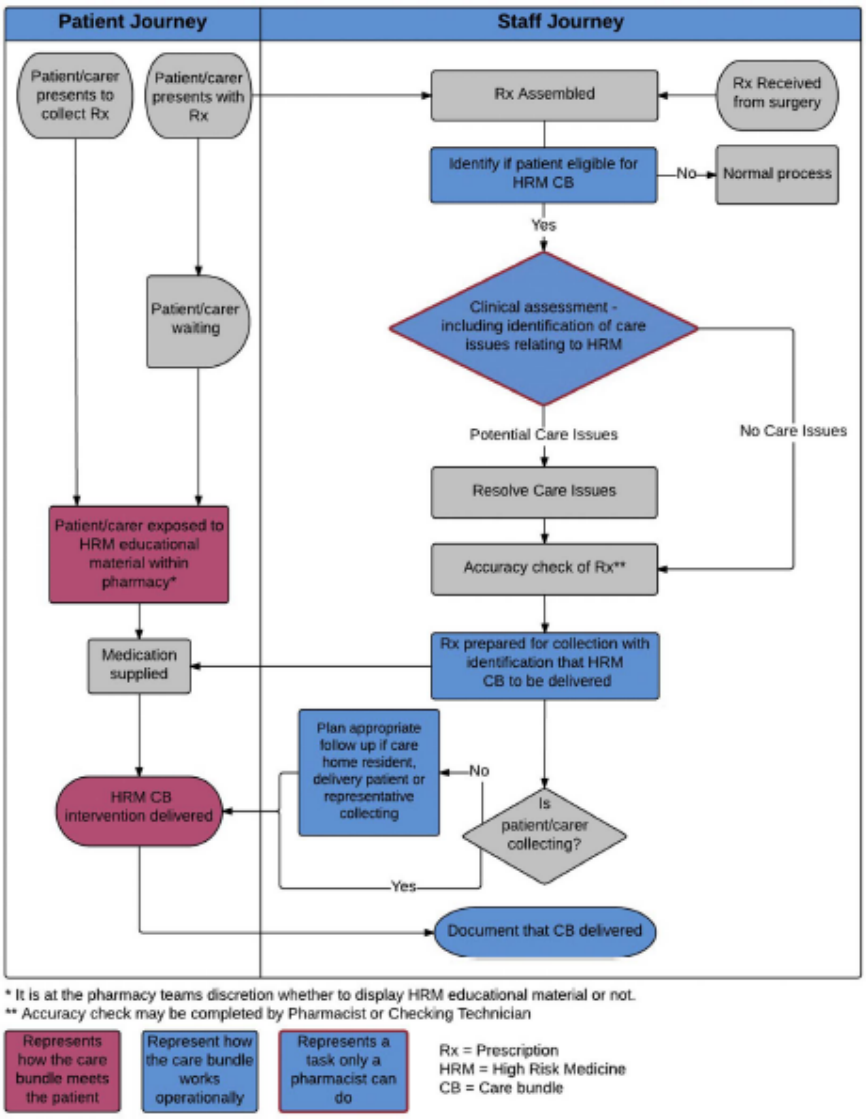

Fig. 2. High risk medicine care bundle generic process map.

"bottom up" approach to understand variation and integration of the CBs.[33] It is acknowledged that other methods of exploring work process variation exist, such as human factors models which aim to understand the complex interactions between people, tasks, technology and the wider environment they work within and how these influence overall system performance and human wellbeing.[34,35] However, this requires significant expertise and effort, while process mapping was selected purposefully as its application within improvement and safety initiatives is well established and feasible.[33,36]

4.2. Implications

The methodology applied has allowed understanding of how the CB process integrated into routine practice. Understanding integration of novel innovations into practice is an important consideration of both local and international significance. Within Scotland, evaluation of a national platform, the Pharmacy Care Record system, suggested a lack of integration into practice when only 13.7% of pharmacists used the system daily.[37] For quality-related initiatives in Canada, integration into community pharmacy practice was identified as one of six supporting factors,[38] and incompatibility with the layout and workflow of the pharmacy was a cited barrier to the provision of written medicine information to patients in an Australian study.[39] The authors propose that further application of the methodological approach outlined in this study within community pharmacy could mitigate barriers for future innovations, especially considering the drive for community pharmacies to offer more clinical services. This could become of greater importance as the emergence of eHealth technology, such as automatic dispensing and electronic prescribing, may challenge and reshape traditional workflows.[34,40–43]

Furthermore, the development of the generic process map may allow senior leaders to visualise the process in practice and thus facilitate strategic decision making when considering the national implementation of the CBs. The identification of the CB core stages allows

for the targeted development of resources and offers understanding to the degree of facilitation required for national implementation. For example, the findings of this study highlighted that variable documentation methods were adopted by the pilot pharmacies, and consequently national implementation may be facilitated by an update of the eHealth system already available nationally within Scottish community pharmacies.[44]

The generic HRM process map highlights the scope for whole team involvement with the HRM CBs, which was an unexpected but positive finding. Within the UK, a potential link has been identified between the involvement of support staff and pharmacy engagement with public health initiatives,[45,46] and internationally the potential benefits of support staff involvement has been recognised. Reviews of community pharmacy services in the United States found involvement of technicians in work that does not require professional judgement lessens the "dispensing burden" and helps overcome time constraints.[47,48] In New Zealand, a survey of pharmacists and pharmacy technicians revealed support for technicians adoption of more advanced roles,[49,50] and Australian community pharmacists and strategists considered task delegation as "essential" for successful implementation of clinical pharmacy services.[51]

However, results from the wider SPSP-PPC evaluation indicate that although whole team involvement was possible, in reality, the onus was often on the pharmacist to deliver the CBs.[52] Within the UK, although task delegation is reported to be widely employed within community pharmacies and support staff are considered competent to absorb further roles, barriers to task delegation exist and include concerns over accountability, with mixed views about the reconfiguration of the skill mix within community pharmacies.[53,54] As participants within this study reported positively that the process map could encourage staff involvement, the generic process map could be disseminated to pharmacies as an operational tool to facilitate implementation by promoting whole-team engagement and task delegation. The use of process maps in community pharmacy has previously been suggested to improve efficiency, identify support staff roles and ensure higher skilled staff perform tasks only themselves can do,[47] echoing some of the participants comments within this study.

The feasibility of developing a generic process map for the CBs, derived in this study from different HRM areas, suggests potential adaptability of the process to varying clinical contexts. Scope therefore lies, once nationally implemented, for the CBs clinical content to be adapted in light of emerging safety concerns. This could be a promising platform to allow for seamless translation of evidence into practice and would benefit from further research.

5. Conclusions

As community pharmacies' contribution within the primary care health sector is increasingly recognised, an understanding of how novel services and approaches to healthcare delivery can integrate into routine practice is crucial. The methods employed in this study were successful in determining the core steps involved, and the contribution of resources and staff members. Overall, it provides an understanding of the extent of variation when considering the adoption of a CB approach to drive quality improvement in patient care. Similar methodology may be utilised further within this, and other settings, to allow those developing novel services to distil the key processes and consider their integration within routine workflows to effect maximal, efficient implementation and benefit to patient care.

Author contribution

RN co-ordinated the research project. RN, PB, AW, MB contributed to study design. EDC, AA-G, AA and NW undertook data collection. NW, RN, EDC, AA-G and AA contributed to data analysis. NW developed the Warfarin, NSAID and generic HRM process map, wrote and prepared the final manuscript and RN contributed to writing the first draft. All authors edited and approved the final manuscript.

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Conflicts of interest

None.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at http://dx.doi.org/10.1016/j.sapharm.2017.11.009.

Appendix 1. Phase 1 semi-structured interview guide:

1) Are you involved in the warfarin/NSAID programme?
   a. If yes,
      i. What are you doing? How are you doing it?
      ii. What is going really well?
      iii. Challenges and how you've overcome them
   b. If no, the interviewer give brief explanation of what's being done
      i. How do you think you could be involved
      ii. Have you been affected by it in any way?
2) How disruptive is this evaluation process – can we do anything differently?

Appendix 2. Phase 3 variation exercise questions:

Q1: What are the differences between this model and the processes within your site? Can you explain why this is?
Q2: Which steps in the process map do you find challenging and how are these overcome?
Q3: What advantages/disadvantages can you see in this approach? Would you consider reviewing/revising your processes in light of this process map?

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Appendix 8.2: On-site visits walkthrough guide

NSAIDs Bundle walk-through guide:

I know that for the NSAIDs bundle it can be delivered to three different types of patients: those who get an NSAID on a prescription, those that choose to purchase it over-the-counter, and those who may get it supplied on the Minor Ailments Service.

1. Can you explain to me the process in your pharmacy for doing the NSAIDs bundle to patients who are PRESCRIBED an NSAID? I would like to know the different steps in the process, what different staff members do, and any resources you may use.

Prompts:

- What parts of the care bundle are done for patients prescribed an NSAID (Communication Bundle [Q1-3] and/or Safer Care Bundle [Q4-6])?
- When different actions are described – clarify who would do that action, and if any resources are used.
- What patients are eligible to be delivered the bundle (e.g. patients who are on an NSAID, or just those who have not been delivered the bundle before?)
- How are eligible patients identified (e.g. from prescription or PMR system)?
- At what stage are eligible patients identified?
- What does the clinical assessment involve (e.g. are patients asked certain questions, or is their PMR checked)?
- At what stage does the clinical assessment happen?
- Is a prompt used throughout the dispensing process indicating that the patient is to be delivered the care bundle (e.g. are stickers or other resources used on the prescription bags)?
- When does the prescription get dispensed?
- When does the dispensed prescription get accuracy checked?
- At what stage is the patient spoken with (i.e. deliver the care bundle)?
- What does speaking to the patient (i.e. delivering the care bundle) actually involve?
- What happens if the patient doesn't come to collect it (e.g. a representative comes to collect it, or the patient gets it delivered or resides in a care home?)
- Is it documented anywhere that the care bundle has been delivered to the patient?

Resource prompts:

- Are any computer programmes used during the process?
- Are any resources used?

2. The interviewer will draft a process map. The interviewer will show this to the participant to confirm/clarify.

3. Is there anything that we have missed?

4. Is there ever a time when something is done differently?

1. Can you explain to me the process in your pharmacy for doing the NSAIDs bundle to patients who buy an NSAID <u>OVER THE COUNTER</u>? I would like to know the different steps in the process, what different staff members do, and any resources you may use.

Prompts:

- What parts of the care bundle are done for patients who buy an NSAID over the counter (Communication Bundle [Q1-3] and/or Safer Care Bundle [Q4-6])?
- When different actions are described – clarify who would do that action, and if any resources are used.
- What patients are eligible to be delivered the bundle (e.g. patients who buy an NSAID, or just those who have not been delivered the bundle before?)
- How are eligible patients identified (e.g. from prescription or PMR system)?
- At what stage are eligible patients identified?
- What does the clinical assessment involve (e.g. are patients asked certain questions, or is their PMR checked)?
- Is the pharmacist, or anyone else, ever referred to?
- At what stage does the clinical assessment happen?
- Is a prompt used throughout the process to indicate that the patient is to be delivered the care bundle (i.e. do you use stickers or other resources)?
- At what stage is the patient spoken with (i.e. deliver the care bundle)?
- What does speaking to the patient (i.e. delivering the care bundle) actually involve?
- What happens if the patient doesn't come to buy it (e.g. a representative comes to collect it, or the patient gets it delivered or resides in a care home)?
- Is it documented anywhere that the care bundle has been delivered to the patient?

Resource prompts:

- Are any computer programmes used during the process?
- Are any resources used?

2. The interviewer will draft a process map. The interviewer will show this to the participant to confirm/clarify.

3. Is there anything that we have missed?

4. Is there ever a time when something is done differently?

1. Can you explain to me the process in your pharmacy for doing the NSAIDs bundle to patients who are supplied an NSAID on the <u>MINOR AILMENTS SERVICE</u>? I would like to know the different steps in the process, what different staff members do, and any resources you may use.

Prompts (essential):

- What parts of the care bundle are done for patients who are supplied an NSAID on the Minor Ailments Service (Communication Bundle [Q1-3] and/or Safer Care Bundle [Q4-6])?
- When different actions are described – clarify who would do that action, and if any resources are used.
- What patients are eligible to be delivered the bundle (e.g. patients who get an NSAID via the Minor Ailments service, or just those who have not been delivered the bundle before)?
- How are eligible patients identified (e.g. from prescription or PMR system)?
- At what stage are eligible patients identified?
- What does the clinical assessment involve (e.g. are patients asked certain questions, or is their PMR checked)?
- At what stage does the clinical assessment happen?
- Is a prompt used throughout the dispensing process to indicate that the patient is to be delivered the care bundle (i.e. do you use stickers or other resources on the prescription bags)?
- When does the prescription get dispensed?
- When does the dispensed prescription get accuracy checked?
- At what stage is the patient spoken with (i.e. deliver the care bundle)?
- What does speaking to the patient (i.e. delivering the care bundle) actually involve?
- What happens if the patient doesn't come to collect it (e.g. a representative comes to collect it, or the patient gets it delivered or resides in a care home?)
- Is it documented anywhere that the care bundle has been delivered to the patient?

Resource prompts:

- Are any computer programmes used during the process?
- Are any resources used?

2. The interviewer will draft a process map. The interviewer will show this to the participant to confirm/clarify.

3. Is there anything that we have missed?

4. Is there ever a time when something is done differently?

Warfarin Bundle walk-through guide:

1. Can you explain to me the process in your pharmacy for doing the warfarin bundle? I would like to know the different steps in the process, what different staff members do, and any resources you may use.

Prompts:

- When different actions are described – clarify who would do that action, and if any resources are used.
- What patients are eligible to be delivered the bundle (e.g. patients who are on warfarin, or just those who have not been delivered the bundle before?)
- How are eligible patients identified (e.g. from prescription or PMR system)?
- At what stage are eligible patients identified?
- What does the clinical assessment involve (e.g. are patients asked certain questions, or is their PMR checked)?
- At what stage does the clinical assessment happen?
- Is a prompt used throughout the dispensing process indicating that the patient is to be delivered the care bundle (e.g. are stickers or other resources used on the prescription bags)?
- When does the prescription get dispensed?
- When does the dispensed prescription get accuracy checked?
- At what stage is the patient spoken with (i.e. deliver the care bundle)?
- What does speaking to the patient (i.e. delivering the care bundle) actually involve?
- What happens if the patient doesn't come to collect it (e.g. a representative comes to collect it, or the patient gets it delivered or resides in a care home?)
- Is it documented anywhere that the care bundle has been delivered to the patient?

Resource prompts:

- Are any computer programmes used during the process?
- Are any resources used?

2. The interviewer will draft a process map. The interviewer will show this to the participant to confirm/clarify.

3. Is there anything that we have missed?

4. Is there ever a time when something is done differently?

Appendix 8.3: NSAIDs care bundle proformas developed by pharmacies

Proforma developed and used by Pharmacy 2:

NSAID Bundle Questions

Patient name: Date of consultation:

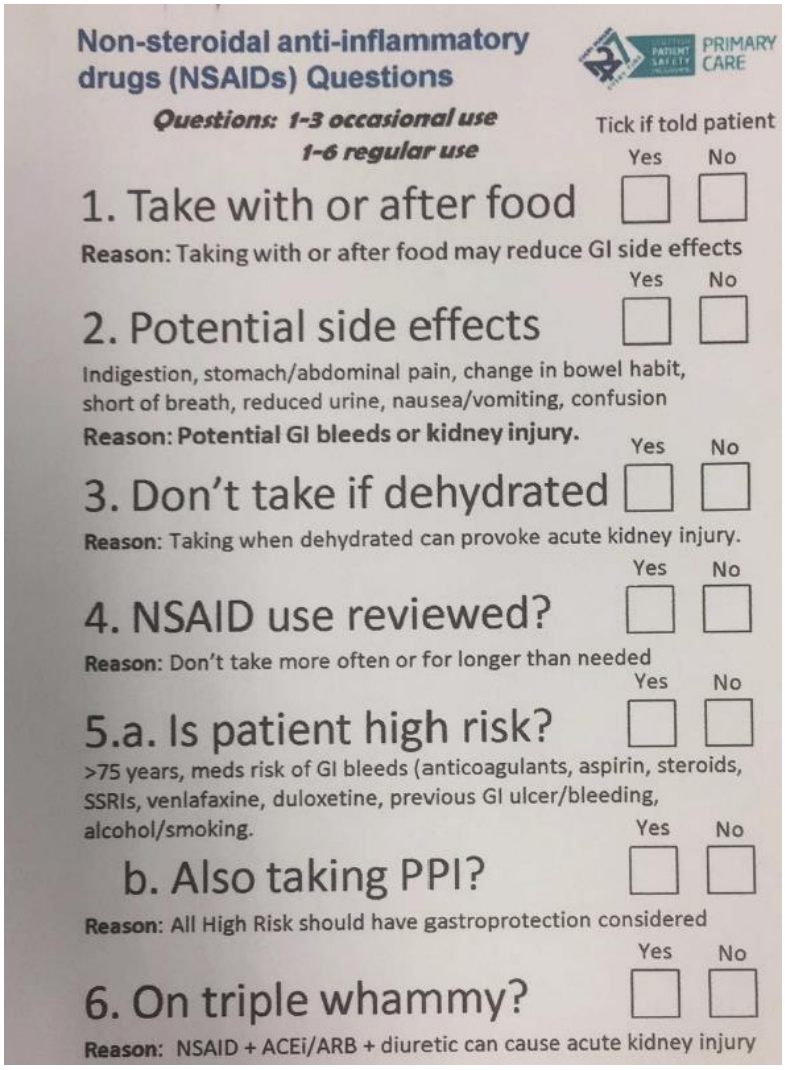
Patient date of birth: Consultation completed by:

No.	Bundle Question	Response	Additional Guidance	Why?
1	Has the patient been informed to take NSAID with or after food?	YES/NO	Has the patient been given verbal advice backed up with a PIL or NSAID card?	Taking NSAIDs with or after food may reduce local gastrointestinal side effects.
2	Have you discussed with the patient the potential adverse drug reactions or side effects?	YES/NO	Dyspepsia/indigestion Gastrointestinal pain Change in bowel habit/change in stool appearance Shortness of breath Reduced urine output Nausea/vomiting Confusion	Early identification of adverse drug reactions or side effects can reduce the likelihood of gastrointestinal bleeds and acute kidney injury.
3	Has the patient been made aware of the risk of a dehydrating illness?	YES/NO	Patients who take NSAIDs regularly should be aware of the Medicine Sick Day Rules. This is not necessary for single, OTC purchases.	Taking an NSAID when dehydrated can provoke acute kidney injury.
	Has the patient got a Medicine Sick Day Rules card?	YES/NO	Ensure patient understands the Medicine Sick Day Rules card and knows when to stop the NSAID and when to restart it	
4	Has the patient's use and/or need of their NSAID been assessed?	YES/NO	Are they taking the NSAID as prescribed? Can the NSAID be taken intermittently? If 'when required' does the patient know how to take it? Action if not compliant, NSAID not required, dose/frequency/quantity can be reduced etc.	Taking NSAIDs with or after food reduces risk of side effects.
5	Is the patient in a high risk group?	YES/NO	Over 75 years Concomitant use of medicines known to increase risk of GI bleeds (aspirin, anticoagulants, corticosteroids, SSRIs, venlafaxine, duloxetine) History of GI ulcer/bleeding Excessive alcohol/smoking	These high risk groups are at increased risk of GI adverse events from NSAIDs.
	If yes, has action been taken to reduce this risk?	YES/NO	Has gastroprotection been prescribed? If not, consider what the best option is – stopping NSAID or starting gastroprotection. Gastroprotection is not without risks and should be limited to these high risk groups and also may not be appropriate for some patients within these groups.	Proton pump inhibitors are linked with increased risk of *Clostridium difficile* infection and their use should be limited to patients at high risk of GI adverse events. Consider other risks for *Clostridium difficile* infections such as frequent use of antibiotics before prescribing PPIs.
6	Is the patient prescribed the triple whammy combination?	YES/NO	NSAID + ACE inhibitor/ARB + diuretic	Concomitant use of the triple whammy combination should be avoided.
	If yes, has the triple whammy combination been highlighted to the prescriber?	YES/NO	Is there evidence that the prescriber has been contacted?	

Actions	Completed by	Date completed

Communication Bundle Questions **NSAID = Non-steroidal anti-inflammatory drug**		**NSAID prescribed**
1	Are you aware that you should take the NSAID with or after food?	Taking NSAIDs with or after food may reduce side effects such as indigestion and stomach pain.
2	Are you aware of the potential adverse drug reactions or side effects?	Indigestion/heartburn Stomach pain Changes in bowel habit/appearance of stools Shortness of breath Reduced urine output Nausea/vomiting Confusion
3	Are you aware of the risk of a dehydrating illness?	Taking NSAIDs when dehydrated can cause serious kidney damage.
	Do you have a Medicine Sick Day Rules card?	If you experience vomiting, diarrhoea, fevers, sweats or shaking you should STOP taking the NSAID and restart when you are well, usually 24 to 48 hours of eating and drinking normally.

Proforma developed and used by Pharmacy 5:



Non-steroidal anti-inflammatory drugs (NSAIDs) Questions

PRIMARY CARE

Questions: 1-3 occasional use
1-6 regular use

Tick if told patient

1. Take with or after food — Yes ☐ No ☐

Reason: Taking with or after food may reduce GI side effects

2. Potential side effects — Yes ☐ No ☐

Indigestion, stomach/abdominal pain, change in bowel habit, short of breath, reduced urine, nausea/vomiting, confusion

Reason: Potential GI bleeds or kidney injury.

3. Don't take if dehydrated — Yes ☐ No ☐

Reason: Taking when dehydrated can provoke acute kidney injury.

4. NSAID use reviewed? — Yes ☐ No ☐

Reason: Don't take more often or for longer than needed

5.a. Is patient high risk? — Yes ☐ No ☐

>75 years, meds risk of GI bleeds (anticoagulants, aspirin, steroids, SSRIs, venlafaxine, duloxetine, previous GI ulcer/bleeding, alcohol/smoking.

b. Also taking PPI? — Yes ☐ No ☐

Reason: All High Risk should have gastroprotection considered

6. On triple whammy? — Yes ☐ No ☐

Reason: NSAID + ACEi/ARB + diuretic can cause acute kidney injury

Appendix 9.1: Semi-structured patient interview schedule

NSAIDs care bundle interview schedule:

Q1. Have you received the NSAIDs service?

If yes – proceed to Q2

If no – prompt as necessary:

- New service which some pharmacies are involved with
- May have been a chat with someone in the pharmacy (e.g. counter assistant/pharmacist/dispenser)
- NSAIDs are anti-inflammatories used to manage pain
- The services is for people on NSAIDs (e.g. ibuprofen, naproxen, diclofenac, but there are others)
- May have been told information (e.g. take with or after food)
- May have been given an information card (e.g. NSAIDs Safety Information card, Medicines Sick Day Rule card)
- May have happened in the pharmacy when collecting a prescription, over the phone, or the pharmacy may have visited you in your home

Q2. Before you were spoken to about your NSAIDs medicine, were you aware that your community pharmacy was involved in the NSAIDs service?

- Awareness of pharmacy services in general

Q3. What are your thoughts of the NSAIDs service?

- willingness to be involved
- expectations
- opinions (if they think it is a good or bad idea)
- Any positives aspects of the service you received
- Any negative aspects of the service you received

Q4. What happened when the person at the pharmacy spoke to you about your NSAIDs medication?

- OTC/Rx/MAS supply
- what did the person at the pharmacy say
- where did it take place (e.g. in person, over the phone, in a consultation room)
- who delivered the service (e.g. pharmacist, another member of the pharmacy team)
- were any resources given (e.g. resources such as information leaflets, information cards)?
- how long did it take?

Q5. Has the NSAIDs service had any impact on you?

- was any of the information new to you?
    - If yes, what?
- impact on the way you feel about your NSAIDs medication? e.g. confidence, concerns.
- any changes to medication? e.g. when taking, what dose/how many tablets, how taking, if other medicines changes.
    - If yes, how do you feel about these changes?

Q6. Do have any suggestions of how the NSAIDs service could be improved?

Warfarin care bundle interview schedule:

Q1. Have you received the warfarin service?

If yes – proceed to Q2

If no – prompt as necessary:

- New service which some pharmacies are involved with
- May have been a chat with someone in the pharmacy (e.g. counter assistant/pharmacist/dispenser)
- Warfarin is an anti-coagulant used to thin the blood, which involves regular blood tests
- May have been told information (e.g. what to do if miss warfarin, side effects)
- May have been given an information leaflet (e.g. flyers telling you about warfarin and antibiotics/diet/when to take/interaction with other medicines) or shown a warfarin YouTube video
- May have happened in the pharmacy when you were collecting a prescription, over the phone, or the pharmacy may have visited you in your home

Q2. Before you were spoken to about your warfarin medicine, were you aware that your community pharmacy was involved in the warfarin service?

- Awareness of pharmacy services in general

Q3. What are your thoughts of the warfarin service?

- willingness to be involved
- expectations
- opinions (if they think it is a good or bad idea)
- Any positives aspects of the service you received
- Any negative aspects of the service you received

Q4. What happened when the person at the pharmacy spoke to you about your warfarin medication?

- what did the person at the pharmacy say
- where did it take place (e.g. in person, over the phone, in a consultation room)
- who delivered the service (e.g. pharmacist, another member of the pharmacy team)
- were any resources given (e.g. resources such as information leaflets, information cards)?
- how long did it take?

Q5. Has the warfarin service had any impact on you?

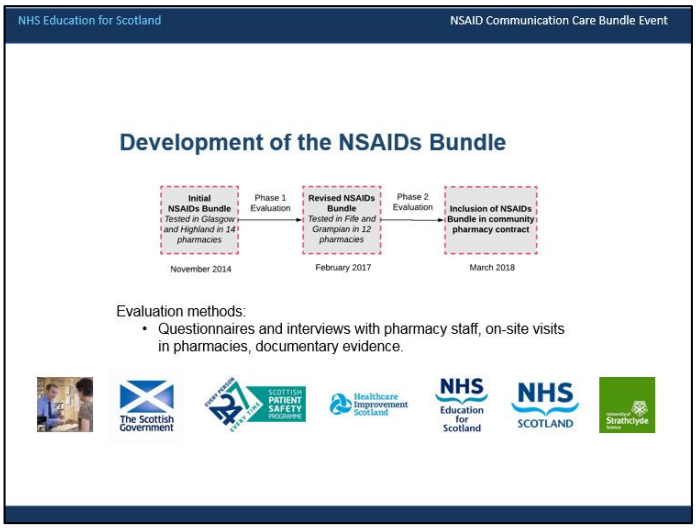
- was any of the information new to you?
    - If yes, what?
- impact on the way you feel about your warfarin medication? e.g. confidence, concerns.
- any changes to medication? e.g. when taking, what dose/how many tablets, how taking, if other medicines changes.
    - If yes, how do you feel about these changes?

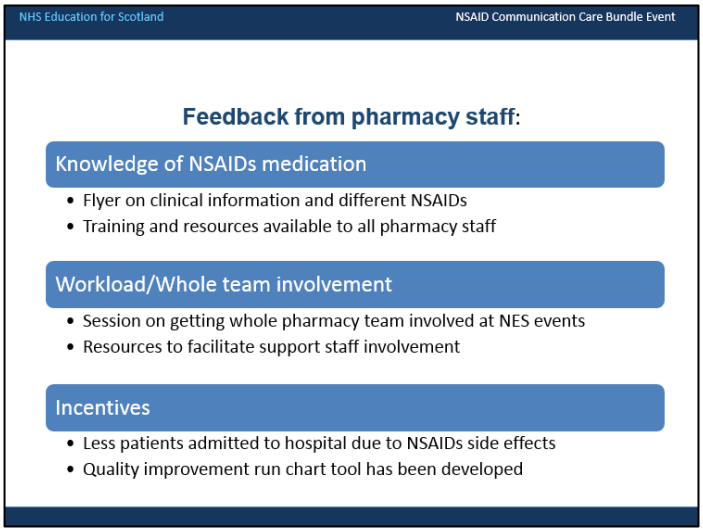
Appendix 9.2: Framework matrix of patient interview data

Category	Codes	Description
Awareness	• Awareness of NSAIDs/warfarin service • Awareness of pharmacy services in general	Participants awareness (or lack of) of the care bundles and generally of pharmacy services available.
Experience of the care bundle	• The consultation • Advice given of what to do if a problem • Opportunity to ask questions • Place delivered • Time (i.e. how long care bundle delivery took) • Resources given • Staff involved • When received the services • How often service delivered to patient • If NSAIDs/warfarin new or not	Participants account of what happened when the care bundle was delivered to them, including the information offered during the consultation and the pharmacy setting, as well as the different advice offered if the medication is newly prescribed or a regular repeat medication.
Perceptions of the care bundle	• Opinions of the care bundles • Willingness to receive care bundles • Expectations of care bundle	Participants opinion of the care bundle (positive and negative), their willingness (or reluctance) to receive the care bundle, and the expectation they had (if any) of what that would involve.
Impact of care bundle	• Awareness • Behaviour • Concerns • Confidence • Desire to stop medication • Gained knowledge • 'General impact' • Not remembering information • Realised role of pharmacy • Change in medication	The positive and negative impact receiving the care bundle had on the participant.
Suggestions for care bundle	• Suggestions for care bundle	Participants suggestions for care bundle.
Other pharmacy care related to NSAIDs/warfarin	• Other pharmacy care related to NSAIDs/warfarin	Example of other care relating to participants' warfarin/NSAIDs medication out with the bundle (e.g. offering advice on NSAIDs and asthma). Shows care bundles are not replacing usual care.
Roles of others in warfarin/NSAIDs care	• Role of other healthcare professionals • Influence of media • Influence of peers	The wider societal influences, including other healthcare professionals, relating to participants warfarin or NSAIDs medicine (e.g. the media/peers/other healthcare professionals as sources of information and influence).

Wider perceptions of healthcare	• Opinion of pharmacy in general • Perception of pharmacy as a shop • Business of pharmacy • Pharmacy short of space • Business of healthcare professionals • Opinions of other healthcare professionals • Perception of being on medication	Participants' perceptions of healthcare in a more general sense, such as their opinions of their pharmacy, other healthcare professionals, and of their thoughts of taking medication.

Appendix 10.1: Key findings and recommendations presented during NES Webinar (March 2018)





Appendix 10.2: NSAIDs Communication Care Bundle A5 flyer

NSAIDs Till Prompt

Safety messages for non-steroidal anti-inflammatory drugs

Drug name	Some common brand names
Aspirin	Anadin, Disprin
Celecoxib	
Diclofenac	
Etodolac	
Flurbiprofen	
Ibuprofen	Nurofen, Some cold/flu treatments
Indometacin	
Mefenamic Acid	
Meloxicam	
Nabumetone	
Naproxen	Feminax Ultra
Piroxicam	
Sulindac	

Keep beside the till - please see overleaf for safety messages.

Healthcare Improvement Scotland

NSAIDs Safety Messages

Message	Why?	Any other information?
Always take this medicine **with** or **after** food.	Helps to reduce or avoid gastrointestinal side effects.	
Tell us if you get any side effects.	Earlier recognition of side effects allows action to be taken before they develop into something more serious.	Side effects to look out for: • nausea, vomiting, stomach pain or acid, black stools. What if the patient reports side effects? • If a patient reports vomiting blood or black stools, this should be referred to a GP urgently as it indicates bleeding in the gastrointestinal tract. • If a patient reports nausea, stomach pain or acid, it would be appropriate to stop the NSAID temporarily to see if this improves the symptoms.
Be aware of the medicine sick day rules.	Some medicines, including NSAIDs, should be stopped temporarily during dehydrating illness. This is because continuing to take them when dehydrated increases the risk of serious adverse events, in particular acute kidney injury.	Explain that dehydration can occur with vomiting and diarrhoea, therefore the NSAID should be stopped until the patient is fully recovered. It can then be restarted. Explain that these rules are to cover situations like sickness bugs and food poisoning: it is separate from the advice above on gastrointestinal side effects. For patients who are buying a single pack of NSAIDs for a single episode of pain like a headache, there is no need to explain the medicine sick day rules. The rules are for people who take NSAIDs every day.