Title: 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.

Key words

Patient safety; Quality improvement; Variation; Primary care; Implementation

Conflicts of interest: None

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, 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 operationalised 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.

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.

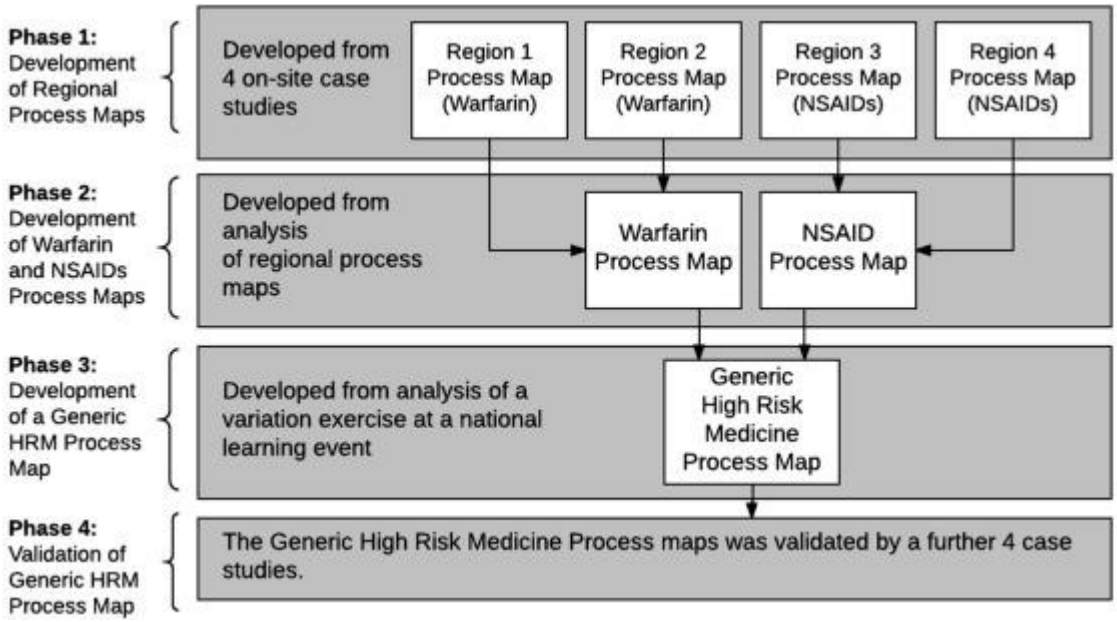
An anticipated challenge to the adoption of new services within pharmacy practice is the potential variation of processes, as it is well established that integration within existing workflow can influence successful implementation of health service innovations.[16-18] Variation in pharmacy practice has 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.

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 Figure 1.

Figure 1. Staged Process Map Development



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 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.

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.

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.

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]

Results

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.

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*	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 †	3-18	5-18	4-11

*Small chain defined as 2-4 pharmacies, Medium chain defined as 5-30 pharmacies, Large chain defined as >30 pharmacies

†Pharmacy staff numbers were determined retrospectively by telephoning participating pharmacies and asking them to provide a best estimate of number of pharmacy staff.

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.

Pharmacy Workflow and CB Core Steps

From Phase One it was apparent that each pharmacy had similar dispensary workflow comprising: (1) prescription received by a member of pharmacy staff; (2) prescription details inputted into the Patient Medical Record (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.

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.

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)

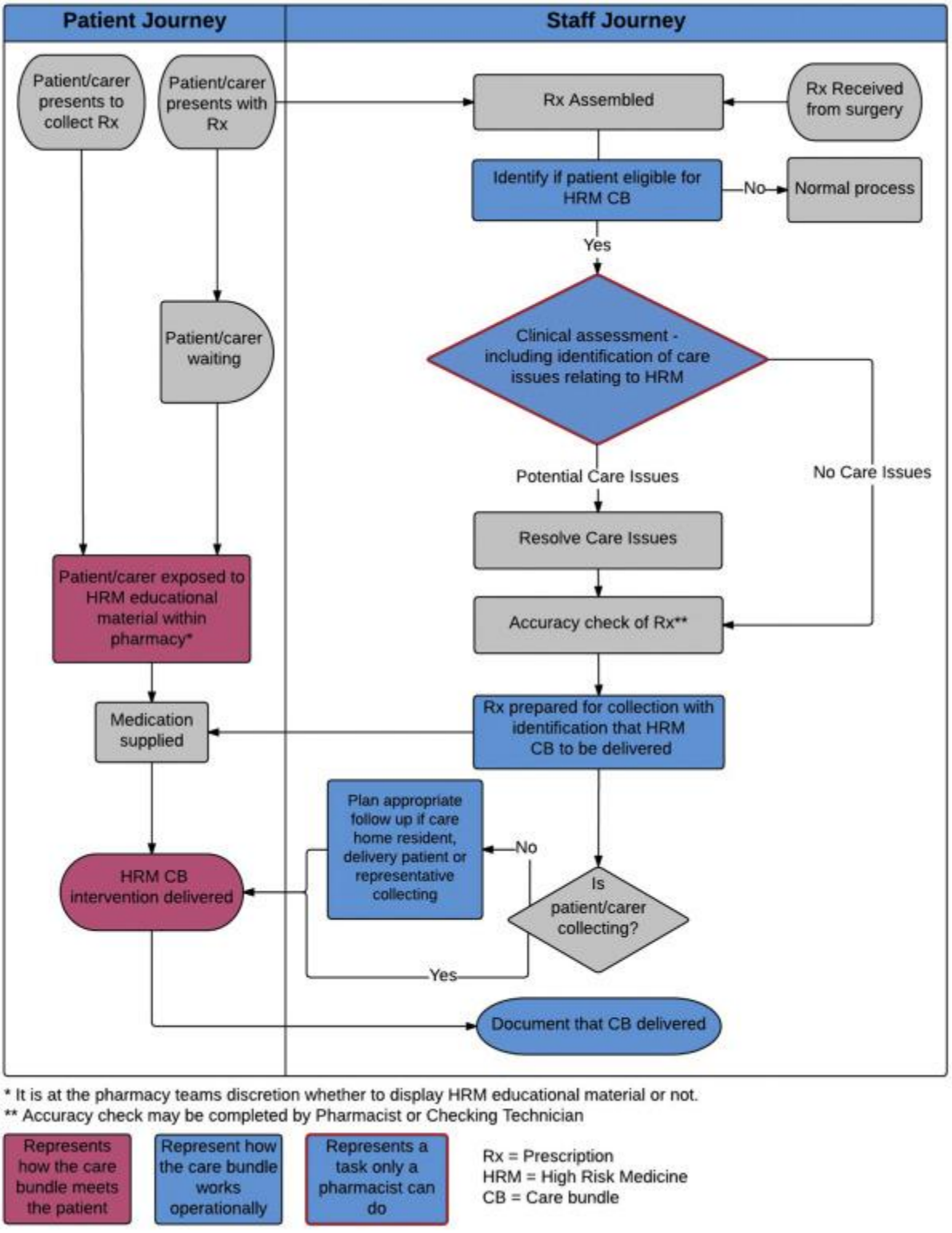
Integration of the CB

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 Figure 2.

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.

Figure 2. High Risk Medicine Care Bundle Generic Process Map



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.

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= 1,253) 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 "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]

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.

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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Appendices

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?

507 **Supplementary Files**

508 **Supplementary File 1.** Demographics of pharmacy staff participants

	Phase 1 Case Study Participants					**Phase 3 Pharmacy Away Team Participants** (n=41)
	Region 1, (n=5)	Region 2, (n=4)	Region 3, (n=5)	Region 4, (n=5)	Total (n=19)	
Gender						
Male	0	1	0	2	3	13
Female	5	3	5	3	16	28
Duration worked in Community Pharmacy (years)						
<1	0	0	1	0	1	3
1 – 5	1	0	4	1	6	8
6 – 10	3	2	0	2	7	9
11 - 15	0	0	0	0	0	6
16 – 20	1	0	0	1	2	4
>20	0	2	0	1	3	9
Unknown	0	0	0	0	0	2
Job Role*						
Pharmacist	1	2	1	3	7	29
Support staff	4	2	4	2	12	12

509 Pharmacy Away Team demographics collected from NLE registration documentation.
510 *Pharmacist includes pre-registration pharmacists, which in the UK is a trainee who has completed
511 their Masters of Pharmacy undergraduate degree and is participating in a one-year placement prior
512 to becoming a fully qualified pharmacist. Support staff includes pharmacy technicians, dispensing
513 assistants and medicine counter assistants.

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516 **Supplementary File 2.** Local variation between regional processes (Phase 1)

Step	Variation	Outcome
Work processes		
Process for delivering the care bundle if the patient/carer didn't present themselves to collect the prescription.	Region 3 and 4 did not stipulate a process for this. The other regions did which involved asking for the patient to attend or telephone the pharmacy.	Deemed important and included in both HRM process maps.
This display of an HRM educational poster was identified as optional.	Region 4 made a conscious decision not to display an educational poster as was not deemed appropriate. All other regions did.	Included but annotated within both HRM process map to show optional.
Consulting Warfarin Record Book during care bundle delivery.	Region 1 specifically required the warfarin yellow book to deliver the care bundle.	Included but annotated within the Warfarin HRM process map to show optional.
Process for repeating the care bundle to patients.	Region 2 did not repeat the care bundle, Region 1 would repeat only in the presence of changes. Region 3 and 4 did not stipulate if the Care Bundle was repeated.	Included with both HRM Process maps to allow others at the NLE validation exercise to elaborate if repeating to patients or not.
Staff Involvement		
Pharmacy support staff involvement was variable throughout all four regions	Involvement included: identifying eligible patients, delivering the care bundle, facilitating enrollment of patients who got medication delivered and documentation.	Only HRM clinical assessment required pharmacist involvement, this was annotated within both HRM process maps.
Resources		
Various staff resources used throughout all four regions. Alert stickers were used to flag an HRM prescription to staff during dispensing and to highlight at point of collection that the care bundle should be delivered.	◦ NSAID stickers ◦ Speak to Pharmacist stickers ◦ SPSP HRM Stickers ◦ Warfarin Stickers ◦ Warfarin Patient List ◦ Care Bundle Checklist ("in house") ◦ Enrollment stickers ("in house")	Staff resources were included within the corresponding HRM Process map to ascertain resources used by other staff. Resources created "in house" for sole use in that pharmacy were not included.
Various Patient resources used throughout all four regions.	◦ Warfarin Yellow Book ◦ NSAID Safety Card ◦ Medicines Sick Day Card	Patient resources were included within the corresponding HRM process map to ascertain resources used by other staff.

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