

Weir, Natalie M. and Newham, Rosemary and Corcoran, Emma D. and Ali Atallah Al-Gethami, Ashwag and Mohammed Abd Alridha, Ali and Bowie, Paul and Watson, Anne and Bennie, Marion (2017) Application of process mapping to understand integration of high risk medicine care bundles within community pharmacy practice. Research in Social and Administrative Pharmacy. ISSN 1551-7411, http://dx.doi.org/10.1016/j.sapharm.2017.11.009

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- 1 Title: Application of Process Mapping to understand integration of high risk medicine care
- 2 bundles within community pharmacy practice
- 3 **DOI:** http://dx.doi.org/10.1016/j.sapharm.2017.11.009

## 4 Can be cited as:

- 5 Weir NM, Newham R, Corcoran ED, Ali Atallah Al-Gethami A, Mohammed Abd Alridha A, Bowie P,
- 6 Watson A, Bennie M, Application of Process Mapping to understand integration of high risk medicine
- 7 care bundles within community pharmacy practice, Research in Social & Administrative Pharmacy
- 8 (2017), doi: 10.1016/j.sapharm.2017.11.009.

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## 40 Abstract

- 41 Objective
- 42 The Scottish Patient Safety Programme Pharmacy in Primary Care collaborative is a quality
- 43 improvement initiative adopting the Institute of Healthcare Improvement Breakthrough Series
- 44 collaborative approach. The programme developed and piloted High Risk Medicine (HRM) Care
- 45 Bundles (CB), focused on warfarin and non-steroidal anti-inflammatories (NSAIDs), within 27
- 46 community pharmacies over 4 NHS Regions. Each CB involves clinical assessment and patient
- 47 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
- 49 practice to inform the development of a generic HRM CB process map.
- 50 Methods
- 51 Regional process maps were developed in 4 pharmacies through simulation of the CB process, staff
- 52 interviews and documentation of resources. Commonalities were collated to develop a process map
- 53 for each HRM, which were used to explore variation at a national event. A single, generic process
- 54 map was developed which underwent validation by case study testing.
- 55 Results
- 56 The findings allowed development of a generic process map applicable to warfarin and NSAID CB
- 57 implementation. Five steps were identified as required for successful CB delivery: patient
- identification; clinical assessment; pharmacy CB prompt; CB delivery; and documentation. The
- 59 generic HRM CB process map encompasses the staff and patients' journey and the CB's integration
- 60 into routine community pharmacy practice. Pharmacist involvement was required only for clinical
- 61 assessment, indicating suitability for whole-team involvement.
- 62 Conclusions
- 63 Understanding CB integration into routine practice has positive implications for successful
- 64 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
- 66 utilised within other settings, to allow those developing novel services to distil the key processes and
- 67 consider their integration within routine workflows to effect maximal, efficient implementation and
- 68 benefit to patient care.
- 69 Key words
- 70 Patient safety; Quality improvement; Variation; Primary care; Implementation
- 71 Conflicts of interest: None
- 72

## 73 Introduction

- 74 Studies within the United Kingdom (UK) show 6.5% of hospital admissions are attributed to adverse
- 75 effects of High Risk Medicines (HRM) including Warfarin and Non-steroidal anti-inflammatory drugs
- 76 (NSAIDs).<sup>1</sup> This figure is not dissimilar to international prospective studies and similar causative
- 77 medicines have been identified as high risk.<sup>2, 3</sup> The pharmacist's potential contribution to patient
- safety within primary care has been highlighted,<sup>4</sup> and internationally community pharmacists' roles
- 79 are expanding to be increasingly integrated within primary care.<sup>5-7</sup>
- 80 Within the UK, this transition has resulted in the introduction of new services including community
- 81 pharmacy minor ailment schemes, with positive feedback from pharmacists and patients.<sup>8-10</sup> The
- 82 drive for community pharmacy to provide enhanced patient safety services aligns with the Scottish
- 83 Government's vision and action plan, Prescription for Excellence.<sup>6</sup> Within Scotland, a national patient
- safety programme has since launched within community pharmacy in 2014, called The Scottish
- 85 Patient Safety Programme Pharmacy in Primary Care (SPSP-PPC) collaborative.<sup>11</sup>
- 86 The SPSP-PPC collaborative is a multi-site quality improvement initiative adopting the Institute of
- 87 Healthcare Improvement Breakthrough Series collaborative approach a structured learning model
- 88 consisting of Learning Sessions to share progress and discuss practice changes and Action Periods
- 89 where those changes are tested in the health care setting.<sup>12</sup> Participating pharmacy teams were
- 90 trained in the Model for Improvement which was the guiding quality improvement framework
- 91 operationalised at pharmacy site level through the application of 'Plan-Do-Study-Act' (PDSA) cycles,
- 92 as a means to facilitate rapid testing of small-scale changes.<sup>13</sup>
- 93 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
- 95 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),
- 97 defined as a "structured way of improving the processes of care and patient outcomes: a small,
- 98 straightforward set of evidence-based practices".<sup>14</sup> Box 1 provides an overview of the programme
- 99 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.<sup>15</sup>

# 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, gastroprotection 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.

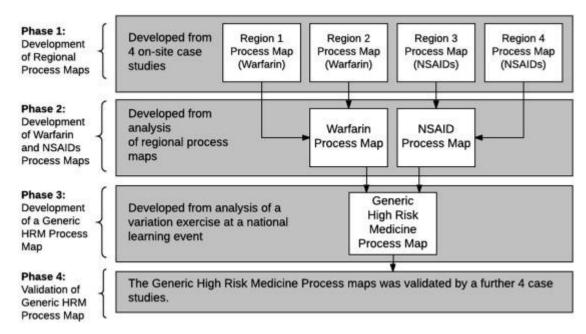
101

- 102 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
- 104 influence successful implementation of health service innovations.<sup>16-18</sup> Variation in pharmacy
- 105 practice has been identified within other health services, <sup>19-21</sup> 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
- 108 the HRM CB by allowing consideration of how this novel service could successfully integrate into 109 routine pharmacy practice.
- 110 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
- 112 national implementation.

# 113 Methods

- 114 A qualitative case-study method was employed.<sup>22</sup> 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.<sup>23</sup> 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.

#### 120 Figure 1. Staged Process Map Development



#### 122 Phase 1: Development of Regional Process Maps

- 123 Pharmacies were selected for case study on-site evaluations based on March 2015 activity data
- 124 reporting on number of patients delivered the CB, CB compliance and reliability. The top 3
- 125 performing pharmacies within each NHS Region were identified, and final selection agreed in
- 126 discussion with the Regional Leads taking account of feasibility of on-site visits. One pharmacy from
- 127 each participating NHS Region was chosen and contacted to arrange suitable dates.
- 128 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
- 131 and duration worked in community pharmacy.
- 132 The simulation exercise involved pharmacy staff providing a "talk and walkthrough" of the CB
- process as it would normally be delivered to a patient.<sup>24</sup> This allowed for resources used within the
- pharmacy environment to act as material probes to prompt discussion, and was thought to allow for
- 135 better understanding of the workflow than with traditional interviews.<sup>25</sup> Photographs of relevant
- pharmacy resources were taken with permission, and identifiable information anonymised. Semi-
- 137 structured interviews with pharmacy staff were guided by a pre-designed interview schedule
- 138 (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-
- 140 recorded. The interviews were transcribed using an intelligent verbatim approach and were
- 141 anonymised to protect participant identity. The resultant data were used to develop a process map
- 142 for each of the 4 NHS Regions.
- 143 Phase 2: Development of Warfarin and NSAID Process Maps
- 144 A process map for each HRM (warfarin and NSAIDs) was developed using Lucidchart software.<sup>26</sup> This 145 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 documentedresources.
- 148 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

- 155 process maps presented and the processes within their pharmacies.
- 156 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.<sup>27</sup> To allow for comparative
- analysis of variation, responses were classified according to NHS Region and HRM. Examination of
- 160 the commonalities between processes was used to create a generic HRM process map detailing the
- 161 core steps fundamental to successful delivery of the CBs.
- 162 Phase 4: Validation
- 163 The generic HRM process map was validated against regional process maps developed from a
- 164 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
- 166 process identified the lower performing pharmacies based on March 2015 reliability data and the
- 167 final decision informed primarily by discussion with the NHS Regional Leads on feasibility of on-site
- 168 visits.
- 169 The same simulation exercise method was applied as before, however for the telephone interviews a
- 170 verbal explanation of the CB process was recorded and participants were asked to email
- 171 photographs of any resources used.<sup>28</sup>
- 172 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
- 174 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.<sup>29</sup>
- 177 Results
- 178 Participants
- 179 Of the 27 community pharmacies participating in the SPSP-PPC pilot, 8 pharmacies participated in
- 180 case studies, representing 30% of all sites. Pharmacy site demographics are shown in Table 1.
- 181

#### 182 **Table 1.** Pharmacy site demographics

Pharmacy site demographics	All sites	Phase 1 case	Validation case	
	(n=27)	studies (n=4)	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	

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

184 defined as >30 pharmacies

185 <sup>†</sup>Pharmacy staff numbers were determined retrospectively by telephoning participating pharmacies

and asking them to provide a best estimate of number of pharmacy staff.

187 Nineteen staff members participated in the Phase One case studies (4-5 from each site). Of which,

188 84% were female (n=16), 37% were pharmacists (n=7) and the remainder were support staff. Most

189 (74%, n=14) had 10 years or less experience in community pharmacy. For the validation case studies,

190 it was the on-site pharmacist who participated in the simulation exercise.

191 At the time of the NLE variation exercise (Phase 3), one of the pharmacies involved in the phase one

192 case studies withdrew participation. Of the remaining 26 pharmacy sites, all had Away Team

193 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

195 pharmacists (n=29, 71%), and most had over 10 years' experience in community pharmacy (n=21,

196 52%). Full demographics of pharmacy staff participants are shown in Supplementary File 1.

197 Pharmacy Workflow and CB Core Steps

198 From Phase One it was apparent that each pharmacy had similar dispensary workflow comprising:

199 (1) prescription received by a member of pharmacy staff; (2) prescription details inputted into the

200 Patient Medical Record (3) medicines assembled including generating labels; (4) clinical and accuracy

201 check; (5) medicines prepared for collection; (6) medicine supplied to patient; and (7) patient

- 202 counselling, if appropriate.
- 203 To synthesise the regional process maps to a single Warfarin and single NSAID process map (Phase
- 204 2), three areas of importance were identified: work processes, staff involvement and resources. This
- 205 is shown in Supplementary File 2. Responses to the variation exercise (Phase 3) where the Warfarin
- 206 and NSAID process maps were presented to participants, revealed that despite differing local
- 207 practices (i.e. variable resources used), there were 5 core steps surrounding CB delivery which
- 208 integrated within each pharmacies local dispensing process, described in Table 2.

#### 210 Table 2. Description of Core Steps involved in CB Delivery

#### 211

(1) Patient	Identification of patients on an HRM (either Warfarin or an NSAID) and		
Identification	eligible to be delivered the CB, either via the presentation of an HRM		
	prescription or via the electronic Patient Medication Record system.		
(2) Clinical	Clinical assessment of the HRM performed by the pharmacist (e.g.		
Assessment	medication suitability, interactions, and contraindications).		
(3) Pharmacy CB	Highlighting during the dispensing process that a patient is to be delivered		
Prompt	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.		

#### 212

213 During the variation exercise, some participants offered their opinion of the NSAID and warfarin

214 process maps as a resource. The presentation was commented to be a "clear and logical"

215 representation of the process, and that "all information was contained in one place". Participants

216 mentioned its ease of use, "it is easy to follow workflow chart", and that it could prompt staff of the

217 required steps. However, 3 participating pharmacies felt the process map was too complex. Also

218 unprompted, 4 participants said that provision of a process map could facilitate staff involvement.

219 "Process map - Biggest advantage will be to get other people involved. Even on your days off
220 everybody can carry on with the care bundle." (Pharmacy site 4, NSAID CB, large chain
221 pharmacy)

## 222 Integration of the CB

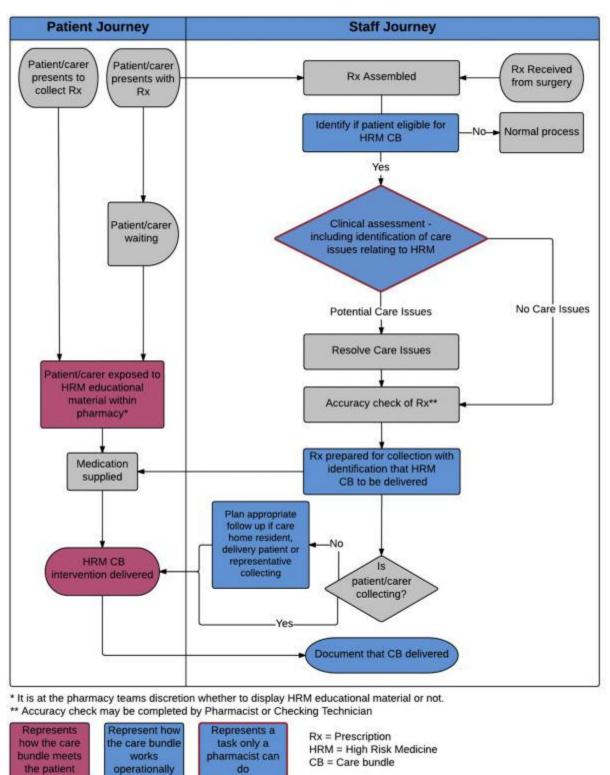
223 The commonalities between the NSAID and Warfarin CB processes and how it integrated into

practice were sufficient to allow a generic process map to be developed, where it is evident thatpharmacist involvement is required only for the clinical assessment stage. The HRM CB generic

- 226 process map developed is shown in Figure 2.
- 227 Validation of the Generic HRM Process Map

228 The generic HRM process map validation (Phase 4) revealed that all sites had a process for each of 229 the 5 core steps, no additional steps were identified, and the order of the steps was comparable. 230 Within one pharmacy there was a two-step patient identification process involving both the support 231 staff and pharmacist. A member of support staff would see an electronic prompt indicating eligibility 232 during the dispensing process (i.e. that the patient was prescribed a HRM) and would gather 233 appropriate resources. This prompt did not indicate if the CB had previously been delivered to the 234 patient. The pharmacist subsequently checked if the patient had previously been delivered the CB; if 235 yes, it would not be repeated. As this two-step process was not reflective of the majority of sites 236 process the generic process map was not altered.

238 Figure 2. High Risk Medicine Care Bundle Generic Process Map





## 241 Discussion

- 242 The study details how the SPSP-PPC pharmacies integrated the CBs into their working practice.
- 243 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
- 246 within their working systems. Despite the heterogeneity of the participating pharmacies, sufficient
- 247 commonalities enabled development of a generic HRM process map to assist national
- 248 implementation.

# 249 Strengths and Limitations

250 The phased development of the generic process map allowed all participating pharmacies to

- 251 contribute. We believe this method reduced the effects of any bias within the data gathered,
- 252 however, as with any simulation exercise the Hawthorn effect is an unavoidable bias which may
- 253 have influenced the data gathered via the "talk and walkthrough" simulation method.<sup>30</sup> Additionally,
- 254 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
- 256 staff participants.
- 257 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
- 259 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
- 262 ownership and size diversity.<sup>31</sup> Therefore, the generic process map was intentionally designed to be
- sufficiently high-level to act as a service blueprint,<sup>32</sup> which avoids being over-prescriptive and could
- accommodate local system adoption on a larger scale. This would allow people to adopt a two-step
- 265 patient identification process, as observed within one of the latter case studies, if they wished.
- 266 Unlike traditional methods of process mapping which focus on identifying system faults, this study267 applied process mapping as a "bottom up" approach to understand variation and integration of the
- 268 CBs.<sup>33</sup> It is acknowledged that other methods of exploring work process variation exist, such as
- 269 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
- 271 performance and human wellbeing.<sup>34, 35</sup> However, this requires significant expertise and effort, while
- 272 process mapping was selected purposefully as its application within improvement and safety
- 273 initiatives is well established and feasible.<sup>33, 36</sup>

# 274 Implications

275 The methodology applied has allowed understanding of how the CB process integrated into routine 276 practice. Understanding integration of novel innovations into practice is an important consideration 277 of both local and international significance. Within Scotland, evaluation of a national platform, the 278 Pharmacy Care Record system, suggested a lack of integration into practice when only 13.7% of 279 pharmacists used the system daily.<sup>37</sup> For quality-related initiatives in Canada, integration into 280 community pharmacy practice was identified as one of six supporting factors,<sup>38</sup> and incompatibility with the layout and workflow of the pharmacy was a cited barrier to the provision of written 281 medicine information to patients in an Australian study.<sup>39</sup> The authors propose that further 282 application of the methodological approach outlined in this study within community pharmacy could 283 284 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.<sup>34, 40-43</sup>

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

- 295 within Scottish community pharmacies.<sup>44</sup>
- 296 The generic HRM process map highlights the scope for whole team involvement with the HRM CBs,

297 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,<sup>45, 46</sup> and internationally the potential benefits of support staff involvement has been
- 300 recognised. Reviews of community pharmacy services in the United States found involvement of
- 301 technicians in work that does not require professional judgement lessens the "dispensing burden"
- and helps overcome time constraints.<sup>47, 48</sup> In New Zealand, a survey of pharmacists and pharmacy
- 303 technicians revealed support for technicians adoption of more advanced roles,<sup>49, 50</sup> and Australian
- 304 community pharmacists and strategists considered task delegation as "essential" for successful
- 305 implementation of clinical pharmacy services.<sup>51</sup>

306 However, results from the wider SPSP-PPC evaluation indicate that although whole team

- 307 involvement was possible, in reality, the onus was often on the pharmacist to deliver the CBs.<sup>52</sup>
- 308 Within the UK, although task delegation is reported to be widely employed within community
- 309 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.<sup>53, 54</sup> As participants within this study
- 312 reported positively that the process map could encourage staff involvement, the generic process
- 313 map could be disseminated to pharmacies as an operational tool to facilitate implementation by
- 314 promoting whole-team engagement and task delegation. The use of process maps in community
- 315 pharmacy has previously been suggested to improve efficiency, identify support staff roles and
- ensure higher skilled staff perform tasks only themselves can do,<sup>47</sup> echoing some of the participants
- comments within this study.
- 318 The feasibility of developing a generic process map for the CBs, derived in this study from different
- 319 HRM areas, suggests potential adaptability of the process to varying clinical contexts. Scope
- 320 therefore lies, once nationally implemented, for the CBs clinical content to be adapted in light of
- 321 emerging safety concerns. This could be a promising platform to allow for seamless translation of
- 322 evidence into practice and would benefit from further research.
- 323 Conclusions
- 324 As community pharmacies' contribution within the primary care health sector is increasingly
- 325 recognised, an understanding of how novel services and approaches to healthcare delivery can

- 326 integrate into routine practice is crucial. The methods employed in this study were successful in
- 327 determining the core steps involved, and the contribution of resources and staff members. Overall, it
- 328 provides an understanding of the extent of variation when considering the adoption of a CB
- 329 approach to drive quality improvement in patient care. Similar methodology may be utilised further
- 330 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.

## 333 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
- 337 manuscript and RN contributed to writing the first draft. All authors edited and approved the final
- 338 manuscript.

# 339 Acknowledgements

- 340 The authors would like to sincerely thank all pharmacy staff who participated throughout the various
- 341 phases within this study, and the SPSP-PPC National Steering Group who helped facilitate this
- 342 evaluation.

## 343 Funding

344 This work was supported by the Health Foundation Closing the Gap in Patient Safety Programme

345 [Award Reference Number: 7271].

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487	Appen	dices
488		idix 1. Phase 1 semi-structured interview guide:
489	1)	Are you involved in the warfarin/NSAID programme?
490		a. If yes,
491		i. What are you doing? How are you doing it?
492		ii. What is going really well?
493		iii. Challenges and how you've overcome them
494		b. If no, the interviewer give brief explanation of what's being done
495		i. How do you think you could be involved
496		ii. Have you been affected by it in any way?
497		
498	2)	How disruptive is this evaluation process – can we do anything differently?
499		
500	Appen	dix 2. Phase 3 variation exercise questions:
501		hat are the differences between this model and the processes within your site? Can you
502	explair	n why this is?
503	Q2: W	/hich steps in the process map do you find challenging and how are these overcome?
504 505		hat advantages/disadvantages can you see in this approach? Would you consider ving/revising your processes in light of this process map?
506		

#### 507 Supplementary Files

	Phase 1 Case Study Participants				Phase 3 Pharmacy	
	Region	Region	Region	Region	Total	Away Team
	1, (n=5)	2, (n=4)	3, (n=5)	4, (n=5)	(n=19)	Participants (n=41)
Gender						
Male	0	1	0	2	3	13
Female	5	3	5	3	16	28
Duration work	ed in Comr	nunity Pha	rmacy (yea	rs)		
<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

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

509 Pharmacy Away Team demographics collected from NLE registration documentation.

<sup>510</sup> \*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

to becoming a fully qualified pharmacist. Support staff includes pharmacy technicians, dispensing

513 assistants and medicine counter assistants.

514

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

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

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