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## Medication reconciliation as a medication safety initiative in a resource limiting settings: the case of Ethiopia - A study protocol

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1       **Medication reconciliation as a medication safety initiative in a resource limiting**  
2       **settings: the case of Ethiopia - A study protocol**

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## ABSTRACT

**Introduction:** Medication-related events are common, particularly at care transitions and have a significant impact on patient outcomes and healthcare costs. Medication reconciliation as a patient safety strategy has been adopted in many developed countries. However, the impact of this strategy in resource limiting settings is scarcely described. The aims of this study are to explore patient safety culture, and to develop, implement and evaluate a theory-informed intervention to minimise the incidence of medication errors when patients are admitted to, and discharged from, a hospital.

**Methods and analyses:** This study is being conducted at ten public hospitals in Ethiopia. There are 3 phases for this project. The first phase is a mixed methods study of healthcare professionals' and patients' perspectives of patient safety culture and strategies to prevent medication-related events. In this phase, we are being conducting a survey (Hospital Survey on Patient Safety Culture) adopted from the Agency for Healthcare Research and Quality, and semi-structured in-depth interviews to assess patient safety culture and experiences of medication-related events. The second phase is also based on a semi-structured interview guide designed according to the 12 domains from the theoretical domains framework, and will be used to conduct a focus group discussion with hospital pharmacists to explore the barriers and facilitators to medication safety activities. The third phase will be an assessment of the impact of pharmacy-led medication reconciliation intervention in hospitalised patients in an internal medicine ward of a teaching hospital. In this phase, a baseline assessment of unjustified medication discrepancies will be conducted for 1 month, and then prospective investigation of pharmacist-led medication reconciliation will be carried out for 2 months.

**Ethics:** The study protocol was approved by the University of Sydney University Human Research Ethics Committee- Project number: 2015/818, and the Institutional Review Board of the University of Gondar, Ethiopia.

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53     **INTRODUCTION**

54     **Patient safety initiatives**

55     Quality care is a priority agenda for all healthcare sectors; however, patient safety is usually  
56     compromised due to medical harms.<sup>1</sup> Patient safety incidents gain more attention after the  
57     works of previous pioneer US studies: the Harvard Medical Practice Study<sup>2, 3</sup> and the  
58     Institute of Medicine Report.<sup>4</sup> It has been reported that 3.7% of all hospitalized patients  
59     experienced an adverse event,<sup>2</sup> and medication errors alone resulted in 7000 deaths annually.<sup>4</sup>  
60     Medication errors constitute the most common preventable cause of patient safety problems,  
61     and has been studied extensively in the developed countries.<sup>2-6</sup> Though a better healthcare to  
62     date, these incidents continue to pose a significant problem globally,<sup>7</sup> and are the concern of  
63     many hospitalists and patient safety activists.

64     **Medication safety in African hospitals**

65     Patient injuries attributed to drug therapy, medication errors and their associated events are  
66     among the most common incidents in hospitals,<sup>2</sup> and have important economic and  
67     humanistic consequences. This is particularly significant for low income countries. There is a  
68     limited of medication safety literature in African countries though there is evidence this is  
69     increasing over the last decade (Mekonnen et al, submitted manuscript). A review of the  
70     African medication safety literature has shown that 1.5% to 6.5% of hospital admissions are  
71     attributed to adverse drug events (ADEs),<sup>8, 9</sup> and 2.5% to 47% of inpatients encountered an  
72     ADE during their hospital stay.<sup>8, 10</sup> One-fifth to more than half of the reported ADEs were  
73     severe events;<sup>9, 11-13</sup> however, up to half were deemed preventable.<sup>9</sup> ADE-related fatalities  
74     were reported in 0.07% to 2.9% of patient admissions to hospital.<sup>11, 14, 15</sup> The most reported  
75     types of medication errors in African healthcare settings were prescribing errors, occurring in  
76     13% to 76% of all prescriptions and most importantly, 1.2% to 57% of the prescriptions were  
77     evaluated to have dosing problems.<sup>16-19</sup>

## 78 Medication reconciliation as a medication safety strategy

79 More than half of the medication errors occurred at transitions in care, when patients move  
80 in, and out of, hospital or transferred to the care of other healthcare professional,<sup>20</sup> and  
81 medication reconciliation as a tool for the prevention of these errors and consequent patient  
82 harm have been advocated internationally.<sup>21, 22</sup> Medication reconciliation has been defined by  
83 the Institute for Healthcare Improvement as *“the process of identifying the most accurate list  
84 of a patient’s current medicines including the name, dosage, frequency and route – and  
85 comparing them to the current list in use, recognizing and documenting any discrepancies,  
86 thus resulting in a complete list of medications”*.<sup>21</sup>

87 Under the leadership of WHO, patient safety programs including medication reconciliation  
88 had been implemented across a range of countries<sup>22-25</sup> and taken-up into their healthcare  
89 policy. For instance, medication reconciliation has been recognised as a priority patient safety  
90 solution for the Australian Commission on Safety and Quality in Healthcare.<sup>25</sup> Prior to  
91 medication reconciliation being routinely practiced in Australia, there was one omitted  
92 medicine from medication chart among every two people at admission and every patient at  
93 discharge.<sup>26</sup> Also, other previous studies showed that between 60% and 80% of patients were  
94 noted to have a discrepancy with their medication history.<sup>27, 28</sup>

95 Medication errors warranting reconciliation have been undertaken across many countries  
96 including developing nations,<sup>29, 30</sup> in a range of settings, such as emergency units,<sup>31- 37</sup>  
97 critical/intensive care,<sup>38</sup> paediatrics<sup>39-41</sup> and geriatrics unit.<sup>42-47</sup> There is evidence that  
98 medication reconciliation decreases the frequency of medication errors<sup>48, 49</sup> and drug-related  
99 readmissions.<sup>37, 38</sup>

100 Medication reconciliation with various approaches have been employed to improve  
101 medication safety including, but not limited to, electronic reconciliation tools,<sup>52-54</sup> use of  
102 standardised forms,<sup>33, 55</sup> collaborative models,<sup>32, 56</sup> as well as patient engagement<sup>57</sup> and

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103 pharmacy-led approaches.<sup>58, 59</sup> Our previous studies have shown benefits from involving  
104 pharmacists in medication reconciliation.<sup>58, 59</sup> However, the impact of medication  
105 reconciliation overall, as well as pharmacist-led medication reconciliation practice, is not yet  
106 described in the sub-Saharan Africa.

107 **Patient safety culture in Ethiopian context**

108 Despite a lack of research, patient safety in Ethiopia is believed to be a serious concern. A  
109 previous local study<sup>60</sup> in the paediatrics ward has shown an incidence of 9.2 ADEs per 100  
110 admissions, of which one-third could be preventable. As healthcare managers strive to  
111 improve the quality of patient care, there is a growing recognition of the importance of  
112 establishing a culture of patient safety. Developing a patient safety culture was one of the  
113 recommendations made by the Institute of Medicine<sup>4</sup> to assist hospitals in improving patient  
114 safety. According to the Agency of Healthcare Research and Quality (AHRQ),<sup>61</sup> patient  
115 safety culture is described as an understanding of the values, beliefs, and norms about what is  
116 important in an organization and what attitudes and behaviours related to patient safety are  
117 supported, rewarded, and expected. It is thus, important for healthcare organizations to assess  
118 their patient safety culture to obtain a clear understanding of the patient safety aspects  
119 requiring urgent attention, identify the strengths and weaknesses of their safety culture<sup>62</sup> and  
120 assist hospitals identify their existing patient safety problems.<sup>63</sup> Studies on patient safety  
121 culture, mostly originated from developed countries,<sup>62-65</sup> has been published. However, there  
122 is no data about the current state of patient safety culture in Ethiopian hospitals. Furthermore,  
123 no studies have specifically investigated the implementation of medication reconciliation  
124 service from a behavioral theory perspective which involved both barriers and facilitators of a  
125 wide range of behavioral determinants in implementation of evidence-based practice.  
126 This project is a medication safety initiative focusing on medication reconciliation at care  
127 transitions in an Ethiopian public hospitals, and the implementation of this service in this

study is guided by a multimethod approach consisting three different but inter-related studies to inform our study objectives. Specifically, the aims of this study are to explore healthcare professional's views of patient safety issues, medical error, and event reporting and patient's experiences of medication-related events, and then to use a theoretical framework to help identify the barriers and facilitators to medication safety activities delivered by hospital pharmacists, and finally to evaluate a pharmacist-led medication reconciliation practice in one of the teaching hospitals in Ethiopia.

## METHODS AND ANALYSES

### Study setting and period

This is a multi-phased study that will be conducted in public hospitals in Amhara region of Ethiopia. Amhara region is one of the nine regions of Ethiopia located in the northern parts of the country. This region has an estimated total population of approximately 18 million people, and the majority (87.4%) of the population is estimated to be rural inhabitants. This region has 17 public hospitals, 520 health centres and 2,941 health posts.<sup>66</sup> There are three phases to this research project. Phase 1 and 2 is being conducted in selected public hospitals of the Amhara region, and phase 3 will be carried out in one teaching hospital. The study is already started in February 2016, and will end in July 2017.

### Phase 1: A study of healthcare professionals' perspectives of patient safety culture and patients' experiences of medication-related problems

This is a mixed methods study consisting a survey and qualitative research. The survey measured dimensional scores of patient safety culture. Using a scale to quantify the scores of patient safety is, however, not explanatory.<sup>67</sup> In addition, a shared decision between the patient and the healthcare professional is central for a sustainable patient safety culture. Therefore, a survey supported with an in-depth interview is well acknowledged to explore a



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152 meaningful assessment of patient safety culture through the eyes of healthcare professionals  
153 and patients.<sup>67</sup>

154 *Questionnaire study*

155 The survey aims to evaluate the patient safety culture of public hospitals in the Amhara  
156 region. We have randomly selected 10 out of 17 public hospitals. The study focus is only on  
157 public hospitals as most of the population in the region used public hospitals. The study  
158 adopted the “Hospital Survey on Patient Safety Culture” (HSOPSC) developed by the  
159 Agency for Healthcare Research and Quality (AHRQ).<sup>68</sup> The HSOPC has been widely used  
160 in assessing patient safety culture and has also been validated in non-US countries.<sup>63, 64</sup>  
161 However, validating this survey is out of the scope of this study, and we will only undertake a  
162 baseline assessment of the extent of patient safety culture. The survey consists 42 items that  
163 measure 12 patient safety culture composites: communication openness, feedback and  
164 communication about errors, frequency of events reported, handoffs and transitions,  
165 management support for patient safety, non-punitive response to error, organizational  
166 learning and continuous improvement, overall perceptions of patient safety, staffing,  
167 supervisor/manager expectations and actions promoting safety, teamwork across and within  
168 units. Background variables of participants included questions related to job category, type of  
169 hospital (teaching, district/tertiary care), years of working experience overall and in the  
170 current working area, work setting and working hours per week. The questionnaire is kept in  
171 English, as English is the main language of communication in Ethiopian hospitals. This  
172 questionnaire together with the participant information statement is being distributed to  
173 conveniently selected healthcare professionals by the research team and required about 10 –  
174 15 minutes to complete. These participants are being recruited from the 10 hospitals of  
175 Amhara region. The *sample size* is estimated to be 480 by considering 95% confidence



176 interval, 5% margin of error and 25% contingency for non-response rate, and assuming that  
177 patient safety culture score is rated as excellent in 50% of respondents.

178 The response to each item in the questionnaire is being assessed by using a 5 point Likert  
179 scale where 1, 'strongly disagree' and 5, 'strongly agree'. The patient safety grade (measured  
180 on a scale of excellent, very good, acceptable, poor and failing), and number of events  
181 reported are the other two outcome variables of interest collected. The collected questionnaire  
182 data will be entered and analysed using SPSS v21. The HSOPS included both positively and  
183 negatively worded items. For easier interpretation of the results, the AHRQ<sup>68</sup> and other  
184 studies<sup>62-65</sup> recommends the use of 'average positive' for calculating each item scores. That  
185 is, the percentage of positive responses for each item will be calculated and negatively  
186 worded items will be reversed when computing percent positive response. We will define  
187 areas of strengths as items for which 75% of respondents answer positively, whereas areas  
188 requiring improvement as those scoring below 50%.<sup>61</sup> Additionally, univariate and  
189 multivariate analyses will be conducted to examine statistical associations between  
190 independent characteristics and patient safety grade and number of events reported. The mean  
191 scores for each of the HSOPC subscales are taken as dependent variables, and these will be  
192 tested against the independent variables such as job characteristics (profession and  
193 qualification), work experience (career length, organization and unit) and workload (working  
194 hours).

### 195 *In-depth interview*

196 The qualitative part of phase 1 will investigate aims to assess the patient safety strategies  
197 employed by those hospitals through in-depth interviews with different stakeholders  
198 (healthcare professionals and patients) working in ten hospitals of the Amhara region. The  
199 contact details of participants (healthcare professionals) will be retrieved from the human  
200 resource office or related office of the respective hospitals. The purposeful sampling method

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201 will be used to identify the initial sample and then the remaining data collection will be aided  
202 with snowball sampling. Letters/e-mails, as appropriate, will be provided for invitation of the  
203 healthcare professionals who are involved in the care of patients. Patients who are in-hospital  
204 at the time of data collection and were taking regular medications before admission will be  
205 invited for an interview by a healthcare professional who is already a participant in this study.  
206 Then, patients will be contacted for further invitation into the study. Semi-structured  
207 interviews informed by the interview guide (Additional file 1) will be employed for the  
208 collection of data. All interview guides have been translated from English versions to the  
209 local language (Amharic) by two non-official translators who are native speakers and  
210 working in the healthcare industry, and validated by two of the research group (ABM, DM).  
211 Interview tools have been translated in order to foster faster communication and expression  
212 of ideas. The respondents will be informed about the interview and consent will be obtained.  
213 Participants will also be given further details on the nature of the study to ensure that  
214 interviewees understand what will be required of them. Face-to-face interviews will be  
215 conducted by the principal investigator at a time and place to suit the participants and  
216 expected to last approximately 30 to 60 minutes. Open-ended questions will be asked to  
217 interviewees to describe their experiences of medication safety issues and strategies  
218 employed to prevent medication-related events. Participants will be encouraged to reflect  
219 upon their own experiences of medication-related events and will be asked to think about an  
220 example of a known medication-related event when answering questions. The interviewer  
221 will use prompts when necessary to encourage further elaboration. Participants will be given  
222 50 ETB in appreciation of their time. All interviews will be conducted by an English/  
223 Amharic speaking investigator (ABM). Data will be collected with each of the two  
224 participant groups until a point of saturation is reached. All interviews will be audiotaped  
225 with the informed consent of participants. The principal investigator will carry out verbatim

Amharic transcriptions of all interviews, which will then be translated to English, and assigned a unique identifier and imported into a computer programme for qualitative data analysis, Nvivo V10. Thematic analysis will then be carried out, and emerging topics will be identified as themes and sub-themes.

## **Phase 2: The barriers and facilitators to medication safety activities delivered by hospital pharmacists**

This is a qualitative study using focus group discussions (FGD) with hospital pharmacists working in selected public hospitals in the region to gather data on the barriers and facilitators to medication safety activities. We will employ FGDs in this phase because the interactive nature of focus groups are specifically important when group norms and cultural values of particular groups are of interest and to explore the degree of consensus on a given topic,<sup>69</sup> including implementation of an intervention to promote medication safety. Many factors can affect an adaptability of an evidence-based intervention, and the success of implementation efforts depends on a careful assessment of barriers to, and facilitators of, the behaviour to be changed.<sup>70</sup> A theory-based identification of such factors provides a theoretically robust evidence-base to inform implementation of an intervention.<sup>70</sup> The underpinning theoretical model used in this study is the Theoretical Domains Framework (TDF).

### ***Theoretical Domains Framework (TDF)***

Increasing the uptake of evidence into clinical practice and improving patient outcomes needs behaviour change. The Theoretical Domains Framework (TDF) from health psychology provides the basis for such an approach ensuring that a wide range of possible theoretical explanations for the behaviours to be considered. Built from 33 behavioural theories, the TDF was developed to make theories more accessible for implementation researchers.<sup>71</sup> According to Michie et al<sup>71</sup>, TDF has 12 domains to explain behaviour change: (1) knowledge, (2) skills,

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251 (3) social/professional role and identity, (4) beliefs about capabilities, (5) beliefs about  
252 consequences, (6) motivation and goals, (7) memory, attention and decision processes, (8)  
253 environmental context and resources, (9) social influences, (10) emotion regulation, (11)  
254 behavioural regulation, and (12) nature of the behavior. After then, TDF has been extensively  
255 used to identify barriers to change in clinical practice in order to develop interventions.<sup>72, 73</sup>

256 To justify implementation of pharmacist-led medication reconciliation, it will be of critically  
257 important to understand the perceived barriers and facilitators underlying individual  
258 pharmacist's roles in medication safety. Thus, this study uses TDF to develop a theory-  
259 informed intervention aimed at improving medication safety of patients at hospital  
260 transitions.

261 ***FGDs***

262 In this study, FGDs will be guided by questions designed based on Theoretical Domains  
263 Framework (TDF) (Table 1). For each of the 12 domains that could act as facilitators or  
264 barriers to current medication safety practices and a successful medication reconciliation  
265 implementation, the authors developed several interview questions. The number of interview  
266 questions ranged between two and five for each of the 12 domains, for a total of 43 questions  
267 to cover a wide range of constructs assigned to each domain. The questions were initially  
268 drafted by one researcher (ABM) and then refined by health service researchers (AM, JB)  
269 and discussed by the research team to check clinical relevance. The discussion questions will  
270 be pilot-tested with at least 2 hospital pharmacists to assess clarity and focus, and revised  
271 accordingly.

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**Table 1** Interview guide questions for focus groups according to Michie's theoretical domains<sup>71</sup>

Domains	Interview questions
Knowledge	<p>Are there any hospital guidelines for pharmacists to deliver clinical pharmacy services?</p> <p>What do you think the level of evidence is for these guidelines?</p> <p>What do you know about medication reconciliation and review?</p> <p>Can you describe pharmacists' roles in medication safety activities?</p>
Skills	<p>Do you know how to deliver clinical pharmacy services?</p> <p>Do you know how to deliver medication reconciliation and review services?</p> <p>Is identification of medication-related problems difficult for you?</p> <p>Have you attended in-service training to deliver clinical pharmacy services?</p>
Social/professional role	<p>Is doing medication reconciliation and review compatible with your professional role?</p> <p>Who is responsible for these services at your hospital?</p> <p>Do you think hospital guidelines supports your professional roles as a pharmaceutical care practitioners?</p>
Beliefs about capabilities	<p>How easy or difficult do you find performing clinical pharmacy activities ?</p>

	<p>What problems have you encountered?</p> <p>How capable are you in performing medication reconciliation and review?</p> <p>How confident are you that you can do these services despite difficulties?</p> <p>How comfortable do you feel to undertake these services?</p>
Beliefs about consequences	<p>What are the likely positive/negative outcomes of reporting/communicating medication-related problems?</p> <p>What are the costs of delivering medication reconciliation and review and what are the costs of the consequences of these services?</p> <p>Are you concerned if these services are not provided at your hospital?</p> <p>Do benefits of doing these services outweigh the costs?</p> <p>Does the evidence suggests that doing these services are beneficial?</p>
Motivation and goals	<p>How motivated are you to deliver medication reconciliation and review?</p> <p>Are there incentives to provide these services?</p> <p>Do you have any other hospital activity that hinders these services?</p>
Memory, attention and decision processes	<p>Will you consider providing medication reconciliation and review services? If so, how frequently would you undertake this activity?</p> <p>How much priority have you given to these services?</p>

Enviromental context and resources	<p>To what extent do physical factors or resources facilitate or hinder to deliver medication reconciliation/review?</p> <p>Are there competing tasks and time constraints?</p> <p>Are the necessary resources available to undertake these services?</p> <p>Do these services have advantages compared with the standard care?</p> <p>Do government and local authorities provide sufficient support for these services?</p>
Social influences	<p>Are clinical pharmacy services in the hospital well acknowledged by other healthcare professionals?</p> <p>Do hospital managers acknowledge your role?</p> <p>Is there any obstruction to these activities in your hospital?</p> <p>Have you observed others doing providing these clinical services?</p>
Emotion	<p>What things worry you the most in providing medication reconciliation/review services?</p> <p>To what extent do emotional factors facilitate or hinder these services?</p>
Behavioural regulation	<p>Have you received feedback from other healthcare professionals regarding these services?</p> <p>What intital steps are needed to deliver these services?</p>
Nature of the behaviours	<p>What do you currently do?</p> <p>How long will changes going to take?</p> <p>Are there any systems in place for sustainable long term</p>



	changes?
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282 The sample population will be all hospital pharmacists in the ten public hospitals across the

283 region. Pharmacists will be selected using a purposive sampling strategy augmented with

284 snowball sampling. Participants will be recruited either by letter/email invitation. Participants

285 willing to be interviewed either by sending an email or by returning a signed consent form

286 will be contacted. The principal investigator (ABM), who is experienced in qualitative study,

287 will conduct and facilitate the focus group discussion using the translated version (Amharic)

288 of the topic guide. Pharmacists will be encouraged to talk about internal beliefs and attitudes

289 that may hinder them from providing clinical pharmacy services including medication safety

290 roles. All discussion sessions will be audiotaped and recorded. Two of the researchers (ABM,

291 ZA) will read all the FGD Amharic transcripts, and will be translated into English.

292 Transcripts will then be coded based on the 12 domains of the TDF, and thematic analysis of

293 pharmacist’s statements into the relevant theoretical domains will be performed.<sup>74</sup> Briefly, the

294 analysis will involve identifying contextualized brief statements related to the barriers and

295 facilitators to medication safety activities, categorizing statements into TDF domains and

296 mapping the underlying theoretical constructs within domains. Both inductive and deductive

297 approaches will be used so as not to miss any themes. To assess agreement between two

298 researchers, all extracted themes and subthemes will be reviewed in a meeting and

299 disagreements will be solved through consensus.

300 **Phase 3: Evaluation of the impact of pharmacist-led medication reconciliation service in**

301 **a teaching hospital**

302 This phase of the project is the main objective of this study, and the aim is to investigate the

303 impact of pharmacist-led medication reconciliation service on the rate and incidence of

304 unjustified medication discrepancies in an internal medicine ward of Gondar University

305 Hospital (GUH), Ethiopia. GUH is located in Gondar town of the Amhara regional state. It is  
306 the primer hospital in the North-west region of Ethiopia. GUH provides specialized health  
307 services through its medical and other clinical and diagnostic departments for a catchment  
308 population of around 5 million people.

309 The sample size calculation is based on the prevalence of medication errors in previous local  
310 studies. Prevalence of medication errors in previous local studies was identified as 52% to  
311 58%.<sup>16, 75</sup> Assuming a reduction of medication errors from 55% to 45%, 80% power, 5%  
312 significance level (two-sided), we required a total of 127 patients, 51 for the baseline and 76  
313 for the intervention. Hospital discharge statistics showed that this sample size would be  
314 achievable in three months. A baseline assessment of medication discrepancies in  
315 hospitalized patients will thus, be conducted for 1 month. Medication discrepancies are  
316 defined as one or more differences (in dosage, frequency, drug, route of administration), as  
317 described by the Institute for Healthcare Improvement (IHI,<sup>21</sup> between the current and  
318 previous medication (s) a patient was taking. A pharmacist-led medication reconciliation will  
319 be then carried out prospectively for 2 months. The inclusion criteria will be that patients  
320 with age of over 18 years, had been hospitalized for at least 24 hours and taking at least two  
321 home/regular medications on admission. One pharmacy staff member will be trained in the  
322 techniques of how to get the best possible medication history (BPMH) by a research  
323 pharmacist (ABM). Medication reconciliation will be conducted after patients are informed  
324 of the study and give written consent. Medication use will be documented within 24 hrs of  
325 patient admission through a data collection tool prepared for the purpose of this study  
326 (Additional file 2). The pharmacist will then compare the BPMH with the admission  
327 prescription order of the patient issued by the physician in charge. All patients will be  
328 followed to hospital discharge. All identified discrepancies will be brought to the attention of  
329 the physician at admission and discharge and verification of these discrepancies will be

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made; that is, intentional vs unintentional changes to medications. Only unintentional medication discrepancies (also called as medication errors) will be reported. The main outcome measure is the incidence of medication errors and the clinical importance of such errors. The clinical consequences of the medication errors will be judged by a consensus between a clinical pharmacist and physician using a tool developed by Cornish et al.<sup>76</sup> Descriptive statistics will be used to characterize the incidence and type of medication errors and chi-square test will be utilised to analyze categorical data.

**Ethics and dissemination**

The study protocol was approved by the University of Sydney University Human Research Ethics Committee (HREC) - Project number: 2015/818, and the Institutional Review Board of the University of Gondar, Ethiopia (O/V/P/RCS/05/624/2016). The data from this study will be disseminated to researchers, clinicians and health planners in peer-reviewed health journals and conference publications. One or more meetings will be held locally to give feedback to participants and contributors to the study.

**DISCUSSION**

Patient safety in general, and medication safety in particular, has become a matter of growing interest and increasing priority for hospital managers. A safety culture is a basic necessary prerequisite for the improvement of patient safety. However, it is unclear how healthcare professionals and patients in Ethiopia perceive patient safety. This study describes the views of healthcare professionals in hospitals about patient safety culture and patients experiences of medication-related events, and to use a behavioural change theory to implement a medication reconciliation service. Medication reconciliation is a complex intervention conducted across a range of hospital care transitions, and will therefore, apply the TDF to a

behaviour that is complex – for example, involving multiple procedures and conducted by various health care professionals.

This study has several strengths. This is the first study in Ethiopia assessing the impact of pharmacist-led medication reconciliation service, and novel in that it uses a theory informed implementation of this new practice as a medication safety strategy. The use of multimethod for the exploration of patient safety culture and practice will add substantial strength to our study. Use of behavioural theory that are commonly used in implementation studies will allowed us to identify and select potentially relevant domains to target the behaviour in detail.

This study will contribute to the knowledge base by providing more evidence to confirm the importance of medication reconciliation for improving the quality use of medicines when patients are admitted to, and discharged from, a hospital. The challenge of designing quality improvement projects in low resource limiting settings is workload among the staffs, and mostly busy of other routine activities. We hope the data from this study will help develop evidence-based medication safety interventions to strengthen the capacity and performance of hospital pharmacists in settings where resources are scarce. This study is not without limitations. The low sample size in phase 3 might not be generalized to other hospitals. However, we will use an iterative process for data collection and analysis for the qualitative studies in phases 1 and 2 until we are sure that there are no new ideas emerging. The sampling technique in the qualitative study may carried a risk of bias by recruiting participants who may have similar opinions and experiences. In order to minimize this, participants will be requested to nominate other participants who might think different in their experience and practice in medication safety.

## Acknowledgment

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**Author’s contribution**

ABM, AM and JB contributed to the conception and design of the study. ABM drafted the first protocol. JB and AM refined the study protocol with contributions from all co-authors (ABM, DM, ZA). All authors read and approved the final manuscript.

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**Competing interests**

The authors declare that they have no competing interests.

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## **Additional file 1**

### **Interview guide questions for healthcare workers**

1. What is your role and how long have you been doing this?
2. Who are the colleagues you work most closely with (physicians, nurses, pharmacists, others)?
3. How do you describe your working relationship with physicians/ nurses/ pharmacists/others?
4. To what extent is patient safety a priority for your hospital? If so, is there any evidence for this?
5. What do you think the main priorities for your hospital in terms of improving patient safety? And what changes would like to see?
6. In your opinion what are the important medication safety problems encountered in your hospital? What kinds of medication related issues worry you the most?
7. What sorts of mistakes/things going wrong occur most commonly?
8. What are the major errors causing medication problems in your practice site?
9. What do you think are the causes of these problems? And how can these be prevented?
10. What does medication safety to you mean?
11. How does medication safety relate to your work? Are you involved in medication safety activities?
12. What are the strengths of the hospital in terms of improving medication safety?
13. Are there any medication safety initiatives in place that you are aware of? If so, how much successful is it/ are these?
14. What are the challenges in improving medication safety in your hospital?

A qualitative study of healthcare professionals' and patients' perspectives in medication safety

Version 2.0 November 6, 2015

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3 15. How do you think about the safety of patients at your practice site?  
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5 16. What are the measures have you taken to ensure the safety of patients?  
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7 17. Could you please tell us how you personally involved in patient safety management  
8  
9 A) When you make mistakes, do you report these? Why?  
10 B) How do you respond when/ if you find others doing things ‘wrongly’?  
11 C) How do you discuss adverse drug events with patients?  
12 D) Could you share any medication incident examples you are aware of that have  
13 occurred in your practice site.  
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15 18. What kind of patient safety strategy do you want to be implemented in your hospital?  
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17 19. How do you think the hospital can do better in patient safety?  
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19 20. What are the roles for other healthcare professionals in patient safety?  
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### **Interview guide for patients**

#### **Thank you for participating in this survey.**

1. What types of services did you receive during your recent visit to the hospital?
  - A. Are you satisfied with the services? Why? (Or Why not?)
  - B. Did you attend other health organizations (other than this hospital) for the same health problems? When and Why?
2. Why did you choose this particular hospital?
  - A. What do you think about the quality of services provided by the hospital?
  - B. Who referred you to this hospital?
3. Did you have any concerns about your safety when you visited the hospital?
  - A. What were your concerns?
  - B. What were you aware of?
  - C. What have you done to make sure you are safe?
  - D. What do you think you can do better to ensure your safety?
  - E. What do you think the hospital can do (or do better) to ensure your safety?

As you know, medicines sometimes cause harm to patients, even without an error being made by a health care professional.

4. Did your doctor, nurse or pharmacist discuss with you the potential adverse impact of your medicines?
  - A. Have you experienced this before?
  - B. Was it easy to understand?
  - C. Did you have to make a decision about taking your medicines? How did you make that decision?

A qualitative study of healthcare professionals' and patients' perspectives in medication safety

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5. Have you experienced or noticed any mistakes/medication errors in your recent visit to the hospital?
- A. Who do you think should be responsible for the problems?
  - B. Do you think the problems preventable? If yes, why and how? If not, why?
  - C. How did the hospital respond to the problems?
  - D. Are you satisfied with the way the hospital handle these problems? Why?
6. What measures are you most satisfied in relation to patient safety?
- A. What was done?
  - B. Who did it? How?
  - C. Why are you satisfied?
7. Have you been consulted about how to improve quality use of medicines?
- A) What suggestions did you make?
  - B) Did you think they were considered by the hospital?
8. How do you think the hospital can do better in patient safety?

**Additional file 2****Data collection tool****1. Socio-demographic, diagnosis and medication therapy data abstraction form**

Patient initials: \_\_\_\_\_ Card. No.: \_\_\_\_\_ Bed No. \_\_\_\_\_

Patient age: \_\_\_\_\_ Sex: M \_\_\_\_\_ F \_\_\_\_\_

Date of admission: \_\_\_\_\_ Date of discharge: \_\_\_\_\_

Current working Diagnosis: \_\_\_\_\_

Other co-morbidities: \_\_\_\_\_

**Medication history form**

Allergy history: \_\_\_\_\_

No. of medications on admission \_\_\_\_\_

**Previous/Home medications** (Includes prescriptions, OTC medications, herbal/dietary supplements)

Ser. No	Previous/Home medications	Dose	Route	Frequency	duration	Treatment continued (Yes/No)

### Current medications

[illegible]

**Discharge medications**

Ser. No	Drug name	Dose, duration	Route, Frequency,	Remarks

N.B. For PRN medication, please include the dose, time and date given

**If there is any patient concerns in the medication use process (eg. Significant drug-drug interactions, any medication related problems), specify**

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**Final Diagnosis (Discharge summary):**

**NB: For this patient, fill the following up on discharge:**

1. Total number of medications the patient took
2. Total number of medication doses s/he took during stay
3. If there is any discrepancies in treatment identified at any time in this patient, please use the medication discrepancy collection form.

A pilot study of medication reconciliation service in an Internal Medicine ward of Gondar University Hospital

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2. Medication discrepancies collection form

I. Patient information:

Age : \_\_\_\_\_

Sex: Male \_\_\_\_\_ Female \_\_\_\_\_

Diagnosis: \_\_\_\_\_

II. Occurrence of medication discrepancies

A) What type (s) of discrepancy (ies) is it?

1) Intentional medication discrepancies

a) Yes

b) No

2) Unintentional medication discrepancies

a) Yes

b) No

B) If it is unintentional medication discrepancy, please describe the error, including description and consequences if any

C) Is this error occurred at admission, or discharge?

III. What type (s) of medication error (s) is occurred in this patient? (tick all that apply)

a) Omitted drug

b) Discrepant in frequency

c) Discrepant in dose

d) Discrepant in route

A pilot study of medication reconciliation service in an Internal Medicine ward of Gondar University Hospital

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- e) Commission error
- f) Different drug from the same therapeutic class without clinical explanation
- g) Others, specify \_\_\_\_\_

### **Clinical severity assessment**

Categorizing the clinical severity of unintentional medication discrepancies (Adapted from Cornish et al 2005 [76])

- a) Class 1=Unlikely to cause patient discomfort/clinical deterioration
- b) Class 2= moderate discomfort/clinical deterioration
- c) Class 3= severe discomfort/clinical deterioration

# BMJ Open

## Medication reconciliation as a medication safety initiative in Ethiopia: a study protocol

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2016-012322.R1
Article Type:	Protocol
Date Submitted by the Author:	16-Aug-2016
Complete List of Authors:	Mekonnen, Alemayehu; University of Sydney, Pharmacy; University of Gondar, Pharmacy McLachlan, Andrew; University of Sydney, Faculty of Pharmacy Brien, Jo-Anne; University of Sydney, Pharmacy Mekonnen, Desalew; Addis Ababa University, Internal Medicine Abay, Zenahbezu; University of Gondar, Internal Medicine
<b>Primary Subject Heading</b>:	Health services research
Secondary Subject Heading:	Global health, Evidence based practice, Medical management, Qualitative research
Keywords:	medication reconciliation, medication history, medication safety, medication review, medication errors, medication discrepancies

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1       **Medication reconciliation as a medication safety initiative in Ethiopia: a study protocol**

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15       **References - 78**

16       **Keywords-** Medication reconciliation, patient safety, medication errors, quality  
17       improvement, pharmacists

18       **Running head-** Medication reconciliation as a medication safety initiative: A study protocol

## ABSTRACT

**Introduction:** Medication-related adverse events are common, particularly during transitions of care and have a significant impact on patient outcomes and healthcare costs. Medication reconciliation (MedRec) is an important initiative to achieve the Quality Use of Medicines, and had been adopted as a standard practice in many developed countries. However, the impact of this strategy is rarely described in Ethiopia. The aims of this study are to explore patient safety culture, and to develop, implement and evaluate a theory-informed MedRec intervention, with the aim of minimizing the incidence of medication errors during hospital admission.

**Methods and analyses:** This study is being conducted in a resource limited setting. There are three phases for this project. The first phase is a mixed-methods study of healthcare professionals' perspectives of patient safety culture and patients' experiences of medication-related adverse events. In this phase, the Hospital Survey on Patient Safety Culture will be used along with semi-structured in-depth interviews to investigate patient safety culture and experiences of medication-related adverse events. The second phase will use a semi-structured interview guide, designed according to the twelve domains from the Theoretical Domains Framework (TDF), to explore the barriers and facilitators to medication safety activities delivered by hospital pharmacists. The third phase will be a single centre, before and after study that will evaluate the impact of pharmacist-conducted admission MedRec in an emergency department (ED). The main outcome measure is the incidence and potential clinical severity of medication errors. We will analyze then the differences in the incidence and severity of medication errors before and after commencement of an ED pharmacy service.

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**Ethics:** The study protocol was approved by the University of Sydney Human Research Ethics Committee - Project number: 2015/818, and the Institutional Review Board of the University of Gondar, Ethiopia (O/V/P/RCS/05/624/2016).

**Strengths and limitations of this study**

- This is the first study in Ethiopia that will assess the impact of pharmacist-led MedRec service.
- This study is novel in that it uses a behavioural change theory for implementation of medication safety programs.
- Multi-method exploration of patient safety issues will add substantial strength to our study.
- The sampling technique in both the interviews and survey may carry risk of bias.

**INTRODUCTION**

**Patient safety initiatives**

Quality patient care is a priority issue in all healthcare sectors; however, clinical errors are known to compromise patient safety.<sup>1</sup> Patient safety incidents gained attention after the works of pioneer US studies: the Harvard Medical Practice Study<sup>2, 3</sup> and the Institute of Medicine Report.<sup>4</sup> In the USA, it has been reported that 3.7% of all hospitalized patients experienced an adverse event,<sup>2</sup> and medication errors alone resulted in 7000 deaths annually.<sup>4</sup> Medication errors constitute the most common preventable cause of patient safety problems, and has been studied extensively in the developed countries.<sup>2-6</sup> Despite current advancements in healthcare, these incidents continue to pose a significant problem globally,<sup>7</sup> and are the concern of many hospitalists and patient safety activists.

**Medication safety in African hospitals**

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3 76 Patient injuries attributed to medication-related adverse events are among the most common  
4  
5 77 incidents in hospitals,<sup>2</sup> and have important economic and humanistic consequences  
6  
7 78 Furthermore, given the morbidity profile, and the high burden of malaria, HIV/AIDS and  
8  
9 79 tuberculosis in Africa along with the level of awareness and patient safety culture, the extent  
10  
11 80 of medication-related adverse events in African hospitals is thought to be higher than the  
12  
13 81 remainder of the globe.<sup>8</sup> For example, studies have shown that 1.5% to 6.5% of hospital  
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15 82 admissions are attributed to adverse drug events (ADEs),<sup>9,10</sup> and 2.5% to 47% of inpatients  
16  
17 83 encountered an ADE during their hospital stay.<sup>9, 11</sup> One-fifth to more than half of the reported  
18  
19 84 ADEs were severe events;<sup>10, 12–14</sup> of which ADE-related fatalities were reported in 0.07% to  
20  
21 85 2.9% of patient admissions to hospital.<sup>12, 15, 16</sup> However, up to half of the ADEs were due to  
22  
23 86 medication errors, and were preventable.<sup>10</sup> The most reported types of medication errors in  
24  
25 87 the African healthcare settings were prescribing errors, occurring in 13% to 76% of all  
26  
27 88 prescriptions.<sup>17–20</sup> Yet, the extent of medication errors and ADEs have not been fully  
28  
29 89 evaluated in African settings,<sup>8</sup> and medication safety programs designed to prevent them  
30  
31 90 appear the first step in improving patient safety.

### 91 **Medication reconciliation as a medication safety strategy**

92 More than half of the medication errors occurred at care transitions, when patients admitted  
93 to, and discharged from, a hospital or transferred to the care of other healthcare professional,  
94 <sup>21</sup> and medication reconciliation as a tool for the prevention of these errors and consequent  
95 patient harm have been advocated internationally.<sup>22, 23</sup> Medication reconciliation (MedRec)  
96 has been defined by the Institute for Healthcare Improvement as “*the process of identifying*  
97 *the most accurate list of a patient’s current medicines including the name, dosage, frequency*  
98 *and route – and comparing them to the current list in use, recognizing and documenting any*  
99 *discrepancies, thus resulting in a complete list of medications*”.<sup>22</sup>



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100 Under the leadership of the WHO, patient safety programs including MedRec have been  
101 implemented across a range of countries,<sup>23–26</sup> and taken-up as healthcare policy. For instance,  
102 MedRec has been recognized as a priority patient safety solution by the Australian  
103 Commission on Safety and Quality in Healthcare.<sup>26</sup> Prior to MedRec being routinely  
104 practiced in Australia, there was one omitted medicine from medication chart among every  
105 two people at hospital admission.<sup>27</sup> Also, other previous studies showed that between 60%  
106 and 80% of patients were noted to have a discrepancy with their medication history.<sup>28, 29</sup>  
107 Studies examining medication errors have been undertaken across many countries including  
108 developing nations,<sup>30, 31</sup> in a range of settings, such as emergency units,<sup>32–38</sup> critical/intensive  
109 care,<sup>39</sup> paediatrics<sup>40–42</sup> and geriatrics unit.<sup>43–48</sup> There is evidence that MedRec decreases the  
110 frequency of medication errors<sup>49, 50</sup> and drug-related readmissions.<sup>51, 52</sup>  
111 MedRec with various approaches have been employed to improve medication safety  
112 including, but not limited to, technology assisted tools,<sup>53–55</sup> use of standardised forms,<sup>34, 56</sup>  
113 collaborative models,<sup>33, 57</sup> as well as patient engagement<sup>58</sup> and pharmacist-led approaches.<sup>59,</sup>  
114 <sup>60</sup> Previous studies have shown benefits from involving pharmacists in MedRec.<sup>59, 60</sup>  
115 However, the impact of MedRec overall, as well as pharmacist-led MedRec practice, is not  
116 yet described in the sub-Saharan Africa.

117 **Patient safety culture in Ethiopian context**

118 Despite a lack of research, patient safety in Ethiopia is believed to be a serious concern. A  
119 previous local study<sup>61</sup> in the paediatrics ward has shown an incidence of 9.2 ADEs per 100  
120 admissions, of which one-third deemed preventable. As healthcare managers strive to  
121 improve the quality of patient care, there is a growing recognition of the importance of  
122 establishing a culture of patient safety. Developing a patient safety culture was one of the  
123 recommendations made by the Institute of Medicine<sup>4</sup> to assist hospitals in improving patient  
124 safety. According to the Agency of Healthcare Research and Quality (AHRQ),<sup>62</sup> patient

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3 125 safety culture is described as an understanding of the values, beliefs and norms about what is  
4  
5 126 important in an organization and what attitudes and behaviours related to patient safety are  
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7 127 supported, rewarded, and expected. It is thus, important for healthcare organizations to assess  
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9 128 their patient safety culture to obtain a clear understanding of the patient safety aspects  
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11 129 requiring urgent attention, identify the strengths and weaknesses of their safety culture<sup>63</sup> and  
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13 130 assist hospitals identify their existing patient safety problems.<sup>64</sup> Studies on patient safety  
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15 131 culture, mostly set in developed countries,<sup>63–66</sup> have been published. However, there are no  
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17 132 data about the current state of patient safety culture in Ethiopian hospitals. Furthermore, no  
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19 133 studies have specifically investigated the implementation of medication reconciliation  
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21 134 services from a behavioral theory perspective involving both barriers and facilitators of a  
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23 135 wide range of behavioral determinants in implementation of evidence-based practice.  
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25 136 This project is a medication safety initiative focusing on MedRec at care transitions in  
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27 137 Ethiopian public hospitals, and the implementation of this service in this study is guided by a  
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29 138 multi-method approach consisting three different but inter-related studies to inform our study  
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31 139 objectives. Specifically, the aims of this study are to explore healthcare professionals' views  
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33 140 of patient safety issues, medical error, and event reporting and patients' experiences of  
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35 141 medication-related adverse events, and then to use a theoretical framework to help identify  
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37 142 the barriers and facilitators to medication safety activities delivered by hospital pharmacists,  
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39 143 and finally to evaluate a pharmacist-led MedRec practice in one of the teaching hospitals in  
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41 144 Ethiopia.

## 42 43 44 45 46 47 145 **METHODS AND ANALYSES**

### 48 49 146 **Study setting and period**

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51 147 This is a multi-phased study that is being conducted in public hospitals in Amhara region of  
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53 148 Ethiopia. Amhara region is one of the nine regions of Ethiopia located in the northern parts of  
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55 149 the country. This region has an estimated total population of approximately 18 million  
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150 people, and the majority (87.4%) of the population is estimated to be rural inhabitants. This  
151 region has 17 public hospitals, 520 health centres and 2,941 health posts.<sup>67</sup> There are three  
152 phases to this research project. Phases 1 and 2 are being conducted in 10 selected public  
153 hospitals of the Amhara region, including 4 teaching or referral (Gondar university, Felege  
154 Hiwot, Debre Markos, and Debre Tabor) and 6 district hospitals (Metema, Debark, Chagni,  
155 Finoteselam, Woldiya, and Enat), and phase 3 will be carried out in one teaching hospital;  
156 that is, Gondar university hospital. The study has commenced in February 2016, and will end  
157 in July 2017.

158 **Phase 1: A study of healthcare professionals’ perspectives of patient safety culture and**  
159 **patients’ experiences of medication-related adverse events**

160 This is a mixed-methods study consisting a survey and qualitative research. The survey  
161 measures dimensional scores of patient safety culture. Using a scale to quantify the scores of  
162 patient safety is, however, not explanatory.<sup>68</sup> In addition, a shared decision between the  
163 patient and the healthcare professional is central for a sustainable patient safety culture.  
164 Therefore, a survey supported with an in-depth interview is well acknowledged to explore a  
165 meaningful assessment of patient safety culture through the eyes of healthcare professionals  
166 and patients.<sup>68</sup>

167 ***Questionnaire study***

168 The survey aims to evaluate the patient safety culture of public hospitals in the Amhara  
169 region. The study focus is only on public hospitals as most of the population in the region  
170 used public hospitals. The study adopted the “Hospital Survey on Patient Safety Culture”  
171 (HSOPSC) developed by the Agency for Healthcare Research and Quality (AHRQ).<sup>69</sup> The  
172 HSOPC has been widely used in assessing patient safety culture and has also been validated  
173 in non-US countries.<sup>64, 65</sup> The survey consists 42 items that measure 12 patient safety culture  
174 composites: communication openness, feedback and communication about errors, frequency

175 of events reported, handovers and transitions, management support for patient safety, non-  
176 punitive response to error, organizational learning and continuous improvement, overall  
177 perceptions of patient safety, staffing, supervisor/manager expectations and actions  
178 promoting safety, teamwork across and within units. Background variables of participants  
179 included questions related to job category, type of hospital (teaching/referral, district), years  
180 of working experience overall and in the current working area, work setting and working  
181 hours per week. The questionnaire was kept in English, as English is the main language of  
182 communication in Ethiopian hospitals. This questionnaire together with the participant  
183 information statement was distributed to conveniently selected healthcare professionals by  
184 the research team and required about 10 – 15 minutes to complete. These participants were  
185 recruited from the 10 hospitals of Amhara region, and included physicians, nurses,  
186 pharmacists and paramedics (e.g. technicians). The *sample size* was estimated to be 480, by  
187 considering 95% confidence interval, 5% margin of error and 25% contingency for non-  
188 response rate, and assuming that patient safety culture score was rated as excellent in 50% of  
189 respondents.

190 The response to each item in the questionnaire was assessed by using a 5 point Likert scale  
191 where 1, ‘strongly disagree’ and 5, ‘strongly agree’. The patient safety grade (measured on a  
192 scale of excellent, very good, acceptable, poor and failing), and number of events reported  
193 were the other two outcome variables of interest collected. Currently, we are entering the  
194 collected data into SPSS v21, and data will be analysed when data entry is accomplished. The  
195 HSOPS included both positively and negatively worded items. For easier interpretation of the  
196 results, the AHRQ<sup>69</sup> and other studies<sup>63-66</sup> recommends the use of ‘average positive’ for  
197 calculating each item scores. That is, the percentage of positive responses for each item will  
198 be calculated and negatively worded items will be reversed when computing percent positive  
199 response. We will define areas of strengths as items for which 75% of respondents answer

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200 positively, whereas areas requiring improvement as those scoring below 50%.<sup>62</sup>  
201 Additionally, univariate and multivariate analyses will be conducted to examine statistical  
202 associations between independent characteristics and patient safety grade and number of  
203 events reported. The mean scores for each of the HSOPC sub-scales are taken as dependent  
204 variables, and these will be tested against the independent variables, such as job  
205 characteristics (profession and qualification), department and type of hospital  
206 (teaching/referral, district), work experience (career length, experience in the current  
207 unit/hospital) and workload (working hours).

208 ***In-depth interview***

209 The qualitative part of phase 1 investigate aims to assess the patient safety strategies  
210 employed by those hospitals through in-depth interviews with different stakeholders  
211 (healthcare professionals and patients) working in ten hospitals of the Amhara region. The  
212 contact details of participants (healthcare professionals) have been retrieved from the human  
213 resource office or related office of the respective hospitals. We are using purposeful sampling  
214 to identify the initial sample and then the remaining data collection is being aided with  
215 snowball sampling. We are providing letters/e-mails, as appropriate, for invitation of the  
216 healthcare professionals who are involved in the care of patients. Patients who are in-hospital  
217 at the time of data collection and were taking regular medications before admission are being  
218 invited for an interview by a healthcare professional who is already a participant in this study.  
219 Then, we are contacting patients for further invitation into the study. We are employing semi-  
220 structured interviews informed by the interview guide (Additional file 1) for the collection of  
221 data. All interview guides have been translated from English versions to the local language  
222 (Amharic) by two non-official translators who are native speakers and working in the  
223 healthcare industry, and validated by two of the research group (ABM, DM). Interview tools  
224 have been translated in order to foster faster communication and expression of ideas. Before

interview, we are informing the respondents about the aim of the interview, and those who consented are being given further details on the nature of the study to ensure that interviewees understand what will be required of them. We are conducting face-to-face interviews at a time and place to suit the participants, and expected to last approximately 30 – 60 minutes. We are forwarding both open and close-ended questions to interviewees to describe their experiences of medication safety issues and strategies employed to prevent medication-related adverse events. We are encouraging participants to reflect their own experiences of medication-related adverse events, and we are asking them to think about an example of a known medication-related adverse event when answering questions. The interviewer is using prompts when necessary to encourage further elaboration. To the participants, we are giving 50 Ethiopian birr (ETB) in appreciation of their time. All interviews are being conducted by an English/ Amharic speaking investigator (ABM). We are collecting data with each of the two participant groups until a point of saturation is reached. We are recording all interviews using audio-tape with the informed consent of participants. After data collection is completed, the principal investigator will carry out verbatim Amharic transcriptions of all interviews, which will then be translated to English, and assigned a unique identifier and imported into a computer programme for qualitative data analysis, Nvivo V10. Thematic analysis will then be carried out, and emerging topics will be identified as themes and sub-themes.

## **Phase 2: The barriers and facilitators to medication safety activities delivered by hospital pharmacists**

This is a qualitative study using focus group discussions (FGD) with hospital pharmacists working in selected public hospitals in the region to gather data on the barriers and facilitators to medication safety activities. We will employ FGDs in this phase because the interactive nature of focus groups are specifically important when group norms and cultural



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250 values of particular groups are of interest, and to explore the degree of consensus on a given  
251 topic,<sup>70</sup> including implementation of an intervention to promote medication safety. Many  
252 factors can affect an adaptability of an evidence-based intervention, and the success of  
253 implementation efforts depends on a careful assessment of barriers to, and facilitators of, the  
254 behaviour to be changed.<sup>71</sup> A theory-based identification of such factors provides a  
255 theoretically robust evidence-base to inform implementation of an intervention.<sup>71</sup> The  
256 underpinning theoretical model used in this study is the Theoretical Domains Framework  
257 (TDF).

258 ***Theoretical Domains Framework (TDF)***

259 Increasing the uptake of evidence into clinical practice and improving patient outcomes needs  
260 behaviour change. The Theoretical Domains Framework (TDF) from health psychology  
261 provides the basis for such an approach ensuring that a wide range of possible theoretical  
262 explanations for the behaviours to be considered. Built from 33 behavioural theories, the TDF  
263 was developed to make theories more accessible for implementation researchers.<sup>72</sup> According  
264 to Michie et al<sup>72</sup>, TDF has 12 domains to explain behaviour change: (1) knowledge, (2) skills,  
265 (3) social/professional role and identity, (4) beliefs about capabilities, (5) beliefs about  
266 consequences, (6) motivation and goals, (7) memory, attention and decision processes, (8)  
267 environmental context and resources, (9) social influences, (10) emotion regulation, (11)  
268 behavioural regulation, and (12) nature of the behavior. After then, TDF has been extensively  
269 used to identify barriers to change in clinical practice in order to develop interventions.<sup>73, 74</sup>  
270 To justify implementation of pharmacist-led medication reconciliation, it will be of critically  
271 important to understand the perceived barriers and facilitators underlying individual  
272 pharmacist's roles in medication safety. Thus, this study uses TDF to develop a theory-  
273 informed intervention aimed at improving medication safety of patients at hospital  
274 transitions.

## 275 *FGDs*

276 In this study, FGDs will be guided by questions designed based on Theoretical Domains  
 277 Framework (TDF) (Table 1). For each of the 12 domains that could act as facilitators or  
 278 barriers to current medication safety practices and a successful medication reconciliation  
 279 implementation, the authors developed several interview questions. The number of interview  
 280 questions ranged between two and five for each of the 12 domains, for a total of 43 questions  
 281 to cover a wide range of constructs assigned to each domain. The questions were initially  
 282 drafted by one researcher (ABM) and then refined by health service researchers (AJM, JEB)  
 283 and discussed by the research team to check clinical relevance. The discussion questions will  
 284 be pilot-tested with at least two hospital pharmacists to assess clarity and focus, and revised  
 285 accordingly.

286 **Table 1** Interview guide questions for focus groups according to Michie's theoretical  
 287 domains<sup>72</sup>

Domains	Interview questions
Knowledge	<p>Are there any hospital guidelines for pharmacists to deliver clinical pharmacy services?</p> <p>What do you think the level of evidence is for these guidelines?</p> <p>What do you know about medication reconciliation and review?</p> <p>What do you think the level of evidence for medication reconciliation and review?</p> <p>Can you describe pharmacists' roles in medication safety activities?</p>
Skills	<p>Do you know how to deliver clinical pharmacy services?</p> <p>Do you know how to deliver medication reconciliation and review services?</p>

	<p>Is identification of medication-related problems difficult for you?</p> <p>Have you attended in-service training to deliver clinical pharmacy services?</p>
Social/professional role	<p>Is doing medication reconciliation and review compatible with your professional role?</p> <p>Who is responsible for these services at your hospital?</p> <p>Do you think hospital guidelines supports your professional roles as a pharmaceutical care practitioners?</p>
Beliefs about capabilities	<p>How easy or difficult do you find performing clinical pharmacy activities ?</p> <p>What problems have you encountered?</p> <p>How capable are you in performing medication reconciliation and review?</p> <p>How confident are you that you can do these services despite difficulties?</p> <p>How comfortable do you feel to undertake these services?</p>
Beliefs about consequences	<p>What are the likely positive/negative outcomes of reporting/communicating medication-related problems?</p> <p>What are the costs of delivering medication reconciliation and review and what are the costs of the consequences of these services?</p> <p>Are you concerned if these services are not provided at your hospital?</p> <p>Do benefits of doing these services outweigh the costs?</p> <p>Does the evidence suggests that doing these services are</p>

	beneficial?
Motivation and goals	<p>How motivated are you to deliver medication reconciliation and review?</p> <p>Are there incentives to provide these services?</p> <p>Do you have any other hospital activity that hinders these services?</p>
Memory, attention and decision processes	<p>Will you consider providing medication reconciliation and review services? If so, how frequently would you undertake this activity?</p> <p>How much priority have you given to these services?</p>
Enviromental context and resources	<p>To what extent do physical factors or resources facilitate or hinder to deliver medication reonciliation/review?</p> <p>Are there competing tasks and time constraints?</p> <p>Are the necessary resources available to undertake these services?</p> <p>Do these services have advantages compared with the standard care?</p> <p>Do government and local authorities provide sufficient support for these services?</p>
Social influences	<p>Are clinical pharmacy services in the hospital well acknowledged by other healthcare professionals?</p> <p>Do hospital managers acknowledge your role?</p> <p>Is there any obstruction to these activities in your hospital?</p> <p>Have you observed others doing providing these clinical services?</p>

Emotion	What things worry you the most in providing medication reconciliation/review services?  To what extent do emotional factors facilitate or hinder these services?
Behavioural regulation	Have you received feedback from other healthcare professionals regarding these services?  What initial steps are needed to deliver these services?
Nature of the behaviours	What do you currently do?  How long will changes going to take?  Are there any systems in place for sustainable long term changes?

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289 The sample population will be all hospital pharmacists in the 10 public hospitals across the  
290 region. Pharmacists will be selected using a purposive sampling strategy augmented with  
291 snowball sampling. Participants will be recruited either by letter/email invitation. Participants  
292 willing to be interviewed either by sending an email or by returning a signed consent form  
293 will be contacted. The principal investigator (ABM), who is experienced in qualitative study,  
294 will conduct and facilitate the focus group discussion using the translated version (Amharic)  
295 of the topic guide. Pharmacists will be encouraged to talk about internal beliefs and attitudes  
296 that may hinder them from providing clinical pharmacy services, including medication safety  
297 roles. All discussion sessions will be audio-taped and recorded. Two of the researchers  
298 (ABM, ZA) will read all the FGD Amharic transcripts, and will be translated into English.  
299 Transcripts will then be coded based on the 12 domains of the TDF, and thematic analysis of  
300 pharmacist's statements into the relevant theoretical domains will be performed.<sup>75</sup> Briefly, the  
301 analysis will involve identifying contextualized brief statements related to the barriers and

302 facilitators to medication safety activities, categorising statements into TDF domains and  
303 mapping the underlying theoretical constructs within domains. Both inductive and deductive  
304 approaches will be used so as not to miss any themes. To assess agreement between two  
305 researchers, all extracted themes and subthemes will be reviewed in a meeting and  
306 disagreements will be solved through consensus.

### 307 **Phase 3: Evaluation of the impact of pharmacist-led MedRec service: single site before** 308 **and after study**

309 This phase of the project is the main objective of this study, and the aim is to investigate the  
310 impact of pharmacist-led MedRec service on the rate and incidence of unintentional  
311 medication discrepancies in an emergency ward of Gondar university hospital (GUH),  
312 Ethiopia. GUH is located in Gondar town of the Amhara regional state. It is the primer  
313 hospital in the North-west region of Ethiopia. GUH provides specialised health services  
314 through its medical and other clinical and diagnostic departments for a catchment population  
315 of around 5 million people.

316 The sample size calculation is based on the prevalence of medication errors in previous local  
317 studies, which was identified as 52% to 58% of all prescriptions.<sup>17, 76</sup> Assuming a reduction  
318 of medication errors from 55% to 45%, 80% power, 5% significance level (two-sided), we  
319 required a total of 127 patients, 51 for the baseline and 76 for the intervention. Hospital  
320 discharge statistics showed that this sample size would be achievable in three months. A  
321 baseline assessment of medication discrepancies will thus, be conducted for one month  
322 during hospital admission. Medication discrepancies are defined as one or more differences  
323 in (dosage, frequency, drug, route of administration), as described by the Institute for  
324 Healthcare Improvement (IHI),<sup>22</sup> between the current and previous medication (s) a patient  
325 was taking. A pharmacist-led MedRec intervention will be then carried out prospectively for  
326 two months. The inclusion criteria will be that patients with age of over 18 years, had been

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327 hospitalized for at least 24 hours and taking at least two home/regular medications on  
328 admission. The standard practice in the current department involve physicians in taking  
329 patient's medication history using patient provided information; however, hospital  
330 pharmacists are not participated in medication history taking and prescription review at the  
331 emergency department. The intervention will involve use of the best possible medication  
332 history (BPMH),<sup>77</sup> which is based on a structured interview with the patient about medication  
333 use and retrieving other sources of medication history, including discharge and referral  
334 letters, patient's own medicines and carrier interview. One pharmacy staff member will be  
335 trained in the techniques of how to get the BPMH by a research pharmacist (ABM). MedRec  
336 will be conducted after patients are informed of the study and give written consent.  
337 Medication use will be documented within 24 hrs of patient admission through a data  
338 collection tool prepared for the purpose of this study (Additional file 2). The pharmacist will  
339 then compare the BPMH with the admission prescription order of the patient issued by the  
340 physician in charge. All identified discrepancies will be brought to the attention of the  
341 physician at admission and verification of these discrepancies will be made; that is,  
342 intentional vs unintentional changes to medications. Intentional medication discrepancies are  
343 medication changes due to new patient's clinical status, and are clinically justifiable but not  
344 documented in the patient's medical record. Thus, only unintentional medication  
345 discrepancies (also called as medication errors) will be reported. The main outcome measure  
346 is the incidence of medication errors and the potential clinical severity of such errors. The  
347 potential clinical severity of medication errors will be judged by a consensus between a  
348 clinical pharmacist and a physician using a tool developed by Cornish et al.<sup>78</sup> Descriptive  
349 statistics will be used to characterise the types of medication errors and chi-square test will be  
350 utilised to analyse differences in the incidence and severity of medication errors between the  
351 baseline and intervention groups. Statistical significance is set at  $p < 0.05$ .



## Ethics and dissemination

The study protocol was approved by the University of Sydney Human Research Ethics Committee (HREC) - Project number: 2015/818, and the Institutional Review Board of the University of Gondar, Ethiopia (O/V/P/RCS/05/624/2016). The data from this study will be disseminated to researchers, clinicians and health planners in peer-reviewed health journals and conference publications. One or more meetings will be held locally to give feedback to participants and contributors to the study.

## DISCUSSION

Patient safety in general, and medication safety in particular, has become a matter of growing interest and increasing priority for hospital managers. A safety culture is a basic necessary pre-requisite for the improvement of patient safety. However, it is unclear how healthcare professionals and patients in Ethiopia perceive patient safety. This study will describe the views of healthcare professionals in hospitals about patient safety culture and patients' experiences of medication-related adverse events, and to use a behavioural change theory to implement a MedRec service. MedRec is a complex intervention conducted across a range of hospital transitions, and will therefore, apply the TDF to a behaviour that is complex – for example, involving multiple procedures and conducted by various health care professionals. This study has several strengths. This is the first study in Ethiopia that will assess the impact of pharmacist-led MedRec service, and novel in that it uses a theory informed implementation of this new practice as a medication safety strategy. The use of multi-method for the exploration of patient safety culture and practice will add substantial strength to our study. Use of behavioural theory that are commonly used in implementation studies will allowed us to identify and select potentially relevant domains to target the behaviour in detail. This study will contribute to the knowledge-base by providing more evidence to confirm the importance of MedRec for improving the Quality Use of Medicines when patients are

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admitted to a hospital. The challenge of designing quality improvement projects in low resource limited settings is workload among the staffs. We hope the data from this study will help develop evidence-based medication safety interventions to strengthen the capacity and performance of hospital pharmacists in settings where resources are scarce. This study is not without limitations. The sampling technique in the qualitative study may carried a risk of bias by recruiting participants who may have similar opinions and experiences. In order to minimize this, participants will be requested to nominate other participants who might think are different in their experience and practice in medication safety. Moreover, we will use an iterative process for data collection and analysis for the qualitative studies in phases 1 and 2 until we are sure that there will no new ideas emerging.

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**Author’s contribution**

ABM, AJM and JEB contributed to the conception and design of the study. ABM drafted the first protocol. JB and AM refined the study protocol with contributions from all co-authors (ABM, DM, ZA). All authors read and approved the final manuscript.

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**Competing interests**

The authors declare that they have no competing interests.

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**Additional file 1**

**Interview guide questions for healthcare workers**

1. What is your role and how long have you been doing this?
2. Who are the colleagues you work most closely with, and how do you describe your working relationship with (physicians, nurses, pharmacists, others)?
3. To what extent is patient safety a priority for your hospital? And, what do you think the main priorities in terms of improving patient safety? What changes would like to see?
4. In your opinion what are the important medication safety problems encountered in your hospital? What kinds of medication related issues worry you the most?
5. What sorts of mistakes/things and medication-related problems going wrong occur most commonly?
6. What do you think are the causes of these problems? And how can these be prevented?
7. How does medication safety relate to your work? Are you involved in medication safety activities? What are the strengths and challenges of your hospital in terms of improving medication safety?
8. Are there any medication safety initiatives in place that you are aware of? If so, how much successful is it/ are these? What type of patient safety strategy do you want to be implemented in your hospital?
9. How do you think about the safety of patients at your practice site, and any measures you have taken to ensure the safety of patients?
10. Could you please tell us how you personally involved in patient safety management
  - A) When you make mistakes, do you report these? Why?
  - B) How do you respond when/ if you find others doing things ‘wrongly’?
  - C) How do you discuss adverse drug events with patients?

D) Could you share any medication-related adverse event examples you are aware that have occurred in your practice site.

11. What are the roles for other healthcare professionals in patient safety?

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**Interview guide for patients**

**Thank you for participating in this survey.**

1. What types of services did you receive during your recent visit to the hospital?
    - A. Are you satisfied with the services? Why? (Or Why not?)
    - B. Did you attend other health organizations (other than this hospital) for the same health problems? When and Why?
  2. Why did you choose this particular hospital?
    - A. What do you think about the quality of services provided by the hospital?
    - B. Who referred you to this hospital?
  3. Did you have any concerns about your safety when you visited the hospital?
    - A. What were your concerns?
    - B. What were you aware of?
    - C. What have you done to make sure you are safe?
    - D. What do you think you can do better to ensure your safety?
    - E. What do you think the hospital can do (or do better) to ensure your safety?
- As you know, medicines sometimes cause harm to patients, even without an error being made by a health care professional.
4. Did your doctor, nurse or pharmacist discuss with you the potential adverse impact of your medicines?
    - A. Have you experienced this before?
    - B. Was it easy to understand?
    - C. Did you have to make a decision about taking your medicines? How did you make that decision?
  5. Have you experienced or noticed any mistakes/medication errors in your recent visit to the hospital?

A qualitative study of healthcare professionals' and patients' perspectives in medication safety



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- A. Who do you think should be responsible for the problems?
  - B. Do you think the problems preventable? If yes, why and how? If not, why?
  - C. How did the hospital respond to the problems?
  - D. Are you satisfied with the way the hospital handle these problems? Why?
6. What measures are you most satisfied in relation to patient safety?
- A. What was done?
  - B. Who did it? How?
  - C. Why are you satisfied?
7. Have you been consulted about how to improve quality use of medicines?
- A) What suggestions did you make?
  - B) Did you think they were considered by the hospital?
8. How do you think the hospital can do better in patient safety?

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**Additional file 2**

**Data collection tool**

**1. Socio-demographic, diagnosis and medication therapy data abstraction form**

Patient initials: \_\_\_\_\_ Card. No.: \_\_\_\_\_ Bed No. \_\_\_\_\_

Patient age: \_\_\_\_\_ Sex: M \_\_\_\_\_ F \_\_\_\_\_

Date of admission: \_\_\_\_\_ Date of discharge: \_\_\_\_\_

Current working Diagnosis: \_\_\_\_\_

Other co-morbidities: \_\_\_\_\_

**Medication history form**

Allergy history: \_\_\_\_\_

No. of medications on admission \_\_\_\_\_

**Previous/Home medications** (Includes prescriptions, OTC medications, herbal/dietary supplements)

Ser. No	Previous/Home medications	Dose	Route	Frequency	duration	Treatment (Yes/No)	continued

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## Current medications

[illegible]

N.B. For PRN medication, please include the dose, time and date given

**If there is any patient concerns in the medication use process (eg. Significant drug-drug interactions, any medication related problems), specify**

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2. Medication discrepancies collection form

I. Patient information:

Age : \_\_\_\_\_

Sex: Male \_\_\_\_\_ Female \_\_\_\_\_

Diagnosis: \_\_\_\_\_

II. Occurrence of medication discrepancies

A) What type (s) of discrepancy (ies) is it?

1) Intentional medication discrepancies

a) Yes

b) No

2) Unintentional medication discrepancies

a) Yes

b) No

B) If it is unintentional medication discrepancy, please describe the error, including description and consequences if any

III. What type (s) of medication error (s) is occurred in this patient? (tick all that apply)

a) Omitted drug

b) Discrepant in frequency

c) Discrepant in dose

d) Discrepant in route

e) Commission error

f) Different drug from the same therapeutic class without clinical explanation

g) Others, specify \_\_\_\_\_

### **Clinical severity assessment**

Categorizing the clinical severity of unintentional medication discrepancies (Adapted from Cornish et al 2005 [76])

- a) Class 1=Unlikely to cause patient discomfort/clinical deterioration
- b) Class 2= moderate discomfort/clinical deterioration
- c) Class 3= severe discomfort/clinical deterioration