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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**

4 Alemayehu B. Mekonnen^{1, 2}, Andrew McLachlan¹, Jo-anne Brien¹, Desalew Mekonnen³,
5 Zenahbezu Abay⁴

6 ¹Faculty of Pharmacy, University of Sydney, Sydney, Australia

7 ²School of Pharmacy, University of Gondar, Gondar, Ethiopia

8 ³Department of Internal Medicine, Addis Ababa University, Addis Ababa, Ethiopia

9 ⁴Department of Internal Medicine, University of Gondar, Gondar, Ethiopia

10 Corresponding author: Alemayehu B. Mekonnen

11 Email: aber5592@uni.sydney.edu.au

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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.¹ Patient safety incidents gain more attention after the
57 works of previous pioneer US studies: the Harvard Medical Practice Study^{2, 3} and the
58 Institute of Medicine Report.⁴ It has been reported that 3.7% of all hospitalized patients
59 experienced an adverse event,² and medication errors alone resulted in 7000 deaths annually.⁴
60 Medication errors constitute the most common preventable cause of patient safety problems,
61 and has been studied extensively in the developed countries.²⁻⁶ Though a better healthcare to
62 date, these incidents continue to pose a significant problem globally,⁷ 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,² 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),^{8, 9} and 2.5% to 47% of inpatients encountered an
72 ADE during their hospital stay.^{8, 10} One-fifth to more than half of the reported ADEs were
73 severe events;^{9, 11-13} however, up to half were deemed preventable.⁹ ADE-related fatalities
74 were reported in 0.07% to 2.9% of patient admissions to hospital.^{11, 14, 15} 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.¹⁶⁻¹⁹

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,²⁰ and
81 medication reconciliation as a tool for the prevention of these errors and consequent patient
82 harm have been advocated internationally.^{21, 22} 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”*.²¹

87 Under the leadership of WHO, patient safety programs including medication reconciliation
88 had been implemented across a range of countries²²⁻²⁵ 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.²⁵ 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.²⁶ Also, other previous studies showed that between 60% and 80% of patients were
94 noted to have a discrepancy with their medication history.^{27, 28}

95 Medication errors warranting reconciliation have been undertaken across many countries
96 including developing nations,^{29, 30} in a range of settings, such as emergency units,^{31- 37}
97 critical/intensive care,³⁸ paediatrics³⁹⁻⁴¹ and geriatrics unit.⁴²⁻⁴⁷ There is evidence that
98 medication reconciliation decreases the frequency of medication errors^{48, 49} and drug-related
99 readmissions.^{37, 38}

100 Medication reconciliation with various approaches have been employed to improve
101 medication safety including, but not limited to, electronic reconciliation tools,⁵²⁻⁵⁴ use of
102 standardised forms,^{33, 55} collaborative models,^{32, 56} as well as patient engagement⁵⁷ and

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103 pharmacy-led approaches.^{58, 59} Our previous studies have shown benefits from involving
104 pharmacists in medication reconciliation.^{58, 59} 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 study⁶⁰ 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 Medicine⁴ to assist hospitals in improving patient
114 safety. According to the Agency of Healthcare Research and Quality (AHRQ),⁶¹ 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 culture⁶² and
120 assist hospitals identify their existing patient safety problems.⁶³ Studies on patient safety
121 culture, mostly originated from developed countries,⁶²⁻⁶⁵ 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.⁶⁶ 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.⁶⁷ 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.⁶⁷

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).⁶⁸ The HSOPC has been widely used
160 in assessing patient safety culture and has also been validated in non-US countries.^{63, 64}
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

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

The response to each item in the questionnaire is being assessed by using a 5 point Likert scale where 1, 'strongly disagree' and 5, 'strongly agree'. The patient safety grade (measured on a scale of excellent, very good, acceptable, poor and failing), and number of events reported are the other two outcome variables of interest collected. The collected questionnaire data will be entered and analysed using SPSS v21. The HSOPS included both positively and negatively worded items. For easier interpretation of the results, the AHRQ⁶⁸ and other studies⁶²⁻⁶⁵ recommends the use of 'average positive' for calculating each item scores. That is, the percentage of positive responses for each item will be calculated and negatively worded items will be reversed when computing percent positive response. We will define areas of strengths as items for which 75% of respondents answer positively, whereas areas requiring improvement as those scoring below 50%.⁶¹ Additionally, univariate and multivariate analyses will be conducted to examine statistical associations between independent characteristics and patient safety grade and number of events reported. The mean scores for each of the HSOPC subscales are taken as dependent variables, and these will be tested against the independent variables such as job characteristics (profession and qualification), work experience (career length, organization and unit) and workload (working hours).

In-depth interview

The qualitative part of phase 1 will investigate aims to assess the patient safety strategies employed by those hospitals through in-depth interviews with different stakeholders (healthcare professionals and patients) working in ten hospitals of the Amhara region. The contact details of participants (healthcare professionals) will be retrieved from the human 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,⁶⁹ 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.⁷⁰ A theory-based identification of such factors provides a theoretically robust evidence-base to inform implementation of an intervention.⁷⁰ 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.⁷¹ According to Michie et al⁷¹, 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.^{72, 73}
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 domains⁷¹

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.⁷⁴ 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%.^{16, 75} 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,²¹ 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.⁷⁶ 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.

REFERENCES

1. Benjamin DM: Reducing medication errors and increasing patient safety: case studies in clinical pharmacology. *J Clin Pharmacol* 2003;43:768-83.

2. Brennan TA, Leape LL, Laird NM, *et al.* Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. *N Engl J Med* 1991;324:370-6.

3. Leape LL BT, Laird N, Lawthers AG, *et al.* The nature of adverse events in hospitalized patients: Results of the Harvard Medical Practice Study II. *N Engl J Med* 1991; 324:377-84.

4. Kohn LT CJ, Donaldson MS, Editors. To Err Is Human: Building A Safer Health System. Washington, DC: National Academy Press; 2000.

5. Roughead EE, Semple SJ. Medication safety in acute care in Australia: where are we now? Part 1: a review of the extent and causes of medication problems 2002-2008. *Aust New Zealand Health Policy* 2009; 6: 18. doi: 10.1186/1743-8462-6-18.

6. Bouvy JC, De Bruin ML, Koopmanschap MA. Epidemiology of adverse drug reactions in Europe: a review of recent observational studies. *Drug Saf* 2015; 38: 437-53.
7. Clancy CM. Ten years after To Err Is Human. *Am J Med Qual* 2009;24: 525-8.
8. Tumwikirize WA, Ogwal-Okeng JW, Vernby A, *et al*. Adverse drug reactions in patients admitted on internal medicine wards in district and regional hospitals in Uganda. *Afr Health Sci*. 2011; 11: 72-8.
9. Mehta U, Durrheim DN, Blockman M, *et al*. Adverse drug reactions in adult medical inpatients in a South African hospital serving a community with a high HIV/AIDS prevalence: prospective observational study. *Br J Clin Pharmacol* 2008; 65: 396-406.
10. Letaief M, El Mhamdi S, El-Asady R, *et al*. Adverse events in a Tunisian hospital: results of a retrospective cohort study. *Int J Qual Health Care* 2010; 22: 380-5.
11. Benkirane RR, Abouqal R, Haimeur CC, *et al*. Incidence of adverse drug events and medication errors in intensive care units: a prospective multicenter study. *J Patient Saf* 2009; 5: 16-22.
12. Jennane N, Madani N, Oulderrkhis R, *et al*. Incidence of medication errors in a Moroccan medical intensive care unit. *Int Arch Med* 2011; 4: 32. doi: 10.1186/1755-7682-4-32.
13. Oshikoya KA, Chukwura H, Njokanma OF, *et al*. Incidence and cost estimate of treating pediatric adverse drug reactions in Lagos, Nigeria. *Sao Paulo Med J* 2011; 129: 153-64.
14. Benkirane R, Pariente A, Achour S, *et al*. Prevalence and preventability of adverse drug events in a teaching hospital: a cross-sectional study. *EMHJ* 2009; 15: 1145-55.
15. Mouton J, Njuguna C, Stewart A, *et al*. Mortality from adverse drug reactions in adult medical inpatients at four hospitals in South Africa: a cross sectional survey. *Br J Clin Pharmacol* 2015; 80: 818-26.

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425 16. Agalu A, Ayele Y, Bedada W, *et al.* Medication prescribing errors in the intensive care
426 unit of Jimma University Specialized Hospital, Southwest Ethiopia. *J Multidiscip Healthc*
427 2011; 4: 377-82.

428 17. Ajemigbitse AA, Omole MK, Erhun WO. An assessment of the rate, types and severity of
429 prescribing errors in a tertiary hospital in southwestern Nigeria. *Afr J Med Med Sci* 2013; 42:
430 339-46.

431 18. Oshikoya KA, Ojo OI. Medication errors in paediatric outpatient prescriptions of a
432 teaching hospital in Nigeria. *Nig Q J Hosp Med* 2007; 17: 74-8.

433 19. Yinusa W. Prescription error in an orthopaedic practice. *Niger Postgrad Med J* 2004; 11:
434 37-9.

435 20. Rozich JD, Howard RJ, Justeson JM, *et al.* Standardization as a mechanism to improve
436 safety in health care. *Jt Comm J Qual Saf* 2004;30:5-14.

437 21. Institute for Healthcare Improvement. Medication Reconciliation Review: Available:
438 <http://www.ihf.org/resources/Pages/Tools/MedicationReconciliationReview.aspx>. Accessed
439 16 Nov 2015.

440 22. Joint Commission on Accreditation for Healthcare Organizations, 2006. National Patient
441 Safety Goals. Available:
442 [http://www.jointcommission.org/Improving_Americas_Hospitals_The_Joint_Commissions](http://www.jointcommission.org/Improving_Americas_Hospitals_The_Joint_Commissions_Annual_Report_on_Quality_and_Safety_-_2006/)
443 [Annual_Report_on_Quality_and_Safety_-_2006/](http://www.jointcommission.org/Improving_Americas_Hospitals_The_Joint_Commissions_Annual_Report_on_Quality_and_Safety_-_2006/). Accessed 16 Nov 2015.

444 23. National Institute of clinical excellence/ National Patient Safety Agency. NICE/NPSA
445 Technical patient safety solutions for medicines reconciliation on admission of adults to
446 hospital. London, 2007. Available: www.nice.org.uk/PSG001 Accessed 16 Nov 2015.

447 24. Canadian Council on Health Services Accreditation. CCHSA Patient Safety Goals and
448 Required Organizational Practices. Ottawa, 2004. Available: www.accreditation.ca. Accessed
449 16 Nov 2015.

25. Australian Commission on Safety and Quality in Healthcare. Medication Reconciliation. Available: <http://www.safetyandquality.gov.au/our-work/medication-safety/medication-reconciliation/>. Accessed 16 Nov 2015.
26. Australian Council on Safety and Quality in Health Care. Second national report on improving patient safety: improving medication safety. In: Australian Council on Safety and Quality in Health Care, editor. Canberra, 2002.
27. Tompson AJ, Peterson GM, Jackson SL, *et al*. Utilizing community pharmacy dispensing records to disclose errors in hospital admission drug charts. *Int J Clin Pharmacol Ther* 2012;50:639-46.
28. Vasileff HM, Whitten LE, Pink JA, *et al*. The effect on medication errors of pharmacists charting medication in an emergency department. *Pharm World Sci* 2009;31:373-9.
29. Abuyassin BH, Aljadhey H, Al-Sultan M, *et al*. Accuracy of the medication history at admission to hospital in Saudi Arabia. *Saudi Pharmaceutical Journal* 2011;19:263-7.
30. Hassali MA, Al-Haddad M, Shafie AA, *et al*. Perceptions among general medical practitioners toward implementation of medication reconciliation program for patients discharged from hospitals in Penang, Malaysia. *J Patient Saf* 2012;8:76-80.
31. Caglar S, Henneman PL, Blank FS, *et al*. Emergency department medication lists are not accurate. *J Emerg Med* 2011;40:613-6.
32. De Winter S, Spriet I, Indevuyst C, *et al*. Pharmacist - versus physician-acquired medication history: a prospective study at the emergency department. *Qual Saf Health Care* 2010;19:371-5.
33. De Winter S, Vanbrabant P, Spriet I, *et al*. A simple tool to improve medication reconciliation at the emergency department. *Eur J Intern Med* 2011;22:382-5.
34. Hummel J, Evans PC, Lee H. Medication reconciliation in the emergency department: opportunities for workflow redesign. *Qual Saf Health Care* 2010;19:531-5.

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475 35. Boyce LE, Knight AT. Audit of general practitioner medication lists for older patients at a
476 regional hospital. *J Pharm Pract and Res* 2013;43:105-8.

477 36. Mazer M, Deroos F, Hollander JE, *et al.* Medication history taking in emergency
478 department triage is inaccurate and incomplete. *Acad Emerg Med* 2011;18:102-4.

479 37. Mills PR, McGuffie AC. Formal medicine reconciliation within the emergency
480 department reduces the medication error rates for emergency admissions. *Emerg Med J*
481 2010;27:911-5.

482 38. Hatch JB, Schulz L, Fish JT. Stress ulcer prophylaxis: reducing non-indicated prescribing
483 after hospital discharge. *Ann Pharmacother* 2010;44:1565-71.

484 39. Rappaport DI, Collins B, Koster A, *et al.* Implementing medication reconciliation in
485 outpatient pediatrics. *Pediatrics* 2011;128:e1600-7. doi: 10.1542/peds.2011-0993.

486 40. Stone BL, Boehme S, Mundorff MB, *et al.* Hospital admission medication reconciliation
487 in medically complex children: an observational study. *Arch Dis Child* 2010;95:250-5.

488 41. Terry DR, Solanki GA, Sinclair AG, *et al.* Clinical significance of medication
489 reconciliation in children admitted to a UK pediatric hospital: observational study of
490 neurosurgical patients. *Paediatr Drugs* 2010;12:331-7.

491 42. Gizzi L, Slain D, Hare J, *et al.* An assessment of a pharmacy-based enhancement to the
492 hospital medication reconciliation process. ASHP Midyear Clinical Meeting. 2009.

493 43. Gizzi LA, Slain D, Hare JT, *et al.* Assessment of a safety enhancement to the hospital
494 medication reconciliation process for elderly patients. *Am J Geriatr Pharmacother*
495 2010;8:127-35.

496 44. Perennes M, Carde A, Nicolas X, *et al.* [Medication reconciliation: an innovative
497 experience in an internal medicine unit to decrease errors due to inaccurate medication
498 histories]. *Presse Med* 2012;41(3 Pt 1):e77-86.

45. Steurbaut S, Leemans L, Leysen T, *et al.* Medication history reconciliation by clinical pharmacists in elderly inpatients admitted from home or a nursing home. *Ann Pharmacother* 2010;44:1596-603.
46. Stitt DM, Elliott DP, Thompson SN. Medication discrepancies identified at time of hospital discharge in a geriatric population. *Am J Geriatr Pharmacother* 2011; 9:234-40.
47. Villanyi D, Fok M, Wong RY. Medication reconciliation: identifying medication discrepancies in acutely ill hospitalized older adults. *Am J Geriatr Pharmacother* 2011;9:339-44.
48. Geurts MM, van der Flier M, de Vries-Bots AM, Brink-van der Wal TI, de Gier JJ. Medication reconciliation to solve discrepancies in discharge documents after discharge from the hospital. *Int J Clin Pharm* 2013;35:600-7.
49. Karapinar-Carkit F, Borgsteede SD, Zoer J, *et al.* Effect of medication reconciliation with and without patient counseling on the number of pharmaceutical interventions among patients discharged from the hospital. *Ann Pharmacother* 2009;43:1001-10.
50. Hellstrom LM, Bondesson A, Hoglund P, Midlov P, Holmdahl L, Rickhag E, Eriksson T. Impact of the Lund Integrated Medicines Management (LIMM) model on medication appropriateness and drug-related hospital revisits. *Eur J Clin Pharmacol* 2011;67:741-52.
51. Jack BW, Chetty VK, Anthony D, Greenwald JL, Sanchez GM, Johnson AE, *et al.* A reengineered hospital discharge program to decrease rehospitalization: a randomized trial. *Ann Intern Med* 2009;150:178-87.
52. Gimenez Manzorro A, Zoni AC, Rodriguez Rieiro C, Duran-Garcia E, Trovato Lopez AN, Perez Sanz C, *et al.* Developing a programme for medication reconciliation at the time of admission into hospital. *Int J Clin Pharm* 2011;33(4):603-9.

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522 53. Schnipper JL, Liang CL, Hamann C, *et al.* Development of a tool within the electronic
523 medical record to facilitate medication reconciliation after hospital discharge. *JAMIA*
524 2011;18(3):309-13.

525 54. Moore P, Armitage G, Wright J, *et al.* Medicines reconciliation using a shared electronic
526 health care record. *J Patient Saf* 2011;7:148-54.

527 55. Bedard P, Tardif L, Ferland A, *et al.* A medication reconciliation form and its impact on
528 the medical record in a paediatric hospital. *J Eval Clin Pract* 2011;17:222-7

529 56. Tessier EG, Henneman EA, Heelon M, *et al.* An evaluation of collaborative nurse-
530 pharmacist intervention for improving the medication reconciliation process: impact on
531 patient safety. ASHP Midyear Clinical Meeting. 2009;220.

532 57. Greenwald JL, Halasyamani L, Greene J, *et al.* Making inpatient medication
533 reconciliation patient centered, clinically relevant and implementable: a consensus statement
534 on key principles and necessary first steps. *J Hospital Med* 2010;5:477-85.

535 58. Mekonnen AB, McLachlan AJ, Brien JE. Effectiveness of pharmacist-led medication
536 reconciliation programmes on clinical outcomes at hospital transitions: a systematic review
537 and meta-analysis. *BMJ Open* 2016; 6:e010003.

538 59. Mekonnen AB, McLachlan AJ, Brien JE. Pharmacy-led medication reconciliation
539 programmes at hospital transitions: a systematic review and meta-analysis. *JCPT* 2016. doi:
540 10.1111/jcpt.12364.

541 60. Eshetie TC, Hailemeskel B, Mekonnen N, *et al.* Adverse drug events in hospitalized
542 children at Ethiopian University Hospital: a prospective observational study. *BMC Pediatrics*
543 2015; 15:83. doi: 10.1186/s12887-015-0401-0.

544 61. Sorra JS, Nieva VF. Hospital Survey on Patient Safety Culture, AHRQ Publication No.
545 04-0041. Rockville, MD: Agency for Healthcare Research and Quality, 2004.

62. Smits M, Wagner C, Spreeuwenberg P, *et al.* Measuring patient safety culture: an assessment of the clustering of responses at unit level and hospital level. *Qual Saf Health Care* 2009; 18:292-6.
63. Deilkas E, Hofoss D: Psychometric properties of the Norwegian version of the Safety Attitudes Questionnaire (SAQ), generic version (short form 2006). *BMC Health Serv Res* 2008; 8:191. doi: 10.1186/1472-6963-8-191.
64. Smits M, Christiaans-Dingelhoff I, Wagner C, *et al.* The psychometric properties of the “Hospital Survey of Patient Safety Culture” in Dutch hospitals. *BMC Health Serv Res* 2008; 8:230. doi: 10.1186/1472-6963-8-230.
65. Wagner C, Smits M, Sorra J, *et al.* Assessing patient safety culture in hospitals across countries. *Int J Qual Health Care* 2013; 25:213–21.
66. Amhara Health Bureau, Ministry of Health, Federal Democratic Republic of Ethiopia. Available: <http://www.moh.gov.et/amharahb>.
67. Liu C, Liu W, Wang Y, *et al.* Patient safety culture in China: a case study in an outpatient setting in Beijing. *BMJ Qual Saf* 2014; 23:556–64.
68. Hospital survey on patient safety culture. Agency for Healthcare Research and Quality. Available: <http://www.ahrq.gov/professionals/quality-patient-safety/patientsafetyculture/hospital/index.html>. Accessed 16 Nov 2015.
69. Bussières AE, Patey AM, Francis JJ, *et al.* Identifying factors likely to influence compliance with diagnostic imaging guideline recommendations for spine disorders among chiropractors in North America: a focus group study using the Theoretical Domains Framework. *Implement Sc* 2012; 7:82.
70. French SD, Green SE, O’Connor DA, *et al.* Developing theory-informed behaviour change interventions to implement evidence into practice: a systematic approach using the theoretical domains framework. *Implement Sci* 2012; 7:38.

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571 71. Michie S, Johnston M, Lawton R, *et al.* Making psychological theory useful for
572 implementing evidence based practice: a consensus approach. *Qual Saf Health Care* 2005;
573 14:26-33.

574 72. Duncan EM, Francis JJ, Johnston M, *et al.* Learning curves, taking instructions, and
575 patient safety: using a theoretical domains framework in an interview study to investigate
576 prescribing errors among trainee doctors. *Implement Sci* 2012; 7:86.

577 73. Mirbaha F, Shalviri G, Yazdizadeh B, *et al.* Perceived barriers to reporting adverse drug
578 events in hospitals: a qualitative study using theoretical domains framework approach.
579 *Implementation Sci* 2015;10:110. doi:10.1186/s13012-015-0302-5.

580 74. Islam R, Tinmouth AT, Francis JJ, *et al.* A cross-country comparison of intensive care
581 physicians' beliefs about their transfusion behaviour: A qualitative study using the theoretical
582 domains framework. *Implementation Sci* 2012;7:93.

583 75. Zeleke A, Chanie T, Woldie M. Medication prescribing errors and associated factors at
584 the pediatric wards of Dessie Referral Hospital, Northeast Ethiopia. *Int Arch Med* 2014; 7:
585 18. doi: 10.1186/1755-7682-7-18.

586 76. Cornish PL, Knowles SR, Marchesano R, *et al.* Unintended medication discrepancies at
587 the time of hospital admission. *Arch Intern Med* 2005;165:424-9.

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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15. How do you think about the safety of patients at your practice site?
16. What are the measures have you taken to ensure the safety of patients?
17. 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 incident examples you are aware of that have occurred in your practice site.
18. What kind of patient safety strategy do you want to be implemented in your hospital?
19. How do you think the hospital can do better in patient safety?
20. What are the roles for other healthcare professionals in patient safety?

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

Ser. No	Drug name	Dose , Route, Frequency, duration	Date started	Date stopped	Remarks

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

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

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

3 Alemayehu B Mekonnen^{1, 2}, Andrew J McLachlan¹, Jo-anne E Brien¹, Desalew Mekonnen³,

4 Zenahbezu Abay⁴

5 ¹Faculty of Pharmacy, University of Sydney, Sydney, Australia

6 ²School of Pharmacy, University of Gondar, Gondar, Ethiopia

7 ³Department of Internal Medicine, Addis Ababa University, Addis Ababa, Ethiopia

8 ⁴Department of Internal Medicine, University of Gondar, Gondar, Ethiopia

9 Corresponding author: Alemayehu B. Mekonnen

10 Email: aber5592@uni.sydney.edu.au

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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.¹ Patient safety incidents gained attention after the works of pioneer US studies: the Harvard Medical Practice Study^{2, 3} and the Institute of Medicine Report.⁴ In the USA, it has been reported that 3.7% of all hospitalized patients experienced an adverse event,² and medication errors alone resulted in 7000 deaths annually.⁴ Medication errors constitute the most common preventable cause of patient safety problems, and has been studied extensively in the developed countries.²⁻⁶ Despite current advancements in healthcare, these incidents continue to pose a significant problem globally,⁷ 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
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5 77 incidents in hospitals,² and have important economic and humanistic consequences
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7 78 Furthermore, given the morbidity profile, and the high burden of malaria, HIV/AIDS and
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9 79 tuberculosis in Africa along with the level of awareness and patient safety culture, the extent
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11 80 of medication-related adverse events in African hospitals is thought to be higher than the
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13 81 remainder of the globe.⁸ 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),^{9,10} and 2.5% to 47% of inpatients
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17 83 encountered an ADE during their hospital stay.^{9, 11} One-fifth to more than half of the reported
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19 84 ADEs were severe events;^{10, 12–14} of which ADE-related fatalities were reported in 0.07% to
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21 85 2.9% of patient admissions to hospital.^{12, 15, 16} However, up to half of the ADEs were due to
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23 86 medication errors, and were preventable.¹⁰ The most reported types of medication errors in
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25 87 the African healthcare settings were prescribing errors, occurring in 13% to 76% of all
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27 88 prescriptions.^{17–20} Yet, the extent of medication errors and ADEs have not been fully
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29 89 evaluated in African settings,⁸ and medication safety programs designed to prevent them
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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 ²¹ and medication reconciliation as a tool for the prevention of these errors and consequent
95 patient harm have been advocated internationally.^{22, 23} 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*”.²²

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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,^{23–26} 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.²⁶ 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.²⁷ Also, other previous studies showed that between 60%
106 and 80% of patients were noted to have a discrepancy with their medication history.^{28, 29}
107 Studies examining medication errors have been undertaken across many countries including
108 developing nations,^{30, 31} in a range of settings, such as emergency units,^{32–38} critical/intensive
109 care,³⁹ paediatrics^{40–42} and geriatrics unit.^{43–48} There is evidence that MedRec decreases the
110 frequency of medication errors^{49, 50} and drug-related readmissions.^{51, 52}
111 MedRec with various approaches have been employed to improve medication safety
112 including, but not limited to, technology assisted tools,^{53–55} use of standardised forms,^{34, 56}
113 collaborative models,^{33, 57} as well as patient engagement⁵⁸ and pharmacist-led approaches.^{59,}
114 ⁶⁰ Previous studies have shown benefits from involving pharmacists in MedRec.^{59, 60}
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 study⁶¹ 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 Medicine⁴ to assist hospitals in improving patient
124 safety. According to the Agency of Healthcare Research and Quality (AHRQ),⁶² patient

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3 125 safety culture is described as an understanding of the values, beliefs and norms about what is
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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 culture⁶³ and
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13 130 assist hospitals identify their existing patient safety problems.⁶⁴ Studies on patient safety
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15 131 culture, mostly set in developed countries,^{63–66} 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.

145 **METHODS AND ANALYSES**

146 **Study setting and period**

147 This is a multi-phased study that is being conducted in public hospitals in Amhara region of
148 Ethiopia. Amhara region is one of the nine regions of Ethiopia located in the northern parts of
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.⁶⁷ 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.⁶⁸ 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.⁶⁸

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).⁶⁹ The
172 HSOPC has been widely used in assessing patient safety culture and has also been validated
173 in non-US countries.^{64, 65} 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 AHRQ⁶⁹ and other studies⁶³⁻⁶⁶ 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%.⁶²
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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values of particular groups are of interest, and to explore the degree of consensus on a given topic,⁷⁰ 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.⁷¹ A theory-based identification of such factors provides a theoretically robust evidence-base to inform implementation of an intervention.⁷¹ 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.⁷² According to Michie et al⁷², TDF has 12 domains to explain behaviour change: (1) knowledge, (2) skills, (3) social/professional role and identity, (4) beliefs about capabilities, (5) beliefs about consequences, (6) motivation and goals, (7) memory, attention and decision processes, (8) environmental context and resources, (9) social influences, (10) emotion regulation, (11) behavioural regulation, and (12) nature of the behavior. After then, TDF has been extensively used to identify barriers to change in clinical practice in order to develop interventions.^{73, 74} To justify implementation of pharmacist-led medication reconciliation, it will be of critically important to understand the perceived barriers and facilitators underlying individual pharmacist's roles in medication safety. Thus, this study uses TDF to develop a theory-informed intervention aimed at improving medication safety of patients at hospital transitions.

FGDs

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

Table 1 Interview guide questions for focus groups according to Michie's theoretical domains⁷²

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.⁷⁵ Briefly, the
301 analysis will involve identifying contextualized brief statements related to the barriers and

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

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

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

The sample size calculation is based on the prevalence of medication errors in previous local studies, which was identified as 52% to 58% of all prescriptions.^{17, 76} Assuming a reduction of medication errors from 55% to 45%, 80% power, 5% significance level (two-sided), we required a total of 127 patients, 51 for the baseline and 76 for the intervention. Hospital discharge statistics showed that this sample size would be achievable in three months. A baseline assessment of medication discrepancies will thus, be conducted for one month during hospital admission. Medication discrepancies are defined as one or more differences in (dosage, frequency, drug, route of administration), as described by the Institute for Healthcare Improvement (IHI),²² between the current and previous medication (s) a patient was taking. A pharmacist-led MedRec intervention will be then carried out prospectively for 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),⁷⁷ 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 techinques 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 physisician at admission and verfication 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.⁷⁸ Descriptive
349 statisitcs 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.

REFERENCES

- 1
2
3 401 1. Benjamin DM: Reducing medication errors and increasing patient safety: case studies in
4
5 402 clinical pharmacology. *J Clin Pharmacol* 2003;43:768–83.
- 6
7 403 2. Brennan TA, Leape LL, Laird NM, *et al.* Incidence of adverse events and negligence in
8
9 404 hospitalized patients. Results of the Harvard Medical Practice Study I. *N Engl J Med*
10
11 405 1991;324:370–6.
- 12
13 406 3. Leape LL BT, Laird N, Lawthers AG, *et al.* The nature of adverse events in hospitalized
14
15 407 patients: Results of the Harvard Medical Practice Study II. *N Engl J Med* 1991; 324:377–84.
- 16
17 408 4. Institute of Medicine. In: Kohn LT, Corrigan JM, Donaldson MS, (eds). *To Err Is*
18
19 409 *Human: Building a Safer Health System: Executive Summary.* Washington, DC: National
20
21 410 Academy Press; 1999, pp 1–14.
- 22
23 411 5. Roughead EE, Semple SJ. Medication safety in acute care in Australia: where are we now?
24
25 412 Part 1: a review of the extent and causes of medication problems 2002–2008. *Aust New*
26
27 413 *Zealand Health Policy* 2009; 6: 18.
- 28
29 414 6. Bouvy JC, De Bruin ML, Koopmanschap MA. Epidemiology of adverse drug reactions in
30
31 415 Europe: a review of recent observational studies. *Drug Saf* 2015; 38: 437–53.
- 32
33 416 7. Clancy CM. Ten years after *To Err Is Human*. *Am J Med Qual* 2009;24: 525–8.
- 34
35 417 8. Isah AO, Pal SN, Olsson S, Dodoo A, Bencheikh RS. Specific features of medicines safety
36
37 418 and pharmacovigilance in Africa. *Ther Adv Drug Saf* 2012; 3: 25–34.
- 38
39 419 9. Tumwikirize WA, Ogwal-Okeng JW, Vernby A, *et al.* Adverse drug reactions in patients
40
41 420 admitted on internal medicine wards in district and regional hospitals in Uganda. *Afr Health*
42
43 421 *Sci.* 2011; 11: 72–8.
- 44
45 422 10. Mehta U, Durrheim DN, Blockman M, *et al.* Adverse drug reactions in adult medical
46
47 423 inpatients in a South African hospital serving a community with a high HIV/AIDS
48
49 424 prevalence: prospective observational study. *Br J Clin Pharmacol* 2008; 65: 396–406.

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425 11. Letaief M, El Mhamdi S, El-Asady R, *et al.* Adverse events in a Tunisian hospital:
426 results of a retrospective cohort study. *Int J Qual Health Care* 2010; 22: 380–5.

427 12. Benkirane RR, Abouqal R, Haimeur CC, *et al.* Incidence of adverse drug events and
428 medication errors in intensive care units: a prospective multicenter study. *J Patient Saf* 2009;
429 5: 16–22.

430 13. Jennane N, Madani N, Oulderrkhis R, *et al.* Incidence of medication errors in a Moroccan
431 medical intensive care unit. *Int Arch Med* 2011; 4: 32.

432 14. Oshikoya KA, Chukwura H, Njokanma OF, *et al.* Incidence and cost estimate of treating
433 pediatric adverse drug reactions in Lagos, Nigeria. *Sao Paulo Med J* 2011; 129: 153–64.

434 15. Benkirane R, Pariente A, Achour S, *et al.* Prevalence and preventability of adverse drug
435 events in a teaching hospital: a cross-sectional study. *EMHJ* 2009; 15: 1145–55.

436 16. Mouton J, Njuguna C, Stewart A, *et al.* Mortality from adverse drug reactions in adult
437 medical inpatients at four hospitals in South Africa: a cross sectional survey. *Br J Clin*
438 *Pharmacol* 2015; 80: 818–26.

439 17. Agalu A, Ayele Y, Bedada W, *et al.* Medication prescribing errors in the intensive care
440 unit of Jimma University Specialized Hospital, Southwest Ethiopia. *J Multidiscip Healthc*
441 2011; 4: 377–82.

442 18. Ajemigbitse AA, Omole MK, Erhun WO. An assessment of the rate, types and severity of
443 prescribing errors in a tertiary hospital in southwestern Nigeria. *Afr J Med Med Sci* 2013; 42:
444 339–46.

445 19. Oshikoya KA, Ojo OI. Medication errors in paediatric outpatient prescriptions of a
446 teaching hospital in Nigeria. *Nig Q J Hosp Med* 2007; 17: 74–8.

447 20. Yinusa W. Prescription error in an orthopaedic practice. *Niger Postgrad Med J* 2004; 11:
448 37–9.

21. Rozich JD, Howard RJ, Justeson JM, *et al.* Standardization as a mechanism to improve safety in health care. *Jt Comm J Qual Saf* 2004;30:5–14.
22. Institute for Healthcare Improvement. Medication Reconciliation Review: Available: <http://www.ihl.org/resources/Pages/Tools/MedicationReconciliationReview.aspx>. Accessed 16 Nov 2015.
23. Joint Commission on Accreditation for Healthcare Organizations, 2006. National Patient Safety Goals. Available: https://www.jointcommission.org/improving_america's_hospitals_the_joint_commissions_annual_report_on_quality_and_safety_-_2006/. Accessed 16 Nov 2015.
24. National Institute of clinical excellence/ National Patient Safety Agency. NICE/NPSA Technical patient safety solutions for medicines reconciliation on admission of adults to hospital. London, 2007. Available: www.nice.org.uk/PSG001. Accessed 16 Nov 2015.
25. Canadian Council on Health Services Accreditation. CCHSA Patient Safety Goals and Required Organizational Practices. Ottawa, 2004. Available: www.accreditation.ca. Accessed 16 Nov 2015.
26. Australian Commission on Safety and Quality in Healthcare. Medication Reconciliation. Available: <http://www.safetyandquality.gov.au/our-work/medication-safety/medication-reconciliation/>. Accessed 16 Nov 2015.
27. Australian Council on Safety and Quality in Health Care. Second national report on improving patient safety: improving medication safety. In: Australian Council on Safety and Quality in Health Care, editor. Canberra, 2002.
28. Thompson AJ, Peterson GM, Jackson SL, *et al.* Utilizing community pharmacy dispensing records to disclose errors in hospital admission drug charts. *Int J Clin Pharmacol Ther* 2012;50:639–46.
29. Vasileff HM, Whitten LE, Pink JA, *et al.* The effect on medication errors of pharmacists charting medication in an emergency department. *Pharm World Sci* 2009;31:373–9.

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475 30. Abuyassin BH, Aljadhey H, Al-Sultan M, *et al.* Accuracy of the medication history at
476 admission to hospital in Saudi Arabia. *Saudi Pharmaceutical Journal* 2011;19:263–7.

477 31. Hassali MA, Al-Haddad M, Shafie AA, *et al.* Perceptions among general medical
478 practitioners toward implementation of medication reconciliation program for patients
479 discharged from hospitals in Penang, Malaysia. *J Patient Saf* 2012;8:76–80.

480 32. Caglar S, Henneman PL, Blank FS, *et al.* Emergency department medication lists are not
481 accurate. *J Emerg Med* 2011;40:613–6.

482 33. De Winter S, Spriet I, Indevuyst C, *et al.* Pharmacist-versus physician-acquired
483 medication history: a prospective study at the emergency department. *Qual Saf Health Care*
484 2010;19:371–5.

485 34. De Winter S, Vanbrabant P, Spriet I, *et al.* A simple tool to improve medication
486 reconciliation at the emergency department. *Eur J Intern Med* 2011;22:382–5.

487 35. Hummel J, Evans PC, Lee H. Medication reconciliation in the emergency department:
488 opportunities for workflow redesign. *Qual Saf Health Care* 2010;19:531–5.

489 36. Boyce LE, Knight AT. Audit of general practitioner medication lists for older patients at a
490 regional hospital. *J Pharm Pract and Res* 2013;43:105–8.

491 37. Mazer M, Deroos F, Hollander JE, *et al.* Medication history taking in emergency
492 department triage is inaccurate and incomplete. *Acad Emerg Med* 2011;18:102–4.

493 38. Mills PR, McGuffie AC. Formal medicine reconciliation within the emergency
494 department reduces the medication error rates for emergency admissions. *Emerg Med J*
495 2010;27:911–5.

496 39. Hatch JB, Schulz L, Fish JT. Stress ulcer prophylaxis: reducing non-indicated prescribing
497 after hospital discharge. *Ann Pharmacother* 2010;44:1565–71.

498 40. Rappaport DI, Collins B, Koster A, *et al.* Implementing medication reconciliation in
499 outpatient pediatrics. *Pediatrics* 2011;128:e1600–7.

41. Stone BL, Boehme S, Mundorff MB, *et al.* Hospital admission medication reconciliation in medically complex children: an observational study. *Arch Dis Child* 2010;95:250–5.
42. Terry DR, Solanki GA, Sinclair AG, *et al.* Clinical significance of medication reconciliation in children admitted to a UK pediatric hospital: observational study of neurosurgical patients. *Paediatr Drugs* 2010;12:331–7.
43. Gizzi L, Slain D, Hare J, *et al.* An assessment of a pharmacy-based enhancement to the hospital medication reconciliation process. ASHP Midyear Clinical Meeting. 2009.
44. Gizzi LA, Slain D, Hare JT, *et al.* Assessment of a safety enhancement to the hospital medication reconciliation process for elderly patients. *Am J Geriatr Pharmacother* 2010;8:127–35.
45. Perennes M, Carde A, Nicolas X, *et al.* [Medication reconciliation: an innovative experience in an internal medicine unit to decrease errors due to inaccurate medication histories]. *Presse Med* 2012;41:e77–86.
46. Steurbaut S, Leemans L, Leysen T, *et al.* Medication history reconciliation by clinical pharmacists in elderly inpatients admitted from home or a nursing home. *Ann Pharmacother* 2010;44:1596–603.
47. Stitt DM, Elliott DP, Thompson SN. Medication discrepancies identified at time of hospital discharge in a geriatric population. *Am J Geriatr Pharmacother* 2011; 9:234–40.
48. Villanyi D, Fok M, Wong RY. Medication reconciliation: identifying medication discrepancies in acutely ill hospitalized older adults. *Am J Geriatr Pharmacother* 2011;9:339–44.
49. Geurts MM, van der Flier M, de Vries-Bots AM, Brink-van der Wal TI, de Gier JJ. Medication reconciliation to solve discrepancies in discharge documents after discharge from the hospital. *Int J Clin Pharm* 2013;35:600–7.

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51
52
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55
56
57
58
59
60

50 Karapinar-Carkit F, Borgsteede SD, Zoer J, *et al.* Effect of medication reconciliation with
525 and without patient counseling on the number of pharmaceutical interventions among patients
526 discharged from the hospital. *Ann Pharmacother* 2009;43:1001–10.

527 51. Hellstrom LM, Bondesson A, Hoglund P, Midlov P, Holmdahl L, Rickhag E, Eriksson T.
528 Impact of the Lund Integrated Medicines Management (LIMM) model on medication
529 appropriateness and drug-related hospital revisits. *Eur J Clin Pharmacol* 2011;67:741–52.

530 52. Jack BW, Chetty VK, Anthony D, Greenwald JL, Sanchez GM, Johnson AE, *et al.* A
531 reengineered hospital discharge program to decrease rehospitalization: a randomized trial.
532 *Ann Intern Med* 2009;150:178–87.

533 53. Gimenez Manzorro A, Zoni AC, Rodriguez Rieiro C, Duran-Garcia E, Trovato Lopez
534 AN, Perez Sanz C, *et al.* Developing a programme for medication reconciliation at the time of
535 admission into hospital. *Int J Clin Pharm* 2011;33:603–9.

536 54. Schnipper JL, Liang CL, Hamann C, *et al.* Development of a tool within the electronic
537 medical record to facilitate medication reconciliation after hospital discharge. *JAMIA*
538 2011;18:309–13.

539 55. Moore P, Armitage G, Wright J, *et al.* Medicines reconciliation using a shared electronic
540 health care record. *J Patient Saf* 2011;7:148–54.

541 56. Bedard P, Tardif L, Ferland A, *et al.* A medication reconciliation form and its impact on
542 the medical record in a paediatric hospital. *J Eval Clin Pract* 2011;17:222–7

543 57. Tessier EG, Henneman EA, Heelon M, *et al.* An evaluation of collaborative nurse-
544 pharmacist intervention for improving the medication reconciliation process: impact on
545 patient safety. ASHP Midyear Clinical Meeting. 2009;220.

546 58. Greenwald JL, Halasyamani L, Greene J, *et al.* Making inpatient medication
547 reconciliation patient centered, clinically relevant and implementable: a consensus statement
548 on key principles and necessary first steps. *J Hospital Med* 2010;5:477–85.

59. Mekonnen AB, McLachlan AJ, Brien JE. Effectiveness of pharmacist-led medication reconciliation programmes on clinical outcomes at hospital transitions: a systematic review and meta-analysis. *BMJ Open* 2016; 6:e010003.
60. Mekonnen AB, McLachlan AJ, Brien JE. Pharmacy-led medication reconciliation programmes at hospital transitions: a systematic review and meta-analysis. *J Clin Pharm Ther* 2016; 41: 128–44. .
61. Eshetie TC, Hailemeskel B, Mekonnen N, *et al.* Adverse drug events in hospitalized children at Ethiopian University Hospital: a prospective observational study. *BMC Pediatrics* 2015; 15:83.
62. Sorra JS, Nieva VF. Hospital Survey on Patient Safety Culture, AHRQ Publication No. 04-0041. Rockville, MD: Agency for Healthcare Research and Quality, 2004.
63. Smits M, Wagner C, Spreeuwenberg P, *et al.* Measuring patient safety culture: an assessment of the clustering of responses at unit level and hospital level. *Qual Saf Health Care* 2009; 18:292–6.
64. Deilkas E, Hofoss D: Psychometric properties of the Norwegian version of the Safety Attitudes Questionnaire (SAQ), generic version (short form 2006). *BMC Health Serv Res* 2008; 8:191.
65. Smits M, Christiaans-Dingelhoff I, Wagner C, *et al.* The psychometric properties of the “Hospital Survey of Patient Safety Culture” in Dutch hospitals. *BMC Health Serv Res* 2008; 8:230. .
66. Wagner C, Smits M, Sorra J, *et al.* Assessing patient safety culture in hospitals across countries. *Int J Qual Health Care* 2013; 25:213–21.
67. Amhara Health Bureau, Minsitry of Health, Federal Democratic Republic of Ethiopia. Available: <http://www.moh.gov.et/amharahb>. Accessed 16 Nov 2015.

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43
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45
46
47
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57
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60

573 68. Liu C, Liu W, Wang Y, *et al.* Patient safety culture in China:a case study in an outpatient
574 setting in Beijing. *BMJ Qual Saf* 2014;23:556–64.

575 69. Hospital survey on patient safety culture. Agency for Healthcare Research and Quality.
576 Available: <http://www.ahrq.gov/professionals/quality-patientsafety/patientsafetyculture/hospital/index.html>. Accessed 16 Nov 2015.

577
578 70. Bussi res AE, Patey AM, Francis JJ, *et al.* Identifying factors likely to influence
579 compliance with diagnostic imaging guideline recommendations for spine disorders among
580 chiropractors in North America: a focus group study using the Theoretical Domains
581 Framework. *Implement Sc* 2012; 7:82.

582 71. French SD, Green SE, O’Connor DA, *et al.* Developing theory-informed behaviour
583 change interventions to implement evidence into practice: a systematic approach using the
584 theoretical domains framework. *Implement Sci* 2012;7:38.

585 72. Michie S, Johnston M, Lawton R, *et al.* Making psychological theory useful for
586 implementing evidence based practice: a consensus approach. *Qual Saf Health Care* 2005;
587 14:26–33.

588 73. Duncan EM, Francis JJ, Johnston M, *et al.* Learning curves, taking instructions, and
589 patient safety: using a theoretical domains framework in an interview study to investigate
590 prescribing errors among trainee doctors. *Implement Sci* 2012; 7:86.

591 74. Mirbaha F, Shalviri G, Yazdizadeh B, *et al.* Perceived barriers to reporting adverse drug
592 events in hospitals: a qualitative study using theoretical domains framework approach.
593 *Implementation Sci* 2015;10:110.

594 75. Islam R, Tinmouth AT, Francis JJ, *et al.* A cross-country comparison of intensive care
595 physicians’ beliefs about their transfusion behaviour: A qualitative study using the theoretical
596 domains framework. *Implementation Sci* 2012;7:93.

76. Zeleke A, Chanie T, Woldie M. Medication prescribing errors and associated factors at the pediatric wards of Dessie Referral Hospital, Northeast Ethiopia. *Int Arch Med* 2014; 7: 18.
77. Australian Commission on Safety and Quality in Healthcare. Taking a Best Possible Medication History. Available: <https://www.safetyandquality.gov.au/our-work/medication-safety/medication-reconciliation/taking-a-best-possible-medication-history/>. Accessed 23 Nov 2016.
78. Cornish PL, Knowles SR, Marchesano R, *et al*. Unintended medication discrepancies at the time of hospital admission. *Arch Intern Med* 2005;165:424–9.

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. 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

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