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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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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.

INTRODUCTION

Patient safety initiatives

Quality care is a priority agenda for all healthcare sectors; however, patient safety is usually compromised due to medical harms.[1] Patient safety incidents gain more attention after the works of previous pioneer US studies: the Harvard Medical Practice Study [2, 3] and the Institute of Medicine Report.[4] 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] Though a better healthcare to date, 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

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

Medication reconciliation as a medication safety strategy

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

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

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

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

pharmacy-led approaches.[58, 59] Our previous studies have shown benefits from involving pharmacists in medication reconciliation.[58, 59] However, the impact of medication reconciliation overall, as well as pharmacist-led medication reconciliation practice, is not yet described in the sub-Saharan Africa.

Patient safety culture in Ethiopian context

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

This project is a medication safety initiative focusing on medication reconciliation at care 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

meaningful assessment of patient safety culture through the eyes of healthcare professionals and patients.[67]

Questionnaire study

The survey aims to evaluate the patient safety culture of public hospitals in the Amhara region. We have randomly selected 10 out of 17 public hospitals. The study focus is only on public hospitals as most of the population in the region used public hospitals. The study adopted the "Hospital Survey on Patient Safety Culture" (HSOPSC) developed by the Agency for Healthcare Research and Quality (AHRQ).[68] The HSOPC has been widely used in assessing patient safety culture and has also been validated in non-US countries.[63, 64] However, validating this survey is out of the scope of this study, and we will only undertake a baseline assessment of the extent of patient safety culture. The survey consists 42 items that measure 12 patient safety culture composites: communication openness, feedback and communication about errors, frequency of events reported, handoffs and transitions, management support for patient safety, non-punitive response to error, organizational learning and continuous improvement, overall perceptions of patient safety, staffing, supervisor/manager expectations and actions promoting safety, teamwork across and within units. Background variables of participants included questions related to job category, type of hospital (teaching, district/tertiary care), years of working experience overall and in the current working area, work setting and working hours per week. The questionnaire is kept in English, as English is the main language of communication in Ethiopian hospitals. This questionnaire together with the participant information statement is being distributed to conveniently selected healthcare professionals by the research team and required about 10 – 15 minutes to complete. These participants are being recruited from the 10 hospitals of 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 AHRQ [68] and other studies[62-65] 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

will be used to identify the initial sample and then the remaining data collection with be aided with snowball sampling. Letters/e-mails, as appropriate, will be provided for invitation of the healthcare professionals who are involved in the care of patients. Patients who are in-hospital at the time of data collection and were taking regular medications before admission will be invited for an interview by a healthcare professional who is already a participant in this study. Then, patients will be contacted for further invitation into the study. Semi-structured interviews informed by the interview guide (Additional file 1) will be employed for the collection of data. All interview guides have been translated from English versions to the local language (Amharic) by two non-official translators who are native speakers and working in the healthcare industry, and validated by two of the research group (ABM, DM). Interview tools have been translated in order to foster faster communication and expression of ideas. The respondents will be informed about the interview and consent will be obtained. Participants will also be given further details on the nature of the study to ensure that interviewees understand what will be required of them. Face-to-face interviews will be conducted by the principal investigator at a time and place to suit the participants and expected to last approximately 30 to 60 minutes. Open-ended questions will be asked to interviewees to describe their experiences of medication safety issues and strategies employed to prevent medication-related events. Participants will be encouraged to reflect upon their own experiences of medication-related events and will be asked to think about an example of a known medication-related event when answering questions. The interviewer will use prompts when necessary to encourage further elaboration. Participants will be given 50 ETB in appreciation of their time. All interviews will be conducted by an English/ Amharic speaking investigator (ABM). Data will be collected with each of the two participant groups until a point of saturation is reached. All interviews will be audiotaped 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 al[71], 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.[72, 73] 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 (AM, JB) and discussed by the research team to check clinical relevance. The discussion questions will be pilot-tested with at least 2 hospital pharmacists to assess clarity and focus, and revised accordingly.

Table 1 Interview guide questions for focus groups according to Michie's theoretical domains[71]

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

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

Enviromental context and resources	To what extent do physical factors or resources facilitate or hinder to deliver medication reconiciliation/review? Are there competing tasks and time constraints? Are the necessary resources available to undertake these services? Do these services have advantages compared with the standard care? Do government and local authorties provide sufficient support for these services?
Social influences	Are clinical pharmacy services in the hospital well acknowledged by other healthcare professionals? Do hospital managers acknowledge your role? Is there any obstruction to these activities in your hospital? Have you observed others doing providing these clinical services?
Emotion	What things worry you the most in providing medication reconciliation/review services? To what extent do emotional factors facilitate or hinder these serivces?
Behavioural regulation	Have you received feeedback from other healthcare professionals regarding these services? What intital 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?

The sample population will be all hospital pharmacists in the ten public hospitals across the region. Pharmacists will be selected using a purposive sampling strategy augmented with snowball sampling. Participants will be recruited either by letter/email invitation. Participants willing to be interviewed either by sending an email or by returning a signed consent form will be contacted. The principal investigator (ABM), who is experienced in qualitative study, will conduct and facilitate the focus group discussion using the translated version (Amharic) of the topic guide. Pharmacists will be encouraged to talk about internal beliefs and attitudes that may hinder them from providing clinical pharmacy services including medication safety roles. All discussion sessions will be audiotaped and recorded. Two of the researchers (ABM, ZA) will read all the FGD Amharic transcripts, and will be translated into English. Transcripts will then be coded based on the 12 domains of the TDF, and thematic analysis of pharmacist's statements into the relevant theoretical domains will be performed.[74] Briefly, the analysis will involve identifying contextualized brief statements related to the barriers and facilitators to medication safety activities, categorizing 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 medication reconciliation service in a teaching hospital

This phase of the project is the main objective of this study, and the aim is to investigate the impact of pharmacist-led medication reconciliation service on the rate and incidence of unjustified medication discrepancies in an internal medicine 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 specialized 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. Prevalence of medication errors in previous local studies was identified as 52% to 58%.[16, 75] 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 in hospitalized patients will thus, be conducted for 1 month. 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, [21] between the current and previous medication (s) a patient was taking. A pharmacist-led medication reconciliation will be then carried out prospectively for 2 months. The inclusion criteria will be that patients with age of over 18 years, had been hospitalized for at least 24 hours and taking at least two home/regular medications on admission. One pharmacy staff member will be trained in the techinques of how to get the best possible medication history (BPMH) by a research pharmacist (ABM). Medication reconiciliation will be conducted after patients are informed of the study and give written consent. Medication use will be documented within 24 hrs of patient admission through a data collection tool prepared for the purpose of this study (Additional file 2). The pharmacist will then compare the BPMH with the admission prescription order of the patient issued by the physician in charge. All patients will be followed to hospital discharge. All identfied discrepancies will be brought to the attention of the phyisician at admission and discharge and verfication of these discrepancies will be

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 consquences 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] Descrptive statisitcs 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-reviewd health journals and conference publications. One or more mettings 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 percieve patient safety. This sudy describes the views of healthcare professionals in hospitals about patient safety culture and patients experiances 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 experiances. In order to minimize this, participants will be requested to nominate other participants who might think different in their experiance and practice in medication safety.

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Author's contribution

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

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Competing interests

The authors declare that they have no competing interests.

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Additional file 1

Interview guide questions for healthcare workers

1. What is your role and how long have you been doing this?
2. Who are the colleagues you work most closely with (physicians, nurses, pharmacists, others)
3. How do you describe your working relationship with physicians/ nurses/ pharmacists/others?
4. To what extent is patient safety is 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?

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?

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, Route, Frequency, duration	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.

2. Medication discrepancies collection form

I. Patient information:

Age : _____

Sex: Male_____ Female ____

Diagnosis: _____

II. Occurrence of medication discrepancies

A) What type (s) of discprenacy (cies) 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

e) Commission error

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

g) Others, specify _____

Clinical severity assessment

Categorizing the clinical seveirty 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

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

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

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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 seveirty 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.

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

Patient injuries attributed to medication-related adverse events are among the most common incidents in hospitals,[2] and have important economic and humanistic consequences Furthermore, given the morbidity profile, and the high burden of malaria, HIV/AIDS and tuberculosis in Africa along with the level of awareness and patient safety culture, the extent of medication-related adverse events in African hospitals is thought to be higher than the remainder of the globe.[8] For example, studies have shown that 1.5% to 6.5% of hospital admissions are attributed to adverse drug events (ADEs),[9,10] and 2.5% to 47% of inpatients encountered an ADE during their hospital stay.[9, 11] One-fifth to more than half of the reported ADEs were severe events; [10, 12–14] of which ADE-related fatalities were reported in 0.07% to 2.9% of patient admissions to hospital. [12, 15, 16] However, up to half of the ADEs were due to medication errors, and were preventable.[10] The most reported types of medication errors in the African healthcare settings were prescribing errors, occurring in 13% to 76% of all prescriptions.[17–20] Yet, the extent of medication errors and ADEs have not been fully evaluated in African settings,[8] and medication safety programs designed to prevent them appear the first step in improving patient safety.

Medication reconciliation as a medication safety strategy

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

Under the leadership of the WHO, patient safety programs including MedRec have been implemented across a range of countries, [23–26] and taken-up as healthcare policy. For instance, MedRec has been recognized as a priority patient safety solution by the Australian Commission on Safety and Quality in Healthcare.[26] Prior to MedRec being routinely practiced in Australia, there was one omitted medicine from medication chart among every two people at hospital admission.[27] Also, other previous studies showed that between 60% and 80% of patients were noted to have a discrepancy with their medication history.[28, 29]

Studies examining medication errors have been undertaken across many countries including developing nations,[30, 31] in a range of settings, such as emergency units, [32–38] critical/intensive care,[39] paediatrics[40–42] and geriatrics unit.[43–48] There is evidence that MedRec decreases the frequency of medication errors [49, 50] and drug-related readmissions.[51, 52]

MedRec with various approaches have been employed to improve medication safety including, but not limited to, technology assisted tools, [53–55] use of standardised forms, [34, 56] collaborative models, [33, 57] as well as patient engagement[58] and pharmacist-led approaches.[59, 60] Previous studies have shown benefits from involving pharmacists in MedRec.[59, 60] However, the impact of MedRec overall, as well as pharmacist-led MedRec practice, is not yet described in the sub-Saharan Africa.

Patient safety culture in Ethiopian context

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

safety culture is described as an understanding of the values, beliefs and norms about what is important in an organization and what attitudes and behaviours related to patient safety are supported, rewarded, and expected. It is thus, important for healthcare organizations to assess their patient safety culture to obtain a clear understanding of the patient safety aspects requiring urgent attention, identify the strengths and weaknesses of their safety culture[63] and assist hospitals identify their existing patient safety problems. [64] Studies on patient safety culture, mostly set in developed countries, [63–66] have been published. However, there are no data about the current state of patient safety culture in Ethiopian hospitals. Furthermore, no studies have specifically investigated the implementation of medication reconciliation services from a behavioral theory perspective involving both barriers and facilitators of a wide range of behavioral determinants in implementation of evidence-based practice.

This project is a medication safety initiative focusing on MedRec at care transitions in Ethiopian public hospitals, and the implementation of this service in this study is guided by a multi-method approach consisting three different but inter-related studies to inform our study objectives. Specifically, the aims of this study are to explore healthcare professionals' views of patient safety issues, medical error, and event reporting and patients' experiences of medication-related adverse 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 MedRec practice in one of the teaching hospitals in Ethiopia.

METHODS AND ANALYSES

Study setting and period

This is a multi-phased study that is being 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.[67] There are three phases to this research project. Phases 1 and 2 are being conducted in 10 selected public hospitals of the Amhara region, including 4 teaching or referral (Gondar university, Felege Hiwot, Debre Markos, and Debre Tabor) and 6 district hospitals (Metema, Debark, Chagni, Finoteselam, Woldiya, and Enat), and phase 3 will be carried out in one teaching hospital; that is, Gondar university hospital. The study has commenced 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 adverse events

This is a mixed-methods study consisting a survey and qualitative research. The survey measures dimensional scores of patient safety culture. Using a scale to quantify the scores of patient safety is, however, not explanatory.[68] 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 meaningful assessment of patient safety culture through the eyes of healthcare professionals and patients.[68]

Questionnaire study

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

of events reported, handovers and transitions, management support for patient safety, non-punitive response to error, organizational learning and continuous improvement, overall perceptions of patient safety, staffing, supervisor/manager expectations and actions promoting safety, teamwork across and within units. Background variables of participants included questions related to job category, type of hospital (teaching/referral, district), years of working experience overall and in the current working area, work setting and working hours per week. The questionnaire was kept in English, as English is the main language of communication in Ethiopian hospitals. This questionnaire together with the participant information statement was distributed to conveniently selected healthcare professionals by the research team and required about 10 – 15 minutes to complete. These participants were recruited from the 10 hospitals of Amhara region, and included physicians, nurses, pharmacists and paramedics (e.g. technicians). The *sample size* was 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 was rated as excellent in 50% of respondents.

The response to each item in the questionnaire was 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 were the other two outcome variables of interest collected. Currently, we are entering the collected data into SPSS v21, and data will be analysed when data entry is accomplished. The HSOPS included both positively and negatively worded items. For easier interpretation of the results, the AHRQ [69] and other studies[63-66] 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%. [62] 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 sub-scales are taken as dependent variables, and these will be tested against the independent variables, such as job characteristics (profession and qualification), department and type of hospital (teaching/referral, district), work experience (career length, experience in the current unit/hospital) and workload (working hours).

In-depth interview

The qualitative part of phase 1 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) have been retrieved from the human resource office or related office of the respective hospitals. We are using purposeful sampling to identify the initial sample and then the remaining data collection is being aided with snowball sampling. We are providing letters/e-mails, as appropriate, for invitation of the healthcare professionals who are involved in the care of patients. Patients who are in-hospital at the time of data collection and were taking regular medications before admission are being invited for an interview by a healthcare professional who is already a participant in this study. Then, we are contacting patients for further invitation into the study. We are employing semi-structured interviews informed by the interview guide (Additional file 1) for the collection of data. All interview guides have been translated from English versions to the local language (Amharic) by two non-official translators who are native speakers and working in the healthcare industry, and validated by two of the research group (ABM, DM). Interview tools 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

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 al[72], 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 domains[72]

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

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

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

Emotion	What things worry you the most in providing medication reconciliation/review services? To what extent do emotional factors facilitate or hinder these serivces?
Behavioural regulation	Have you received feeedback from other healthcare professionals regarding these services? What intital 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?

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

hospitalized for at least 24 hours and taking at least two home/regular medications on admission. The standard practice in the current department involve physicians in taking patient's medication history using patient provided information; however, hospital pharmacists are not participated in medication history taking and prescription review at the emergency department. The intervention will involve use of the best possible medication history (BPMH),[77] which is based on a structured interview with the patient about medication use and retrieving other sources of medication history, including discharge and referral letters, patient's own medicines and carrier interview. One pharmacy staff member will be trained in the techinques of how to get the BPMH by a research pharmacist (ABM). MedRec will be conducted after patients are informed of the study and give written consent. Medication use will be documented within 24 hrs of patient admission through a data collection tool prepared for the purpose of this study (Additional file 2). The pharmacist will then compare the BPMH with the admission prescription order of the patient issued by the physician in charge. All identified discrepancies will be brought to the attention of the phyisician at admission and verfication of these discrepancies will be made; that is, intentional vs unintentional changes to medications. Intentional medication discrepancies are medication changes due to new patient's clinical status, and are clinically justifiable but not documented in the patient's medical record. Thus, only unintentional medication discrepancies (also called as medication errors) will be reported. The main outcome measure is the incidence of medication errors and the potential clinical severity of such errors. The potential clinical severity of medication errors will be judged by a consensus between a clinical pharmacist and a physician using a tool developed by Cornish et al.[78] Descriptive statisitcs will be used to characterise the types of medication errors and chi-square test will be utilised to analyse differences in the incidence and severity of medication errors between the 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-reviewd health journals and conference publications. One or more mettings 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 percieve patient safety. This sudy will describe the views of healthcare professionals in hospitals about patient safety culture and patients experiances 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

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 experiances. In order to minimize this, participants will be requested to nominate other participants who might think are different in their experiance and practice in medication safety. Moreover, we will use an iterative process for data collection and analysis for the qualitative studies in phases 1 and 2 until we are sure that there will no new ideas emerging.

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Author's contribution

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

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Competing interests

The authors declare that they have no competing interests.

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Additional file 1

Interview guide questions for healthcare workers

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

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

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

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?

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

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 discprenacy (cies) 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 seveirty 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