Medication safety practices in healthcare facilities in Kaduna State, Nigeria: a study protocol

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Abstract

Background: In recent years, there has been growing concern about patient safety and this is becoming a global problem. Medication safety can be used to describe systematic assessments of healthcare professionals' practices as related to safe use of medicines. Identification and prevention of medication errors is the key component of medication safety. This includes multiple aspects of medication practice and other factors that affect it, such as organisational structure, communication, technologies such as those used for dispensing, and strategies pursued by leadership in cultivating and promoting a culture of safety.

Methods: The study adopted a mixed method approach divided into three phases. Phase I is a quantitative phase and involves an assessment of core medication safety practices in the study sites together with an assessment of patient safety culture through the use of the Hospital Survey on Patient Safety Culture (HSOPSC) developed by US Agency for Health Care Research and Quality (AHRQ). Phase II will involve semi-structured interviews with health care providers and focus group discussions with patients to explore their perspectives on medication safety and to explore their experiences concerning medication safety respectively. Phase III will be an intervention study and will utilise the World Health Organisation (WHO) *Patient Safety Curriculum Guide: Multi professional edition* as the intervention tool.

Discussion: The study findings will offer substantial opportunity for improvements. The study will also open up an area of patient safety culture, where not much research has been conducted in Nigeria.

Keywords: healthcare, HSOPSC, mixed methods, patient safety, quality, safety culture

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Lay summary

Exploring medication safety practices in public healthcare facilities in Kaduna State, Nigeria: a study protocol

Patient safety is a global problem and there has been growing concern regarding it in recent years. Much less is known about medication safety in Nigeria. We are conducting this study in four public health facilities in Kaduna State, Nigeria in multiple phases that involve multiple stakeholders and data collection methods. In phase Ia, we assessed the presence of basic medication safety practices (such as use of information technology, transition in care practices, and others) by having structured questionnaire based interviews with the Head of Pharmacy department of each of the health facilities. In phase Ib, we are conducting a survey to assess patient safety culture amongst doctors, nurses and pharmacists of the selected health facilities.

In phase IIa, we will be conducting one-on-one interviews with healthcare providers to explore their perspectives on medication safety, while phase IIb will involve group discussions with patients to explore their experiences regarding their safety in healthcare.

Phase III will be the final phase, which will be an educational intervention phase that will be carried out as a pre- and post-intervention study. We will distribute a questionnaire to participants (pharmacists only), after which we will conduct seminars with the study participants using a patient safety curriculum developed by the World Health Organisation (WHO). Three (3) months later, we will distribute the same pre intervention questionnaire to participants who had responded to the earlier questionnaire and participated in the educational sessions.

This study is the first to be conducted in Kaduna State that explores medication safety and patient safety culture. On completion, it will open up an area of patient safety where not much research has been conducted in Nigeria. We expect that the study findings will offer substantial opportunity for making improvements in healthcare safety and quality.

Background

In recent years, there has been growing concern about patient safety and this is becoming a global problem.[1] It is estimated that 10 million patients worldwide are harmed unnecessarily and suffer from disabling injuries or death each year as a result of unsafe medical practices and care.[2] The Institute of Medicine (IOM) in the United States (US) reported that around 44,000–98,000 patients die each year as a result of medical errors in various hospitals.[3]

The discipline of patient safety has emerged in response to the high burden of avoidable adverse events.[4] The World Health Organisation (WHO) defined patient safety as 'the absence of preventable harm to a patient during the process of health care'.[5] Patient safety has also been defined by the Institute of Medicine as 'freedom from accidental injury'.[5] In the last two decades, patient safety has received a significant amount of attention. The 1999 publication *To Err is Human* by the Institute of Medicine, shed light on preventable medical errors and on the importance of safe medical care, and, since its release, patient safety has become the prominent issue for health care. The IOM suggested that the biggest challenge to moving toward a safer health care system is changing the patient safety culture from one in which individuals are blamed for errors to one in which errors are treated as opportunities to improve the system and prevent harm.[6]

Another key principle for quality and patient safety that has emerged is 'patient-centred care'.[6,7] In its report the IOM suggested that patients and their families should be informed about uncertainties, risks, and treatment choices.[6] It also stressed that safety and quality should be seen from the perspective of the eyes of patients as well.

In 2004, the WHO and its partners launched the World Alliance for Patient Safety in response to patient safety issues, and its goal was to improve patient care worldwide by proposing measures to reduce risks, organising concepts and definitions on patient safety and suggesting that countries pay greater attention to the theme.[8] The WHO has also established the 'WHO Patient Safety Curriculum for Medical Schools' and also the 'WHO multi-professional patient safety curriculum guide'.[9,10] The Guides have the capacity to provide health-care professionals with the underpinning and applied knowledge that will facilitate the incorporation of patient safety principles into their practice, in a wide range of health-care delivery environments and health systems.[11] The Guides target education in the fields of dentistry, medicine, midwifery, nursing and pharmacy, and other related health-care professions.

In low- and middle-income countries, the little evidence available shows there is a deficiency of safety culture and this is compromising patient safety. However, a steadily growing knowledge base indicates the need for improvement on patient safety.[12]

The African Partnerships for Patient Safety was introduced to shape and lead the implementation of the WHO programme focussed on improving patient safety in Africa through the use of hospital partnerships. This is being implemented through a phased approach through establishment of mutually beneficial hospital partnerships. The

initial phase consisted of six hospitals in six African countries (Cameroon, Ethiopia, Malawi, Mali, Senegal and Uganda) and partner hospitals in England and Switzerland. By 2013, five more African countries (Ghana, Mozambique, Rwanda, Tanzania and Zambia) were in the partnership, with five more hospitals in England.[13]

In Nigeria, the overall incidence of adverse drug events (ADEs) is unknown and poorly documented.[14] A study identified a mean prescribing error rate of 28.7% and concluded there was poor compliance with the Nigeria Standard Treatment Guidelines.[15] Furthermore, a large-scale multi-centre study with 2386 participating healthcare providers (HCPs; doctors, nurses and pharmacists) identified a prevalence of self-reported medication errors amongst HCPs in Nigeria of 47%.[16] The study also found that overwork was the most reason for HCPs being error prone (59.2%), only 35.5% of HCPs had ever reported medication error and 33.4% did not think reporting was necessary and suggested that interventions were necessary for knowledge gaps and practice deficiencies.

This present study is based on the premise that medication error is a serious problem in Nigeria, as it is elsewhere in the world. The findings from this study will provide baseline information of current medication safety practices in healthcare facilities in Kaduna State, Nigeria, and explore patient safety culture amongst healthcare professionals. The findings will not only provide a baseline from which to work, they will also help raise patient safety awareness. The study also intends to make a case for the need of national initiatives and support from national healthcare bodies to promote the implementation of medication safety practices.

Aim and objectives

The aim of the study is to explore medication safety practices in healthcare facilities in Kaduna State, Nigeria, which will answer the questions 'What core medication safety practices are present in these healthcare facilities, what are the perspectives of healthcare practitioners on current issues about medication safety and the challenges regarding medication safety and modes of making improvement?'. The objectives of the study are as follows.

- To assess core medication safety practices in the selected healthcare facilities.

- To evaluate patient safety culture of the selected healthcare facilities.
- To explore the factors influencing medication safety practices and medication error reporting.
- To explore the perspectives of patients on their safety in the healthcare facilities.
- To assess the effect of an educational intervention on healthcare providers to promote medication safety.

Methods

This study is being carried out as mixed methods study across four (two tertiary and two secondary) healthcare facilities located in Kaduna State, Nigeria. Kaduna state is the third most populous state in Nigeria, with an estimated population of 8.6 million people as at 2018. There are 1692 healthcare facilities; 40.2% being of the private sector; 3.2% secondary healthcare; 0.3% tertiary healthcare facilities.

The healthcare facilities for this study were selected from the three Senatorial zones of the State. These are:

Zone 1: Ahmadu Bello University Teaching Hospital, Zaria
Zone 2: Barau Dikko Teaching Hospital and Yusuf Dantsoho Memorial Hospital, Kaduna
Zone 3: Patrick Yakowa Hospital, Kafanchan

The choice of these healthcare facilities was based on selection of the largest healthcare facility from each zone. However, two facilities were selected in Zone 2 as it is the zone with the largest population and houses the State capital.

There are three phases to the study. Phase I is a quantitative phase further subdivided into 1a and 1b and was conducted in the four healthcare facilities. Phase II is also subdivided into 2a and 2b. This phase will be conducted in one tertiary facility and one secondary facility. Phase III will be an educational intervention phase and will be conducted in the four facilities.

Phase la: a study to assess the presence of core medication safety practices in the selected healthcare facilities
This phase is a structured questionnaire based interview with heads of pharmacy department of

the four study sites using an adopted question-naire.[17] The questionnaire was developed by Aljadhey *et al.*,[17] based on recommendations of WHO patient safety solutions, the Joint Commission International (JCI), and the Institute for Safe Medication Practices (ISMP).[18–20] The questionnaire contains two sections, with section one asking background questions about the facility and section two containing seven parts with a total of 44 questions. The questions relate to medication safety practices, such as presence of medication safety officer, medication safety committee, availability of a look-alike-sound-alike (LASA) medications list, availability of information technology and availability of drug information resources, amongst other questions.

Prior to data collection, the questionnaire was pre-tested at two non-participating healthcare facilities to ascertain understanding and its local suitability for adoption in Nigeria. The questionnaire was administered in a face-to-face interaction after an appointment had been made with the participants at their convenient time and place. The interview was in English as it is the official language in Nigeria and took approximately 45–60 min to complete. A written consent was obtained from participants prior to the interview.

Phase Ib: a cross-sectional study to assess patient safety culture amongst HCPs in healthcare facilities

This survey study aims to assess patient safety culture in Kaduna State healthcare facilities. The study adopted the Hospital Survey on Patient Safety Culture (HSOPSC) developed by the Agency for Healthcare Research and Quality (AHRQ).[21] It has been used widely in assessing patient safety culture and has also been validated in non-US countries.[22] It is composed of 42 items that measure 12 composites of patient safety culture. Seven of the composites measure patient safety at departmental level and three composites at hospital level. Two composites (frequency of events reported and overall perception of safety), in addition to questions on patient safety grade and number of events reported, are the four outcome variables. The survey will be administered in English as it is the official language in Nigeria. The questionnaire will be distributed to HCPs (doctors, nurses and pharmacists) in the four facilities based on stratified proportionate to size allocation of sample size, followed by a convenience

sampling. The sample size was calculated to be 422 by considering 95% confidence interval (CI), a 5% margin of error, and a 10% contingency for non- response, while assuming that patient safety was scored at 50% by respondents.

The HSOPSC survey is considered to be valid as it had been piloted on 1419 hospital employees from 20 hospitals across the US. The results showed that all 12 dimensions had high levels of reliability (Cronbach's alpha ranging from 0.63 to 0.84).[21] The survey items are measured on a 5-point Likert scale and range from (1) 'Strongly Disagree' to (5) 'Strongly Agree' and take an average of about 15 min to complete. Beside the 12 listed dimensions, the survey includes an item that asks about the number of events reported the past 12 months. Participants are also asked to grade patient safety in their work area on a 5-point Likert scale ranging from 'Excellent' to 'Failing'.

The survey data will be entered into SPSS version 23, where it will take the form of descriptive statistics (frequency of positive response and their percentages) of 12 patient safety culture dimensions measured on three HCP groups from four different facilities. The raw data will be analysed in a number of different ways. Firstly, composite frequencies of positive response will be calculated by grouping the 42 survey items into 12 patient safety culture dimensions. Each dimension includes three or four survey items, which will be used for the calculation of one overall frequency for each dimension. Univariate analyses will be conducted to summarise demographic characteristics of healthcare facilities and respondents. Bivariate analyses [*t* test and analysis of variance (ANOVA)] will be used to examine differences in patient safety culture composites across facilities. Pearson's chi-squared test will be used to examine statistical associations between healthcare facility characteristics, patient safety grade and number of events reported. The tests will be carried out at 5% level of significance.

Phase IIa: a study to explore the factors influencing medication safety practices and medication error reporting

This phase will be conducted as key informant interviews with HCPs (doctors, nurses and pharmacists) working in one tertiary facility and once secondary facility. It aims to explore factors influencing medication safety practices and error

reporting amongst HCPs by exploring the barriers and facilitators. Initial sample will be identified by purposive sampling of participants followed by snowball sampling. Data will be collected until saturation is achieved, that is, when no additional new information is obtained.[23] An interview guide will be developed based on a similar study.[24] Prior to the interview, participants will be informed about the aim of the interview, those who consent will be given further information about the study. The interview will take place at a place convenient for the respondents and will last approximately 20–40 min. Participants will be assured of confidentiality and will be asked for permission for the use of a tape recorder to record the interview session. They will also be assured that their views are of utmost importance, and there are no right or wrong answers. Interviews will be conducted by the principal researcher (BKL) in English, and participants will be given refreshments at the end of the interview. Data will be collected until a point of saturation is reached. After data collection is completed, data will be transcribed and thematic analysis will be conducted.

Phase IIb: a study on perspectives of patients on their safety in the healthcare facilities

This study aims to explore the perspectives of patients on their safety in healthcare facilities. Data will be collected through focus group discussions (FGDs) with patients in one tertiary facility and one secondary facility. There will be separate FGD sessions for female and male patients of each facility, thereby making a total of four FGD sessions. Patients will be those who are admitted in medical wards and are relatively well enough to participate. Participants will be informed about the aim of the FGD and those who consent will be given further information on the study. The FGD will take place at a convenient place for the participants in groups of 6–8 persons and will last for about 60 min. The sessions will all be conducted in the local language, which is Hausa. A topic guide for the FGD will be developed based on a similar study.[24] This includes questions relating to general patient safety, patient's experience with any medication related adverse event, improvement strategies on medicines use, etc. The topic guide will be translated by the principal researcher and also by another member of the research team who is highly proficient in Hausa and also familiar with the conduct of FGDs. All FGD sessions will be audiotaped after obtaining verbal consent from participants. Each session

will be moderated by the principal researcher and another member will serve as the note taker. Data from FGD sessions will be transcribed and thematic analysis will be conducted.

Phase III: an educational intervention using the WHO multi-professional patient safety curriculum guide

This phase will take place in the four healthcare facilities but will be amongst pharmacists only. It will be in the form of a pre- and post-intervention study where a questionnaire (adopted from the WHO patient safety curriculum assessment) will be administered to participants.[10] Total sampling will be targeted with all pharmacy staff with a Bachelor of Pharmacy degree working at the four healthcare facilities at the time of data collection. The questionnaire will consist of a demographic section that asks questions about staff position, level of education, years of experience and whether the participant has ever participated in a patient safety course before. The survey section on participants' perceptions and attitudes contains a total of 23 questions grouped in four domains (Patient safety knowledge; Health-care system safety; Personal influence over safety; and Personal attitudes about safety). For the patient safety knowledge questions, questions will be selected based on the topics considered for this research as the intervention topics.

The educational curriculum will be adopted from WHO Patient Safety Curriculum Guide: multi-professional edition, which contains 11 topics.[10] However, for this study, three topics will be chosen as the educational intervention: Topic 1 (What is Patient Safety), Topic 5 (How we understand and learn from errors to prevent harm) and Topic 11 (Improving medication safety).[10] Handouts will be given to participants immediately after they have completed the pre-intervention survey and then a seminar session will take place to explain the topics further. After 3 months, the same questionnaire will be administered to the participants who participated in the pre-intervention phase. The post-intervention survey will include an additional third section that asks for general feedback concerning the educational intervention.

Data analysis for pre- and post-intervention will be conducted using SPSS software Version 23, where Student's *t* tests will be carried out. The analysis of the pre- and post-intervention data will consist of comparisons of the pre- and

post-intervention average means score of the four domains of the questionnaire. Differences in values for the two time periods will be tested for statistical significance. For the knowledge questions, the measures to assess changes will be the percentages of the relevant questions that each participant answers correctly. These percentages will be calculated for the aggregate of all topics that will be taught. The analysis of these knowledge questions will consist of comparisons of the percentages of correct answers given on the pre- and post-intervention surveys. Differences in values for the two time periods will be tested for statistical significance.

Discussion

The concept of patient safety as a whole, and also medication safety continues to become a matter of growing interest and increasing priority for hospital managers.[24] Safety culture in healthcare settings is usually assessed through quantitative questionnaires based on a combination of the dimensions. Some studies suggest focusing on the unit-level for the study and assessment of safety culture because culture is a local phenomenon, that is, culture often varied between units of a single hospital.[25,26]

Medication safety can be used to describe systematic assessments of HCPs' practices as related to safe use of medicines. Identification and prevention of medication errors is the key component of medication safety. This includes multiple aspects of medication practice and other factors that affect it such as, organisational structure, communication, technologies such as those used for dispensing, and strategies pursued by leadership in cultivating and promoting a culture of safety. Medication safety can thus be said to be the responsibility of all members of the healthcare team.

Over previous years, research has shown that many interventions could decrease the frequency of medication errors. Many of these interventions, particularly in developed countries, include the use of information technology and automation, while others use methods such as involving a pharmacist with the medical team or the application of core practices aimed at preventing ADEs.[27–30] One study suggested that the use of computerised physician order entry reduced the serious medication error rate by 55%,[27] whereas another suggested having a medication safety officer in the hospital may be associated with lower levels of ADEs.[28]

This study has several strengths, amongst which is that it is the first study in Kaduna State to assess presence of medication safety practices and safety culture. The use of a multi-phased mixed-methods research approach will also add substantial strength. The educational intervention will provide an avenue to inform and educate health care workers about patient safety. However, the study is not without some limitations. The number of healthcare facilities sampled to participate in the study, although representing the various zones of the State may still be limited. The convenience sampling technique in phase Ib may also create some bias, although efforts will be made to collect data from all clinical departments of the hospitals.

Author contributions

BKL, UII, BBM, AAA, and SM were actively involved in the study design. BKL prepared the initial manuscript. BKL, UII and SM critically read through and revised the manuscript. All authors have read the manuscript for publication.

Conflict of interest statement

The authors declare that there is no conflict of interest.

Ethical approval and consent to participate

Ethical approval was obtained from the selected healthcare facilities and also from the Ministry for Health and Human Services, Kaduna State (MOH/ADM/744/VOL.1/499). All study participants will be provided with information regarding the study and their consent sought. Consent will be in the form of verbal consent, and in some cases written consent.

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