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Patient-Reported Incident Measure (PRIM) tools for reporting patient safety incidents: protocol for a scoping review

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ABSTRACT

Introduction Patient safety incidents during healthcare cause a high burden and mortality, but many go unreported. Involving patients and caregivers in the identification and reporting of safety incidents would add value to the current incident reporting systems used by health professionals. Identifying and analysing patient safety incidents is essential to prevent future events, allowing organisations to apply a learning-from-error approach and to implement improvement plans. Patient-Reported Incident Measures are tools for patients and caregivers to report safety issues related to their healthcare. In accordance with WHO's patient safety taxonomy, the term patient safety incidents is used throughout this protocol to encompass events that do and do not reach the patient, including what are commonly referred to as near misses and adverse events. We aim to identify and describe the published literature about tools for patients or caregivers to report patient safety incidents in healthcare.

Methods and analysis We will conduct a scoping review. We have developed inclusion criteria using the PCC (population, concept and context) format, where population includes adult patients or caregivers; concept refers to documents describing formal tools used to report patient safety incidents; and context includes any healthcare setting, such as hospitals or mental health centres, during or immediately after care. The scoping review will be reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews guidelines. Evidence sources include primary research, systematic reviews, meta-analyses, conference abstracts, letters, guidelines, as well as policy documents, reports, blogs and websites, without language restriction. An initial database search in Medline, Embase, CINAHL, and Cochrane Library from database inception up to June 2023 identified 4500 initial citations, of which 4103 were selected for evaluation after duplicates were removed. We will supplement the search by checking the reference lists of included studies for additional sources of evidence and an additional search in Google to identify non-peer-reviewed documents. This initial search will be updated before completing the review. We will use a self-created data collection form for data extraction and perform a narrative synthesis to integrate and summarise the review findings. We will describe the general characteristics of the tool: setting, scope, format, content, type of patient safety incident and severity, the moment of notification, relation to patient safety incident reporting and learning systems, development process, testing, validation, or piloting, among other characteristics. As a result of this scoping review, we intend to provide an index of patient/caregiver-reported safety notification tools and a list of descriptive or evaluation studies.

Ethics and dissemination We will only use published data. Approval from the human research ethics committee is not required. The results of this scoping review will be submitted for publication in an international peer-reviewed journal and scientific meetings. Findings will also be disseminated through digital science platforms and academic social media.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The scoping review will map the existing literature on tools that allow patients and caregivers to report patient safety incidents detected while receiving healthcare.
⇒ The implementation of a comprehensive, multi-database search strategy improves the study's overall coverage and robustness.
⇒ Inclusion of studies irrespective of language strengthens the review's comprehensiveness and external validity.
⇒ Despite planned efforts to include grey literature, it is possible that some relevant non-indexed sources will not be captured.
⇒ The scoping review will be reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews guidelines.

INTRODUCTION

Patient safety incidents are events or circumstances stemming from the processes of healthcare that resulted or could have resulted in unnecessary harm to a patient.[1] In the spectrum of patient safety incidents,

on one side, near misses are those that did not reach the patient (eg, detecting that hand hygiene has not been performed before manipulating an intravenous line with no infectious disease as consequence). On the other side, adverse events are defined as harm caused to the patient associated with care or services provided, such as operating on the wrong limb.[1] There are hundreds of near misses for each detected adverse event.[2] In this protocol, we use the term patient safety incidents in accordance with the WHO's taxonomy,[1] encompassing both events that do and do not reach the patient. Unsafe care is responsible for an important burden of death and disability worldwide. It is estimated that 1 in 10 patients has an adverse event during hospitalisation in high-income countries.[3] This problem is even more concerning in low-income and middle-income countries, where 134 million adverse events a year take place in hospitals, contributing to around 2.6 million deaths a year.[4]

Identifying and analysing patient safety incidents is essential to prevent future events, allowing organisations to apply a learning-from-error approach and to implement improvement plans. Even though most health systems and organisations have reporting systems, the most common format is based on health professional reporting, and good reporting rates are a constant challenge.[5]

Patients, along with their families and caregivers, are the most interested in preventing safety incidents, as they are the first and most affected when such incidents occur. Evidence suggests that they can recognise safety issues related to healthcare delivery.[6–9] In relation to this fact, in its Global Patient Safety Action Plan 2021–2030, the WHO promotes patients' and caregivers' engagement and empowerment to help and support safer healthcare.[10] The above mentioned plan recommends allowing patients and caregivers to escalate concerns within a healthcare organisation and actively submit reports to patient safety reporting systems.

Patient-Reported Incident Measures (PRIMs) enable patients and caregivers to report safety concerns about their care to healthcare providers.[11 12]

Initiatives to involve patients and caregivers in identifying and reporting safety incidents have been published in primary and secondary care,[13–15] but the information is scattered. Knowing and contrasting these initiatives and their characteristics would facilitate their implementation in health systems. Tool characteristics that are of interest include the scope, types of incidents included, whether the tool has been tested or validated, and their connection to patient safety incident reporting and learning systems.[16] The objective of this scoping review is to map existing PRIM tools that allow patients or caregivers to report patient safety incidents in healthcare settings.

METHODS AND ANALYSIS

This article describes the protocol for a scoping review that is currently underway. The proposed scoping review will be conducted in accordance with the Joanna Briggs Institute (JBI) methodology for scoping reviews,[17] and reported in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR).[18] For this scoping review, the term PRIMs is defined broadly to include any direct input from patients or caregivers, whether non-standardised or gathered with a structured questionnaire. We adopted the following WHO's definition for 'patient safety'[1]: 'the reduction of risk of unnecessary harm associated with health care to an acceptable minimum', and for patient safety incident as 'an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient'. For other definitions and taxonomy for patient safety, we will also apply the WHO Conceptual Framework for the International Classification for Patient Safety.[1]

The main research question is: What PRIMs are available for patients or caregivers to report patient safety incidents in healthcare settings?

Eligibility criteria

We developed inclusion criteria according to the PPC format for scoping reviews, where population (P) is combined with concept (C) and context (C).[18]

1. Population: This scoping review's population consists of patients (adults) or caregivers, including caregivers reporting on behalf of children. Tools designed specifically for children to report incidents are excluded.
2. Concept: We will include documents describing the development, implementation or validation of a tool (ie, questionnaire, interview) to be used systematically by patients (adults) or caregivers to report patient safety incidents. We are interested in the scope of the tool (eg, setting), format (eg, paper or digital), content (ie, type of incident), and the development and validation process, if applicable. Reports about initiatives that do not employ systematically a formal assessment tool, such as case reports, case series or testimonies, will be excluded.
3. Context: Patient safety incident reporting includes patient safety incidents occurring during healthcare services provided in any healthcare facility (ie, hospital, primary care centre, mental health centre) and at any setting (emergency department, hospitalisation, long-term stay). Reporting may take place either during or after receiving healthcare services (up to 30 days after).
4. Types of evidence sources:
   - Research sources: All methodological studies that describe or assess tools: primary research, systematic reviews, or meta-analyses of quantitative or qualitative studies, conference abstracts, letters, and guidelines.
   - Non-research sources: Reports, policy documents, websites or blogs that describe or assess questionnaires.

Information sources and search strategy

We planned to conduct a comprehensive search using a combination of Medical Subject Headings (MeSH) and

free-text terms to identify research and non-research sources of evidence. Relevant MeSH terms such as 'Self Report' and 'Patient Safety' and related free-text terms ('Patient-Report', 'Patient self-report', 'Safety Reporting', 'Patient participation' and 'Patient safety') have been used. To capture incidents related to the topic, key terms such as 'near miss', 'incident', 'adverse', 'risk', 'harm', 'error' and 'hazard' have been considered. An expert information specialist reviewed the search strategy, which was then peer-reviewed using the Peer Review of Electronic Search Strategies checklist.[19] The search strategy for Medline is provided in online supplemental material 1. The strategy was further adapted to other databases. We will report each database, the date of search and the search strategy for all databases and registers. The search will be updated before completing the review. If additional keywords, sources, and potentially applicable search terms are discovered and incorporated into the search strategy during the search process, they will be reported and detailed within the review results. We will supplement the search by checking the reference lists of included studies for additional sources of evidence. We will not carry out a hand search of the literature. We will search Google using the advanced search options and the private/incognito window mode to avoid automatic settings and cookies that may bias the search. We will limit the search to the first 100 entries. We will not apply any filter by date or language in the search. We will use reliable automated translation tools (eg, DeepL) as needed to assess eligibility and extract relevant data.

The initial search of databases (Medline, Embase, Cumulative Index to Nursing and Allied Health Literature (CINAHL) and Cochrane Library) from database inception up to June 2023 identified 4500 citations. We exported the results into EndNote, and after removing duplicates, 4103 citations were included for screening. The following steps in the review process will be to conclude the Google search and proceed with the screening phase, as detailed below.

Evidence screening and selection

We will develop an instructions manual based on the review protocol explaining the criteria and process of citation screening, selection and data extraction. Citation screening will be done in duplicate by pairs of researchers in Step 1—Titles and abstracts screening, and Step 2—Full text screening. In Step 1, each researcher will independently screen citations and decide whether they are eligible based on the review protocol. A third researcher will discuss discrepancies. Citations selected in Step 1 will be searched for full text to carry out Step 2, where every full text will be reviewed in duplicate by pairs of researchers, applying the eligibility criteria. Again, discrepancies will be discussed by a third researcher, and the reason for exclusion will be registered. If the agreement between a couple of researchers is less than 80%, we will conduct a second training session for the two researchers. Every researcher will do the citation screening independently using a separate Excel file. Once Step 2 is completed, one of the review authors will convert the list of citations into a list of studies, grouping those related to the same study under the same study ID. Pairs of researchers will review the study list again to conclude the study selection process.

Data extraction and charting

Data from studies will be extracted from the full text in duplicate, by pairs of reviewers, using a self-created data collection form (online supplemental material 2). We will pilot the form with the first five results from the study selection and make revisions as needed. The review team will be trained for data extraction with the help of the manual. A third researcher will discuss discrepancies in data extraction. If the agreement between a couple of researchers is less than 80%, we will conduct a second training session for the two researchers.

We will contact the study authors for additional data if some information is missing in the full text of selected studies. The authors' list and contact data will be reported within the review results.

The search, screening and selection results will be reported using a PRISMA flow diagram.

Critical appraisal of individual sources of evidence

Given its objective of identifying and describing the published literature about tools for patient-reported or caregiver-reported incidents on patient safety, we will not carry out a critical appraisal or risk of bias assessment of evidence sources.

Data analysis, collating, summarising and reporting the results

We will describe the general characteristics of the tool: type (eg, questionnaire, interview, etc), authoring (country, type of institution, funding), setting (emergency, hospital use, ambulatory care, primary care, long-term facilities), scope (patient/caregivers), type of patient safety incident (near-misses, incidents or adverse events) and severity, the moment of notification (on the spot, at discharge, after discharge), relation to patient safety incident reporting and learning systems, format (paper or web-based), content (eg, related to medication, identification, etc), development process, and whether they have been tested, validated, or piloted in clinical practice, and how (validity and reliability). Results will be shown in charts and visual summaries (bubble plots). We will also stratify them by setting and type of incident. Any assumptions or simplifications made during data synthesis will be reported.

As a result of this scoping review, we intend to provide an index of patient/caregiver-reported safety notification tools and a list of descriptive or evaluation studies (eg, development, validation, replication, implementation, systematic review).

Patient and public involvement

None.

ETHICS AND DISSEMINATION

We will only use published data. Approval from a human research ethics committee is not required. The results of

this scoping review will be submitted for publication in an international peer-reviewed journal and at scientific meetings. Findings will also be disseminated through digital science platforms and academic social media.

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