



Background Paper

Developing a patient safety incident classification system for primary care. A literature review and Delphi-survey by the LINNEAUS collaboration on patient safety in primary care

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KEY MESSAGE:

- Classification systems are key tools in the analysis of patient safety incidents.
- A patient safety incident classification system that has relevance for primary care has been made available by the LINNEAUS collaboration.

ABSTRACT

Background: Despite awareness that comparative analysis of patient safety data from several data sources would promote risk reduction, there has been little effort to establish an incident classification system that is generally applicable to patient safety data in European primary care.

Objective: To describe the development of a patient safety incident classification system for primary care.

Methods: A systematic review was followed by an expert group discussion and a modified Delphi survey, to provide consensus statements.

Results: We developed a classification system providing a mechanism for classifying patient safety incidents across Europe, taking into account the varying organizational arrangements that exist for primary care. It takes into account organizational processes and outcomes related to patient safety incidents and can supplement existing classification systems.

Conclusion: Classification systems are key tools in the analysis of patient safety incidents. A system that has relevance for primary care is now available.

Keywords: Patient safety, classification, taxonomy, medical error, primary healthcare, LINNEAUS collaboration

INTRODUCTION

Since the release of the Institute of Medicine (IOM) report ‘To err is human: Building a safer health system’ in 1999, the issue of patient safety has received considerable attention in healthcare research throughout the world (1). This is reflected in the increasing number of patient safety-related publications over the last decade (2).

To bring about improvements in patient safety, the National Patient Safety Agency (NPSA) has identified seven

crucial steps as a guide to good practice in improving patient safety in primary care (3). Step three emphasizes the necessity to describe and analyse things that may go wrong, as well as to develop systems and processes for this purpose. A classification system is an important descriptive tool and a first step towards an appropriate analysis of patient safety incidents. It categorizes a patient safety incident into distinct dimensions, which describe well-defined aspects of the incident such as type of the

incident or its impact on patients and health care provider. Each dimension is populated with classes and subclasses to specify the aspect in question.

Classification systems allow the integration of patient safety data from numerous sources such as error reporting, chart reviews, claims data, routine data, and survey data from various settings. They are thus an important tool for patient safety research, and they promote the identification of weaknesses and faulty processes in increasingly complex healthcare systems. An example of the value of classification systems is provided by Smits et al. (4), who used the Eindhoven classification model, which is part of the root cause analysis tool PRISMA-medical, to analyse unintended events in emergency departments. They identified human, organizational and technical factors to be the dominant underlying causes of adverse events.

A review conducted by the World Health Organization (WHO) in 2003 provided an overview of the status of patient safety incident classification systems in healthcare concluded that existing classification systems were underdeveloped and focused primarily on medication errors (5). Their review also concluded that most classification systems in use had theoretical and methodological flaws, their validity was inadequate, and their reliability was not reported upon.

The WHO review also identified the lack of classification systems appropriate for the primary care setting. Although the vast majority of patients receive healthcare in an outpatient setting, patient safety research is conducted in hospitals. However, results from secondary care cannot easily be extrapolated to primary care owing to differences in the nature of the respective environments and patients' characteristics. The settings differ in types of incidents, provider–patient relationships, organizational structures, and regulatory and legislative requirements. The outpatient setting also presents greater challenges in terms of information transfer between parties involved (6). These factors all need to be considered when developing and using classification systems.

Following their review 10 years ago, the WHO developed the International Classification of Patient Safety (ICPS), although reports on its use in primary care have not yet been published. Several studies on patient safety incidents in primary care have been performed that applied various classification systems. However, an international commonly used system did not exist.

We, therefore, conducted a systematic review to identify existing patient safety incident classification systems that were developed either for the use in primary care or health care in general and compared their prominent features. Based on this review, we developed recommendations for a classification system, which is relevant to the needs of primary care, and subsequently used consensus techniques to develop a classification

system for patient safety incidents in this setting. This paper represents an overarching summary of the classification development process.

METHODS

We used a mixed-methods approach, comprising a literature search, expert group discussions and a Delphi survey, in order to develop a classification system for patient safety incidents. A detailed description of the development process and the resulting patient safety incident classification for primary Care will be published elsewhere.

Literature review

Search strategy. We systematically searched for published systems to classify patient safety incidents. Articles eligible for inclusion were required to address the development, description, implementation, application or testing of a classification system for safety-related incidents. We searched PubMed, Cinahl and Embase up to 2010, using blocks of search terms covering a range of synonyms for medical error and classification (details of the literature search will be published elsewhere). In 2012, we conducted an update of the previous review using the same search terms.

Data extraction. Publications were analysed with respect to the followings questions: Which principles were followed in the development of the tools? What settings were they developed for? What was the object of classification? Which main classes were used? How were the classes populated? Were class definitions and manuals provided? Was information available on whether the systems have been put into practice and/or tested?

Expert advisory group on recommendations on content and structure of a classification system for patient safety incidents

In February 2010, we invited a panel of international (New Zealand, UK, Poland and Germany) experts in classification and patient safety in primary care to discuss and define desirable aspects of classification systems in general, and for primary care in particular. The results obtained from the literature review were used to provide a basis for this discussion.

The resulting list of propositions was forwarded to additional experts in classification from The World Organization of National Colleges, Academies and Academic Associations of General Practitioners/Family Physicians (Wonca) classification group and the WHO International Classification for Patient Safety Group (ICPS). They were asked to critically assess the recommendations with regard to completeness and in terms of structure and content (e.g. what aspects are missing, what wording or definitions would they recommend).

Their input was fed back to the expert advisory group, and the recommendations were adapted accordingly.

Delphi survey

Using the recommendations, the authors developed a draft of an incident classification system that is suitable for use in primary care. We then conducted an online Delphi survey with an international panel of 36 experts to discuss their recommendations as well as the drafted classification system to identify its necessary characteristics. The panellists were identified during the initial literature search; i.e. they had published articles regarding the development, description, implementation, application or testing of a classification system for safety-related incidents.

The central question was: Which dimensions and classes should be included in such a classification system for primary care and how should they be defined? Panellists were provided the experts' recommendations and an initial draft of the classification system.

We conducted the survey in two rounds. Round 1 comprised two sections and it was used as a basis to develop the final classification system. The first section asked for the level of agreement with the recommendations on content and structure, and the second section addressed the assessment and opinions on the first draft of an incident classification system. The latter section included questions relating to the adequacy and relevance of dimensions, classes and subclasses, as well as to the appropriateness of definitions of dimensions and classes. Round two of the survey was conducted with respondents to the first round. Then panellists were provided an adapted version of the classification system. The questionnaire included questions from the second section of round one, as well as additional questions resulting from amendments to the classification system draft.

RESULTS

Current classification systems for primary care

The initial search identified more than 60 000 articles, but after adjusting for duplication, relevance and availability, and an update of the search in 2012, 70 articles reporting on 20 classification systems remained. Six of the 20 systems were specifically developed for primary care, family medicine or general practice; whereas eight classifications had no limitations in terms of the setting. The remaining six systems were dedicated to intensive care, paediatrics, nursing errors and medications error, with one system developed for military aviation.

The classification systems can be divided into those that were developed empirically (nine systems) and those that were based on a theoretical framework or

model (four systems). However, hybrid forms also exist (six systems). For one system, no information was available. All systems provide a definition of the event to be classified, but only nine provide definitions or at least descriptions of the categories contained within them. Instructions for use are provided for only three of the 20 classification systems. Eight classifications had been tested for reliability.

Expert advisory group

First, the expert advisory group defined the object of the classificatory process as follows: 'A patient safety incident in primary care is any unintended event or hazardous condition resulting from the process of care, rather than the patient's underlying disease, that led or could have led to unintended health consequences for the patient.' It was further agreed that the term 'error' should be avoided, because it implies that someone has made a mistake and neglects underlying systemic weaknesses.

Based on the findings of the systematic review, the International expert group compiled a list of preconditions for a useful patient safety incident classification for primary care (PSIC-PC). These recommendations were followed when designing the draft of an incident classification system.

Delphi survey

In this paper, we report the results of round two of the Delphi survey. A panel of 36 experts from 16 countries responded to the second round of the online questionnaire. The members of the panel were experts in a variety of fields, including development and/or management of patient safety reporting systems, classification and/or taxonomy, health policy and others. They represented different professional backgrounds of healthcare, such as primary care, public health, administrative services and general practice. The participants had worked for an average of nine years in the field of patient safety.

More than two-thirds of the participants in the survey agreed or strongly agreed with the definition of a patient safety incident. They also largely agreed with the expert advisory group's recommendations.

A patient safety incident classification for primary care (PSIC-PC)

The agreed incident classification system covered the following five dimensions:

- type of incident,
- contributing/causal factors to the incident,
- outcome of the incident,
- details of the patient safety incident, and
- incident prevention strategies for future events.

Each of the five dimensions included a number of classes and sub-classes, which were defined to ensure it was clear to what they referred. An introduction to the classification explained its purpose, structure and application.

More than 90% of respondents to the second round of the survey believed that the dimensions were sufficient to identify the constitutive aspects of patient safety incidents. On average, more than 90% of respondents rated the proposed five dimensions as relevant or highly relevant. More than two-thirds stated the proposed classes were sufficient to identify the constitutive aspects of the dimension concerned.

The patient safety incident classification for primary care is available under the following link: http://www.linneaus-pc.eu/Tools_Resources.html

DISCUSSION

We developed a classification system through the consensus views of an international expert panel that aims to overcome some of the shortfalls of current systems, e.g. by providing the definition of dimensions and classes. The system was designed to be independent of the source of data, covering for instance incident reporting and audits of medical records. The resulting classification system contains the common dimensions of most of the identified classifications intended for use in primary care and healthcare, in general.

Strengths and limitations

The classification system takes into account the different organizations and professions that are involved in a care episode in the setting. In this manner, the resulting PSIC-PC is comprehensive by covering all relevant dimensions that are required for learning purposes, in particular.

The literature search was limited to publications in the English and German language, and, therefore, eligible articles could have been missed. Since the system has not yet been evaluated or pre-tested, we cannot provide

information on its feasibility and validity. This task remains for future research.

CONCLUSION

The PSIC-PC that we have described is a classification system for patient safety incidents that goes beyond existing classification systems for primary care and healthcare, in general. The classification system offers researchers and practitioners the opportunity to compare and learn from patient safety incidents in the primary care setting both within and between countries.

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