Development of a theoretical framework of factors affecting patient safety incident reporting: a theoretical review of the literature

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ABSTRACT

Objectives The development and implementation of incident reporting systems within healthcare continues to be a fundamental strategy to reduce preventable patient harm and improve the quality and safety of healthcare. We sought to identify factors contributing to patient safety incident reporting.

Design To facilitate improvements in incident reporting, a theoretical framework, encompassing factors that act as barriers and enablers of reporting, was developed. Embase, Ovid MEDLINE(R) and PsycINFO were searched to identify relevant articles published between January 1980 and May 2014. A comprehensive search strategy including MeSH terms and keywords was developed to identify relevant articles. Data were extracted by three independent researchers; to ensure the accuracy of data extraction, all studies eligible for inclusion were rescreened by two reviewers.

Results The literature search identified 3049 potentially eligible articles; of these, 110 articles, including >29 726 participants, met the inclusion criteria. In total, 748 barriers were identified (frequency count) across the 110 articles. In comparison, 372 facilitators to incident reporting and 118 negative cases were identified. The top two barriers cited were fear of adverse consequences (161, representing 21.52% of barriers) and process and systems of reporting (110, representing 14.71% of barriers). In comparison, the top two facilitators were fear of adverse consequences (161, representing 21.52% of facilitators) and process and systems of reporting (110, representing 14.71% of facilitators). In comparison, the top two barriers cited were fear of adverse consequences (161, representing 21.52% of barriers) and process and systems of reporting (110, representing 14.71% of barriers). In comparison, the top two facilitators were fear of adverse consequences (161, representing 21.52% of facilitators) and process and systems of reporting (110, representing 14.71% of facilitators).

Conclusion A wide range of factors contributing to engagement in incident reporting exist. Efforts that address the current tendency to under-report must consider the full range of factors in order to develop interventions as well as a strategic policy approach for improvement.

BACKGROUND

The development and implementation of incident reporting systems within healthcare continues to be a fundamental strategy to reduce preventable patient harm and improve the quality and safety of healthcare on a local, regional and national basis.1,2 Although coverage and sophistication vary widely, incident reporting systems have now been in place for more than a decade in a number of countries.3

A key factor that compromises the ability of incident reporting systems to improve patient safety is under-reporting. In the USA, it is estimated that 50%–96% of incidents are not reported.4–5 Failure to report patient safety incidents significantly hinders the underlying goals of incident reporting systems; low levels of reporting make it difficult at best to identify and prioritise patient safety risks and hamper learning from such incidents and ultimately improvements in patient safety. While debate continues to exist regarding whether all patient safety incidents should be reported,6,7 it is extremely important to understand the factors that act as barriers and facilitators to incident reporting so that ‘sufficient’ levels of reporting exist to facilitate learning and improvement.

A number of studies exploring barriers and facilitators to incident reporting have been conducted.8–11 In addition, a number
of literature reviews to identify barriers and facilitators to incident reporting have been published.\textsuperscript{12-14} Although previous work has made a valuable contribution to our understanding of factors affecting incident reporting, previous work has been limited in scope (eg, focusing on the psychological factors affecting incident reporting;\textsuperscript{14} focusing on perceived barriers influencing incident reporting by nurses;\textsuperscript{13} factors affecting reporting of incidents related to medical devices and other healthcare technologies).\textsuperscript{12} As such, to date, there has been no definitive synthesis and evaluation of the factors that prevent or promote reporting.

The primary aim of this theoretical review was to systematically identify factors affecting patient safety incident reporting. The secondary aims were, first, to develop a theoretical framework of factors acting as barriers and facilitators to incident reporting to guide implementation of interventions to increase engagement, and, second, to determine the prevalence of factors to guide the development of interventions and policies to improve incident reporting.

METHODS

Theoretical review

A theoretical review was conducted as the overarching goal of the review was to build explanation of factors affecting incident reporting. In line with a theoretical review, both quantitative and qualitative data were eligible for inclusion and interpretive methods were used to synthesise findings.

Study searches and selection

A systematic search strategy was developed and an electronic search was carried out in three databases: Embase, Ovid MEDLINE(R) and PsycINFO. The last search was conducted on 29 May 2014; while the last search was conducted 3 years ago, this reflects the sheer volume of articles that were included in this review. Search terms included those related to patient safety incidents, incident reporting systems, and barriers and facilitators to engagement in reporting (see table 1 for full search terms). Time and language of publications was restricted from 1980 and to English language.

Eligibility criteria

Inclusion criteria

1. Studies reporting factors influencing the likelihood of incident report engagement in any healthcare setting (eg, primary and secondary healthcare) and employing any study design (eg, qualitative, quantitative, mixed methods).

Exclusion criteria

1. Studies reporting aspects of incident reporting systems and/or incident reporting perceived positively and/or negatively by healthcare professionals (HCPs)
without data relating perceptions to incident reporting engagement.

2. Studies reporting data relating to disclosure of patient safety incidents to patients or their families (a systematic review of the literature on patient/family disclosure has previously been published).

3. Studies reporting data relating to the effectiveness of interventions to improve incident reporting (a systematic review of the literature on the effectiveness of interventions to increase clinical incident reporting in healthcare has previously been published).

4. Studies reporting statistical models where the impact of individual barriers and facilitators to engagement in incident reporting was unable to be determined.

The eligibility criteria were developed to maintain a focus on factors having a direct impact on incident reporting engagement rather than simply identifying and listing factors of incident reporting which were perceived positively or negatively by HCPs. Identifying elements of incident reporting perceived positively or negatively by HCPs does not equate to identifying factors that have an impact on reporting behaviour. In such studies, it is not possible to determine the impact on reporting behaviour—the primary focus of this review.

Data extraction
After the removal of duplicates, two authors (SA and LH) independently reviewed all articles on the basis of the titles and abstracts. Three authors (SA, LH and TS) reviewed the articles at full-text stage. Data were extracted using an extraction template. The following data were extracted: first author’s name, year of publication, country, study design, study population, sample size and factors that decrease (barriers), increase (facilitators) or were neither a barrier nor facilitator to engagement in incident reporting (negative cases).

To ensure the accuracy of data extraction, all studies eligible for inclusion were rescreened by two reviewers (SA and LH).

Quality assessment
Many assessment tools and checklists have been developed to appraise the quality and susceptibility to bias of studies (eg, the Cochrane Collaboration’s tool for assessing risk of bias in randomised trials; AMSTAR tool to assess the methodological quality of systematic reviews; tools to assess the quality of qualitative research studies). The decision not to assess the quality of studies was made for a number of reasons. First, the large heterogeneity of study designs would have made comparisons between study designs difficult at best. Second, quality appraisal is not considered necessary for theoretical reviews. Third, it has been argued that it is important, but difficult, to distinguish between ‘quality of reporting’ and the ‘quality of a study’. As such, articles were not excluded from the current review based on ‘quality’ nor was weight assigned to studies based on quality.

Data analysis and initial theoretical framework development
A grounded theory approach was used to guide the development of the theoretical framework. Grounded theory is associated with the discovery of theory from data systematically obtained from social research. It has been identified as a method where thorough and theoretically relevant analysis of a topic can be reached, specifically within literature reviews. In light of this, a three-stage approach was undertaken to develop a theory of factors contributing to engagement in patient safety incident reporting. The first stage, coding, includes identifying parts of the data that relate the phenomena in question (in this case, incident reporting). During this stage, known as open coding in the grounded theory literature, three authors (SA, LH and TS) read and re-read each paper and identified sections of the paper that were relevant to the research question. Initial concepts developed from these were noted down at this stage; in some cases, these were consistent with pre-existing literature (eg, in the case of a standardised scale), but in others allowed for unseen insights to develop across the data corpus (eg, in qualitative studies). In the second stage, conceptualising or axial coding, focused on grouping together the initial codes where there were relationships to form higher-order categories. These were given names. Stage 3, categorising, or selective coding focused on linking together similar higher-order categories that contained similar concepts which could underpin the reasoning behind the way that the phenomena (in this case, incident reporting) could be explained. Figure 1 displays an example of how these stages were applied.

Engagement in these three stages allowed constant comparison between the articles in the data set to be performed until a theoretical framework was confirmed.

The final theoretical framework was reviewed by another member of the research team (NS) and feedback regarding the category descriptors was incorporated. The final theoretical framework of factors contributing to patient safety incident reporting engagement is displayed in table 2.

The theoretical framework developed was used to organise the identification of factors found to affect incident reporting and to quantify their prevalence. This approach is consistent with existing frameworks in the patient safety literature. For example, Lawton et al employed a similar approach to quantify the prevalence of factors contributing to patient safety incidents in hospital settings.

Patient and public involvement
No patients were involved in setting the research question or the outcome measures, nor were they involved in the design and implementation of the study. We do not anticipate patients and the public being involved in the dissemination of the work.

Findings
The search identified 5335 records. After duplicates and limits were applied (English language, date restrictions
1980–May 2014), 3049 records were considered for inclusion. Of these 3049 records, 2700 were excluded based on title and abstract screening. A total of 349 articles were considered potentially relevant and were assessed at full-text by two researchers (kappa 0.70, p<0.001). Of 349 publications, 33 were not obtainable (requested through the British Library), leaving 314 articles assessed at full-text stage. From these, 80 articles met inclusion criteria.

The reference lists of all included articles were screened for potentially relevant publications, resulting in a further 30 articles that met the inclusion criteria. A total of 110 articles, including >29 726 participants, were included in the final review (Figure 2). The total number of participants per study ranged from 8 to 2185 (mean=285.83; median: 134.00). Six studies did not report sample size, thus the sample size calculations represented above are based on 104 articles. See online supplementary table 1 for full data extraction.

**Study characteristics**

**Empirical study types and design**

In total, 110 articles were included; these consisted of 76 quantitative studies (including 72 questionnaire-based studies, 1 secondary analysis of data study, 1 case control study, 1 descriptive study and 1 cohort study), 21 qualitative studies (including 11 interview-based studies and 10 focus group studies) and 13 mixed-methods studies (1 semistructured interview and documentary analysis-based study; 1 semistructured interview and retrospective review of error reports-based study; 2 semistructured interview and questionnaire-based studies; 3 focus group and questionnaire-based studies; 1 semistructured and structured interview-based study; 1 interview, focus group and analysis of event reports-based study; 1 focus group and semistructured interview-based study; 1 retrospective analysis of routinely collected data and questionnaire-based study; 2 focus groups, interview and questionnaire-based studies).

**Countries**

The review encompassed research spanning 4 continents and >20 countries. The four countries contributing the most studies were the USA (n=33), the UK (n=24), Australia (n=8) and Canada (n=8), table 3.

**Year of publication**

A steady increase in articles was evident over decades: 1980s (n=1), 1990s (n=12), 2000s (n=58), and 2010–May 2014 (n=39). This increase is likely to reflect the growing integration of incident reporting systems in healthcare systems worldwide and the increasing realisation that HCPs’ engagement in incident reporting is far from ideal.

The frequency of barriers and facilitators to incident reporting across the 110 articles was calculated and rank ordered across the data (Figure 3). Where contributing factors were found not to be barriers or facilitators to incident reporting (eg, if fear was found not to be a...
### Table 2 Theoretical framework of factors determining engagement in patient safety incident reporting

| Category                      | Descriptions and examples                                                                                                                                                                                                 |
|-------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Organisational                | Organisational values, beliefs and policies around incident reporting. This also encompasses any organisational factor which may act as a barrier or facilitator to reporting behaviour, such as structure (eg, size of hospital) and organisational culture. |
| Work environment              | Features of the work environment that act as barriers or facilitators to engagement in incident reporting. Examples of such factors include level of activity, staffing levels and visual prompts.                                      |
| Process and systems of reporting | Any characteristics or features of the reporting system/process which enables or hinders incident reporting. This includes the complexity of the reporting system, the level of information required and the mode of incident reporting (eg, paper based or electronic). |
| Team factors                  | Any factor related to the functioning of different professionals within a group which influences incident reporting behaviour. For example, support and encouragement by team members to report incidents, and levels of teamwork and communication. |
| Knowledge and skills          | The acquisition and development of knowledge and skills that enables incident reporting. This includes participation in specific (eg, form completion) and general (eg, identifying which incidents warrant reporting) training/educational activities. |
| Individual HCP characteristics | Characteristics of the HCP that may contribute in some way to engagement in incident reporting. Examples of such factors include seniority, personality and attitudes.                                                                 |
| Professional ethics           | The accepted standards of personal and professional behaviour, values and guiding principles that promote incident reporting. For example, the adoption of sound and consistent ethical practices, such as duty of care. |
| Fear of adverse consequences  | Any unpleasant emotion (eg, guilt) or outcome (eg, litigation) associated with individual HCPs’ incident reporting behaviour. A reduction in the likelihood of experiencing fear (eg, the existence of a non-punitive policy) results in increased incident reporting participation. |
| Incident characteristics      | Characteristics of the patient safety incident which may make HCPs more or less likely to report. These include frequency of error, level of harm and the cause of error.                                                        |

HCP, healthcare professional.
significant predictor of decreased or increased incident reporting), these were counted as negative cases. These negative cases were included to provide a more complete view of the data, and to prevent reporting bias.

When the same barrier, facilitator or negative case (eg, fear of adverse consequences) was mentioned more than once within an article, this was reflected in the frequency data presented. In total, 748 barriers to incident reporting were identified (frequency count) compared with 372 facilitators. A total of 118 negative cases were identified. The top two barriers cited were fear of adverse consequences (161, representing 21.52% of barriers) and process and systems of reporting (110, representing 14.71% of barriers). In comparison, the top two facilitators were organisational (97, representing 26.08% of facilitators) and process and systems of reporting (75, representing 20.16% of facilitators). These results illustrate that the factors identified in this review of the literature can act as both a barrier and a facilitator to incident reporting systems depending on context; for example, process and systems of reporting was found to be the second most frequently cited barrier, as well as the second most frequently cited facilitator to incident reporting engagement. While this may initially appear contradictory, when considering the complexity/simplicity of reporting it was found that highly complex incident reporting processes and systems were a barrier to incident reporting, whereas simple processes and systems were found to be a facilitator.

**Figure 2** Flow diagram of the theoretical literature review process.

**Frequency of barriers to patient safety incident reporting**

Barriers to incident reporting were mentioned 748 times across the 110 articles (see online supplementary table 2). The three most frequently mentioned barriers to incident reporting included fear of adverse consequences (161/748), process and systems of reporting (110/748) and incident characteristics (92/748).

**Fear of adverse consequences**

Fear of adverse consequences, as a barrier, was mentioned 161 times and included a general fear of adverse consequences associated with incident reporting (51/161),8 10 11 27 31 33 39 41 42 44 45 47 48 51–53 59–61 63 64 69 71 72 76 79 87 94 98 102 108 109 114 116 118 120 122 126 fear of litigation (30/161),8–11 24 27 30 32 35 37–40 44 47 56 67 70 77 80 81 84 86 92 98 108 109 116 119 129 and
Table 3  Frequency of articles by country

| Country       | Count (%)       |
|---------------|-----------------|
| USA           | 33 (30.00)      |
| UK            | 24 (21.82)      |
| Australia     | 8 (7.27)        |
| Canada        | 8 (7.27)        |
| Taiwan        | 4 (3.64)        |
| Netherlands   | 4 (3.64)        |
| Saudi Arabia  | 4 (3.64)        |
| International | 4 (3.64)        |
| Israel        | 2 (1.82)        |
| Japan         | 2 (1.82)        |
| New Zealand   | 2 (1.82)        |
| Sweden        | 2 (1.82)        |
| Italy         | 1 (0.91)        |
| Denmark       | 1 (0.91)        |
| Norway        | 1 (0.91)        |
| Pakistan      | 1 (0.91)        |
| Portugal      | 1 (0.91)        |
| Jordan        | 1 (0.91)        |
| China         | 1 (0.91)        |
| Germany       | 1 (0.91)        |
| Spain         | 1 (0.91)        |

the fear of blame (24/161), the fear of judgement (22/161), the fear of the negative impact that incident reporting could have on relationships with other HCPs, patients and the public (12/161), and the fear of a detrimental impact that reporting an incident could have on HCPs’ career (10/161), and the fear of job loss, were also cited as common barriers. Other less frequently mentioned barriers included protection of self (7/161), avoidance of discussion in meetings (4/161), and apprehension of sending an inappropriate form (1/161).

Process and systems of reporting

Process and systems of reporting was mentioned as a barrier to reporting 110 times. The most frequently identified barrier to incident reporting was the time required to complete an incident report (29/110), followed by the complexity of the reporting process (28/110), and the type of reporting system (eg, paper-based) (5/110).

Other process and systems of reporting barriers included lack of anonymity and/or confidentiality in reporting (22/110), reporting format (10/110), and the type of reporting system (eg, paper-based) (5/110). Less frequently mentioned barriers included lack of information to complete report (3/110), the focus of reporting (1/110), and information to complete report not readily being available (1/110).

Incident characteristics

Incident characteristics were mentioned as a barrier to reporting 92 times. Level of harm, cause of incident and frequency of incident were the most frequent incident characteristics acting as barriers to reporting (40/92, 19/42 and 18/92, respectively). HCPs were less likely to report an incident if the patient experienced no or minimal harm (31/112). Incidents that were deemed to occur frequently were considered too well-known to report, and the way HCPs perceive themselves can act as a barrier to reporting (9/89), the perception that incident reporting does not result in improvements typically underlined such negative attitudes and values. A number of studies found that HCPs fail to report incidents because they simply forget (9/89), and that the fear of blame (24/161), lack of value placed on incident reporting (53/89), and the fear of judgement (22/161), the fear of the negative impact that incident reporting could have on relationships with other HCPs, patients and the public (12/161), and the fear of a detrimental impact that reporting an incident could have on HCPs’ career (10/161), and the fear of job loss, were also cited as common barriers. Other less frequently mentioned barriers included protection of self (7/161), avoidance of discussion in meetings (4/161), and apprehension of sending an inappropriate form (1/161).

Knowledge and skills

Knowledge and skills were cited as barriers to incident reporting 84 times. The two most frequently mentioned barriers related to a lack of reporting clarity (36/84), and a lack of clarity regarding what constitutes an adverse event and/or near miss (31/84). This suggests that a lack of knowledge about what should be reported and how to do this act as barriers. Less frequently cited barriers included an inability in error recognition (7/84), lack of training in reporting (5/84), and lack of awareness (4/84).

Work environment

Work environment was mentioned 80 times as a barrier to incident reporting. Workload/priority (50/80), and accessibility (27/80), followed by the complexity of the reporting process (28/110), and the type of reporting system (eg, paper-based) (5/110).
Figure 3  Continued

Barriers to Reporting

- Fear of adverse consequences: 161
- Process and systems of reporting: 110
- Incident characteristics: 92
- Individual HCP characteristics: 89
- Knowledge/skills: 84
- Work environment: 80
- Organisational: 76
- Team Factors: 33
- Professional ethics: 23
Figure 3  Continued
Figure 3

Frequency of categories influencing engagement in patient safety incident reporting. HCP, healthcare professional.
mentioned work environment barriers, suggesting that high workload does not allow for incident reporting to be prioritised, and that access to the reporting system is problematic (eg, not enough computer work stations to access reporting forms).

Organisational factors
Organisational factors were mentioned 76 times as a barrier to incident reporting. Lack of feedback and communication following incident reporting (26/76), 8 9 11 39 47 64 47 45 67 71 76 79 80 98 99 107 108 111 116 120 121 128 was the most frequently mentioned organisational barriers to reporting. Less frequently mentioned were lack of organisational learning and improvement (7/76), 27 39 47 67 98 102 116 poor organisational use of data (7/76), 52 64 76 79 98 and poor management response to reports (5/76). 60 72 76 83 102

Team factors
Team factors were mentioned as barriers to engagement in incident reporting 33 times. The three most frequently mentioned barriers included the negative impact that incident reporting could have on working relationships (13/33), 11 15 44 60 65 66 68 108 109 111 116 the influence of seniors not to report (7/33), 48 51 68 73 82 120 and how HCPs feel about reporting their peers (5/33). 39 66 72

Professional ethics
Professional ethics was the least frequently mentioned barrier to incident reporting (23/748). The most prevalent factor was a lack of personal responsibility to report (15/23), 9 32 41 46 47 55 77 78 87 92 103 116 116 with studies suggesting that HCPs are less likely to report when they feel that reporting is the responsibility of someone else within the team. Concealment was also mentioned as a barrier (5/23). 39 108 126

Frequency of facilitators in patient safety incident reporting
Facilitators of reporting were mentioned 572 times across the 110 articles (see table 2). Organisational factors were the most frequently mentioned facilitator to incident reporting (97/372), followed by process and systems of reporting (75/372) and incident characteristics (55/372) (online supplementary table 1).

Organisational factors
Organisational factors were mentioned as facilitators 97 times. The two most frequently cited factors included the provision of feedback/communication following incident reporting (29/97), 9 11 36 42 45 50 53 55 57 69 70 80 88 89 112 103 108 116 and a non-punitive incident reporting policy (22/97). 9 11 20 36 38 42 44 45 49 54 63 69 70 80 81 102 108 120 129 The existence of a reporting culture (16/97), 29 41 45 66 69 82 96 113 116 120 121 127 and a focus on learning and improvement from incidents (13/97), 9 39 43 49 82 98 102 103 116 were also facilitators to reporting.

Process and systems of reporting
Process and systems of reporting was mentioned as a facilitator 75 times. Reporting format, ensuring anonymity and/or confidentiality, and simplification of reporting were the three most frequently cited facilitators accounting for 21/75, 9 11 25 42 53 54 63 69 81 86 98 101–103 108 116 120 16/75, 9 11 29 43 49 53 68 86 101 102 108 116 120 and 15/75. 9 11 38 42 79 80 86 95 101 102 105 116 166 facilitators within this category. Less frequently mentioned process and systems of reporting facilitators included the type of reporting system used (eg, electronic reporting) (11/75). 45 46 49 53 80 86 102 105

Incident characteristics
Incident characteristics were mentioned as a facilitator to reporting 55 times. Level of harm and frequency of an incident were the most frequently cited incident characteristics identified as facilitators to reporting (26/55), 11 39 41 43 49 51 55 58 63 66 69 70 75 84 89 92 109 112 129 and 13/55, 11 41 66 69 70 84 129 respectively). Incidents resulting in severe harm (including death) were more likely to be reported and HCPs were more likely to report incidents that occur infrequently rather than frequently. Less frequently mentioned facilitators included the type of incident (8/55), 11 41 75 cause of the incident (6/55), 36 49 66 70 89 and level of risk (1/55). 65

Individual HCP characteristics
Individual HCP characteristics were mentioned 41 times as a facilitator. A positive attitude towards incident reporting and a high value placed on incident reporting was found to increase the likelihood of reporting (21/41). 9 11 49 63 73 77 81 89 102 109 111 114 115 123 HCPs’ emotional response to a patient safety incident was also found to increase the likelihood of reporting in a number of studies (5/41). 43 63 116 The professional group of HCPs was also found to act as a facilitator to reporting (5/41). 28 104 Less frequently cited facilitators included previous reporting behaviour (1/41), 39 number of hours worked (1/41), 32 and demographics (eg, gender and age) (2/41). 48 115

Knowledge and skills
Training in reporting was identified as the most frequently mentioned facilitator in this category (21/36). 9 35 36 45 69 80 86 91 103 105 108 128 Other facilitators included knowledge regarding what constitutes an adverse event/near miss and the ability to recognise an error has occurred (7/36, 9 42 53 54 103 108 116 and 4/36, 36 69 70 129 respectively).

Team factors
Team factors were mentioned 20 times as a facilitator to reporting. Good teamwork/communication (7/20), 69 70 96 127 and a positive team culture (4/20), 81 115 123 127 were the most frequently cited facilitators.

Professional ethics
Professional ethics was cited as a facilitator 17 times. A strong sense of duty (8/17), 39 69 80 81 109 112 and responsibility (5/17), 70 75 78 111 to report increased the likelihood
of reporting. Less frequently cited facilitators included accountability (2/17), and a legal obligation to report (1/17).

Work environment
Work environment was mentioned as a facilitator 18 times. Access to the incident reporting system (11/18), and those whose workloads allowed for and those that prioritised incident reporting increased the likelihood of reporting.

Fear of adverse consequences
Fear of adverse consequences was mentioned as a facilitator to reporting 13 times and included a fear of litigation and fear of blame increasing the likelihood of reporting (8/13), and satisfaction with work environment (1/10), and accessibility (1/10).56

Frequency of negative cases
Negative cases were identified 118 times across the 110 articles (see table 2). The three most frequently mentioned factors included individual HCP characteristics (43/118), organisational factors (22/118), and knowledge and skills (15/118).48

Individual HCP characteristics were mentioned as a negative case 45 times. HCPs’ attitude and value of incident reporting did not have an impact on reporting behaviour (12/43).33 35 48 56 72 93 113  Similarly, HCPs’ demographics (eg, age, gender) had no impact on the likelihood of reporting (12/43).30 32 48 57 58 80 89 93 113 35 39 48 Other less frequently mentioned factors included seniority (4/43), 48 56 93 107 56 93 113 35 39 48 56 72 93 126 35 39 48 56 72 93 113 35 39 48 56 72 93 113 35 39 48 56 72 93 113 35 39 48 56 72 93 113 35 39 48 56 72 93 113

Fear of adverse consequences was cited as having no impact on engagement in incident reporting systems.130 Based on such prospective analysis, strategies to enhance the adoption, implementation and sustainability of incident reporting systems can

DISCUSSION
It has been suggested that there is a tendency in healthcare to encourage reporting of any and all patient safety incidents, to celebrate large quantities of incident reports and to aim for ever-increasing overall reporting rates. While there are numerous problems associated with this approach2 (eg, flooding the system to such a degree that the thorough investigation of each incident reporting is unachievable), it is clear that high levels of under-reporting seriously compromise the ability of incident reporting systems to facilitate learning and improvements in patient safety.

This is the first theoretical literature review of factors contributing to patient safety incident reporting. Based on the evidence from 110 articles, we developed a theoretical framework, based on the principles of grounded theory, which summarises a wide range of factors contributing to incident reporting. We purposely sought publications from a range of countries, covering diverse health systems and study populations with a view to incorporating these into one broad theoretical framework. We argue that this is an appropriate approach for this initial explorative work, as multiple theoretical frameworks for individual counties, settings and populations (eg, nurses working in mental health settings in Australia), would have limited application at this point in time. However, we suggest that those interested in exploring barriers and facilitators in specific settings conduct further research using the theoretical framework presented here.

To improve incident reporting (both the quantity and/or quality) and facilitate the successful implementation of incident reporting systems, we suggest that the theoretical framework is best used to prospectively and systematically identify factors within a given context that are likely to affect incident reporting. Those responsible for the effective implementation of incident reporting systems should explore each of the factors listed in our framework for salience. Rather than the framework being used in isolation, we recommend that it be used in conjunction with other implementation theories/frameworks and models to guide, understand and evaluate implementation of incident reporting systems.120 Based on such prospective analysis, strategies to enhance the adoption, implementation and sustainability of incident reporting systems can
be tailored and selected according to a given setting. As such, using the developed framework will advance our understanding of how to optimally implement incident reporting systems into practice.

We used the developed theoretical framework, based on the evidence base, to organise our findings and have presented the frequency and rank order (ie, prevalence) of factors contributing to incident reporting. While this approach is consistent with other frameworks in the patient safety literature,14 23 it may be considered as a crude analysis of the existing literature and needs to be interpreted with caution. We acknowledge that it is possible, although unlikely, that a relationship between the number of times a given factor is mentioned in the literature and its impact on incident reporting behaviour might not exist. However, we have been able to provide the first high-level overview of a large heterogeneous body of evidence. Furthermore, we acknowledge that weighting the impact of each factor would have been advantageous; however, the data did not lend itself to this possibility and we propose that it might not be possible to simply weight factors because of the complex and dynamic interrelationships that are likely to exist between them. Alternatively, we suggest that modelling the interrelationships between factors affecting incident reporting engagement is an avenue for future research.

Our results suggest that fear of adverse consequences and ineffective processes/systems of reporting are high-priority areas that require consideration to improve engagement in incident reporting. Changes to policy should be considered at an institutional or national level to prevent fear of litigation and blame, as fear of adverse consequences was found to inhibit incident reporting. We believe that it is unlikely that changes made within a single hospital or healthcare system would instil significant reassurance to promote incident reporting. In addition, at an organisational level we found that appropriate systems and processes for reporting need to be implemented to improve incident reporting; simultaneously, lack of or poorly designed systems significantly hinder reporting. These aspects of reporting rely on well-designed processes and technologies and are arguably the responsibility of organisational leaders. There is no ‘optimum model’ for incident reporting systems (eg, electronic, confidential, anonymous)—systems need to be responsive to users and organisational needs.

Organisational factors and processes/systems of reporting were identified as the two most frequently cited facilitators of reporting, which suggests that healthcare organisations consider these as high-priority areas which should be the target of increased focus and resources. For example, our results suggest that organisational policies that foster a reporting and learning culture as well as providing feedback following a report will promote incident reporting. Interestingly, we found that individual HCP characteristics have little impact on engagement in incident reporting. This suggests that organisations should be cautious before investing significant resources in these factors as such investment may result in minimal returns.

Although we have considered the above factors in isolation as illustrative examples, it is important to consider the interconnecting relationships between factors in order to develop intervention packages to improve engagement in incident reporting. Our results suggest that a comprehensive intervention/policy package which targets more than one contributing factor (eg, establishing a supportive work environment, with mechanisms which optimise shared learning, alongside a national policy to minimise the fear of adverse consequence) is far more likely to result in increased engagement in incident reporting compared with interventions that simply target one factor.

Strengths and limitations
In order to identify as much relevant literature as possible, we have included quantitative, qualitative and mixed-methods research and have not restricted the literature to specific incident reporting systems, that is, departmental, local, regional and national. In addition, the studies included a vast array of healthcare settings and providers, maximising the generalisability of the results. The resulting evidence has been synthesised into a practical output, that is, a theoretical framework to guide efforts to improve engagement in incident reporting.

The results and recommendations proposed in this evidence synthesis must be considered in light of several limitations. First, only articles published in English were included, which may generate bias. However, articles spanning 4 continents from >20 countries were identified, hence we are confident that our findings are of high external validity to guide safety policy globally. Second, the last systematic search for literature was conducted on 29 May 2014, meaning that literature published since this date will not have been included. We suggest that literature published after the last search could be useful to test the validity of the theoretical framework. Third, the decision not to include studies detailing interventions to improve incident reporting and studies detailing variations in engagement in incident reporting may skew the findings. This decision was made as it was not possible to determine the relative contribution of individual factors on engagement in incident reporting within such studies. Fourth, large heterogeneity across studies in terms of outcome measures and methodologies meant conduction of meta-analysis was precluded. This having been said, the synthesis of barriers and facilitators into frequency of reporting provides some evidence towards their respective relative importance, although it is accepted that the frequency of factors may represent those that have been the subject of more research. We recommend that future research applies and evaluates the usefulness of the developed theoretical framework in exploring and improving incident reporting in a variety of settings (eg, primary and secondary healthcare).
Future research
There are many ways in which future research could test the validity of the theoretical framework presented in the current study. For example, content validity of the theoretical framework could be assessed using expert consensus methods (e.g., Delphi study). In addition, predictive validity could be tested quantitatively by assessing the correlation between, for example, fear of adverse consequences (level of fear) and incident reporting behaviour (i.e., number of incidents reported). A negative correlation between number of incidents reported (low) and fear of adverse consequence (high) would provide evidence for predictive validity of the theoretical framework.

SUMMARY/CONCLUSION
A wide range of factors contributing to engagement in incident reporting exist across varying levels of the healthcare system. Efforts aimed at addressing the current tendency to under-report must consider the full range of factors in order to develop tailored interventions and policy packages for improvement. We suggest the theoretical framework developed here would be useful in understanding factors affecting incident reporting engagement, increasing engagement in incident reporting and ultimately learning from patient safety incidents.

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REFERENCES
1. Barach P, Small SD. Reporting and preventing medical mishaps: lessons from non-medical near miss reporting systems. BMJ 2000;320:759–63.
2. Leape LL. Error in medicine. JAMA 1994;272:1851–7.
3. Department of Health. An organisation with a memory: report of an expert group on learning from adverse events in the NHS. https://psnet.ahrq.gov/resources/resource/1568 (accessed March 2017).
4. Noble DJ, Pronovost PJ. Underreporting of patient safety incidents reduces health care’s ability to quantify and accurately measure harm reduction. J Patient Saf 2010;6:247–50.
5. Institute of Medicine. To err is human: building a safety health system. Washington, DC: National Academy Press, 1999.
6. Howell AM, Burns EM, Hull L, et al. International recommendations for national patient safety incident reporting systems: an expert Delphi consensus-building process. BMJ Qual Saf 2017;26.
7. Macrae C. The problem in incident reporting. BMJ Qual Saf 2016;25:71–5.
8. Evans SM, Berry JG, Smith BJ, et al. Attitudes and barriers to incident reporting: a collaborative hospital study. Qual Saf Health Care 2006;15:39–43.
9. Kingston MJ, Evans SM, Smith BJ, et al. Attitudes of doctors and nurses towards incident reporting: a qualitative analysis. Med J Aust 2004;181:36–9.
10. Waring JJ. Beyond blame: cultural barriers to medical incident reporting. Soc Sci Med 2005;60:1927–35.
11. Jefferies DB, Dunagan WC, Garbutt J, et al. Using focus groups to understand physicians’ and nurses’ perspectives on error reporting in hospitals. Jt Comm J Qual Saf 2004;30:471–9.
12. Polisena J, Gagliardi A, Urbach D, et al. Factors that influence the recognition, reporting, and resolution of incidents related to medical devices and other healthcare technologies: a systematic review. Syst Rev 2015;4:37.
13. Fung WM, Koh SS, Chow YL. Attitudes and perceived barriers influencing incident reporting by nurses and their correlation with reported incidents: A systematic review. JBI Libr Syst Rev 2012;10:1–65.
14. Pfeiffer Y, Manser T, Wehner T. Conceptualising barriers to incident reporting: a psychological framework. Qual Saf Health Care 2010;19:e60.
15. O’Connor E, Coates HM, Yardley LE, et al. Disclosure of patient safety incidents: a comprehensive review. Int J Qual Health Care 2010;22:371–9.
16. Higgins JP, Altman DG, Gøtzsche PC, et al. The Cochrane Collaboration’s tool for assessing risk of bias in randomised trials. BMJ 2011;343:d5928.
17. Shea B, Grimshaw JM, Wells GA, et al. Development of AMSTAR: A measurement tool to assess the methodological quality of systematic reviews. BMC Med Res Methodol 2007;7:10.
18. Long AF, Godfrey M. An evaluation tool to assess the quality of qualitative research studies. Int J Soc Res Methodol 2004;7:181–96.
19. Paré G, Trudel M-C, Jaana M, et al. Synthesizing information systems knowledge: A typology of literature reviews. Inf Manage 2015;52:183–99.
20. Sanderson S, Tatt ID, Higgins JP. Tools for assessing quality and susceptibility to bias in observational studies in epidemiology: a systematic review and annotated bibliography. Int J Epidemiol 2007;36:666–76.
21. Glaser B, Strauss A. The Discovery of Grounded Theory. Hawthorne, New York: Aldine Publishing Company, 1967.
22. Wolfswinkel JF, Furtmüller E, Wilderom CPM. Using grounded theory as a method for rigorously reviewing literature. Eur J Inf Syst 2013;22:45–55.
23. Lawton R, McEachan RR, Giles SJ, et al. Development of an evidence-based framework of factors contributing to patient safety incidents in hospital settings: a systematic review. BMJ Qual Saf 2012;21:369–80.
24. Belton KJ. Attitude survey of adverse drug-reaction reporting by health care professionals across the European Union. Eur J Clin Pharmacol 1997;52:423–7.
25. Fukuda H, Imanaka Y, Hirose M, et al. Impact of system-level activities and reporting design on the number of incident reports for patient safety. Qual Saf Health Care 2010;19:122–7.
26. Gaal S, van den Hombrek P, Verstappen W, et al. Patient safety features are more present in larger primary care practices. Health Policy 2010;97:87–91.
27. Jennings PA, Stella J. Barriers to incident notification in a regional prehospital setting. Emerg Med J 2011;28:526–9.
28. Rowin DJ, Lucier D, Pauker SG, et al. Does error and adverse event reporting by physicians and nurses differ? Jt Comm J Qual Patient Saf 2008;34:537–45.
29. Hutchinson A, Young TA, Cooper KL, et al. Trends in healthcare incident reporting and relationship to safety and quality data in acute hospitals: results from the National Reporting and Learning System. *Qual Saf Health Care* 2009;18:5–10.

30. Rogers AS, Burke-Smith CR, et al. Physician knowledge, attitudes, and behavior related to reporting adverse drug events. *Arch Intern Med* 1988;148:1596–600.

31. Schulmeister L. Chemotherapy medication errors: descriptions, severity, and contributing factors. *Oncol Nurs Forum* 1999;26:1033–42.

32. Generali JA, Danish MA, Rosenbaum SE. Knowledge of and attitudes about adverse drug reaction reporting among Rhode Island pharmacists. *Ann Pharmacother* 1995;29:365–9.

33. Osborne J, Blais K, Hayes JS. Nurses’ perceptions: when is it a medication error? *J Nurs Adm* 1999;29:33–8.

34. Gladstone J. Drug administration errors: a study into the factors underlying the occurrence and reporting of drug errors in a district general hospital. *J Adv Nurs* 1995;22:628–37.

35. Vincent C, Stanhope N, Crowley-Murphy M. Reasons for not reporting adverse incidents: an empirical study. *J Eval Clin Pract* 1999;5:13–21.

36. Green CF, Mottram DR, Raval D, et al. Community pharmacists’ attitudes to adverse drug reaction reporting. *Int J Pharm Pract* 1999;7:92–9.

37. Belton KJ, Lewis SC, Payne S, et al. Attitudinal survey of adverse drug reaction reporting by medical practitioners in the United Kingdom. *Br J Clin Pharmacol* 1995;39:223–6.

38. Bateman DN, Sanders GL, Rawlins MD. Attitudes to adverse drug reaction reporting in the Northern Region. *Br J Clin Pharmacol* 1992;34:421–6.

39. Walker SB, Lowe MJ. Nurses’ views on reporting medication incidents. *J Int Nurs Pract* 1998;4:97–102.

40. Eland IA, Belton KJ, van Grootheest AC, et al. Attitudinal survey of voluntary reporting of adverse drug reactions. *Br J Clin Pharmacol* 1998;46:823–7.

41. Cosentino M, Leoni O, Barfi F, et al. Attitudes to adverse drug reaction reporting by medical practitioners in a Northern Italian district. *Pharmacol Res* 1997;35:85–8.

42. Beasley JW, Escoto KH, Karsh BT. Design elements for a primary care medical reporting system. *WMJ* 2004;103:56–8.

43. Elder NC, Graham D, Brandt E, et al. Barriers and motivators for making error reports from family medicine offices: a report from the American Academy of Family Physicians National Research Network (AAFP NRN). *J Am Board Fam Med* 2007;20:115–23.

44. Fairbanks PJ, Crittenman CV, O’Gara KG, et al. Emergency medical services provider perceptions of the nature of adverse events and near-misses in out-of-hospital care: an ethnographic view. *Acad Emerg Med* 2008;15:633–40.

45. Karsh BT, Escoto KH, Beasley JW, et al. Toward a theoretical approach to medical error reporting system research and design. *Appl Ergon* 2006;37:283–95.

46. Kennedy AG, Littenberg B. Medication error reporting by community pharmacists in Vermont. *J Am Pharm Assoc* 2004;44:434–8.

47. Handler SM, Peraer S, Olahansky EF, et al. Identifying modifiable barriers to medication error reporting in the nursing home setting. *J Am Med Dir Assoc* 2007;8:568–74.

48. Daly JM, Jogerst GJ. Association of knowledge of adult protective services legislation with rates of reporting of abuse in Iowa nursing homes. *J Am Med Dir Assoc* 2005;6:113–20.

49. Garbutt J, Brownstein DR, Klein EJ, et al. Reporting and disclosing medical errors: pediatricians’ attitudes and behaviors. *Arch Pediatr Adolesc Med* 2007;161:179–85.

50. Kaldjian LC, Jones EW, Wu BJ, et al. Reporting medical errors to improve patient safety: a survey of physicians in teaching hospitals. *Arch Intern Med* 2008;168:40–6.

51. Hohenhaus SM. Emergency nursing and medication error–a survey of two states. *J Emerg Nurs* 2008;34:20–5.

52. Patrician PA, Brosch LR. Medication error reporting and the work environment in a military setting. *J Nurs Care Qual* 2009;24:277–86.

53. Schechtman JM, Plews-Ogan ML. Physician perception of hospital safety and barriers to incident reporting. *Jt Comm J Qual Patient Saf* 2006;32:337–43.

54. Taylor JA, Brownstein D, Christakis DA, et al. Use of incident reports by physicians and nurses to document medical errors in pediatric patients. *Pediatrics* 2004;114:729–35.

55. Throckmorton T, Etchegary J. Factors affecting incident reporting by registered nurses: the relationship of perceptions of the environment for reporting errors, knowledge of the reporting practice act, and demographics on intent to report errors. *J Perianesth Nurs* 2007;22:400–12.

56. Uribe CL, Schweikhart SB, Pathak DS, et al. Perceived barriers to medical-error reporting: an exploratory investigation. *J Healthc Manag* 2002;47:263–79.

57. Vogus TJ, Sutcliffe KM. The impact of safety optimizing, trusted leadership teams, and care pathways on reported medication errors in hospital nursing units. *Med Care* 2007;45:997–1002.

58. Weissman JS, Annas CL, Epstein AM, et al. Error reporting and disclosure systems: views from hospital leaders. *JAMA* 2005;293:1359–66.

59. Maye AM, Duncan D. Nurse perceptions of medication errors: what we need to know for patient safety. *J Nurs Care Qual* 2004;19:209–17.

60. Blegen MA, Vaughn T, Pepper G, et al. Patient and staff safety: voluntary reporting. *Am J Med Qual* 2004;19:67–74.

61. King ES, Moyer DV, Coutriere MJ, et al. Getting doctors to report medical errors: project DISCLOSE. *Jt Comm J Qual Patient Saf* 2006;32:382–92.

62. Coley KC, Pringle JL, Weber RJ, et al. Perceived barriers in using a region-wide medication error reporting system. *J Patient Saf* 2006;2:39–44.

63. Elder NC, Brungs SM, Nagy M, et al. Nurses’ perceptions of error communication and reporting in the intensive care unit. *J Patient Saf* 2008;4:162–8.

64. Stratton KM, Blegen MA, Pepper G, et al. Reporting of medication errors by pediatric nurses. *Pediatr Nurs* 2004;19:385–92.

65. Waring JJ. A qualitative study of the intra-hospital variations in incident reporting. *Int J Qual Health Care* 2004;16:347–52.

66. Ashcroft DM, Morecroft C, Parker D, et al. Likelihood of reporting adverse events in community pharmacy: an experimental study. *Qual Saf Health Care* 2006;15:48–52.

67. Kreckler S, Catchpole K, McCulloch P, et al. Factors influencing incident reporting in surgical care. *Qual Saf Health Care* 2009;18:116–20.

68. Sharma A, Jain P, Parmar B, et al. Incident Reporting in Surgical Trainees-Revisited. *J Patient Saf* 2008;4:191–4.

69. Green CF, Mottram DR, Rowe FH, et al. Attitudes and knowledge of hospital pharmacists to adverse drug reaction reporting. *Br J Clin Pharmacol* 2001;51:81–6.

70. Swei D, Wong IC. A survey on factors that could affect adverse drug reaction reporting according to hospital pharmacists in Great Britain. *Drugs Saf* 2000;23:165–72.

71. McDermott CJ, Burns N, Ireland A. Attitudes and beliefs of doctors towards medication error reporting. *Int J Health Care Qual Assur* 2003;16:326–33.

72. Sanghera IS, Franklin BD, Dhillon S. The attitudes and beliefs of healthcare professionals on the causes and reporting of medication errors in a UK intensive care unit. *Anaesthesia* 2007;62:53–61.

73. Haines TP, Cornwall P, Fleming J, et al. Documentation of in-hospital falls on incident reports: qualitative investigation of an imperfect process. *BMJ Health Serv Res* 2008;8:254.

74. Johnstone MJ, Kantsakis O. Patient safety and the integration of graduate nurses into effective organizational clinical risk management systems and processes: an Australian study. *Qual Manag Health Care* 2008;17:162–73.

75. Espin S, Levinson W, Regehr G, et al. Error or ‘act of God’? A study of patients’ and operating room team members’ perceptions of error definition, reporting, and disclosure. *Surgery* 2006;139:6–14.

76. Covell CL, Ritchie JA. Nurses’ responses to medication errors: suggestions for the development of organizational strategies to improve reporting. *J Nurs Care Qual* 2009;24:287–97.

77. Merchant RN, Gully PM. A survey of British Columbia anesthesiologists on a provincial critical incident reporting program. *Can J Anaesth* 2005;52:680–4.

78. Espin S, Regehr G, Levinson W, et al. Factors influencing perioperative nurses’ error reporting preferences. *AORN J* 2007;85:527–43.

79. Chang HY, Pepper GA. Barriers to nurses’ reporting of medication administration errors in Taiwan. *J Nurs Scholar* 2006;38:392–9.

80. Mes K, Berg LT. WdeJ-van, Grootheest AC. Attitudes of community pharmacists in the Netherlands towards adverse drug reaction reporting. *Int J Pharm Pract* 2002;10:267–72.

81. Bawazir SA. Attitude of community pharmacists in Saudi Arabia towards adverse drug reaction reporting. *Saudi Pharm J* 2006;14:75–83.

82. Kagan I, Barnyo S. Factors associated with reporting of medication errors by Israeli nurses. *J Nurs Care Qual* 2008;23:353–61.

83. Iaveh E, Katz-Nass, Stern Z. Readiness to report medical treatment errors: the effects of safety procedures, safety information, and priority of safety. *Med Care* 2006;44:2117–23.
84. Vossal G, Mardani Z, Mollai M. Knowledge, attitudes, and perceptions of pharmacists to adverse drug reaction reporting in Iran. *Pharm World Sci* 2009;31:183–7.

85. Soleiman F. Learning from mistakes in New Zealand hospitals: what do we need besides “no-fault”? *NZ Med J* 2006;119:U2099.

86. Yong H, Kluger MT. Incident reporting in anaesthesia: a survey of practice in New Zealand. *Anaesth Intensive Care* 2003;31:555–9.

87. Söderberg J, Grankvist K, Brulin C, et al. Incident reporting practices in the preanalytical phase: Low reported frequencies in the primary health care setting. *Scand J Clin Lab Invest* 2009;69:731–5.

88. Bäckström M, Mjöndal T, Dahlqvist R, et al. Attitudes to reporting adverse drug reactions in northern Sweden. *Eur J Clin Pharmacol* 2000;56:729–32.

89. Hasfor T, Bahr JS, Bajaj V, Heidel P, et al. Patient safety and incident reporting practices in the preanalytical phase: Low reported frequencies in the primary health care setting. *Int J Qual Health Care* 2013;25:141–50.

90. Khan TM. Community pharmacists’ knowledge and perceptions about adverse drug reactions and barriers towards their reporting in Eastern region, Alahsa, Saudi Arabia. *Ther Adv Drug Saf* 2013;4:45–51.

91. Li Q, Zhang SM, Chen HT, et al. Awareness of the health professionals in Wuhan, China to the reporting of adverse drug reactions. *Chin Med J* 2004;117:856–61.

92. Arlanis K, Smith A. Informal risk assessment strategies in health care staff: an unrecognized source of resilience? *J Eval Clin Pract* 2012;18:1140–6.

93. Armitage G, Newell R, Wright J. Improving the quality of drug error reporting. *J Clin Pharm* 2010;16:411–16.

94. Anderson JE, Kodate N, Walters R, et al. Can incident reporting improve safety? Healthcare practitioners’ views of the effectiveness of incident reporting. *Int J Qual Health Care* 2013;25:141–50.

95. Arfas et al. Anticipating the reporting of adverse medical events to the FDA Adverse Events Reporting System by nurse practitioners and physician assistants. *Expert Opin Drug Saf* 2012;11:177–83.

96. Turner S, Ramssay A, Fulop N. The role of professional communities in governing patient safety. *J Health Organ Manag* 2013;27:527–43.

97. Williams SD, Phipps DL, Ashcroft DM. Understanding the attitudes of hospital pharmacists to reporting medication incidents: a qualitative study. *Res Social Adm Pharm* 2013;9:80–9.

98. Holmström AR, Airaksinen M, Weiss M, et al. National and local medication error reporting systems: a survey of practices in 16 countries. *J Patient Saf* 2012;8:165–76.

99. Parvisi, Robertson I, McWilliams RG. Medical device adverse incident reporting in interventional radiology. *Clin Radiol* 2014;69:263–7.

100. Sarvadikar A, Prescott G, Williams D. Attitudes to reporting medication error among differing healthcare professionals. *Eur J Clin Pharmacol* 2010;66:843–53.

101. Winchester SA, Tomkins S, Cliffe S, et al. Healthcare workers’ perceptions of occupational exposure to blood-borne viruses and reporting barriers: a questionnaire-based study. *J Hosp Infect* 2012;82:36–9.

102. Tariq A, Georgiou A, Westbrook J. Medication incident reporting in residential aged care facilities: limitations and risks to residents’ safety. *BMC Geriatr* 2012;12:67.

103. Braithwaite J, Westbrook MT, Travaglia JF, et al. Cultural and associated enablers of, and barriers to, adverse incident reporting. *Qual Saf Health Care* 2010;19:229–33.

104. Heard GC, Sanderson PM, Thomas RD. Barriers to adverse event and error reporting in anesthesia. *Anesth Analg* 2012;114:604–14.

105. Hartnell N, MackKinnon N, Sketris I, et al. Identifying, understanding and overcoming barriers to medication error reporting in hospitals: a focus group study. *BMJ Qual Saf* 2012;21:361–9.

106. Wallis R, Boon H, Barnes J, et al. Reporting natural health product related adverse drug reactions: is it the pharmacist’s responsibility? *Int J Pharm Pract* 2011;19:383–91.

107. Waters NF, Hall WA, Brown H, et al. Perceptions of Canadian labour and delivery nurses about incident reporting: a qualitative descriptive focus group study. *Int J Nurs Stud* 2012;49:811–21.

108. Espin S, Wickson-Griffiths A, Wilson M, et al. To report or not to report: a descriptive study exploring ICU nurses’ perceptions of error and error reporting. *Intensive Crit Care Nurs* 2010;26:1–9.

109. Chang IC, Hsu HM. Predicting medical staff intention to use an online reporting system with modified unified theory of acceptance and use of technology. *Telemed J E Health* 2012;18:67–73.

110. Chang HY, Lin SY, Hsu SC, et al. Factors determining hospital nurses’ failures in reporting medication errors in Taiwan. *Nurs Outlook* 2010;58:17–25.

111. Chieng HY, Lin SY, Haio YC, et al. Culture influence and predictors for behavioral involvement in patient safety among hospital nurses in Taiwan. *J Nurs Qual Care* 2012;27:359–67.

112. Martowircono K, Jansma JD, van Luijk SJ, et al. Possible solutions for barriers in incident reporting by residents. *J Eval Clin Pract* 2012;18:76–81.

113. Zwart DL, Heddemas WS, Vermeulen MI, et al. Lessons learnt from incidents reported by postgraduate trainees in Dutch general practice. A prospective cohort study. *BMJ Qual Saf* 2011;20:857–62.

114. Alsaleh A, Bahrooo SA, Tamim H, et al. Physicians’ attitudes toward reporting medical errors—an observational study at a general hospital in Saudi Arabia. *J Patient Saf* 2011;7:143–7.

115. Khan TM. Community pharmacists’ knowledge and perceptions about adverse drug reactions and barriers towards their reporting in Eastern region, Alahsa, Saudi Arabia. *Ther Adv Drug Saf* 2013;4:45–51.

116. Tobiagyi M, Stewart D. Exploring health professionals’ experiences of medication errors in Saudi Arabia. *Int J Clin Pharm* 2013;35:542–5.

117. Davies EC, Chandler CI, Innocent SH, et al. Designing adverse event forms for real-world reporting: participatory research in Uganda. *PloS One* 2012;7:e32704.

118. Clark M, Gray M, Mooney J. New graduate occupational therapists’ perceptions of near-misses and mistakes in the workplace. *Int J Health Care Qual Assur* 2013;26:584–76.

119. Kagan I, Barnoy S. Organizational safety culture and medical error reporting by Israeli nurses. *J Nurs Scholarsh* 2013;45:273–80.

120. Joolaei S, Hajibabaei F, Peyrovio H, et al. The relationship between incidence and report of medication errors and working conditions. *Int Nurs Rev* 2011;58:37–44.

121. Okuyama A, Sasaki M, Kanda K. The relationship between incident reporting by nurses and safety management in hospitals. *Qual Manag Health Care* 2010;19:164–72.

122. Albolino S, Tartaglia R, Bellandi T, et al. Patient safety and incident reporting: survey of Italian healthcare workers. *Qual Saf Health Care* 2010;19(Suppl 3):i8–12.

123. Rasmussen K, Pedersen AH, Pape L, et al. Work environment influences adverse events in an emergency department. *Dan Med J* 2014;61:A4812.

124. Ballangrud R, Hedelin B, Hall-Lord ML. Nurses’ perceptions of patient safety climate in intensive care units: a cross-sectional study. *Intensive Crit Care Nurs* 2012;28:344–54.

125. Mustafa GR, Rasheed S, Aziz MT. Adverse drug reaction reporting system at different hospitals of Lahore, Pakistan - An evaluation and patient outcome analysis. *J App Pharm* 2013;4:713–9.

126. Nilsen P. Making sense of implementation theories, models and frameworks. *Implement Sci* 2015;10:53.
Development of a theoretical framework of factors affecting patient safety incident reporting: a theoretical review of the literature
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