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BMJ Open

Development of a Theoretical Framework of Factors Affecting Patient Safety Incident Reporting: A Theoretical Review of the Literature

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Key Words: Incident reporting, Patient Safety, Service Quality

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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 3,049 potentially eligible articles; of these, 110 articles, including over 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 organisational (97, representing 26.08% of facilitators) and process and systems of reporting (75, representing 20.16% 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.

Article Summary – strengths and limitations

- The synthesis included quantitative, qualitative and mixed methods research and have not restricted the literature to specific incident reporting systems.
- Only articles published in English were included.
- The last systematic search for literature was conducted on 29/05/2014,
 meaning that literature published since this date will not have been included.
- Studies detailing interventions to improve incident reporting and studies detailing variations in engagement in incident reporting were not included.
- Large heterogeneity across studies in terms of outcome measures and methodologies meant conduction of meta-analysis was precluded.

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 underreporting. In the United States it is estimated that 50-96% of incidents are not reported. [2, 4, 5] Failure to report patient safety incidents significantly hinders the underlying goals of incident reporting systems; low levels of reporting makes it is difficult at best to identify and prioritise patient safety risks, and hampers learning from such incidents and ultimately improvements in patient safety. Whilst 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. [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 (e.g. focusing on the psychological factors affecting incident reporting[14]; focusing on perceived barriers influencing incident reporting by nurses; [13] factors affecting reporting of incidents

related to medical devices and other healthcare technologies).^[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 the factors affecting patient safety incident reporting. The secondary aims were, firstly, to develop theoretical framework, of factors acting as barriers and facilitators to incident reporting to guide implementation of interventions to increase engagement, and, secondly, to determine the prevalence of factors to guide the development of interventions and policies to improve incident reporting.



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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 synthesize 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 29/05/2014; whilst the last search was conducted 2 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 English language.

TABLE 1 HERE

Eligibility criteria

Inclusion Criteria

 Studies reporting factors influencing the likelihood of incident report engagement in any healthcare setting (e.g. primary and secondary healthcare) and employing any study designs (e.g. qualitative, quantitative, mixed-methods)

Exclusion Criteria

- Studies reporting aspects of incident reporting systems and/or incident reporting perceived positively and/or negatively by healthcare professionals without data relating perceptions to incident reporting engagement
- 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)^[15]
- 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 health care has previously been published.^[13]

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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 was developed to maintain a focus on factors having a direct impact upon incident reporting engagement rather than simply identifying and listing factors of incident reporting which were perceived positively or negatively by healthcare professionals. Identifying elements of incident reporting perceived positively or negatively by healthcare professionals does not equate to identify 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 abstract. Three authors (SA, LH and TS) reviewed the articles at full-text stage. Data was extracted using an extraction template. The following data was 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 (e.g. The Cochrane Collaboration's tool for assessing risk of bias in randomized trials;^[16] AMSTAR tool to assess the methodological quality of systematic reviews;^[17] tools to assess the quality of qualitative research studies).^[18] 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.^[19] Third, it has been argued that it is important, but difficult, to distinguish between 'quality of reporting' and the 'quality of a study'.^[20] 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. [21] It has been identified as a method where thorough and theoretically relevant analysis of a topic can be reached, specifically within literature reviews. [22] 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 & 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 (e.g. in the case of a standardised scale), but in others allowed for unseen insights to develop across the data corpus (e.g. 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 three, 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. BMJ Open: first published as 10.1136/bmjopen-2017-017155 on 27 December 2017. Downloaded from http://bmjopen.bmj.com/ on April 10, 2024 by guest. Protected by copyright.

FIGURE 1 HERE

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

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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.

TABLE 2 HERE

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.^[23]

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

Findings

The search identified 5,335 records. After duplicates and limits were applied (English language, date restrictions 1980-May 2014), 3,049 records were considered for inclusion. Of these 3,049 records, 2,700 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 over 29,726 participants, were included in the final review (Figure 2). The total number of participants per study ranged from 8-2185 (mean=286.54; median: 134.00). Six studies did not report sample size, thus the sample size calculations represented above are based on 104 articles. [24-29] See eTable 1 for full data extraction.

FIGURE 2 HERE

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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 semi-structured interview and documentary analysis-based study; 1 semi-structured interview and retrospective review of error reports-based study; 2 semi-structured interview and questionnaire-based study; 3 focus group and questionnaire-based studies; 1 semi-structured and structured interview-based study; 1 interview, focus group and analysis of event reports-based study; 1 focus group and semi-structured interview-based study; 1 retrospective analysis of

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routinely collected data and questionnaire-based study; 2 focus groups, interview and questionnaire-based studies).

Countries (Table 3)

The review encompassed research spanning four continents and over 20 countries.

The four countries contributing the most studies were the United States of America (n=33), the United Kingdom (n=24), Australia (n=8), and Canada (n=8).

TABLE 3 HERE

Year of Publication

A steady increase in articles was evident over decades: 1980's (n=1),^[51] 1990's (n=12),^[24, 45, 52, 54, 67, 72, 76, 80, 81, 85, 103, 121] 2000's (n=58), ^[8-11, 28-35, 37, 40-44, 46-50, 53, 55-59, 64, 66, 69, 74, 75, 77-79, 82, 84, 91-94, 99, 101, 107, 110, 112, 114, 116-119, 125-129] 2010-May 2014 (n=39).^[25-27, 36, 38, 39, 60-63, 65, 68, 70, 71, 73, 83, 86-90, 95-98, 100, 102, 104-106, 108, 109, 111, 113, 115, 120, 122-124] This increase is likely to reflect the growing integration of incident reporting systems in healthcare systems worldwide and the increasing realisation that healthcare professionals (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 (e.g. if fear was found not to be a 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 (e.g. 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. Whilst 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.

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FIGURE 3 HERE

Frequency of Barriers to Patient Safety Incident Reporting (eTable 2)

Barriers to incident reporting were mentioned 748 times across the 110 articles (see eTable 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, 30, 32, 33, 35-37, 42-45, 53-56, 58, 59, 61, 68, 75, 78, 79, 85, 87, 88, 92, 97, 99, 100, 104, 106, 109, 118, 120, 121] fear of litigation (30/161), [8-11, 24, 27, 32, 35, 48, 51, 52, 61, 69, 72, 77, 80, 81, 85, 87, 88, 93, 100, 101, 103, 105, 107, 114, 117, 124, 128] and the fear of blame (24/161). [8, 10, 32, 35, 43, 44, 46, 58-61, 68, 70, 72, 78, 79, 82, 87, 90, 92, 99, 106] Additionally, the fear of judgment (22/161), [10, 24, 35, 43, 53, 59, 67, 79, 80, 88, 92, 99, 104, 107, 109, 116, 126], the fear of the negative impact that incident reporting could have on relationships with other HCPs, patients and the public (12/161), [10, 11, 36, 44, 46, 48, 54, 59, 92, 104, 116, 120] and the fear of a detrimental impact that reporting an incident could have on HCPs career (10/161), [10, 11, 27, 58, 59, 79, 86, 92, 93, 126] such as for example fear of job loss, were also cited as common barriers. Other less frequently mentioned barriers included protection of self (7/161), [24, 76, 80, 107, 122, 127] avoidance of discussion in meetings (4/161), [8, 69, 87, 117] 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), ^[8, 11, 27, 38, 43, 48, 57, 69, 74, 78, 79, 81, 85, 87, 88, 90, 92, 93, 99-101, 105-107, 114, 118, 121] followed by the complexity of the reporting process (28/110). ^[8, 9, 11, 31, 33, 35, 38, 44, 46, 51, 73, 78, 79, 88-90, 93, 100, 101, 105-107, 117, 118, 125] Other process and systems of reporting barriers included lack of anonymity and/or confidentiality in reporting (22/110), ^[8, 11, 24, 27, 35, 48, 50, 68, 73, 74, 76-78, 80, 87, 101, 106, 107, 127] reporting format

(10/110), ^[31, 44, 82, 85, 90, 93, 100, 117] and the type of reporting system (e.g. paper-based) (5/110). ^[38, 50, 92, 117] Less frequently mentioned barriers included lack of information to complete report (3/110), ^[94, 107, 114] the focus of reporting (1/110), ^[78] and information to complete report not readily being available (1/110). ^[31]

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. [8, 11, 24, 31, 35, 42-48, 50, 51, 53, 54, 58, 65, 66, 69, 70, 72, 73, 80, 85, 87, 88, 92, 100, 103, 105, 106, 109, 114, 126, 128, 129] Incidents that were deemed to occur frequently were considered too well-known to report. [31, 51, 66, 70, 75, 76, 84, 100, 101, 103, 114, 119, 121, 127-129] Furthermore, if the cause of the incident was deemed unpreventable this acted as a barrier to incident reporting. [35, 52, 66, 81, 82, 85, 100, 101, 103, 107, 114, 119, 124, 128, 129] Other barriers included the type of incident (13/92) [8, 33, 34, 52, 69, 81, 85, 92, 93, 100, 107, 117, 121] and the level of risk (2/110). [11, 58]

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Individual HCP Characteristics

Barriers reflective of individual HCP characteristics were cited 89 times. Barriers included a negative attitude/lack of value placed on incident reporting (53/89), ^{[8, 9, 35, 44, 46, 56, 61, 63, 64, 66, 68, 70, 73, 74, 76, 79, 81, 86-88, 92, 93, 99-101, 103, 105, 107, 109, 117, 118, 120, 121, 128] and 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), ^[8, 27, 31, 72, 87, 93, 117, 119, 129]}

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and that the way HCPs perceive themselves can act as a barrier to reporting (9/89). [24, 36, 55, 80, 87, 107, 127] Less frequently mentioned barriers included emotional responses to the incident (6/89), [31, 58, 79, 82, 100] previous reporting behavior (5/89), [34, 37, 52, 60, 74] exposure to errors (2/89), [38, 97] and length of time in employment (2/89).

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) ^{[9, 11, 24, 27, 31, 35, 38, 44, 46, 51, 52, 70, 73, 76, 79, 80, 87, 88, 100, 101, 103, 105, 107, 114, 119, 121, 127, 128] and a lack of clarity regarding what constitutes an adverse event and/or near miss (31/84). ^[9, 11, 31, 35, 43, 44, 46, 51, 69, 74, 82, 85, 87, 88, 92, 93, 95, 99, 100, 105, 117, 121] 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), ^[35, 75, 79, 92, 99, 106, 124] lack of training in reporting (5/84), ^[68, 76, 82, 86, 97] and lack of awareness (4/84). ^[35, 43, 106, 114]}

Work Environment

Workload/Priority (50/80) ^{[9, 11, 24, 27, 31, 34, 35, 43, 48, 49, 51, 55-58, 61, 68-70, 72, 75-77, 80, 82, 83, 88-90, 92, 93, 100, 103, 117, 119, 120, 125, 127-129] and accessibility (27/80) ^[24, 27, 31, 34, 35, 51, 52, 56, 74, 75, 80, 82, 86, 93, 101, 105-107, 114, 117, 119, 121, 127] were the most frequently 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 (e.g. 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, 35, 37, 43, 44, 56, 58, 59, 61, 62, 69, 78, 85-87, 90, 92, 99, 100, 106, 108, 117, 123] and the absence/lack of a positive reporting culture (17/76) ^[9, 10, 34, 35, 49, 66, 70, 81, 86, 90, 92, 114, 117, 118, 123] were the two most frequently mentioned organisational barriers to reporting. Less frequently mentioned were lack of organisational learning and improvement (7/76), ^[27, 35, 61, 68, 69, 85, 100] poor organisational use of data (7/76), ^[43, 59, 61, 92, 99] and poor management response to reports (5/76). ^[55, 68, 79, 92, 112]

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, 27, 32, 55, 58, 66, 74, 87, 88, 90, 100] the influence of seniors not to report (7/33), [37, 42, 74, 82, 106, 110] and how HCPs feel about reporting their peers (5/33). [79, 85, 103]

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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) [8, 9, 34, 35, 44, 52, 70, 93, 94, 100, 104, 118, 121, 128] 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). [85, 87, 120]

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Frequency of Facilitators in Patient Safety Incident Reporting (Table e1)

Facilitators of reporting were mentioned 372 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).

Organisational Factors

Organisational factors were mentioned as facilitators 97 times. The two most frequently cited facilitators included the provision of feedback/communication following incident reporting (29/97) ^[9, 11, 30, 33, 41, 44, 46, 61, 65, 68, 70, 75-77, 87, 100, 101, 107, 112, 117] and a non-punitive incident reporting policy (22/97). ^[9, 11, 29, 30, 32, 33, 40, 46, 58, 68, 75-77, 81, 87, 101, 106, 107] The existence of a reporting culture (16/97) ^[29, 33, 39, 66, 75, 96, 100, 106, 110-112, 121, 122] and a focus on learning and improvement from incidents (13/97) ^[9, 31, 40, 61, 68, 70, 85, 90, 100, 110] 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, 30, 44, 46, 58, 61, 65, 68, 70, 75, 87, 100, 106, 107, 117] 16/75, [9, 11, 29, 31, 40, 44, 65, 68, 74, 87, 100, 106, 117] and 15/75 [9, 11, 30, 38, 65, 68, 73, 77, 81, 100, 101, 117] facilitators within this category. Less frequently mentioned process and systems of reporting facilitators included the type of reporting system used (e.g. electronic reporting) (11/75). [33, 34, 40, 44, 68, 73, 101, 117]

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, 31, 40, 42, 47, 50, 58, 66, 75, 77, 82, 85, 88, 95, 114, 121, 124, 125, 128] and 13/55, [11, 66, 75, 77, 114, 121, 124] 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), [82, 85, 121] cause of the incident (6/55), [40, 66, 76, 77, 125] and level of risk (1/55).[58]

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, 40, 58, 68, 82, 88, 90, 93, 95, 97, 98, 107, 111, 125] HCPs emotional response to a patient safety incident was also found to increase the likelihood of reporting in a number of studies (5/41). ^[31, 58, 100] The professional group of HCPs was also found to act as a facilitator to reporting (5/41). ^[28, 71] Less frequently cited facilitators included previous reporting behavior (1/41), ^[29] number of hours worked (1/41), ^[52] and demographics (e.g. gender and age) (2/41).

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Knowledge and Skills

Training in reporting was identified as the most frequently mentioned facilitator in this category (21/36). [9, 25, 33, 70, 73, 75, 76, 87, 101, 106, 117, 127] Other facilitators included knowledge regarding what constitutes an adverse event/near miss and the ability to

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recognise an error has occurred (7/36 ^[9, 30, 44, 46, 70, 87, 100] and 4/36, ^[75-77, 124] respectively).

Team Factors

Team factors were mentioned 20 times as a facilitator to reporting. Good teamwork/communication (7/20) [39, 75, 77, 122] and a positive team culture (4/20) [98, 107, 111, 122] were the most frequently cited facilitators.

Professional Ethics

Professional ethics was cited as a facilitator 17 times. A strong sense of duty (8/17) [75, 85, 88, 95, 101, 107] and responsibility (5/17) [77, 90, 91, 94] to report increased the likelihood of reporting. Less frequently cited facilitators included accountability (2/17) [88, 121] and a legal obligation to report (1/17). [37]

Work Environment

Work environment was mentioned as a facilitator 18 times. Access to the incident reporting system (11/18), [30, 68, 73-75, 87, 100, 101, 117] 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 [9, 11, 27, 33, 82, 88, 90] and 4/13, [9, 11, 87, 88] respectively).

Frequency of Negative Cases (Table e1)

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).

Individual HCP characteristics were mentioned as a negative case 43 times. HCP's attitude and value of incident reporting did not have an impact on reporting behavior (12/43). [37, 48, 54, 72, 79, 96, 129] Similarly, HCPs demographics (e.g. age, gender) had no impact on the likelihood of reporting (12/43). [37, 49, 51, 52, 77, 96, 97, 125, 129] Other less frequently mentioned factors included seniority (4/43), [37, 77, 125, 129] forgetfulness (1/43), [129] previous reporting behavior (1/43), [129] and number of hours worked (1/43). [26] Organisational factors were cited as having no impact on incident reporting 22 times. The most frequently mentioned were the ownership of the organisation (e.g. private/public funded) (6/22) [25, 77] and management response towards incident reporting (4/22). [29, 97, 115] Knowledge and skills were mentioned 15 times. These included the clarity of the reporting mechanism (5/15), [29, 48, 72, 129] knowledge of what constitutes an adverse event/near miss (2/15). [48, 72] ability in error recognition (1/15), [48] and training in error reporting (7/15). [25, 77, 86, 129]

Fear of adverse consequences was cited as having no impact on engagement in incident reporting 12 times. These included a fear of litigation (4/12),^[24, 40, 48, 90] a general fear of adverse consequences (3/12),^[72, 85, 96] blame (1/12) [48], judgment (1/12),^[101] and impact on career (1/12).^[125] Work environment was mentioned as as having no impact on reporting 10 times, including workload/priority (3/10)^[51, 123, 125] and unit type (3/10).^[49, 112] Other less frequently cited work environment factors

Across all studies, process and systems of reporting was mentioned 7 times as having no impact on incident reporting; these included reporting format (3/7). [25, 68, 125] complexity/simplification of reporting (1/7), [68] and anonymity and/or confidentiality (1/7).[24] Professional ethics were only mentioned four times as having no impact on the likelihood of incident reporting; these were legal obligation (2/4), [37] duty (1/4), [125] and responsibility (1/4). [26] Team factors were cited as having no impact on the likelihood of reporting 3 times, including teamwork and communication (2/3)[123] and support/encouragement to report (1/3).[109] Incident characteristics were the least frequently mentioned factor which had no impact on reporting. Cause of incident was found to have no impact on engagement in reporting (2/2).[125, 129]

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. Whilst there are numerous problems associated with this approach^[7] (e.g. flooding the system to such a degree that the thorough investigation of each incident reporting is unachievable), it is clear that high levels of underreporting seriously compromises the ability of incident reporting systems to facilitate learning and improvement 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 (e.g. 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

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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. [130] 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 (i.e. prevalence) of factors contributing to incident reporting. Whilst 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 instill 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 the organisational leaders. There is no 'optimum model' for incident reporting systems (e.g. electronic, confidential, anonymous) - systems need to be responsive to users and organisational needs.

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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.

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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 (e.g. 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 in comparison to 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, i.e. departmental, local, regional and national. In addition, the studies included a vast array of health care settings and providers, maximising the generalisability of the results. The resulting evidence has been synthetised into a practical output i.e. 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 four continents from

over 20 countries were identified, hence we are confident that our findings are of high external validity to guide safety policy globally. Secondly, the last systematic search for literature was conducted on 29/05/2014, meaning that literature published since this date will not have been included. Thirdly, 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. Fourthly, 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 (e.g. primary and secondary healthcare).

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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 underreport 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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Data sharing

All data from this systematic review and theoretical framework is presented within the publication.

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Table 1: Se	earch Strategy
Category A	Patient Safety Incident: near adj miss* (MeSH heading), adverse adj event*, never adj event* (MeSH entry term), medical adj mistake* (MeSH entry term), error*, mistake* (MeSH entry term), negligen* (MeSH entry term), malpractice* (MeSH heading), failure*, injur* (MeSH entry term), critical adj incident* (MeSH entry term), sentinel adj event*, incident*, harm*, accident* (MeSH heading), medical adj error* (MeSH heading), patient adj safety (MeSH heading)
Category B	Incident Reporting System: risk adj management (MeSH heading), incident adj reporting adj system*, error adj report*, critical adj incident adj technique (MeSH entry term), safety adj report*, incident adj report* (MeSH entry term), reporting adj system, NRLS, national adj reporting adj2 learning adj system.
Category	Barrier/Facilitator: communication adj barrier* (MeSH heading), feedback (MeSH heading), safety adj culture (MeSH entry term), reporting adj culture, attitude (MeSH heading)*, preventive adj measure* (MeSH entry term), mandatory, voluntary, under-reporting, willingness, blame, obstacle*, incident adj type, level adj of adj harm, fear* (MeSH heading), responsibi*, workload (MeSH heading), trust* (MeSH heading), anonym*, confidential* (MeSH heading), facilit*, barrier*, enabl*, legal, law (MeSH entry term).

Table 2: Theoretical framework of factors determining engagement in patient safety incident reporting

Category	Descriptions & 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 behavior, such as structure (e.g. 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 (e.g. paper based or electronic).
Team factors	Any factor related to the functioning of different professionals within a group which influences incident reporting behavior. 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 (e.g. form completion) and general (e.g. 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 behavior, 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 (e.g. guilt) or outcome (e.g. litigation) associated with individual HCPs' incident reporting behavior. A reduction in the likelihood of experiencing fear (e.g. the existence of a non-punitive policy) results in increased incident reporting participation.
Incident Characteristics	Characteristics of the patient safety incident which may make HCP's more or less likely to report. These include frequency of error, level of harm and the cause of error.

Note: HCP=Healthcare Professional

Table 3: Frequency of Articles by Country

Country	Count (percentage)
United States of America ^[9, 11, 28, 30-59]	33 (30.00 %)
United Kingdom ^[10, 29, 60-81]	24 (21.82 %)
Australia ^[8, 27, 82-87]	8 (7.27%)
Canada ^[88-95]	8 (7.27 %)
Taiwan ^[96-99]	4 (3.64 %)
Netherlands ^[100-103]	4 (3.64 %)
Saudi Arabia ^[104-107]	4 (3.64 %)
International ^[24, 26, 108, 109]	4 (3.64 %)
Israel ^[110-112]	3 (2.73 %)
Iran ^[113, 114]	2 (1.82 %)
Japan ^[25, 115]	2 (1.82 %)
New Zealand ^[116, 117]	2 (1.82 %)
Sweden ^[118, 119]	2 (1.82 %)
Italy ^[120, 121]	2 (1.82 %)
Denmark ^[122]	1 (0.91 %)
Norway ^[123]	1 (0.91 %)
Pakistan ^[124]	1 (0.91 %)
Portugal ^[125]	1 (0.91 %)
Jordan ^[126]	1 (0.91 %)
China ^[127]	1 (0.91 %)
Germany ^[128]	1 (0.91 %)
Spain ^[129]	1 (0.91 %)

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Figure 1: Example of data coding, conceptualisation and categorisation for theory development

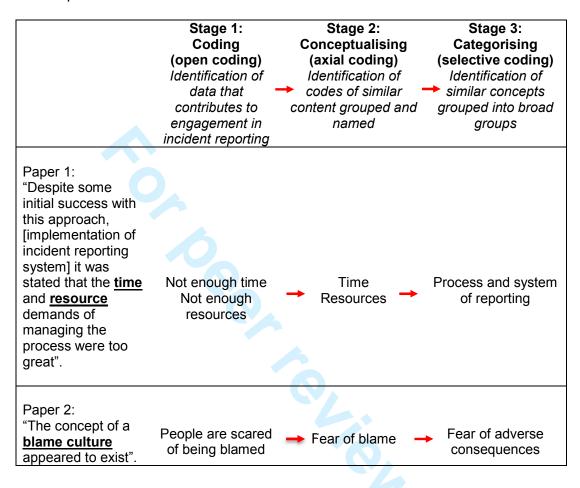


Figure 2: Flow diagram of the theoretical literature review process

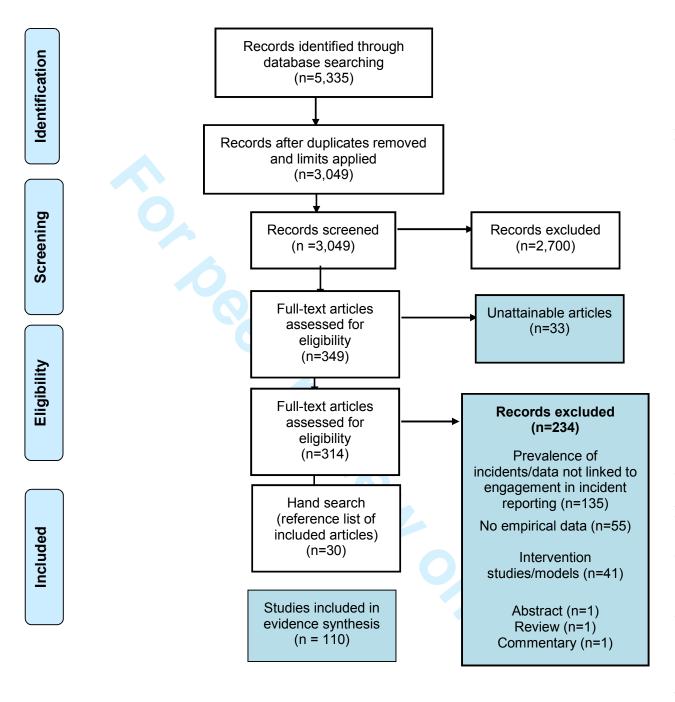
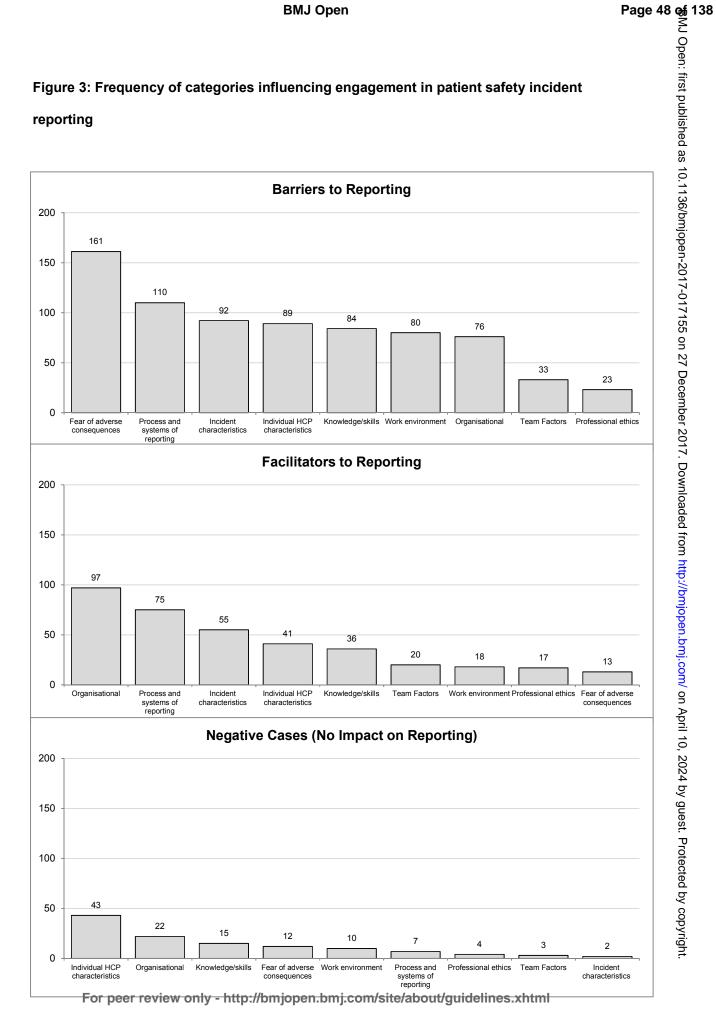


Figure 3: Frequency of categories influencing engagement in patient safety incident reporting



eTable1: Full data extraction table of included articles

Author, Year	Study Design, Sample Size, Country	Barriers to Incident Reporting	Facilitators of Incident Reporting	Negative cases (No impact)
Albolino et al., 2010 [120]	Questionnaire based-study 820	Fear of mistrust in colleagues		
	Italy	Not considered a priority		
		Fear of punishment		
		Does not help to improve safety		
		Lack of time		
Alsafi et al., 2011	Questionnaire based-study. 107	Not my responsibility		
	Saudi Arabia	I do not want to lose my good relationship with my colleague		
		I might be reported by my colleague in turn		
		No incentive to error disclose		
		Avoiding punishment		
		Avoiding damage to reputation		
		It will not be discovered		
Anderson et al., 2013 [60]	Semi-structured interviews and documentary analysis	Experienced in using IR systems (Mental health staff)		

	62 United Kingdom	Blame culture (mental health staff)	
Arfanis et al., 2012	Semi-structured interviews 48 United Kingdom	Not used as learning tools to prevent similar occurrences elsewhere. Pressures on time Resources A lack of faith in the established system Fruitless and often pointless exercise that has little or no impact on improving patient safety and welfare Fear of litigation Fear of disciplinary action Blame The availability and ease of identifying the information No feedback	Feedback Learning and improvement Anonymous web based forum as an add on to IR system
Armitage et al., 2010 [62]	Semi-structured interviews and retrospective review of error reports	Lack of feedback	

	United Kingdom		
Ashcroft et al., 2006 [66]	Questionnaire-based	Local reporting	Local reporting
2006 (84)	Study 275 United Kingdom	Good patient outcome less likely to be reported than poor or bad patient outcome. Compliance with a protocol less likely to be reported than a violation or error. 'Fault-led' attitude One-off situations by individuals not report Loyalty to colleagues National reporting system	Poor or bad patient outcome more likely to be reported than good patient outcome Violation of protocol or error more likely to be reported than compliance with protocol. 'Learn from mistakes' culture
		Confidence in National Patient Safety Agency	Individuals making continual mistakes National reporting system
Backstrom et al., 2000 [119]	Questionnaire-based study. 748 Sweden	Assessment that the reaction is already well known	
	0003.1	Forgetting to report	

Ballangrud et al., 2012 [123]	Questionnaire-based study. 220 Norway	Hesitance to report on suspicion Lack of time Giving preference to other matters Uncertainty about the existing rules for reporting Difficulty in finding the right form Supervisor/manager expectations, actions promoting safety Feedback and communication about error		Organisational learning and continuous improvement Teamwork within hospital units Communication openness Non punitive response to errors Staffing
Bateman et al., 1992 [81]	Questionnaire-based study. 1181	One case cannot contribute to medical knowledge	Should be financially	

	United Kingdom		reimbursed	
	o mos migaoni	Impossible to determine responsible drug	Would report if	
		Serious ADRs well known when the drug is marketed	easier method	
		Professional obligation		
		Reporting increases personal liability		
		Reporting results by badgering by Committee of safety of medicines		
		Takes too much time to ADR report		
Bawazir et al., 2006 ^[107]	Questionnaire-based study. 172	No reporting forms available	An obligation to do so	
	Saudi Arabia	Reporting address unknown	There was a fee	
		Reporting form too complicated	Saw colleagues	
		Reporting ADRs is too time consuming	doing so	
		All ADRs are known	Attention drawn by publication	
		Want to publish myself	Receiving feedback	
		Confidentiality	Report through the internet	
		Patient confidence		

		Difficult to admit harm to patient Reporting could show ignorance	
		Fear of liability	
		No motivation	
		Insufficient clinical knowledge	
		Do not know how to report	
		Causality uncertain	
		One report make no difference	
Beasley et al., 2004 [30]	Focus groups 14 United States of America	Punitive system	A feedback system for submitters is necessary to
			maintain interest.
			Safe and secure access
			There needs to be easy access
			What to report needs to be clearly
			defined
			The reporting forms

			must be simple
	10 ₀		Error reporting must fit into a clinicians current work flow
			A non-punitive system is essential
		10 ₀	Reporter should only be required to report once if there are multiple systems
Belton et al., 1995	Questionnaire-based study 284	Report forms are not available when needed	
	United Kingdom	Doctor does not like reporting confidential information	2/2
		Doctor unsure how to report an ADR	
		Doctor fear he/she may appear foolish about reporting a suspected reaction	
		Doctor fears he/she may be exposed to legal liability by reporting reaction	
		Doctor too busy to send an ADR	

	~O	report Doctor is reluctant to admit he/she may have caused a patient harm Doctor would rather collect and publish personally Doctor believe that only safe drugs are marketed	
Belton et al., 1997 [24]	Questionnaire-based study Sample size not reported International: Denmark, France, Ireland, Italy, Netherlands, Portugal, Spain, Sweden, United Kingdom	Telephone number unavailable Report forms unavailable Address of reporting agency unavailable Unsure how to report Patient confidentiality Worried about appearing foolish Worried about legal liability (Not Denmark or Spain) Too busy to report ADRs Reluctant to admit they have caused a patient harm	Worried about legal liability (Not Denmark or Spain) Ambition to publish a personal series of cases (Not Spain, Sweden or Portugal) Patient confidentiality (Not Spain)

	A _O _A	Ambition to publish a personal series of cases (Not Spain, Sweden or Portugal) Believes that all marketed drugs are safe		
Blegen et al., 2004 [55]	Questionnaire-based study 1105 United States of America	Administrative response Personal fear Quality management Staffing resources Physical resources Peer relations		
Braithwaite et al., 2010 [86]	Questionnaire-based study. 2185 Australia	Job satisfaction IIMS training Accessibility of reporting system Security of IIMS Feedback from reports Workplace reporting culture Value placed on IIMS	0,	Form of training received

Chang et al	Questionnaire-based study		Level of support	Age
Chang et al., 2012 ^[96]	183 Taiwan		Level of Support	Age
Chiang et al., 2006	Questionnaire-based study. 597	Being blamed for MAE results		
	Taiwan	Adverse consequences from reporting		
		Patient's negative attitude		
		Physicians' reprimand		
		Not recognised MAEs occurred		
		Being recognised as incompetent		
		Too much time for filling reports		
		Think MAEs not important enough to be reported	4	
		Too much time for contacting physicians	0,	
		Unclear MAE definition		/,
		Disagreement over MAE		
		Unrealistic expectation for administering drugs correctly		

		No positive feedback Much emphasis on MAE as nursing quality provided Focus on individual rather than system factors to MAEs Administrators' responses to MAEs do not match the severity of the errors		
Chiang et al., 2010 [97]	Questionnaire-based study 838 Taiwan	Experience of making MAEs Nursing professional development Fear	Same attitude towards self and co-workers MAE reporting rate Nursing quality	Age Management and leadership Administrative barriers Reporting process
Chiang et al., 2012 [98]	Questionnaire-based study 1049 Taiwan		High scores on the safety organising scale Tenure of present position Self-evaluated IR rates	5

	~ O_		Those more willing to report their own incidents are more likely to report coworkers incidents
Church et al., 2013 [36]	Questionnaire-based study 546 United States of America	Hierarchical structure Poor communication	
		Fear of reprimand Reprimand of other therapists and	
		dosimetrists Personality	
		Lack of reporting system	
Clark et al., 2013 [109]	Questionnaire-based study 228	Fear of being judged by colleagues	4
	International: Australia and New Zealand	Personal Guilt	0.
		Feel it as unnecessary	
		Near misses are part of life	
Coley et al., 2006	Focus groups 8	Time consuming	
	United States of America	Inadequate staffing	

Cosentino et al., 1997 [121]	Questionnaire-based study 207	Reaction not clinically relevant		
1997	Italy	Awareness of similar reactions		
		Unavailability of report forms		
		Doubtfulness about which ADRs should be reported		
		Confidence about ADRs being well documented before marketing		
		Ignorance about reporting procedures		
		Too much time required to fill in the report form		
		Don't feel obliged to report		
		Don't want to create undue alarm	1/2	
		Uselessness of ADR spontaneous reporting	OA	
Covell et al., 2009 [92]	Semi-structured interviews and questionnaire based study 50 Canada	Adverse consequences		1
Daly et al., 2005 [37]	Questionnaire-based study 598	Administrators' length of time in position	Directors of nursings'	Administrators' knowledge of

[108]		T	
[100]	19		
	International: United		
	Kingdom/Uganda		
Ehrenpreis et al., 2012 [38]	Questionnaire-based study 92	Unsure how to report appropriately	Easier to use
	United States of America	Did not see adverse events on a regular basis	
		Too busy to make reports	
	· ·	The existing method was too cumbersome	
		Voluntary reporting was not an important process	
Eland et al., 1999 [103]	Questionnaire-based study 1357	Uncertain association	
	Netherlands	Too trivial to report	
		Too well known to report	
		Unaware of the existence of a nation ADR reporting system	OA
		Unaware of the need to report ADRs	
		Did not know how to report ADRs	
		Too bureaucratic	
		Not enough time	

		Concerned that the report could be used in legal case for damages by the patient	
	O _A	If another physician had prescribed the medicine	
		Medication brought over counter rather than prescribed	
Fider et al. 2007 [31]	Facus graups	Durdon of offert	Perceived benefit
Elder et al., 2007 [31]	Focus groups 139	Burden of effort	of reporting –
	United States of America	Lack of time	learning and
	Office States of Afficiate	Edok of time	improvement
		Forgetfulness	
			Emotional benefit
		Information not readily available	
			Guilt
		Computer problems	
			Personal
		Online access	responsibility
		What to report	Anonymous reporting
		Who should report	roporting
			Easing the burden
		What is an AE	of reporting
		What information is needed	The more harm, the more likely to
		Common problems	report

	~O	Rare errors Less serious errors unlikely to be reported Feeling personally responsible	
Elder et al., 2008 [58]	Focus groups and questionnaire-based study 125 United States of America	Too busy with other activities Didn't reach the patient Risk of harm is none or little Error made my someone new-give them a break Feel worse emotionally Feel like a failure Fear punishment Blame Name on permanent record Risk losing friends Will make enemies on unit No feedback so no personal benefits	Asked by management to make specific reports Harm actually occurred Risk of harm is great Error made by someone unable to be spoken to one- to-one Feel better emotionally Outlet for irritation at situation or person Honesty is a virtue

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			Get a "there but for the grace of god" understanding Improve clinical practice Could be a learning experience for others No known penalty for making a report	
Erler et al., 2013 [39]	Questionnaire-based study 51 United States of America		Higher levels of teamwork Communication openness Perception of manager actions promoting safety	
Espin et al., 2010 [95]	Semi-structured interviews 37 Canada	Did not feel it was an error	Patient negligence Threat of potential or actual harm to the patient Patient advocacy	

	^o_		Following proper procedure Error prevention Learning opportunities
Espin, et al., 2007	Semi-structured interviews 13 Canada	Domain-specific expertise is a necessary pre-requisite for reporting the error Part of the surgeon's responsibility as it fell within the surgical scope of practice.	Events outside of professional boundaries were more likely to be reported Responsible for error
Espin et al., 2006	Semi-structured and structured interviews 28 Canada	Responsibility	
Evans et al., 2006 ^[8]	Questionnaire-based study 773 Australia	I never get any feedback on what action is taken I don't feel confident it is kept anonymous The incident form takes too long to fill out and I just don't have time I am worried about litigation	

	The incident was too trivial		
	When the ward is busy I forget to make a report		
	It's not my responsibility to report someone else's mistakes		
	I don't know whose responsibility it is to make a report		
	I don't want to get into trouble		
	When it is a near miss, I don't see any point in reporting it		
	Even if I don;t give my details, I am sure that they'll track me down		
	The AIMS+ form is too complicated and requires too much detail	h.	
	Junior staff are often blamed unfairly for adverse incidents	0,	
	I wonder about who else is privy to the information that I disclose		
	If I discuss the case with the person involved nothing else needs to be done		

	*	I don't want the case discussed in meetings I am worried about disciplinary action Adverse incident reporting is unlikely to lead to system changes My co-workers may be unsupportive		
Fairbanks et al., 2008 [32]	Interviews, focus groups and events reports from an anonymous system 15 United States of America	Blame and Shame Punishment Legal factors Reluctance to tell on colleagues	Non punitive system	
Fukuda et al., 2010 [25]	Questionnaire-based study Sample size not stated Japan		Decreased time for reporting (nurses and physicians) Electronic reporting (physicians) Attendance at educational seminars (physicians) Hospital size	Non-punitive policy (physicians/nur ses) Rate of recommendations derived from reported incidents (physicians/nur ses) Electronic

	Ownership – university hospital (physicians) Ownership – national hospital (nurses) Assignment of patient safety manager (physicians)	reporting (nurses) Attendance at educational seminars (nurses) Elapsed years of incident reporting system (physicians and nurses) Attendance at conference (Physicians/nurses) Ward rounds (Physicians/nurses) Ownership – university hospital (nurses) Ownership –
		Ownership – national

Gaal et al., 2010 [26]	Observational study Sample size not stated International: Austria, Belgium, England, France, Germany, Israel, The Netherlands, Slovenia, Switzerland, and Wales	Private practice	Group (>3) practice	hospital (physicians) Ownership – municipal + public hospitals + healthcare corporation + other (physicians/nur se) Assignment of patient safety manager (nurses) Practice setting Amount of responsibility Hours of work Physical working conditions Single+ dual practice
Garbutt et al., 2007	Questionnaire-based study	Private practice	Belief that errors	Perceived risk

[40]	557	are one of the most	for personal
	United States of America	serious issues in	malpractice
		healthcare	risk
		Belief that they	Personal involvement in
		should report serious errors	an error
		Schous chors	an enoi
		Belief that they	
		should report minor	
		errors	
		Belief that they	
		should report near	
		misses	
		System change to	
		improve patient	
		safety after errors	
		reported	
		If error was caused	
		by system rather	
		than individual	
		failures	
		Personal	
		involvement in	
		serious errors	
		Assurance that the	
		information was	

Generali et al., 1995 ^[52]	Questionnaire-based study 235 United States of America	Unsure drug caused reaction Do not have forms Do not know how Reaction was expected Reporting would not occur to me Fear of legal liability Not my responsibility Hours worked per week (>49 or <40)	confidential A non-punitive reporting system A process that takes less than 2 minutes to use Local to the clinician's unit or department Hours worked per week (43-49 hours) Work setting	Age Gender Number of years in practice
Gladstone, 1995	Structured interviews 107 United Kingdom	Fear of management reaction		

Croop et al. 1000	Ctrustured interview	Look of time/too busy	Cortainty of ADD
Green et al., 1999 [76]	Structured interview 30	Lack of time/too busy	Certainty of ADR
	United Kingdom	Well recognised reaction	Suspicious of a reaction
	UA	Limited time to spend with patients	Training
		Lack of motivation	
		More information about ADR needed	Fee for reporting
		Lack of confidence in making report	Access to patient records
		Patient confidentiality	Feedback
		Patient suffered an ADR to a product counter prescribed by the pharmacists being interviewed	More time
Green et al., 2001 [75]	Questionnaire-based study 322 United Kingdom	Concern that a doctor gets a copy of reporting form	Reaction is of a serious nature
	o.m.ca rungas	Lack of confidence in discussing the ADR with the prescriber	The reaction is unusual
		Apprehension about sending in an inappropriate report	The reaction is to a new product
		Lack of time to fill in a report	Certainty that the reaction is a ADR
		Concern that a report will generate	
		extra work	The reaction is well

The change of a fee for	recognised for a
The absence of a fee for ADRs	reporting particular agent
	Education/training/
Lack of time to actively lo	
ADRs while in clinical pra	actice evenings
Lack of clinical knowledge	e makes it More time to spend
difficult to decide whether	
ADR has occurred	patients
Don't feel the need to rep	
recognised reactions	reminders and increased
Reporting cards not avail	
needed	
	Encouragement from managers and
	from managers and departments
	Increased collaboration with
	prescribers and
	participation on
	ward round
	Increased
	accessibility of
	reporting cards
	Cards specifically
	designed for the

	use of pharmacists More publicity in journal about reporting scheme Online access or telephone based reporting Development of local incentives Increased confidence in dealing with medical staff Making reporting a professional responsibility A fee for reporting ADR specialist pharmacists Increasing awareness among awareness among awareness among atternances.

van Grootheest et	Questionnaire-based study	Causality uncertain	Feedback	Reporting
al., 2002 ^[101]	Notherlands	Too time consuming	Publications	could show
	Netherlands	Too time-consuming	Publications	ignorance
	OA	No reporting forms available	Information about the national centre	
		Reporting address unknown	the national centre	
			Simplification of	
		Reporting form too complicated	reporting procedure	
		All all and an artist and are larger	Dan and the se	
		All adverse reactions are known	Promoting reporting as part of	
		Want to publish myself	professional duty	
		Train to pasiion injecti	processional daty	
		Confidentiality	Financial	
		E 60 100	compensation	
		Fear of liability	More attention to	
		No motivation	ADR reporting in	
		Tro mourdaon	university	
		Insufficient clinical knowledge	curriculum	
		Do not know how to report	Database of	
		To not mon to report	national centre	
			available on the	
			internet	
			Compulsory	
			Compulsory reporting	
l			reporting	
			Peer reporting	

Comment [L1]: This is the senior author. Should be MES et al. Needs to be moved up.

Haines et al., 2008	Questionnaire-based study 212	Time	Staff believe that completing IRs
	Australia	If the ward is very busy	improves patient safety
		Patients' responsibility for adverse	dicty
		events	Staff belief that competing IRs
		Cause of the incident	protects against legal liability
		Other methods of documentation	
		A A distribution of the confession of	If the patients was
		Access to previous reports (non filing of incident reports in the notes)	harmed/injured
		or mordone reports in the notes,	Patient factors
		Poor user friendliness of computer	5
		reporter systems	Protect staff
		Made staff feel personally	Type of incident -
		responsible for the form	preventable
		Poor access to computers	
		Non reporting by role models	O _A
		Absence of a definition of a fall	
		Blame	
		Absence of training	

Handler et al.,	Focus group and	Lack of readily available medication	
2007 [35]	questionnaire-based study 132	error reporting system or forms	
	United States of America	Lack of information on how to report	
		a medication error	
		Lack of feedback to the reporter or	
		rest of facility on medication errors that have been reported	
		that have been reported	
		Lack of knowledge of which	
		medication errors should be reported	
		Systems or forms used to report	
		medication error are long and time	
		consuming	
		Lack of knowledge of the usefulness	
		of reporting medication errors	
		Lack of a consistent definition of a	
		medication error	
		Lack of an anonymous medication	
		error reporting system	
		Lack of recognition that a medication	
		Lack of recognition that a medication error has occurred	
		Lack of a culture of reporting	
		medication errors	

Hartnell et al., 2012	Focus group and semi- structured interviews 30	Extra time required to report Extra work required to report	Improved care/improved patient safety	
		Lack of recognition of the actual or potential harm of a medication error Belief that reporting medication errors has little contribution to improving the quality of care Difficulty in proving that a medication error actually occurred Fear of losing respect of co-workers		
		Fear of being blamed Fear of liability or lawsuits Not knowing who is responsible for reporting a medication error Belief that it is unnecessary to report medication errors not associated with patient harm		
		Extra time involved in documenting a medication error Fear of disciplinary action		

Cumbersome IR forms	To prevent patient from receiving
Hesitancy about 'telling on' someone else	wrong medication
Fear of loss of reputation/perceived incompetence	Provides immunity/protection from legal action
Perceived severity of error (less severe errors are less likely to be	Fear of censure (harsh criticism or
reported)	blame)
Inability to recognise or identify medication errors	Perceived severity of error (more severe errors are
Lack of definitions or standards for reporting	more likely to be reported because a report will be
Lack of belief that reporting makes a difference	expected) Follow rules or
lack of trust about how error reports will be used	policies Ensures
Reporting is the responsibility of someone else	accountability
Fear of reprisal from management/administration	
Fear of exposure to malpractice suits	

Hasford et al., 2002 [128]	Questionnaire-based study 588	ADR too well known	Serious unknown ADR to a new drug	
	Germany	ADR too trivial	7.2.1 10 4 4.49	
			Serious unknown	
		Uncertain causality	ADR to an	
		Reporting too bureaucratic	established drug	
		Reporting too bureaucratic	Serious known	
		Lack of time	ADR to a new drug	
		Rules of conduct unknown		
		Suspect that drug prescribed by		
		colleague		
		Reporting process unknown		
		Lack of financial reimbursement		
		Suspect drug was self-medication		
		Reports considered useless		
		Reporting system unknown	OA	
		Fear of legal liability		
		Non-serious adverse reaction to established drug		
Heard et al., 2012	Questionnaire-based study 433	I am worried about litigation		Generalised de-identified

Australia	I don't want to get into trouble	feedback about reports
	My colleagues may be unsupportive	received from the anaesthetic
	I am worried about disciplinary action	community
	I may be blamed unfairly for the event	Role models e.g. senior colleagues and
	I do not want to be discussed in meetings.	department directors who openly
	Adverse events reporting makes little contribution to quality care	encourage reporting
	I don't know whose responsibility it is to make a report	Legislated protection of information you
	A good outcome of the case makes reporting unnecessary	provide from use in litigation
	I do not know which adverse events should be reported.	Ability to report anonymously
	Even if I don't give my details I'm worried they will track me down	Clear guidelines about what
	The forms take too long to fill in and just don't have time	adverse events are errors to report
	When I am busy I forget to make a report	Information on

	I don't feel confident that they information I provide will be kept	how confidentiality will be
	confidential	maintained if
OA	I never get any feedback after I report an adverse event	you supply your name
		Individualised
	I wonder about who else will have	feedback to
	access to information I disclose	you about reports you
	As long as the staff involved learn from incidents it is unnecessary to	submit
	discuss them further	Paper forms for
	allocate arem rarane.	reporting
	I would protect my self-interests	provided in
	ahead of the interests of the patient if	each theatre
	I could (by hiding or denying error)	Management
	Competition with my peers could	More support from
	prevent me from disclosing an error	colleagues
	provent me from allocioning arrefres	comoagaco
	If a doctor is careful enough he or	Less blame
	she will not make an error	attached to
		those who
	It would affect my identity as a doctor to admit to an error	report errors
	to autilit to all error	ANZCA
	Other don't need to know about	continuing
	errors I have made	professional
		development
	Disclosing an error, if you don't have	point for

	to, is an optional act of heroism I would cover up an error I had made if I could If I admit to an error I will feel like a failure It would affect my self-esteem to admit to an error Doctors who make errors are humiliated my their colleagues Medicine has a culture of silence where errors are not talked about Doctors who make errors are blamed by their colleagues Doctors should not make errors.		reports. Access to computer based reporting systems for home Education about the purpose of reporting Computer based reporting systems Training on how to use computer based system Training on how to fill in papers forms
	Doctors should not make errors.	0/7	computer based system Training on

Herdeiro et al., 2006 [125]	Questionnaire-based study 256	Lack of time	Workplace (hospital	Gender
	Portugal	Complexity of reporting	pharmacists more likely to report than	Age
			community	Job function
			pharmacists)	(registered, assistant or
			Really serious	other
			ADRs are not well	pharmacists)
			documented by the	
			time a drug is	Possible to
			marketed'	determine if a
			Serious and not	drug is responsible for
			expected ADRs	a particular
			expected ADINS	adverse
			Report an ADR if I	reaction'
			were unsure that it	
			was related to the	Cannot
			use of a particular	contribute to
			drug	pharmaceutica
				knowledge
				Interested in
				articles about
				ADRs'
				Most correct
				way to report
				ADRs in is the
				pharmaceutica

obligation to report ADRs Reporting ADRs puts career at risk I do not have time to complete the report card I do not know how the information in the report card is used I talk to pharmaceutica companies about possible ADRs with thei
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				drugs
Hohenhaus et al., 2008 [42]	Questionnaire-based study 175 United States of America	Afraid to report a medical error they had made	Error resulting patient harm	
	Officed States of Afficia	Afraid to report a medical error made by someone else	Error by novice nurse	
		Might not report if there was no harm to the patient and the error was recognised quickly		
		Might not report if a physician told them not to report the error		
		Would not report if their supervisor told them not to		
Holmstrom et al., 2012 [68]	Questionnaire-based study	Fear of consequences	Provides opportunity for	Paper-based
	United Kingdom	Culture of blame	evaluating causes of errors (e.g. root	Quick and easy to use
		Lack of training in MER for health- care professionals	cause analysis)	
		Lack of time for reporting	punitive approach to reporting	
		Lack of organizational leadership and support	Provides feedback of results of error	
		Lack of legal protection for individual health-care professionals who have	analysis for those involved in	

made an error	reporting
Lack of understanding why reporting is needed	Easy to use
Concern that no beneficial action will follow	Provides opportunity for error data analysis
Non-anonymous reporting Perceived to be bureaucratic	Produces recommendations and guidelines for
Lack of health-care staff	improving medication safety
Lack of financial resources	Provides confidentiality of
	reported information
	Provided and maintained by one
	national organisation
	Integral part of patient safety reporting system
	Reporting of errors is voluntary

BMJ Open

		Reporting of errors is mandatory Allows all healthcare professionals to report errors Available in electronic format Independent reporting system dedicated for medication error reporting Provides a choice of reporting anonymously Includes reporting of both potential and actual errors	
Hutchinson et al., 2009 [29]	Retrospective analysis of routinely collected data and questionnaire-based study Sample size not stated United Kingdom	Employer treats fairly staff involved in error near miss or incident Employer encourages staff to	Knows how to report errors, near misses and incidents When errors are reported,

			report errors, near misses or incidents Employer treats reports of errors, near misses or incidents confidentially Employer does not blame or punish people who make errors. Access to a counselling service were also more likely to report. Previous reporting behaviours Level of risk management	employer takes action to ensure that they do not happen again
Irujo et al., 2007 [129]	Case control study 78	Not serious ADR		Age
	Spain	Already well known ADR		Working experience as
		Uncertain about causality		pharmacist
		Forgot to report		Participation in



	A0/-			causally related to the use of a particular drug Basic knowledge about ADR reporting
Jeffe et al., 2004	Focus groups 109 United States of America	Not knowing what to report Errors that pose little risk to the patient Errors that do not end up harming the patient Not knowing how to report Fear of disciplinary repercussions (nurse and physicians) Fear of legal repercussions (nurse and physicians) Fear of repercussions from doctors (nurses) Link between reporting and performance reviews (nurses)	Severity of the situation (nurses) Likelihood of reoccurrence (nurses) Severe events reported as the error would be 'found' out anyway Self-protection The importance of reporting errors for educational purposes Anonymous (physician and nurses)	

		Protecting colleagues from disciplinary action(nurses) Lack of confidentiality Name, blame, shame culture Fear of public exposure Staff shortages Lack of time The lack of simple procedure for reporting errors Lack of feedback	Simple (physician and nurses) Fast reporting procedures(physici an and nurses) Receipt of critical feedback about the errors Anonymous, phone in system (physicians) Educational rather than punitive system (physicians) System that was 'lawyer proof' Blame free reporting (nurses)
Jennings et al., 2011 ^[27]	Focus groups, interviews and questionnaire based study Sample size not stated Australia	Burden of reporting in terms of time Lack of accessibility of reporting forms	Clarity of indemnity from prosecution

Johnstone et al., 2008 [84]	Focus groups, semi- structured interviews and questionnaire-based study 35	Frequency of incident-more frequent less likely to report	Seniority of graduate nurses
Johnstone et al.,			
	A	Time elapsed following incident Priority of reporting over other work tasks Forgetting to report	

	Australia			
Joolaee et al., 2011 ^[113]	Questionnaire-based study 286 Iran			Perceived work conditions
Kagan et al., 2008 ^[110]	Questionnaire-based study 201 Israel	The practice of ward nurse managers to cover up error, that is dealing with the error themselves without reporting to a higher authority	How the ward's and hospital's dealt with medication error How their ward handles error reporting	
Kagan et al., 2013 [111]	Questionnaire-based study 247 Israel	Medical error incidence	Patient safety culture index PSC at organisational level PSC at departmental level PSC at respondents personal performance level Nurses' place of birth and their professional status (academic or nonacademic	

			registered nurse)
Kaldjian et al., 2009 ^[41]	Questionnaire-based study 338 United States of America		Feedback
Karsh et al., 2006	Focus group 14	Length of report	Feedback
	United States of America	Punishment	Mandatory system
		Reporting near misses	Financial incentives
			Other incentives (protection from malpractice and disciplinary action) Support in using system Education in using system
Kennedy et al., 2004 [34]	Questionnaire-based study 113 United States of America	Not their responsibility to report Never thought to report/not required to do so	
		Handle errors internally i.e. no corporate system	
		No errors worth reporting	

		No time to report Forms not available or convenient	
Khan, 2013 ^[105]	Questionnaire-based study 50 Saudi Arabia	Unavailability of professional environment to discuss ADR Reporting forms are not available I do not know how to report Reporting forms are too complicated Reporting is time consuming I am not motivated to report I fear legal liability of the reported ADR I am not confident whether it is an ADR Insufficient knowledge of pharmacotherapy in detecting ADR Belief that only safe drugs are marketed-not cause of reaction	
King et al., 2006 [56]	Questionnaire-based study 39	Time constraints	

	United States of America	Difficulty locating forms	
		Lack of closure/feedback	
		Not important	
		Fear of disclosure to risk management	
Kingston et al., 2004 ^[9]	Focus groups 33 Australia	Lack of knowledge about the reporting process and	Effective and efficient IRS
	Australia	Lack of knowledge about what constitutes an incident	IRS with threat or blame
		"Nursing form" by association (not identified as being part of doctors role)	Prompt, relevant feedback
		Time constraint	IRS that drive improvements
		Complexity of reporting form	Monetary payment
		Lack of feedback	Simplification
		Lack of legal privileges afforded to the reporting process	Less time consuming
		Culture of blame	Clear definitions of what constitutes an
		No value	adverse event/near-miss

Kreckler et al., Que	uestionnaire-based study	I am too busy to fill out the form	Evidence of value of IRS Reporting process to be made more relevant to doctors Reporting process less threatening by renaming the form Increased awareness and knowledge of IR process Protection from liability System that doesn't require input from doctors (nurses) Education at orientation (nurses) Anonymous reporting	
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2009 [69]	137		
	United Kingdom	The form takes too long to complete	
		I am worried about litigation	
	O	I do not want the case discussed in meetings	
		I never get any feedback	
		It makes little contribution to the quality of care	
		I am not sure what incidents to report	
		The incident was too trivial	
		The incident did not result in any harm	
Li et al., 2004 [127]	Questionnaire-based study 1653	Address of reporting agency not available	Increasing awareness among
	China	Report forms unavailable	administrators, doctors & nurses
		Reporting process unknown	Establishing ADR institutes
		Unaware of a national ADR reporting	
		system	Education and
			training in ADR
		Patient confidentiality	knowledge and related topics

		Too busy to report ADR	
		ADR sufficiently well documented	
	^O _A	Reluctant to admit that they have caused a patient harm	
		Worried about feeling foolish	
		Reluctant to admit they may have made a medical error	
		Personal ambition to publish a case study	
Martowirono et al., 2012 [100]	Focus group	Negatively valued	Reporting process- ability to report
2012	Netherlands	Costs time	over the phone or
		Perceived as another administrative	send an email
		task that they have to complete	Anonymous reporting
		Priority	reporting
		- · · · · · · · · · · · · · · · · · · ·	Provide the
		Do not always agree with the definition of incident	possibility to report without identifying
		definition of molderit	the person involved
		Incidents that had no major patient consequence	Provide feedback
		Incidents that have happened before and has already been reported	Provide feedback to the reporter if an

	incident on how the	
Incidents that was not preventable	report will be	
	handled	
The cause of the incident Is already		
clear	Feedback-	
	communicate the	
Incidents is unlikely to happen again	results in terms of	
merating is arminely to mappen again	systems changes	
Was not an incident but a	Systems smanges	
complication	Create an incident	
Complication	reporting culture	
Incident already been discussed with	Toporting duitaro	
the people involved	Create a culture in	
the people involved	which IR is less	
The lack of feedback on a report	emotionally	
The lack of recuback of a report	charged e.g. by	
Absence of visible system changes	systematically	
were also issues	discussing IR	
were also issues	within a ward and	
Disloyal to colleagues	stimulating role of	
Disidyal to colleagues	supervisors	
Not their reapposibility	supervisors	
Not their responsibility	Cimplify the	
logal lightlity	Simplify the	
legal liability	procedure	
	Danissa a sanatahan	
Unpleasant working conditions	Design a procedure	
	in which it is	
Lack of encouragement from	possible to only	
superiors to report incidents.	report the	
	essentials of an	
Incident reporting is emotionally	incident, e.g. by	
charged	making a call or	

		Some residents stated that they did not complete IR because they did not think of it whereas others said Did not know what to report. Did not know how to report IRS complicated Workload	filing out a card or compact form with standard incidents. If necessary, the resident can be contacted for more information Make it easy for a resident to find out if an incident has already been reported Clarification what to report Clarification about and how to report Excite residents to report Draw attention to IR e.g. putting up posters with a	
Mayo et al. 2004	Questionnaire based study	Afraid of manager reaction	catchy slogan	
Mayo et al., 2004	Questionnaire-based study 983 United States of America	Afraid of manager reaction Afraid of co-workers' reactions		

		Not thinking an error was serious enough		
		Fear of disciplinary action		
McArdle et al., 2003 [78]	Semi-structured interviews	It takes too long		
	United Kingdom	Lack of feedback received		
		Lack on incentive		
		Cumbersome		
		Non-anonymous		
		Fear of blame		
		Description of medication did not fall into IRS formats-scope of reporting		
Merchant et al., 2005 [93]	Questionnaire-based study 207	I think of reporting too late	4/	Unnecessary as anesthesia
	Canada	Don't know where CIRS forms are		is safe
		Fear of lawyers getting information		futile as anesthesia is
		I don't know what sort of incident to report		safe
		I'm too busy		
		Fear of record of problem		

		Don't have CIRS forms My incidents are too minor Too long No value will come of this Too much writing Incidents I see are other's problem Too many tick boxes Unsure what 'critical incident' is Effort is doomed to failure Too difficult
		Form is confusing
		Unimportant to me Nothing can be learned from me
		CIRS asks wrong questions
Mrayyan et al., 2007 ^[126]	Questionnaire-based study 779 Jordan	Fear of disciplinary action/lose job Errors not serious to warrant

		reporting		
		Fear of reaction from co-workers		
	OA	Fear of reaction from nurse managers		
Mustafa et al., 2013 ^[124]	Questionnaire-based study 136 Pakistan	Uncertain association Awareness	Seriousness of ADRs Unusual reaction	
		Concern about legal liability	Reaction to a new product	
		(e).	Confidence in the diagnosis of ADR	
Naveh et al., 2006 [112]	Questionnaire-based study 632 Israel	Perceived safety procedures	Perceived safety information flow	Perceived priority of safety
Olympia at al	Overting a based study		Orfoto	Unit type
Okuyama et al., 2010 [115]	Questionnaire-based study 430 Japan		Safety management at ward level	Safety management at the hospital level
				Attitudes of ward safety managers

Osborne et al., 1999 ^[54]	Questionnaire-based study 57	Error not serious		Perceptions of medication
	United States of America	Afraid of repercussions		errors
		Afraid of reactions from		
		managers/co-workers		
Parvizi et al., 2014	Questionnaire-based study	Did not know they were expected to	Better education of	
[70]	119 United Kingdom	do this	the means of adverse IR	
	Office Hingdom	Did not know how to report to MHRA	daverse ii c	
		I do not see the purpose of reporting	Improvements in the feedback sent	
		I do not see the purpose of reporting	to the reporter on	
		Lack of time	the outcomes of	
		Blame	the adverse incidents	
		B		
		Direct reporting to the manufacturer	Improvements in the guidance on	
		Not reporting if the types of device	the type of adverse	
		failure were considered to be common knowledge	device related incidents to report	
		common knowledge	incidents to report	
		Reporting only those that were	Improvements in	
		unexpected failures or failures that may affect the patient or user	the electronic means of adverse	
			IR	
		Reported by either a nurse or other doctor	Improvements in	
		doctor	the clinical and	

	_		adverse incidence governance	
Patrician et al., 2009 [43]	Questionnaire-based study 43 United States of America	Perceptions that the administration focuses on the individual and not the system Nurses are blamed when something bad happened to patients Fear adverse consequences for reporting errors Nurses believe that their peers will think them incompetent Nurses do not think the error was important enough to report		
		Fear of administrative response	4	
		Disagreement over error		
		Reporting effort Lack of agreement about definition of error	9/	
		Lack of error recognition Excessive length of time for contacting physician		
Rasmussen et al.,	Questionnaire-based study		Safety climate	

2014 ^[122]	124			
	Denmark		Team climate	
	^O_		Inter-departmental working relationships	
		50	Increased cognitive demands	
Rogers et al., 1988	Questionnaire-based study 1121	Reporting forms not available		Age
	United States of America	Event already documented		Time in direct patient care
		Did not get to it/got busy		patient care
		Did not believe it was important		
		Forms were too much trouble		
		Minor or expected side effect	1/1	
		Did not like interacting with the government	OA	
		Liability concerns		
		Did not know how to report		
		Undetermined as ADE		
		Not primary physician		

Rowin et al., 2008	Descriptive study Sample size not stated United States of America		More likely to report no harm (nurses) More likely to report permanent harm, near death, death and unsafe environment (doctors) Type of incident: falls and medication (nurse) Type of incident: adverse clinical event (doctors)	Temporary harm Near miss
Sanghera et al., 2007 ^[79]	Semi-structured interviews 13 United Kingdom	Not being aware that an error had occurred Detailed paperwork Time constraints	10/	
		Not understanding incident reporting process No benefit (perception that nothing is done with the data)		

Sarvadikar et al.,	Questionnaire-based study	No encouragement by management Fear of loss of professional registration Fear of being in trouble Fear of looking incompetent Feeling upset Fear will be blamed Not wanting to report colleagues' errors	Doctors more likely	Nurses and
2010 [71]	56 United Kingdom		to report errors with worsening patient outcome	pharmacists likely to report error regardless of patient outcome
Schectman et al., 2006 [44]	Questionnaire-based study 120 United States of America	Unsure of reporting mechanism No actual harm came to the patient Reporting too difficult and time consuming Unsure of what is considered AE/NM	Allow electronic reporting of adverse events and near misses Clarify reporting mechanism	

		Inadequate MD participation in scheme	Clarify what constitutes an AE/NM	
	0,	Concern about consequences of reporting others' error	Allow anonymous reporting	
		Reporting makes no difference (nothing will change)	Increase physician involvement in QI	
		Concern about being blamed or judged less competent	Provide feedback on QI projects arising from reports	
		Weaknesses in the reporting system	Provide individual	
		Professional behaviours	feedback following report	
		Fear of retribution	D	
		Lack of feedback and the perception	Provide summary feedback on a	
		that change would not result from reports.	regular basis	
			Make reporting mandatory	
Schulmeister et al., 1999 [45]	Questionnaire-based study 160	Minor error		
	United States of America	Fear of disciplinary action		
Sharma et al., 2008 [74]	Questionnaire-based study 81	Does not achieve anything	Anonymous system	
	United Kingdom	Not in physicians culture	Easily accessible	

		Do not wish to incriminate others Do not know how to access forms Not bothered Do not wish to ask nurse staff Lack of time Do not know which incidents need to be reported Lack of anonymity Not in habit of considering it Discouraged by senior nurses	Forms not held by nursing staff
Soberberg et al., 2009 ^[118]	Questionnaire-based study 317 Sweden	I did not have enough time I am concerned about possible consequences Someone else did it It is too complicated No one else files incident reports It would not make any difference	

		Insufficient routines for reporting	
Soleimani., 2006	Questionnaire-based study 128 New Zealand	Threat of public outcry Professional consequences/discipline Embarrassment in front of colleagues	
Stratton et al., 2004 [59]	Questionnaire-based study 284 United States of America	No positive feedback is given for passing medications correctly Nurse administration focuses on the person rather than looking at the system Too much emphasis is placed on medication errors as a measure of the quality of care Responses by nursing administration do not match the severity of the error Individual/personal reasons Nurses could be blamed if something happened to the patient Nurse believe other nurses will think they are incompetent	

		Nurses fear adverse consequences from reporting Patient might develop a negative attitude Nurses fear reprimand from physician Nurses fear losing their license Nurses want to avoid potential publicity of medication errors in the media		
Sweis et al., 2000	Questionnaire-based study 280 United Kingdom	Busy Legal liability Fear of breaching patient confidentiality	Serious ADR rather than trivial Rarely occurring ADR rather than common ADR Confidence in recognising an ADR ADR to an established drug rather than new drug Active support of	Training in reporting Gender Type of hospital Age

	medical/pharmacy staff Written hospital policy for pharmacist ADR reporting Training and ADR meeting Increasing seniority Allocation of time for ADR monitoring Publicity and promotion by hospital and CSM Better cooperation with clinicians Support and encouragement by the pharmacy department More ward rounds
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	A0,-		Simplify reporting system ADR reporting team Feedback
Tariq et al., 2012 [83]	Semi structured interviews 23 Australia	Lack of time	
Taylor et al., 2004	Questionnaire-based study 140 United States of America	Not important to report error that did not harm patient	Make reporting of errors mandatory
		Reporting errors does not make any difference	Different format for IR
		Unsure about what is considered medical	Use of electronic format for reports
		Incident report form too complicated	Reward for reporting medical errors
		Concerned about being blamed or judged incompetent	Better education about what is
		Concerned about implicating others	considered a medical error that
		Unsure whose responsibility it is to report errors	should be reported
			Evidence that reporting of errors

			led to system changes Feedback on regular basis and frequencies of reported errors Feedback regarding outcome of a specific error that has been reported
Throckmorton et al., 2007 [47]	Questionnaire-based study 435 United States of America	Level of harm: no harm	Level of harm Working closely to the patient Higher scores on the Wakefield's scale Fewer years since initial license
Tobaigy et al., 2013 ^[106]	Questionnaire-based study 61 Saudi Arabia	Lack of awareness Workload/time constraints Unavailability of reporting form	Continuing education events An internet/web based reporting facility

		Reporting system complexity		
			Training focused	
		Error too trivial	on error prevention	
		Lack of anonymity	Anonymity of	
		Lack of anonymity	reporting	
		Fear of blame	reporting	
		real of blattle	A non-punitive	
		Concerns over penalization	reporting culture	
		Concerns over penalisation	reporting culture	
		Difficulty in recognising errors	Financial incentives	
		Difficulty in recognising errors		
			linked to reporting	
		Senior staff advised not to report		
		Lack of feedback from authority		
Turner et al.,	Semi-structured interviews	Value-not convinced that the		
(2013) ^[63]	32	reporting system would deliver		
	United Kingdom	improvements in clinical care		
Uribe et al., 2002	Questionnaire-based study	Time involved in documenting an		Thinking that
[48]	122 United States of America	error		reporting has
				little
		Extra work involved in reporting		contribution for
				improvement of
		Hesitancy regarding 'telling' on		quality care
		somebody else		
				Not knowing
		Thinking that it is unnecessary to		the usefulness
		report error because it had no		of the report
		negative outcome		or the report
		Tiogative outcome		Lack of
			1	Lack of

	Not being able to report anonymously Fear of lawsuits		knowledge of what should be reported Lack of recognition that a medical error has occurred Fear of being blamed Fear of disciplinary
		0,7	how to report Lack of interest or motivation for reporting Forms or computer locations not available to report medical errors

				Not knowing who is responsible for reporting error
Vessal et al., 2009 [114]	Questionnaire-based study 110 Iran	Uncertain association Too trivial to report Too well known to report Yellow card not available Not enough information from the patient Not enough time Unaware of the existence of a national ADR reporting system Too bureaucratic Did not know how to report Fear of legal liability Unaware of the need to report and ADR	The reaction is of a serious nature The reaction is unusual The reaction is to a new product Reaction not reported before for a particular drug Reaction is well recognised for a particular drug Any reaction	
Vincent et al., 1998 [72]	Questionnaire-based study 198	Unnecessary		Unsupported colleagues

	United Kingdom	Increased workload Blame Worry litigation Busy/forgot		Not knowing which incidents to report As long as staff learn from incident it is unnecessary to
		CONTRACTOR		discuss/report Fear disciplinary Not wanting incident to be discussed
			h 0.	Who's responsibility Little contribution
Vogus et al., 2007	Questionnaire-based study 1033 United States of America	Safety organising Unit type (emergency)	Trust in managers RN experience	Care pathways % of RNs with
		Safety organising and trust	Unit type (IC)	Unit type
		Safety organising and pathways	Number of beds	(surgery)

	_	Patient-to-RN ratio		
Walji et al., 2011	Semi- structured interviews 12 Canada	Lack of knowledge about natural health products Lack of time/priorities Complexity of reporting process	Pharmacists who saw themselves as 'knowledge generators' rather than just 'knowledge users' were more likely to report and less likely to allow workplace challenges to prevent their taking an extra step	
Walker et al., 1998 [85]	Focus groups and questionnaire-based study 43 Australia	Minor incidents (documentation and minor variation from the prescription) Negative past experience of reporting Fear of getting into trouble Fear they will somehow stand out from the crowd in the eyes of those in authority Feelings of discomfort or uncertainty about being required to report an incident that involved a colleague	More likely to report an incident if patient safety compromised Capacity to feedback and improve the situation Reporting might help raise people's awareness of problems that could be occurring	Fear of possible punishment senior staff

This is more difficult if the colleague		
is a more experienced nurse	Wrong drug	
Others expressed with view that they	Wrong route	
wouldn't report a friend, perhaps	,,,	
perceiving that the friend would be in	Wrong person	
trouble if the incident was reported	Mrana daga	
Did not always want to admit their	Wrong dose	
Did not always want to admit their mistake	Harm to the patient	
IIIstake	riaini to the patient	
Might not even realise that an error	A desire to target	
had occurred	an individual or	
	professional group	
Incident might be highly incriminating	to improve practice	
If the patient actually came to harm	Legal obligation of	
as a result of the error	the nurse to report	
If the adequations from the properties of		
If the departure from the prescribed		
therapy seemed reasonable		
If the problem could be sorted out		
ii iio piosioni oodid so oortod odt		
Concern about the time taken to fill		
in the incident report form		
·		
Inadequate understanding of what		
constituted an error		
A lack of feedback on the number of		
medication errors was a problem		

		Perceived inaction on reported errors incidents	
Waring, 2004 ^[64]	Semi- structured interviews 37 United Kingdom	Acute medicine and rehab: IR system was regarded as nurse led, dealing with ward issues and the work of non-medical groups Anaesthesia: Physicians remained sceptical about the hospital wide reporting system and were generally disinclined to participate in this approach	
Waring, 2005 [10]	Semi-structured interviews 28 United Kingdom	Fear of blame Blame culture Peer of punishment	
		Fear of blame from pubic	1/2
		·	
		Fear of litigation	
		Fear of professional competence being questioned	
		Fear of poor references	
		Reprimands from a senior colleague	

		Fear of use of reports-could be used at a later date in the event in medicolegal disputes		
Waters et al., 2012	Focus groups 16 Canada	Time Fatigue	Previous experience of litigation	Risk of litigation
		High workload Relevance of reporting form Complexity of reporting-gathering many pieces of information. Unit culture Fear of blame Close knit team Other methods of reporting-verbal reporting and team debrief Lack of feedback	Protection against future litigation Professional responsibility IR perceived as learning opportunity Desire for practice improvement	
Weissman et al., 2005 ^[50]	Questionnaire-based study 203 United States of America	Mandatory Non-confidential system State run	Serious harm	

		Less harm	
Williams et al., 2013 [65]	Focus groups 17 United Kingdom	Severity (more likely to report if serious harm	Simpler reporting system Targeted report Feedback Drug-specific error reporting forms Electronic forms/systems (easier than paper) Anonymous reporting
Winchester et al., 2012 [73]	Questionnaire-based study 120 United Kingdom	Concerned about confidentiality Did not know the procedure for reporting Did not think anything could be done Did not feel incident was important enough to report Believed source to be low risk Reporting was inconvenient	Education Adverts/posters Training Compulsory reporting Simple reporting system An electronic

			reporting system
Yong et al., 2003	Questionnaire-based study	Time constraints	Total anonymity
[117]	136	lin and formation	and confidentiality
	New Zealand	Laziness and forgetfulness	Protection against
		Dislike form filling	punitive action
	· ·	A lot of work for little practical benefit	Simplify forms and
			bring up to date
		Forms too complicated	Facul access to
		Do not believe the system is working	Easy access to forms
		Many incidents not worth reporting	Electronic data entry
		Many other tools exist for correcting	
		errors and improving standards	Incorporating IR form filling at
		Dislike the published interpretation of	regular M&M
		results with diagnostic views by	meetings
		some anaesthetists	Mandatory
		Qualitative result not acceptable	
		Feel that the main benefit of IR is	Local analysis rather than
		local analysis and that very rare	Australasian wide
		events distilled by multi-site	
		monitoring are less important	More aggressive follow up and
		Difficulty defining what constitutes	reviewing
		incident	

		Inadequate feedback Medico-legal implications Forms not available/hard to locate Lack of appropriate culture within department Not accepted as part of private practice culture Use of local IR system, hospital based audit Incidents are discussed at department level confidentially	Publication of problems Aims and purpose should be clarified explicitly Select a few incidents to monitor frequency	
Zwart et al., 2011 [102]	Prospective cohort study 66 Netherlands		Expertise	Communicator Collaborator Manager Health advocate Scientist Professional

verse Event (AE); Aus.
راز Critical Incident Reportin,
بودtions Appeals (IDIA); Incident Ir.
(MAE); Medication and Healthcare Produ.
پراس); Near Miss (NM); Patient Safety Culture (Pد Adverse Drug Event (ADE); Adverse Drug Reaction (ADR); Adverse Event (AE); Australia and New Zealand College of Anesthetists (ANZCA); Bachelor of Science in Nursing (BSN); Critical Incident Reporting Service (CIRS); Drug related problems (DRP); Incident Reporting (IR); Iowa Department of Inspections Appeals (IDIA); Incident Information Management System (IIMS); Intensive Care (IC); Medication Administration Error (MAE); Medication and Healthcare Products Regulatory Agency (MHRA); Medical Doctor (MD); Morbidity and Mortality (M&M); Near Miss (NM); Patient Safety Culture (PSC); Quality Improvement (QI); Register Nurse (RN)

eTable 2: Frequency of factors influencing engagement in incident reporting

		Impact on Reporting Engagement		
Factor		Barrier Frequency Count (%)	Facilitator Frequency Count (%)	Negative Case (no impact) Frequency Count (%)
	Adverse consequences	51 (31.68%) [8, 10, 11, 27, 30, 32, 33, 35-37, 42-45, 53-56, 58, 59, 61, 68, 75, 78, 79, 85, 87, 88, 92, 97, 99, 100, 104, 106, 109, 118, 120, 121]	-	3 (25.00%) [72, 85, 96]
	Litigation	30 (18.63%) [8-11, 24, 27, 32, 35, 48, 51, 52, 61, 69, 72, 77, 80, 81, 85, 87, 88, 93, 100, 101, 103, 105, 107, 114, 117, 124, 128]	8 (61.54%) ^[9, 11, 27, 33, 82, 88, 90]	4 (33.33%) ^[24, 40, 48, 90]
	Blame	24 (14.91%) [8, 10, 32, 35, 43, 44, 46, 58-61, 68, 70, 72, 78, 79, 82, 87, 90, 92, 99, 106]	4 (30.77%) ^[9, 11, 87, 88]	1 (8.33%) ^[48]
Fear of Adverse Consequences	Judgment	22 (13.66%) [10, 24, 35, 43, 53, 59, 67, 79, 80, 88, 92, 99, 104, 107, 109, 116, 126]		1 (8.33%) [101]
	Relationships	12 (7.45%) ^[10, 11, 36, 44, 46, 48, 54, 59, 92, 104, 116, 120]	6	-
	Impact on career	10 (6.21%) ^{[10, 11,} 27, 58, 59, 79, 86, 92, 93, 126]	-	1 (8.33%) ^[125]
	Protection of self	7 (4.35%) ^[24, 76, 80, 107, 122, 127]	-	
	Avoid discussion in meetings	4 (2.48%) ^[8, 69, 87, 117]	-	1 (8.33%) [72]
	Apprehension about sending inappropriate form	1 (0.62%) [75]	-	-
	Non-punitive	-	1 (7.69%) [117]	1 (8.33%) [123]
	Total	161 (100%)	13 (100%)	12 (100%)
Process and Systems of Reporting	Time	29 (26.36%) ^[8, 11, 27, 38, 43, 48, 57, 69, 74, 78, 79, 81, 85, 87, 88, 90, 92, 93, 99-101, 105-107, 114, 118, 121]	5 (6.67%) ^[9, 11, 25, 40]	-
	Complexity/simplification of reporting	28 (25.45%) [8, 9, 11, 31, 33, 35, 38, 44, 46,	15 (20.00%) ^{[9,} 11, 30, 38, 65, 68, 73,	1 (14.29%) [68]

	T	F4 70 70 7	77 04 405	
		51, 73, 78, 79, 88-90, 93, 100, 101, 105-107, 117, 118, 125]	77, 81, 100, 101, 117]	
	Anonymity and/or confidentiality	22 (20.00%) ^[8, 11, 24, 27, 35, 48, 50, 68, 73, 74, 76-78, 80, 87, 101, 106, 107, 127]	16 (21.33%) ^{[9,} 11, 29, 31, 40, 44, 65, 68, 74, 87, 100, 106, 117]	1 (14.29%) [18]
	Reporting format	10 (9.09%) ^[31, 44, 82, 85, 90, 93, 100, 117]	21 (28.00%) [9, 11, 25, 30, 44, 46, 58, 61, 65, 68, 70, 75, 87, 100, 106, 107, 117]	3 (42.86%) [24]
	Type of reporting system	5 (4.55%) ^{[38, 50, 92,}	11 (14.67%) [33, 34, 40, 44, 68, 73, 101, 117]	-
	Unknown destination of report	4 (3.64%) ^{[24, 70,} 101, 107]	-	-
	Not enough information to complete report	3 (2.73%) ^{[94, 107,}	1 (1.33%) ^[76]	-
	Sharing/access of reports	3 (2.73%) [51, 75, 87]	-	-
	Insufficient routines for reporting	1 (0.91%) [118]	-	-
	Lack of reporting system	1 (0.91%) [36]	-	-
	Administrative task	1 (0.91%) [100]	-	1 (14.29%) ^[97]
	Relevant to different HCPs	1 (0.91%) [64]	2 (2.67%) [9, 75]	-
	Reporting focus	1 (0.91%) [78]	2 (2.67%) [68]	-
	Information not readily available	1 (0.91%) [31]		-
	Not specified	-	-9	1 (14.29%) ^[97]
	When/where to report	-	1 (1.33%) [117]	-
	Doesn't require input from doctors	-	1 (1.33%) ^[9]	-
	Total	110 (100%)	75 (100%)	7 (100%)
	Level of harm	40 (43.48%) [8.11, 24, 31, 35, 42-48, 50, 51, 53, 54, 58, 65, 66, 69, 70, 72, 73, 80, 85, 87, 88, 92, 100, 103, 105, 106, 109, 114, 126, 128, 129]	26 (47.27%) [11, 31,40,42,47,50,58, 66,75,77,82,85,88, 95,114,121,124, 125,128]	
Incident Characteristics	Cause of incident	19 (20.65%) [35, 52, 66, 81, 82, 85, 100, 101, 103, 107, 114, 119, 124, 128, 129]	6 (10.91%) ^{[40,} 66, 76, 77, 125]	2 (100%) [125, 129]
	Frequency of incident	18 (19.57%) [31, 51, 66, 70, 75, 76, 84, 100, 101, 103, 114, 119, 121, 127-129]	13 (23.64%) [11, 66, 75, 77, 114, 121, 124]	-
	Type of incident	13 (14.13%) [8, 33,	8 (14.55%) [82,	-

		34, 52, 69, 81, 85, 92, 93, 100, 107, 117, 121]	85, 121]	
	Level of risk	2 (2.17%) [11, 58]	1 (1.82%) [58]	-
	Patient characteristics	-	1 (1.82%) [82]	-
	Total	92 (100%)	55 (100%)	2 (100%)
	Value/attitude towards reporting	53 (59.55%) [8, 9, 35, 44, 46, 56, 61, 63, 64, 66, 68, 70, 73, 74, 76, 79, 81, 86-88, 92, 93, 99-101, 103, 105, 107, 109, 117, 118, 120, 121, 128]	21 (51.22%) ^{[9,} 11, 40, 58, 68, 82, 88, 90, 93, 95, 97, 98, 107, 111, 125]	12 (27.91%) [37, 48, 54, 72, 79, 96, 129]
	Forgetfulness	9 (10.11%) ^[8, 27, 31, 72, 87, 93, 117, 119, 129]	-	1 (2.33%) ^[129]
	Perception of self	9 (10.11%) ^{[24,} 36, 55, 80, 87, 107, 127]	2 (4.88%) ^{[89,}	6 (13.95%) [24, 102]
	Emotional response	6 (6.74%) ^{[24, 36,} 55, 80, 87, 107, 127]	5 (12.20%) ^{[31,} _{58, 100]}	-
Individual HCP	Previous reporting behaviors	5 (5.62%) ^[34, 37, 37, 32, 60, 74]	1 (2.44%) [29]	1 (2.33%) [129]
Characteristics	Exposure to errors	2 (2.25%) [38, 97]	1 (2.44%) [90]	-
	Length of time in employment	2 (2.25%) [37]		1 (2.33%)[37]
	Seniority	1 (1.12%) ^[37]	3 (7.32%) ^[49, 77, 84]	4 (9.30%) ^{[37, 52,} 125, 129]
	Data required for own purposes	1 (1.12%)[101]		-
	Work hours	1 (1.12%)[52]	1 (2.44%) [52]	1 (2.33%) [26]
	Demographics	-	2 (4.88%) [37, 98]	12 (27.91%) ^{[37, 49,} 51, 52, 77, 96, 97, 125, 129]
	Profession	-	5 (12.20%) [28, 71]	5 (11.63%) ^[28, 71, 102]
	Total	89 (100%) 41 (100%)		43 (100%)
Knowledge and Skills	Clarify reporting mechanism	36 (42.86%) ^[9, 11, 24, 27, 31, 35, 38, 44, 46, 51, 52, 70, 73, 76, 79, 80, 87, 88, 100, 101, 103, 105, 107, 114, 119, 121, 127, 128]	2 (5.56%) ^{[44,}	5 (33,33%) [29,48,
	Adverse event/near miss clarity	31 (36.90%) [9, 11, 31, 35, 43, 44, 46, 51, 69, 74, 82, 85, 87, 88, 92, 93, 95, 99, 100, 105, 117, 121]	7 (19.44%) ^[9, 30, 44, 46, 70, 87, 100]	2 (13.33%) [48, 72]
	Ability in error recognition	7 (8.33%) [35, 75, 79, 92, 99, 106, 124]	4 (11.11%) ^{[75-} 77, 124]	1 (6.67%) [48]
	Training	5 (5.95%) [68, 76, 82,	21 (58.33%) [9,	7 (46.67%) [25, 77,

		86, 97]	25, 33, 70, 73, 75, 76, 87, 101, 106, 117, 127]	86, 129]
	Awareness	4 (4.76%) [35, 43, 106, 114]	2 (5.56%) [75, 85]	-
	Not enough information about product being reported	1 (1.19%) [89]	-	-
	Total	84 (100%)	36 (100%)	15 (100%)
	Workload/priority	50 (62.50%) [9, 11, 24, 27, 31, 34, 35, 43, 48, 49, 51, 55-58, 61, 68-70, 72, 75-77, 80, 82, 83, 88- 90, 92, 93, 100, 103, 117, 119, 120, 125, 127-129]	6 (33.33%) ^{[31,} _{75-77, 122]}	3 (30.00%) ^{[51, 123,} 125]
Work	Accessibility	27 (33.75%) [24,27, 31,34,35,51,52,56,74, 75,80,82,86,93,101, 105-107,114,117,119, 121,127]	11 (61.11%) [30, 68, 73-75, 87, 100, 101, 117]	1 (10.00%) [48]
Environment	Not specified	2 (2.50%) [61, 105]	-	-
	Unit type	ne 1 (1.25%) [49] 1 (5.56%) [49]		3 (30.00%) [49, 112]
	Physical working conditions	-	-	1 (10.00%) [26]
	Satisfaction with work environment	- 6	-	1 (10.00%) [113]
	Care pathways	-		1 (10.00%) [49]
	Total	80 (100%)	18 (100%)	10 (100%)
Organization	Feedback/communication	26 (34.21%) [8, 9, 11, 35, 37, 43, 44, 56, 58, 59, 61, 62, 69, 78, 85-87, 90, 92, 99, 100, 106, 108, 117, 123]	29 (29.90%) [9, 11, 30, 33, 41, 44, 46, 61, 65, 68, 70, 75-77, 87, 100, 101, 107, 112, 117]	2 (9.09%) [25, 125]
	Reporting culture	17 (22.37%) [9, 10, 34, 35, 49, 66, 70, 81, 86, 90, 92, 114, 117, 118, 123]	16 (16.49%) [29, 33, 39, 66, 75, 96, 100, 106, 110-112, 121, 122]	1 (4.54%) [96]
	Learning/improvement	7 (9.21%) [20, 59, 76, 90, 94, 102, 103]	13 (13.40%) ^{[9,} 31,40,61,68,70,85, 90,100,110]	2 (9.09%) [29, 123]
	Use of data	7 (9.21%) [43, 59, 61, 92, 99]	2 (2.06%) ^{[65,}	-
	Policy	6 (7.89%) ^[11, 68, 75, 78, 104, 128]	22 (22.68%) ^{[9,} 11, 29, 30, 32, 33, 40, 46, 58, 68, 75-77, 81, 87, 101, 106, 107]	2 (9.09%) [25, 125]
	Management response	5 (6.58%) [55, 68, 79, 92, 112]	2 (2.06%) [58, 115]	4 (18.18%) ^[29, 97, 115]
	Outcomes of analysis	4 (5.26%) ^{[10, 88,}	1 (1.03%) [100]	-

	Resource	2 (2.63%) [55, 68]	3 (3.09%) ^{[25, 75,} 127]	1 (4.54%) [25]
	Ownership	1 (1.32%) [40]	4 (4.12%) ^{[25, 52,} 125]	6 (27.27%) [25, 77
	Hierarchy	1 (1.32%) [36]	-	-
	Size	-	3 (3.09%) [25, 26, 49]	1 (4.54%) [26]
	Nursing quality	-	1 (1.03%) [97]	-
	Awareness	-	1 (1.03%) [100]	-
	Location	-	-	1 (4.54%) [26]
	Elapsed time of IRS integration	-	-	1 (4.54%) [25]
	Ward rounds	-	-	1 (4.54%) [25]
	Total	76 (100%)	97 (100%)	22 (100%)
	Relationships	13 (39.39%) [11, 27, 32, 55, 58, 66, 74, 87, 88, 90, 100]	2 (10.00%) ^{[49,}	-
Team Factors	Influence of Seniors	7 (21.21%) ^{[37, 42,} 74, 82, 106, 110]	1 (5.00%) [87]	-
	Peer reporting	5 (15.15%) [79, 85,	3 (15.00%) ^{[97,} 98, 101]	-
	Teamwork/communication	3 (9.09%) [11, 36, 75]	7 (35.00%) ^{[39,} 75, 77, 122]	2 (66.67%) [123]
	Support/encouragement	3 (9.09%) [8, 87, 100]	1 (5.00%) [87]	1 (33.33%) [72]
	Medical doctor involvement	1 (3.03%) [44]	1 (5.00%) [44]	-
	Error committed by junior staff	1 (3.03%) ^[58]	1 (5.00%) [42]	-
	Team culture	-	4 (20.00%) ^{[98,} 107, 111, 122]	-
	Total	33 (100%)	20 (100%)	3 (100%)
	Concealment	5 (21.74%) [85, 87, 120]	1 (5.88%) [11]	
Professional Ethics	Duty	1 (4.35%) [81]	8 (47.06%) ^{[75,} 85, 88, 95, 101, 107]	1 (25.00%) [125]
	Accountability	-	2 (11.76%) ^{[88,}	-
	Responsibility	15 (65.22%) [8, 9, 34, 35, 44, 52, 70, 93, 94, 100, 104, 118, 121, 128]	5 (29.41%) [77, 90, 91, 94]	1 (25.00%) [26]
	Culture	2 (8.70%) [74, 87]	-	-
	Legal	-	1 (5.88%) [37]	2 (50.00%) [37]
	Total	23 (100%)	17 (100%)	4 (100%)



PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	4
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	4
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	N/A
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	5-6
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	5
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	5
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	5-6
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	6-7
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	6-7
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	7
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	7-8
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I ²) for each meta-analysis. \(\text{Ag} \) \(\text{PCO} \) \(\text{Allow} \	7-9



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PRISMA 2009 Checklist

Page 1 of 2

Section/topic	#	Page 1 of 2 Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective	N/A
Additional analyses	16	reporting within studies). Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	9-10
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	9-10
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	N/A
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	10
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	12-21
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	N/A
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	22-25
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	25-26
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	26-27
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	27-28

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Development of a Theoretical Framework of Factors Affecting Patient Safety Incident Reporting: A Theoretical Review of the Literature

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Key Words: Incident reporting, Patient Safety, Service Quality

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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 3,049 potentially eligible articles; of these, 110 articles, including over 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 organisational (97, representing 26.08% of facilitators) and process and systems of reporting (75, representing 20.16% 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.

Article Summary – strengths and limitations

- The synthesis included quantitative, qualitative and mixed methods research and have not restricted the literature to specific incident reporting systems.
- Only articles published in English were included.
- The last systematic search for literature was conducted on 29/05/2014,
 meaning that literature published since this date will not have been included.
- Studies detailing interventions to improve incident reporting and studies detailing variations in engagement in incident reporting were not included.
- Large heterogeneity across studies in terms of outcome measures and methodologies meant conduction of meta-analysis was precluded.

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 underreporting. In the United States it is estimated that 50-96% of incidents are not reported.^[2, 4, 5] Failure to report patient safety incidents significantly hinders the underlying goals of incident reporting systems; low levels of reporting makes it is difficult at best to identify and prioritise patient safety risks, and hampers learning from such incidents and ultimately improvements in patient safety. Whilst 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. [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 (e.g. focusing on the psychological factors affecting incident reporting [14]; focusing on perceived barriers influencing incident reporting by nurses; [13] factors affecting reporting of incidents

related to medical devices and other healthcare technologies).^[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 the factors affecting patient safety incident reporting. The secondary aims were, firstly, to develop theoretical framework, of factors acting as barriers and facilitators to incident reporting to guide implementation of interventions to increase engagement, and, secondly, to determine the prevalence of factors to guide the development of interventions and policies to improve incident reporting.



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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 synthesize 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 29/05/2014; whilst the last search was conducted 2 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 English language.

TABLE 1 HERE

Eligibility criteria

Inclusion Criteria

 Studies reporting factors influencing the likelihood of incident report engagement in any healthcare setting (e.g. primary and secondary healthcare) and employing any study designs (e.g. qualitative, quantitative, mixed-methods)

Exclusion Criteria

- Studies reporting aspects of incident reporting systems and/or incident reporting perceived positively and/or negatively by healthcare professionals without data relating perceptions to incident reporting engagement
- 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)^[15]
- 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 health care has previously been published.^[13]

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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 was developed to maintain a focus on factors having a direct impact upon incident reporting engagement rather than simply identifying and listing factors of incident reporting which were perceived positively or negatively by healthcare professionals. Identifying elements of incident reporting perceived positively or negatively by healthcare professionals does not equate to identify 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 abstract. Three authors (SA, LH and TS) reviewed the articles at full-text stage. Data was extracted using an extraction template. The following data was 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 (e.g. The Cochrane Collaboration's tool for assessing risk of bias in randomized trials; [16] AMSTAR tool to assess the methodological quality of systematic reviews; [17] 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. [21] It has been identified as a method where thorough and theoretically relevant analysis of a topic can be reached, specifically within literature reviews. [22] 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 & 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 (e.g. in the case of a standardised scale), but in others allowed for unseen insights to develop across the data corpus (e.g. 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 three, 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.

FIGURE 1 HERE

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

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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.

TABLE 2 HERE

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.^[23]

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 5,335 records. After duplicates and limits were applied (English language, date restrictions 1980-May 2014), 3,049 records were considered for inclusion. Of these 3,049 records, 2,700 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 over 29,726 participants, were included in the final review (Figure 2). The total number of participants per study ranged from 8-2185 (mean=286.54; median: 134.00). Six studies did not report sample size, thus the sample size calculations represented above are based on 104 articles. [24-29] See eTable 1 for full data extraction.

FIGURE 2 HERE

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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 semi-structured interview and documentary analysis-based study; 1 semi-structured interview and retrospective review of error reports-based study; 2 semi-structured interview and questionnaire-based study; 3 focus group and questionnaire-based studies; 1 semi-structured and structured interview-based study; 1 interview, focus group and analysis of event reports-based study; 1 focus group and semi-structured interview-based study; 1 retrospective analysis of

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routinely collected data and questionnaire-based study; 2 focus groups, interview and questionnaire-based studies).

Countries (Table 3)

The review encompassed research spanning four continents and over 20 countries.

The four countries contributing the most studies were the United States of America (n=33), the United Kingdom (n=24), Australia (n=8), and Canada (n=8).

TABLE 3 HERE

(Please note that this table includes all 110 references)

Year of Publication

A steady increase in articles was evident over decades: 1980's (n=1), $^{[51]}$ 1990's (n=12), $^{[24, 45, 52, 54, 67, 72, 76, 80, 81, 85, 103, 121]}$ 2000's (n=58), $^{[8-11, 28-35, 37, 40-44, 46-50, 53, 55-59, 64, 66, 69, 74, 75, 77-79, 82, 84, 91-94, 99, 101, 107, 110, 112, 114, 116-119, 125-129]}$ 2010-May 2014 (n=39). $^{[25-27, 36, 38, 39, 60-63, 65, 68, 70, 71, 73, 83, 86-90, 95-98, 100, 102, 104-106, 108, 109, 111, 113, 115, 120, 122-124]}$ This increase is likely to reflect the growing integration of incident reporting systems in healthcare systems worldwide and the increasing realisation that healthcare professionals (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 (e.g. if fear was found not to be a 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 (e.g. 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. Whilst 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.

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FIGURE 3 HERE

Frequency of Barriers to Patient Safety Incident Reporting (eTable 2)

Barriers to incident reporting were mentioned 748 times across the 110 articles (see eTable 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, 30, 32, 33, 35-37, 42-45, 53-56, 58, 59, 61, 68, 75, 78, 79, 85, 87, 88, 92, 97, 99, 100, 104, 106, 109, 118, 120, 121] fear of litigation (30/161), [8-11, 24, 27, 32, 35, 48, 51, 52, 61, 69, 72, 77, 80, 81, 85, 87, 88, 93, 100, 101, 103, 105, 107, 114, 117, 124, 128] and the fear of blame (24/161). [8, 10, 32, 35, 43, 44, 46, 58-61, 68, 70, 72, 78, 79, 82, 87, 90, 92, 99, 106] Additionally, the fear of judgment (22/161), [10, 24, 35, 43, 53, 59, 67, 79, 80, 88, 92, 99, 104, 107, 109, 116, 126], the fear of the negative impact that incident reporting could have on relationships with other HCPs, patients and the public (12/161), [10, 11, 36, 44, 46, 48, 54, 59, 92, 104, 116, 120] and the fear of a detrimental impact that reporting an incident could have on HCPs career (10/161), [10, 11, 27, 58, 59, 79, 86, 92, 93, 126] such as for example fear of job loss, were also cited as common barriers. Other less frequently mentioned barriers included protection of self (7/161), [24, 76, 80, 107, 122, 127] avoidance of discussion in meetings (4/161), [8, 69, 87, 117] 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), ^[8, 11, 27, 38, 43, 48, 57, 69, 74, 78, 79, 81, 85, 87, 88, 90, 92, 93, 99-101, 105-107, 114, 118, 121] followed by the complexity of the reporting process (28/110). ^[8, 9, 11, 31, 33, 35, 38, 44, 46, 51, 73, 78, 79, 88-90, 93, 100, 101, 105-107, 117, 118, 125] Other process and systems of reporting barriers included lack of anonymity and/or confidentiality in reporting (22/110), ^[8, 11, 24, 27, 35, 48, 50, 68, 73, 74, 76-78, 80, 87, 101, 106, 107, 127] reporting format

(10/110), ^[31, 44, 82, 85, 90, 93, 100, 117] and the type of reporting system (e.g. paper-based) (5/110). ^[38, 50, 92, 117] Less frequently mentioned barriers included lack of information to complete report (3/110), ^[94, 107, 114] the focus of reporting (1/110), ^[78] and information to complete report not readily being available (1/110). ^[31]

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. [8, 11, 24, 31, 35, 42-48, 50, 51, 53, 54, 58, 65, 66, 69, 70, 72, 73, 80, 85, 87, 88, 92, 100, 103, 105, 106, 109, 114, 126, 128, 129] Incidents that were deemed to occur frequently were considered too well-known to report. [31, 51, 66, 70, 75, 76, 84, 100, 101, 103, 114, 119, 121, 127-129] Furthermore, if the cause of the incident was deemed unpreventable this acted as a barrier to incident reporting. [35, 52, 66, 81, 82, 85, 100, 101, 103, 107, 114, 119, 124, 128, 129] Other barriers included the type of incident (13/92) [8, 33, 34, 52, 69, 81, 85, 92, 93, 100, 107, 117, 121] and the level of risk (2/110). [11, 58]

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Individual HCP Characteristics

Barriers reflective of individual HCP characteristics were cited 89 times. Barriers included a negative attitude/lack of value placed on incident reporting (53/89), ^{[8, 9, 35, 44, 46, 56, 61, 63, 64, 66, 68, 70, 73, 74, 76, 79, 81, 86-88, 92, 93, 99-101, 103, 105, 107, 109, 117, 118, 120, 121, 128] and 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), ^[8, 27, 31, 72, 87, 93, 117, 119, 129]}

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and that the way HCPs perceive themselves can act as a barrier to reporting (9/89). [24, 36, 55, 80, 87, 107, 127] Less frequently mentioned barriers included emotional responses to the incident (6/89), [31, 58, 79, 82, 100] previous reporting behavior (5/89), [34, 37, 52, 60, 74] exposure to errors (2/89), [38, 97] and length of time in employment (2/89).

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) ^{[9, 11, 24, 27, 31, 35, 38, 44, 46, 51, 52, 70, 73, 76, 79, 80, 87, 88, 100, 101, 103, 105, 107, 114, 119, 121, 127, 128] and a lack of clarity regarding what constitutes an adverse event and/or near miss (31/84). ^[9, 11, 31, 35, 43, 44, 46, 51, 69, 74, 82, 85, 87, 88, 92, 93, 95, 99, 100, 105, 117, 121] 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), ^[35, 75, 79, 92, 99, 106, 124] lack of training in reporting (5/84), ^[68, 76, 82, 86, 97] and lack of awareness (4/84). ^[35, 43, 106, 114]}

Work Environment

Workload/Priority (50/80) [9, 11, 24, 27, 31, 34, 35, 43, 48, 49, 51, 55-58, 61, 68-70, 72, 75-77, 80, 82, 83, 88-90, 92, 93, 100, 103, 117, 119, 120, 125, 127-129] and accessibility (27/80) [24, 27, 31, 34, 35, 51, 52, 56, 74, 75, 80, 82, 86, 93, 101, 105-107, 114, 117, 119, 121, 127] were the most frequently 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 (e.g. 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, 35, 37, 43, 44, 56, 58, 59, 61, 62, 69, 78, 85-87, 90, 92, 99, 100, 106, 108, 117, 123] and the absence/lack of a positive reporting culture (17/76) ^[9, 10, 34, 35, 49, 66, 70, 81, 86, 90, 92, 114, 117, 118, 123] were the two most frequently mentioned organisational barriers to reporting. Less frequently mentioned were lack of organisational learning and improvement (7/76), ^[27, 35, 61, 68, 69, 85, 100] poor organisational use of data (7/76), ^[43, 59, 61, 92, 99] and poor management response to reports (5/76). ^[55, 68, 79, 92, 112]

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, 27, 32, 55, 58, 66, 74, 87, 88, 90, 100] the influence of seniors not to report (7/33), [37, 42, 74, 82, 106, 110] and how HCPs feel about reporting their peers (5/33). [79, 85, 103]

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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) [8, 9, 34, 35, 44, 52, 70, 93, 94, 100, 104, 118, 121, 128] 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). [85, 87, 120]

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Frequency of Facilitators in Patient Safety Incident Reporting (Table e1)

Facilitators of reporting were mentioned 372 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).

Organisational Factors

Organisational factors were mentioned as facilitators 97 times. The two most frequently cited facilitators included the provision of feedback/communication following incident reporting (29/97) ^[9, 11, 30, 33, 41, 44, 46, 61, 65, 68, 70, 75-77, 87, 100, 101, 107, 112, 117] and a non-punitive incident reporting policy (22/97). ^[9, 11, 29, 30, 32, 33, 40, 46, 58, 68, 75-77, 81, 87, 101, 106, 107] The existence of a reporting culture (16/97) ^[29, 33, 39, 66, 75, 96, 100, 106, 110-112, 121, 122] and a focus on learning and improvement from incidents (13/97) ^[9, 31, 40, 61, 68, 70, 85, 90, 100, 110] 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, 30, 44, 46, 58, 61, 65, 68, 70, 75, 87, 100, 106, 107, 117] 16/75, [9, 11, 29, 31, 40, 44, 65, 68, 74, 87, 100, 106, 117] and 15/75 [9, 11, 30, 38, 65, 68, 73, 77, 81, 100, 101, 117] facilitators within this category. Less frequently mentioned process and systems of reporting facilitators included the type of reporting system used (e.g. electronic reporting) (11/75). [33, 34, 40, 44, 68, 73, 101, 117]

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, 31, 40, 42, 47, 50, 58, 66, 75, 77, 82, 85, 88, 95, 114, 121, 124, 125, 128] and 13/55, [11, 66, 75, 77, 114, 121, 124] 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), [82, 85, 121] cause of the incident (6/55), [40, 66, 76, 77, 125] and level of risk (1/55).[58]

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, 40, 58, 68, 82, 88, 90, 93, 95, 97, 98, 107, 111, 125] HCPs emotional response to a patient safety incident was also found to increase the likelihood of reporting in a number of studies (5/41). ^[31, 58, 100] The professional group of HCPs was also found to act as a facilitator to reporting (5/41). ^[28, 71] Less frequently cited facilitators included previous reporting behavior (1/41), ^[29] number of hours worked (1/41), ^[52] and demographics (e.g. gender and age) (2/41).

Knowledge and Skills

Training in reporting was identified as the most frequently mentioned facilitator in this category (21/36). [9, 25, 33, 70, 73, 75, 76, 87, 101, 106, 117, 127] Other facilitators included knowledge regarding what constitutes an adverse event/near miss and the ability to

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recognise an error has occurred (7/36 ^[9, 30, 44, 46, 70, 87, 100] and 4/36, ^[75-77, 124] respectively).

Team Factors

Team factors were mentioned 20 times as a facilitator to reporting. Good teamwork/communication (7/20) [39, 75, 77, 122] and a positive team culture (4/20) [98, 107, 111, 122] were the most frequently cited facilitators.

Professional Ethics

Professional ethics was cited as a facilitator 17 times. A strong sense of duty (8/17) [75, 85, 88, 95, 101, 107] and responsibility (5/17) [77, 90, 91, 94] to report increased the likelihood of reporting. Less frequently cited facilitators included accountability (2/17) [88, 121] and a legal obligation to report (1/17). [37]

Work Environment

Work environment was mentioned as a facilitator 18 times. Access to the incident reporting system (11/18), [30, 68, 73-75, 87, 100, 101, 117] 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 [9, 11, 27, 33, 82, 88, 90] and 4/13, [9, 11, 87, 88] respectively).

Frequency of Negative Cases (Table e1)

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Individual HCP characteristics were mentioned as a negative case 43 times. HCP's attitude and value of incident reporting did not have an impact on reporting behavior (12/43). [37, 48, 54, 72, 79, 96, 129] Similarly, HCPs demographics (e.g. age, gender) had no impact on the likelihood of reporting (12/43). [37, 49, 51, 52, 77, 96, 97, 125, 129] Other less frequently mentioned factors included seniority (4/43), [37, 77, 125, 129] forgetfulness (1/43), [129] previous reporting behavior (1/43), [129] and number of hours worked (1/43). [26] Organisational factors were cited as having no impact on incident reporting 22 times. The most frequently mentioned were the ownership of the organisation (e.g. private/public funded) (6/22)[25, 77] and management response towards incident reporting (4/22). [29, 97, 115] Knowledge and skills were mentioned 15 times. These included the clarity of the reporting mechanism (5/15), [29, 48, 72, 129] knowledge of what constitutes an adverse event/near miss (2/15). [48, 72] ability in error recognition (1/15), [48] and training in error reporting (7/15).

Fear of adverse consequences was cited as having no impact on engagement in incident reporting 12 times. These included a fear of litigation (4/12),^[24, 40, 48, 90] a general fear of adverse consequences (3/12),^[72, 85, 96] blame (1/12) [48], judgment (1/12),^[101] and impact on career (1/12).^[125] Work environment was mentioned as as having no impact on reporting 10 times, including workload/priority (3/10)^[51, 123, 125] and unit type (3/10).^[49, 112] Other less frequently cited work environment factors

included physical work conditions (1/10),^[26] satisfaction with work environment (1/10),^[113] and accessibility (1/10).^[48]

Across all studies, process and systems of reporting was mentioned 7 times as having no impact on incident reporting; these included reporting format (3/7),^[25, 68, 125] complexity/simplification of reporting (1/7),^[68] and anonymity and/or confidentiality (1/7).^[24] Professional ethics were only mentioned four times as having no impact on the likelihood of incident reporting; these were legal obligation (2/4),^[37] duty (1/4),^[125] and responsibility (1/4).^[26] Team factors were cited as having no impact on the likelihood of reporting 3 times, including teamwork and communication (2/3)^[123] and support/encouragement to report (1/3).^[109] Incident characteristics were the least frequently mentioned factor which had no impact on reporting. Cause of incident was found to have no impact on engagement in reporting (2/2).^[125, 129]

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. Whilst there are numerous problems associated with this approach^[7] (e.g. flooding the system to such a degree that the thorough investigation of each incident reporting is unachievable), it is clear that high levels of underreporting seriously compromises the ability of incident reporting systems to facilitate learning and improvement 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 (e.g. 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

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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. [130] 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 (i.e. prevalence) of factors contributing to incident reporting. Whilst 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 instill 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 the organisational leaders. There is no 'optimum model' for incident reporting systems (e.g. electronic, confidential, anonymous) - systems need to be responsive to users and organisational needs.

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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.

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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 (e.g. 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 in comparison to 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, i.e. departmental, local, regional and national. In addition, the studies included a vast array of health care settings and providers, maximising the generalisability of the results. The resulting evidence has been synthetised into a practical output i.e. 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 four continents from

over 20 countries were identified, hence we are confident that our findings are of high external validity to guide safety policy globally. Secondly, the last systematic search for literature was conducted on 29/05/2014, 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. Thirdly, 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. Fourthly, 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 (e.g. primary and secondary healthcare).

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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

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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 underreport 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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Data sharing

All data from this systematic review and theoretical framework is presented within the publication.



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Table 1: Search Strategy

Patient Safety Incident: near adj miss* (MeSH heading), adverse adj
vent*, never adj event* (MeSH entry term), medical adj mistake* MeSH entry term), error*, mistake* (MeSH entry term), negligen* MeSH entry term), malpractice* (MeSH heading), failure*, injur* (MeSH ntry term), critical adj incident* (MeSH entry term), sentinel adj event*, ncident*, harm*, accident* (MeSH heading), medical adj error* (MeSH eading), patient adj safety (MeSH heading)
ncident Reporting System: risk adj management (MeSH heading), ncident adj reporting adj system*, error adj report*, critical adj incident dj technique (MeSH entry term), safety adj report*, incident adj report* MeSH entry term), reporting adj system, NRLS, national adj reporting dj2 learning adj system.
carrier/Facilitator: communication adj barrier* (MeSH heading), seedback (MeSH heading), safety adj culture (MeSH entry term), eporting adj culture, attitude (MeSH heading)*, preventive adj neasure* (MeSH entry term), mandatory, voluntary, under-reporting, villingness, blame, obstacle*, incident adj type, level adj of adj harm, ear* (MeSH heading), responsibi*, workload (MeSH heading), trust* MeSH heading), anonym*, confidential* (MeSH heading), facilit*, arrier*, enabl*, legal, law (MeSH entry term).
M M n n n e e e e e e e e e e e e e e e

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Table 2: Theoretical framework of factors determining engagement in patient safety incident reporting

latety incluent reporting			
Category	Descriptions & 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 behavior, such as structure (e.g. 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 (e.g. paper based or electronic).		
Team factors	Any factor related to the functioning of different professionals within a group which influences incident reporting behavior. 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 (e.g. form completion) and general (e.g. 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 behavior, 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 (e.g. guilt) or outcome (e.g. litigation) associated with individual HCPs' incident reporting behavior. A reduction in the likelihood of experiencing fear (e.g. the existence of a non-punitive policy) results in increased incident reporting participation.		
Incident Characteristics	Characteristics of the patient safety incident which may make HCP's more or less likely to report. These include frequency of error, level of harm and the cause of error.		

Note: HCP=Healthcare Professional

Table 3: Frequency of Articles by Country

Country	Count (percentage)
United States of America ^[9, 11, 28, 30-59]	33 (30.00 %)
United Kingdom ^[10, 29, 60-81]	24 (21.82 %)
Australia ^[8, 27, 82-87]	8 (7.27%)
Canada ^[88-95]	8 (7.27 %)
Taiwan ^[96-99]	4 (3.64 %)
Netherlands ^[100-103]	4 (3.64 %)
Saudi Arabia ^[104-107]	4 (3.64 %)
International ^[24, 26, 108, 109]	4 (3.64 %)
Israel ^[110-112]	3 (2.73 %)
Iran ^[113, 114]	2 (1.82 %)
Japan ^[25, 115]	2 (1.82 %)
New Zealand ^[116, 117]	2 (1.82 %)
Sweden ^[118, 119]	2 (1.82 %)
Italy ^[120, 121]	2 (1.82 %)
Denmark ^[122]	1 (0.91 %)
Norway ^[123]	1 (0.91 %)
Pakistan ^[124]	1 (0.91 %)
Portugal ^[125]	1 (0.91 %)
Jordan ^[126]	1 (0.91 %)
China ^[127]	1 (0.91 %)
Germany ^[128]	1 (0.91 %)
Spain ^[129]	1 (0.91 %)

Figure 1: Example of data coding, conceptualisation and categorisation for theory development

Figure 2: Flow diagram of the theoretical literature review process

Figure 3: Frequency of categories influencing engagement in patient safety incident reporting

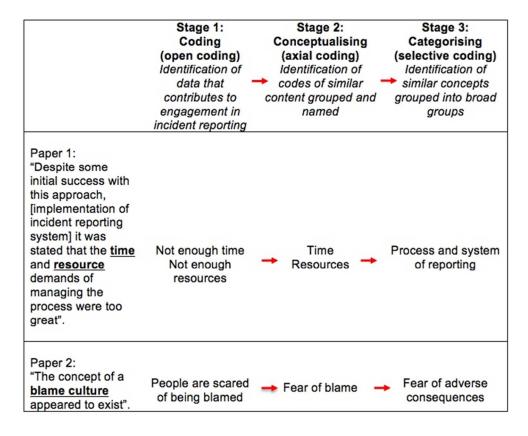


Figure 1: Example of data coding, conceptualisation and categorisation for theory development $57x46mm (300 \times 300 DPI)$

Identification

Screening

Eligibility

Included

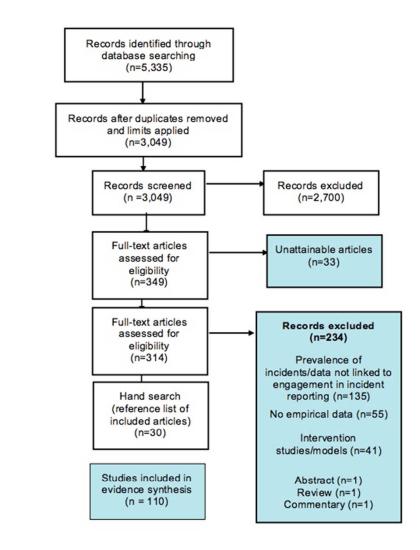


Figure 2: Flow diagram of the theoretical literature review process

54x55mm (300 x 300 DPI)

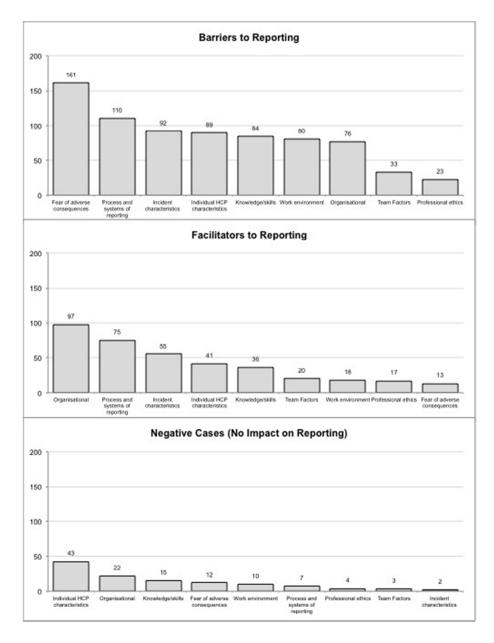


Figure 3: Frequency of categories influencing engagement in patient safety incident reporting 42x55mm (300 x 300 DPI)

		,	D	
Author, Year	Study Design, Sample Size, Country	Barriers to Incident Reporting	©Facilitators of ber Incident ⊠ Reporting	Negative cases (No impact)
Albolino et al., 2010 [120]	Questionnaire based-study 820	Fear of mistrust in colleagues		
	Italy	Not considered a priority	wnloa	
	D -	Fear of punishment	17. Downloaded from http://bm	
	~6	Does not help to improve safety	m http	
		Lack of time	://bm	
Alsafi et al., 2011	Questionnaire based-study.	Not my responsibility	open.t	
	Saudi Arabia	I do not want to lose my good relationship with my colleague	omj.cc	
		relationship with my colleague	om/ o	
		I might be reported by my colleague in turn	open.bmj.com/ on April 10, 2024 by guest. Protected by	
		No incentive to error disclose	0, 2024	
		Avoiding punishment	oy gues	
		Avoiding damage to reputation	st. Prot	
		It will not be discovered	ected by	
Anderson et al.,	Semi-structured interviews	Experienced in using IR systems	copyrig	
2013 [60]	and documentary analysis	(Mental health staff)	<u>Уг.</u>	

	62		on 27
	United Kingdom	Blame culture (mental health staff)	7 Decer
Arfanis et al., 2012 [61]	Semi-structured interviews 48	Not used as learning tools to prevent similar occurrences elsewhere.	Feedback
	United Kingdom	Pressures on time	Learning and improvement
	O /A	Resources	Agonymous web
	100	A lack of faith in the established system	aod on to IR system
		Fruitless and often pointless exercise that has little or no impact on improving patient safety and welfare	tp://bmjopen.bmj.com/ on April 10, 2024 by guest.
		Fear of litigation Fear of disciplinary action	.com/ on .
		Blame	April 10, 2
		The availability and ease of identifying the information	024 by gu
		No feedback	
Armitage et al., 2010 ^[62]	Semi-structured interviews and retrospective review of error reports	Lack of feedback	Protected by copyright

<u> </u>	United Kingdom		27
	233		7 D
Ashcroft et al., 2006 ^[66]	Questionnaire-based Study	Local reporting	Local reporting
2000	275	Good patient outcome less likely to	Poor or bad patient
	United Kingdom	be reported than poor or bad patient	outcome more
		outcome.	likely to be reported
			than good patient
		Compliance with a protocol less	o\text{gcome}
		likely to be reported than a violation	e d
	<i>V</i>	or error.	Vigilation of
		h= 11 11 11 11 11 1	protocol or error
		'Fault-led' attitude	more likely to be
		One off situations by individuals not	reported than
		One-off situations by individuals not report	compliance with protocol.
		report	piotocoi.
		Loyalty to colleagues	'Learn from
			mistakes' culture
		National reporting system	5 >
			Individuals making
		Confidence in National Patient	continual mistakes
		Safety Agency	202
			National reporting
			svetem
			est.
			Pro
Backstrom et al.,	Questionnaire-based study.	Assessment that the reaction is	Protected by copyright.
2000 ^[119]	748	already well known	<u>ă</u>
	Sweden		9 8
		Forgetting to report	l γά γ

	^o_	Hesitance to report on suspicion Lack of time Giving preference to other matters Uncertainty about the existing rules for reporting Difficulty in finding the right form	on 27 December 2017. Downloaded from http	
Ballangrud et al., 2012 ^[123]	Questionnaire-based study. 220 Norway	Supervisor/manager expectations, actions promoting safety Feedback and communication about error	27 December 2017. Downloaded from http://bmjopen.bmj.com/ on April 10, 2024 by guest. Protected b	Organisational learning and continuous improvement Teamwork within hospital units Communication openness Non punitive response to errors Staffing
Bateman et al.,	Questionnaire-based study.	One case cannot contribute to	Sgould be	
1992 [81]	1181	medical knowledge	firancially	

			O _T
	United Kingdom	Impossible to determine responsible	reimbursed
		drug	Wຶ້ອuld report if
		Serious ADRs well known when the	essier method
		drug is marketed	017. [
		Professional obligation) Ownlo:
	10/A 10/A	Reporting increases personal liability	2017. Downloaded from http://bmjopen
	~0,	Reporting results by badgering by Committee of safety of medicines	om http
	C		s://bm
		Takes too much time to ADR report	lopen.
Bawazir et al., 2006 ^[107]	Questionnaire-based study. 172	No reporting forms available	An obligation to do
2000	Saudi Arabia	Reporting address unknown	o l
		Reporting form too complicated	There was a fee
			Saw colleagues
		Reporting ADRs is too time consuming	dang so
		All ADRs are known	Aftention drawn by properties of the properties
			יי
		Want to publish myself	Receiving feedback
		Confidentiality	Report through the internet
		Patient confidence	pyright.
			gh t.

			On Contract of the Contract of
		Difficult to admit harm to patient	27 December 2017. Downloaded from http://bmjopen
		Reporting could show ignorance	ember 2
		Fear of liability	2017. D
	10/ 100/	No motivation	ownloa
	D -	Insufficient clinical knowledge	ided fro
	70	Do not know how to report	m http:
		Causality uncertain	//bmjop
		One report make no difference	en.t
Beasley et al., 2004 [30]	Focus groups 14 United States of America	Punitive system	Affeedback system for submitters is no cessary to maintain interest. Safe and secure access There needs to be easy access What to report needs to be clearly defined The reporting forms
	,	,	ght.

Belton et al., 1995	Questionnaire-based study 284 United Kingdom	Report forms are not available when needed Doctor does not like reporting confidential information Doctor unsure how to report an ADR Doctor fear he/she may appear foolish about reporting a suspected	must be simple Emor reporting must fit into a clipicians current work flow Amon-punitive system is essential Reporter should only be required to report once if there are multiple systems April 10, 2024 by guest. Protected by copyright
		Doctor fear he/she may appear	10, 2024 by guest. Pro
		Doctor fears he/she may be exposed to legal liability by reporting reaction Doctor too busy to send an ADR	otected by copyrig

			9	
		report	27 December 2017. Downloaded from http://bmjopen.bmj.com/ on April 10, 2024 by guest. Protected by copyr	
		Doctor is reluctant to admit he/she	ecei	
		may have caused a patient harm	nbe	
			r 20	
		Doctor would rather collect and	17.	
		publish personally	Dow	
		Doctor believe that only safe drugs	'nloa	
		are marketed	adec	
			fror	
Belton et al., 1997	Questionnaire-based study	Telephone number unavailable	htt	Worried about
[24]	Sample size not reported		fb:///	legal liability
	International: Denmark,	Report forms unavailable	bmjc	(Not Denmark
	France, Ireland, Italy,	Address of reporting agency	pper	or Spain)
	Netherlands, Portugal, Spain, Sweden, United Kingdom	Address of reporting agency unavailable	ı.bm	Ambition to
	- Oweden, Onited Kingdom	diavallable	<u>j.</u> co	publish a
		Unsure how to report	m/ o	personal series
			n ≯	of cases (Not
		Patient confidentiality	oril 1	Spain, Sweden
		Married about appearing facilish	, , 2	or Portugal)
		Worried about appearing foolish	024	Patient
		Worried about legal liability (Not	by g	confidentiality
		Denmark or Spain)	Jues	(Not Spain)
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		Too busy to report ADRs	otec	
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		Reluctant to admit they have caused a patient harm	by c	
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L		I .	' '2 '	

		Ambition to publish a personal series of cases (Not Spain, Sweden or Portugal) Believes that all marketed drugs are safe	on 27 December 2017. Downloaded from http://bmjopen.bmj.com/ on April 10, 2024 by guest. Protected by copyright	
Blegen et al., 2004 [55]	Questionnaire-based study 1105	Administrative response	ownloade	
	United States of America	Personal fear Quality management	d from htt	
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	Australia	Accessibility of reporting system	24 by g	
		Security of IIMS	luest. F	
		Feedback from reports	³ rotect	
		Workplace reporting culture	ed by o	
		Value placed on IIMS	opyr	

Chang et al	Questionnaire-based study		L∰vel of support	Age
Chang et al., 2012 ^[96]	183		240.0.0.0apport	7.90
	Taiwan		cembe	
Chiang et al., 2006	Questionnaire-based study. 597	Being blamed for MAE results	,	
	Taiwan	Adverse consequences from reporting	. Downlo	
	6	Patient's negative attitude	aded fro	
	700	Physicians' reprimand	m http:	
		Not recognised MAEs occurred	://bmjoj	
		Being recognised as incompetent	oen.bm	
		Too much time for filling reports	ıj.com/	
		Think MAEs not important enough to be reported	2017. Downloaded from http://bmjopen.bmj.com/ on April 10, 2024 by guest. Protected by copyrght	
		Too much time for contacting physicians), 2024 by	
		Unclear MAE definition	guest.	
		Disagreement over MAE	Protect	
		Unrealistic expectation for	ed by	
		administering drugs correctly	сору	

			97	
		No positive feedback	27	
		Much emphasis on MAE as nursing quality provided	December	
		Focus on individual rather than system factors to MAEs	27 December 2017. Downloaded from h	
	0,	Administrators' responses to MAEs do not match the severity of the	vnloaded f	
	No	errors	rom t	
Chiang et al., 2010 [97]	Questionnaire-based study 838	Experience of making MAEs	Same attitude towards self and	Age
	Taiwan	Nursing professional development	comworkers	Management and leadership
		Fear	MAE reporting rate	Administrative
		10/4	Nursing quality	barriers
			April 10, 203	Reporting
			0, 202	process
Chiang et al., 2012	Questionnaire-based study 1049 Taiwan		High scores on the safety organising scale	
			Tenure of present	
			ું Self-evaluated IR	
			rates	•

			9
			Those more willing togreport their own ingidents are more likely to report cowarkers incidents
			Do
Church et al., 2013 [36]	Questionnaire-based study 546	Hierarchical structure	wnload
	United States of America	Poor communication	ded fro
	700	Fear of reprimand	om http:
		Reprimand of other therapists and dosimetrists	wnloaded from http://bmjopen.bmj.com/ on
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		Lack of reporting system	m/ on A
Clark et al., 2013	Questionnaire-based study 228	Fear of being judged by colleagues	April 10,
	International: Australia and New Zealand	Personal Guilt	, 2024
	Trow Zodiana	Feel it as unnecessary	2024 by guest.
		Near misses are part of life	
Coley et al., 2006	Focus groups 8	Time consuming	Protected by copyright
	United States of America	Inadequate staffing	у сору

Cosentino et al.,	Questionnaire-based study	Reaction not clinically relevant	on 27 I	
1997 [121]	207 Italy	Awareness of similar reactions	Dece	
	,		mber	
		Unavailability of report forms	2017	
		Doubtfulness about which ADRs should be reported	. Downlo:	
	10/0 100	Confidence about ADRs being well documented before marketing	aded from	
		Ignorance about reporting procedures	http://bmjc	
		Too much time required to fill in the report form	pen.bmj.c	
		Don't feel obliged to report	om/ on	
		Don't want to create undue alarm	April 10	
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Covell et al., 2009	Semi-structured interviews and questionnaire based study 50 Canada	Adverse consequences	December 2017. Downloaded from http://bmjopen.bmj.com/ on April 10, 2024 by guest. Protected by	
Daly et al., 2005 [37]	Questionnaire-based study 598	Administrators' length of time in position	Digectors of negroings'	Administrators' knowledge of

United States of America Administrators' and Directors' length of time in facility Administrators' length of time in profession After internal investigation abuse was thought not to exist Told not to report the abuse by my boss Told not to report the abuse by my boss Reported abuse in the past and IDIA did nothing Reported abuse in the past and it led to a bad outcome Reported abuse in the past and IDIA ruled it out Reported abuse in the past and IDIA ruled it out Director of nursings' length of time in position Director of nursings' length of time in profession Director of nursings' length of time in profession Director of nursings' level of education Administrators' keye
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Element of all	Kingdom/Uganda	Harasa barata arasa 2-1-1	1 2
Ehrenpreis et al., 2012 [38]	Questionnaire-based study	Unsure how to report appropriately	Eर्ब्रुsier to use
2012 [66]	92	B: 1 ()	201
	United States of America	Did not see adverse events on a	7. [
		regular basis	Jow
		Too because modes non-orde	nlo
		Too busy to make reports	ade
		The existing method was too	d fr
	1 0	The existing method was too cumbersome	om
		cumbersome	http
		Voluntary reporting was not an	://bn
		important process	njop
		important process	oen.
Eland et al., 1999	Questionnaire-based study	Uncertain association	<u> </u>
[103]	1357		.com
	Netherlands	Too trivial to report	m/ c
			n A
		Too well known to report	pril
			10,
		Unaware of the existence of a nation	202
		ADR reporting system	24 b
			y 9u
		Unaware of the need to report ADRs	Jest
			2017. Downloaded from http://bmjopen.bmj.com/ on April 10, 2024 by guest. Protected by copyright
		Did not know how to report ADRs	otec
			上 xted
		Too bureaucratic	ьу
			СОР
		Not enough time	\(\rightarrow\)

			On .
		Concerned that the report could be used in legal case for damages by the patient	27 December 2017. Downloaded fro
		If another physician had prescribed the medicine	7. D
	10 ₂	Medication brought over counter rather than prescribed	ownloaded from
Elder et al., 2007 [31]	Focus groups	Burden of effort	Perceived benefit
,	139		of eporting –
	United States of America	Lack of time	learning and
			improvement
		Forgetfulness	an.t
			Emotional benefit
		Information not readily available	CO
			Guilt
		Computer problems	n A
			P e rsonal
		Online access	responsibility
			Argonymous
		What to report	
			reporting
		Who should report	est
		\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	Easing the burden
		What is an AE	of reporting
		What information is needed	The more harm,
		Windt inioiniation is needed	the more likely to
		Common problems	report
	1	1	(g)
			

			or
		Rare errors Less serious errors unlikely to be reported Feeling personally responsible	27 December 2017. Down
Elder et al., 2008	Focus groups and	Too busy with other activities	Agked by
[58]	questionnaire-based study 125 United States of America	Didn't reach the patient	management to make specific reports
	States of America	Risk of harm is none or little	t di di
			Harm actually
		Error made my someone new-give	occurred
		them a break	Risk of harm is
		Feel worse emotionally	great
		Tool words amountainy	9.34
		Feel like a failure	Egror made by
			someone unable to
		Fear punishment	bespoken to one-
		Blame	toeone
		Biamo	Feel better
		Name on permanent record	emotionally
		Risk losing friends	Optlet for irritation at situation or
		Will make enemies on unit	person
			8
		No feedback so no personal benefits	Henesty is a virtue

			6 0
Erler et al., 2013	Questionnaire-based study		Get a "there but for the grace of god" understanding Improve clinical practice Could be a learning experience for others No known penalty formaking a report Higher levels of
[39]	51 United States of America		teamwork Communication openness Perception of manager actions promoting safety
Espin et al., 2010 [95]	Semi-structured interviews 37 Canada	Did not feel it was an error	Patient negligence Threat of potential orgactual harm to the patient Patient advocacy

			9
	1 000		Following proper procedure Ergor prevention Learning opportunities
Espin, et al., 2007 [94]	Semi-structured interviews 13 Canada	Domain-specific expertise is a necessary pre-requisite for reporting the error Part of the surgeon's responsibility as it fell within the surgical scope of practice.	Events outside of professional boundaries were more likely to be reported Responsible for every
Espin et al., 2006	Semi-structured and structured interviews 28 Canada	Responsibility	com/ on April
Evans et al., 2006 ^[8]	Questionnaire-based study 773 Australia	I never get any feedback on what action is taken I don't feel confident it is kept anonymous The incident form takes too long to fill out and I just don't have time I am worried about litigation	10, 2024 by guest. Protected by copyright.

The incident was too trivial	,
When the ward is busy I forget to make a report	, מכמוויסכי
It's not my responsibility to report someone else's mistakes	
I don't know whose responsibility it is to make a report	
I don't want to get into trouble	
When it is a near miss, I don't see any point in reporting it	,, 5111,000
Even if I don;t give my details, I am sure that they'll track me down	
The AIMS+ form is too complicated and requires too much detail	1
Junior staff are often blamed unfairly for adverse incidents	, -0-1 2
I wonder about who else is privy to the information that I disclose	
If I discuss the case with the person involved nothing else needs to be done	AT DOCUMENT AND IT. DOWN HOUSE OF THE THE ATTENDANCE OF THE TO, AND THE TO, AND THE TO, AND THE TO, AND THE TO,

			9	
		I don't want the case discussed in meetings	27	
		I am worried about disciplinary action	ember 2	
		Adverse incident reporting is unlikely	017.	
		to lead to system changes	Dow	
	Op	My co-workers may be unsupportive	December 2017. Downloaded	
Fairbanks et al.,	Interviews, focus groups and	Blame and Shame	Nฐิ๊n punitive	
2008 [32]	events reports from an		system	
	anonymous system 15	Punishment)://bi	
	United States of America	Legal factors	njop	
		10,	en.b	
		Reluctance to tell on colleagues	p://bmjopen.bmj.con	
Fukuda et al., 2010	Questionnaire-based study	167	Decreased time for	Non-punitive
[23]	Sample size not stated		reporting (nurses	policy
	Japan		aឝd physicians)	(physicians/nur ses)
			Electronic reporting	000)
			(physicians)	Rate of
			9 January	recommendatio
			Attendance at educational	ns derived from reported
			seminars	incidents
			(physicians)	(physicians/nur
			(d by	ses)
			Hgspital size	
,			pyright.	Electronic



			0 0	
Gaal et al., 2010 [26]	Observational study Sample size not stated International: Austria, Belgium, England, France, Germany, Israel, The Netherlands, Slovenia, Switzerland, and Wales		or 27 December 2017. Downloaded from http://bmjopen.bmj.com/ on April 10, 2024 by guest. Protected by coping the coping of the c	hospital (physicians) Ownership — municipal + public hospitals + healthcare corporation + other (physicians/nur se) Assignment of patient safety manager (nurses) Practice setting Amount of responsibility Hours of work Physical working conditions Single+ dual practice
Garbutt et al., 2007	Questionnaire-based study	Private practice	Belief that errors	Perceived risk
			ght.	

ΓΙΔΟΙ	1	
[40]	557 United States of America	

	öi or	
	aাছ one of the most sঞ্জুious issues in	for personal malpractice
	healthcare	risk
	Belief that they	Personal
	should report	involvement in
	serious errors	an error
	Belief that they	
	should report minor	
	ergors	
	Belief that they	
	should report near	
	misses	
	System change to	
	ingprove patient	
	safety after errors	
	reported	
	If ĕ rror was caused	
	bygsystem rather	
4	than individual	
	failures	
	Përsonal	
	in § olvement in	
	serious errors	
	Assurance that the	
	in <u>₹</u> ormation was	

			9	
	^o,		Amon-punitive reporting system Aprocess that takes less than 2 minutes to use Local to the clinician's unit or department	
Generali et al., 1995 ^[52]	Questionnaire-based study 235 United States of America	Unsure drug caused reaction Do not have forms Do not know how Reaction was expected Reporting would not occur to me Fear of legal liability Not my responsibility Hours worked per week (>49 or <40)	Hours worked per week (43-49 hours) Work setting M. com/ on April 10, 2024 by guest. Protected by copyright	Age Gender Number of years in practice
Gladstone, 1995 [67]	Questionnaires and semi- structured interviews 107 United Kingdom	Fear of management reaction	эд by соруг	

			27
Green et al., 1999 [76]	Structured interview 30	Lack of time/too busy	Certainty of ADR
	United Kingdom	Well recognised reaction	Sਛ਼ੋspicious of a
		Living the second of the section to	regiction
		Limited time to spend with patients	∵ T⊠aining
	0,0	Lack of motivation	¥
			Fee for reporting
		More information about ADR needed	
	MA	Lack of confidence in making report	Access to patient records
		Lack of confidence in making report	ft.
		Patient confidentiality	Feedback
		Detient suffered on ADD to a product	O D D D D D D D D D D D D D D D D D D D
		Patient suffered an ADR to a product counter prescribed by the	More time
		pharmacists being interviewed	nj.com
		· (8)	0
Green et al., 2001	Questionnaire-based study 322	Concern that a doctor gets a copy of	Reaction is of a
	United Kingdom	reporting form	sĕious nature う
	Critica ranguem	Lack of confidence in discussing the	The reaction is
		ADR with the prescriber	umusual
		Approhension about conding in an	The reaction is to a
		Apprehension about sending in an inappropriate report	Tige reaction is to a
		mappropriate report	rote
		Lack of time to fill in a report	Cgrtainty that the
		Concern that a report will go a set	reaction is a ADR
		Concern that a report will generate extra work	The reaction is well
		CALIC WOIN	Ω Ω

		or
	The absence of a fee for reporting ADRs	recognised for a particular agent
	Lack of time to actively look for ADRs while in clinical practice	Education/training/ study days or evenings
	Lack of clinical knowledge makes it difficult to decide whether or not an ADR has occurred	Mare time to spend on wards with
100	Don't feel the need to report well recognised reactions	patients Signature Mare feedback, reminders and
	Reporting cards not available when	ingreased awareness
	needed	Encouragement
	10 12	from managers and departments
		Inereased collaboration with
		prescribers and participation on
		ward round โก๊greased
		accessibility of reporting cards
		ਨੂੰ Cards specifically designed for the
		1 - 2 - 3 - 2 - 2 - 2 - 2 - 2 - 2 - 2 - 2

other professionals

could report ADRs

that pharmacists

van Grootheest et al., 2002 ^[101]	Questionnaire-based study 147	Causality uncertain	Fedback	Reporting could show
di., 2002	Netherlands	Too time-consuming	Pgblications	ignorance
		No reporting forms available	্ষ Information about th্ছ national centre	
	704	Reporting address unknown	Signplification of	
	10,	Reporting form too complicated	reporting procedure	
	70	All adverse reactions are known	Promoting	
		Want to publish myself	reporting as part of perfessional duty	
		Confidentiality	Figancial	
		Fear of liability	compensation	
		No motivation	More attention to ABR reporting in	
		Insufficient clinical knowledge	u華versity cஞ்riculum	
		Do not know how to report	Database of	
			national centre	
			internet	
			Campulsory resorting	
			Peer reporting	

Haines et al., 2008	Questionnaire-based study	Time	Staff believe that
32]	212	Tillie	completing IRs
	Australia	If the ward is very busy	inproves patient
	Additional	in the ward to very busy	sætety
		Patients' responsibility for adverse	17
		events	Staff belief that
			competing IRs
	10 ₀	Cause of the incident	pretects against
			legal liability
		Other methods of documentation	Y fror
			If ∄he patients was
		Access to previous reports (non filing	harmed/injured
		of incident reports in the notes)	ma'
			Patient factors
		Poor user friendliness of computer	n.b
		reporter systems	Petect staff
			S S
		Made staff feel personally	Tvo of incident -
		responsible for the form	présventable
		Decree to the same	_ <u>-</u>
		Poor access to computers	0, 2
		Non reporting by role models	024
		Non reporting by role models	by
		Absence of a definition of a fall	gue
		Absence of a definition of a fair	<u>8</u>
		Blame	rot
			ecte
		Absence of training	<u>ä</u> <u>g</u>
			oril 10, 2024 by guest. Protected by copyright
			руг

			On Contract of the Contract of
Handler et al.,	Focus group and	Lack of readily available medication	27
2007 [35]	questionnaire-based study 132	error reporting system or forms	Decei
	United States of America	Lack of information on how to report	nbe
		a medication error	December 2017. Downloaded from http://bmjopen.bmj.com/ on April 10, 2024 by guest. Protected by copyright
		Lack of feedback to the reporter or	D
		rest of facility on medication errors	wnic
		that have been reported	Daded
		Lack of knowledge of which	fron
	1.00	medication errors should be reported	n http://
		Systems or forms used to report	/bmj
		medication error are long and time	ope
		consuming	n.b m j
		Lack of knowledge of the usefulness	.com
		of reporting medication errors	N on A
		Lack of a consistent definition of a	\\Pri
		medication error	10, 20
		Lack of an anonymous medication)24 t
		error reporting system	by gue
		Lack of recognition that a medication	»st. P
		error has occurred	otect
		Lack of a culture of reporting	ed by
		medication errors	/ copy
		1	ght.

			9
		Extra time involved in documenting a	27
		medication error	Dece
		Fear of disciplinary action	mber
		Fear of being blamed	2017. [
	^ 0.	Fear of liability or lawsuits	Jownlo
	10 ₁ 0 ₀	Not knowing who is responsible for	aded fr
	No	reporting a medication error	om T
		Belief that it is unnecessary to report	nttp:/
		medication errors not associated with	/bmj
		patient harm	o o o o o o o o o o o o o o o o o o o
		Lack of recognition of the actual or	i.bmj
		potential harm of a medication error	.com/
		Belief that reporting medication	9 A
		errors has little contribution to	pril .
		improving the quality of care	10, 2
		Difficulty in proving that a medication	024
		error actually occurred	by gue
		Fear of losing respect of co-workers	December 2017. Downloaded from http://bmjopen.bmj.com/ on April 10, 2024 by guest. Protection
Hartnell et al., 2012	Focus group and semi-	Extra time required to report	Inaproved
88]	structured interviews		cඈීe/improved
	30	Extra work required to report	pagtient safety
	Canada		pyright.

	9
Cumbersome IR forms	Toprevent patient
	from receiving
Hesitancy about 'telling on' someone	wgong medication
else	ber
	Provides
Fear of loss of reputation/perceived	in i
incompetence	fr&m legal action
	<u> </u>
Perceived severity of error (less	Fear of censure
severe errors are less likely to be	(harsh criticism or
reported)	blame)
' '	1
Inability to recognise or identify	Perceived severity
medication errors	oferror (more
	severe errors are
Lack of definitions or standards for	more likely to be
reporting	reported because a
roportang	report will be
Lack of belief that reporting makes a	expected)
difference	
difference	Fallow rules or
lack of trust about how error reports	policies
will be used	
will be used	Egsures
Reporting is the responsibility of	
someone else	accountability
Someone eise	yst.
Foor of reprised from	Pro
Fear of reprisal from	xtec
management/administration	ted.
Francis and the Control of the Contr	by
Fear of exposure to malpractice suits	CO
	Protected by copyright
	yht.

Hasford et al.,	Questionnaire-based study	ADR too well known	Serious unknown	
2002 [128]	588		APR to a new drug	
	Germany	ADR too trivial	cerr :	
			S∰rious unknown	
		Uncertain causality	ABR to an	
			established drug	
		Reporting too bureaucratic	Do	
			Serious known	
		Lack of time	AਊR to a new drug	
	10 ₀		ed f	
	\mathcal{U}_{Δ}	Rules of conduct unknown	ron	
			htt	
		Suspect that drug prescribed by	//:d:	
		colleague	bmj.	
			ope	
		Reporting process unknown	n.b	
			mj.c	
		Lack of financial reimbursement	öm	
		O and the second of the first	ed from http://bmjopen.bmj.com/ on April 10, 2024 by guest.	
		Suspect drug was self-medication	Ар	
		Departs considered uppless	rii 1	
		Reports considered useless	0, 2	
		Deporting evetem unknown	024	
		Reporting system unknown	by	
		Foor of local liability	gue	
		Fear of legal liability	est.	
		Non-serious adverse reaction to	Protected	
		established drug	tect	
		established drug	:ed	
Heard et al., 2012	Questionnaire-based study	I am worried about litigation	b y c	Generalised
[87]	433	i aiii woined about iitigation	copyright	de-identified
	1 00		<u> </u>	uc-iuci illiicu

Australia	I don't want to get into trouble	27	feedback about
	Microsillo con con processo de compositivo	Dec	reports
	My colleagues may be unsupportive	emb	received from the anaesthetic
	I am worried about disciplinary action	er 2	community
	· · ·	017	ooariity
	I may be blamed unfairly for the	Dog	Role models
	event	vnlo	e.g. senior
	I do not want to be discussed in	ade	colleagues and
	meetings.	d frc	department directors who
	Theodings.	m h	openly
	Adverse events reporting makes little	t t p://	encourage
	contribution to quality care	bmjc	reporting
	I don't know whose responsibility it is	ppen	Legislated
	to make a report	.bmj	protection of
		.com	information you
	A good outcome of the case makes	v on	provide from
	reporting unnecessary	Apri	use in litigation
	I do not know which adverse events	110,	Ability to report
	should be reported.	27 December 2017. Downloaded from http://bmjopen.bmj.com/ on April 10, 2024 by guest. Protected by copyright	anonymously
	Even if I don't give my details I'm	by (Clear
	worried they will track me down	gues	guidelines
		. P	about what
	The forms take too long to fill in and	otec	adverse events
	just don't have time	ĭed	are errors to
	When I am busy I forget to make a	by c	report
	report	оруг	Information on

I don't feel confident that they information I provide will be kept confidential

I never get any feedback after I report an adverse event

I wonder about who else will have access to information I disclose

As long as the staff involved learn from incidents it is unnecessary to discuss them further

I would protect my self-interests ahead of the interests of the patient if I could (by hiding or denying error) 27 December 2017. Downloaded from http://bmjopen.bmj.com/ on April 10, 2024 by guest. Protected by copyright

Competition with my peers could prevent me from disclosing an error

If a doctor is careful enough he or she will not make an error

It would affect my identity as a doctor to admit to an error

Other don't need to know about errors I have made

Disclosing an error, if you don't have

how confidentiality will be maintained if you supply your name

Individualised feedback to you about reports you submit

Paper forms for reporting provided in each theatre

More support from colleagues

Less blame attached to those who report errors

ANZCA continuing professional development point for

 	9	
to, is an optional act of heroism	27 [reports.
I would cover up an error I had made	December 2017. Downloaded from http://bmjopen.bmj.com/ on April 10, 2024 by guest. Protected by copyright	Access to
if I could	ame.	
II I Could	ĕ	computer
If I admit to an amount will foot like a	201	based
If I admit to an error I will feel like a	7. [reporting
failure	Ow	systems for
	'nlc	home
It would affect my self-esteem to	ade	
admit to an error	bd f	Education
	ron	about the
Doctors who make errors are) 	purpose of
humiliated my their colleagues	ф: <u>/</u>	reporting
	mď	
Medicine has a culture of silence	jo po	Computer
where errors are not talked about	en.k	based
	<u> </u>	reporting
Doctors who make errors are blamed	.cor	systems
by their colleagues	m/ c	
	n ≻	Training on
Doctors should not make errors.	, prii	how to use
	10	computer
	20	based systen
	24	
	by	Training on
	gue	how to fill in
	st.	papers forms
	Pro:	for reporting
	tect	lor reporting
	ed C	Payment for
	by o	time taken to
	ООР	
	<u>Yn</u> .	report

			9	
			27	
Herdeiro et al.,	Questionnaire-based study	Lack of time	W ⊘ rkplace	Gender
2006 [125]	256		(မြဲတွဲspital	
	Portugal	Complexity of reporting	plarmacists more	Age
			likely to report than	
			community	Job function
			plarmacists)	(registered,
			, nwo	assistant or
			Really serious	other
	10 ₀		ABRs are not well	pharmacists)
			documented by the	
			time a drug is	Possible to
			markotod'	determine if a
			//bm	drug is
			Serious and not	responsible fo
		10	expected ADRs	a particular
			<u> </u>	adverse
		Te View	Report an ADR if I	reaction'
			were unsure that it	
			was related to the	Cannot
			use of a particular	contribute to
			dreiga '	pharmaceutica
			20	knowledge
			24	
			у с	Interested in
			Jues	articles about
			** F	ADRs'
)rot	
			ecte	Most correct
			<u>å</u>	way to report
) ý 00	ADRs in is the
			g 2024 by guest. Protected by copyright	pharmaceutica
	1	1		11 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2

companies about possible ADRs with their		For peor teview of	55 or 27 December 2017. Downloaded from http://bmjopen.bmj.com/ on April 10, 2024 by guest. Protected by copyr <mark>i</mark> ght	about possible
--	--	--------------------	---	----------------

			27	drugs
			De	
Hohenhaus et al., 2008 ^[42]	Questionnaire-based study 175 United States of America	Afraid to report a medical error they had made	Egor resulting patient harm	
	Officed States of America	Afraid to report a medical error made by someone else	ਲ Eਜ਼ਿੰor by novice nਯੂse	
	0,00	Might not report if there was no harm to the patient and the error was recognised quickly	e Swnloaded from http://bmjopen.bmj.co	
		Might not report if a physician told them not to report the error	http://bmjc	
		Would not report if their supervisor told them not to	pen.bmj.cc	
Holmstrom et al., 2012 [68]	Questionnaire-based study 16	Fear of consequences	Provides opportunity for	Paper-based
	United Kingdom	Culture of blame	evaluating causes of errors (e.g. root	Quick and eas to use
		Lack of training in MER for health- care professionals	cause analysis)	to use
		Lack of time for reporting	punitive approach	
		Lack of organizational leadership and support	Provides feedback	
		Lack of legal protection for individual health-care professionals who have	angalysis for those in volved in	

	on
made an error	reporting
Lack of understanding why reporting is needed	nbe
Concern that no beneficial action will follow	P୍ଷ୍ଟିvides ll opportunity for ergor data analysis
Non-anonymous reporting Perceived to be bureaucratic	Produces recommendations
Perceived to be bureaucratic	ลเฐี guidelines for
Lack of health-care staff	improving medication safety
Lack of financial resources	Provides
'elien	confidentiality of
101	reported intormation
	Provided and
	maintained by one national
	orbanisation
	Integral part of patient safety
	reporting system
	Reporting of errors
	is voluntary
	- ight

		9	
Hutchinson et al	Retrospective analysis of	Reporting of errors is mandatory Altows all healthcare professionals to report errors Available in electronic format Independent reporting system dedicated for medication error reporting Provides a choice of reporting anonymously Includes reporting of both potential and actual errors	Knows how to
Hutchinson et al., 2009 [29]	Retrospective analysis of routinely collected data and questionnaire-based study Sample size not stated United Kingdom	Employer treats fairly staff involved ingerror near miss offincident Employer efficurages staff to	Knows how to report errors, near misses and incidents When errors are reported,

			9	
			report errors, near messes or incidents Employer treats reports of errors, near misses or incidents confidents confidentially Employer does not blame or punish people who make errors. Access to a counselling service were also more likely to report. Previous reporting behaviours 1.0. Level of risk management	employer takes action to ensure that they do not happen again
Irujo et al., 2007	Case control study 78	Not serious ADR	guest. Protected by copyright	Age
	Spain	Already well known ADR	rotecte	Working experience as
		Uncertain about causality	d by c	pharmacist
		Forgot to report	оруг	Participation in
			yht.	

		95 95	
	Lack of time		a programme for detection and resolution of DRPs
10		2017. Downloade	Education on detection and resolution of DRPs
1000		27 December 2017. Downloaded from http://bmjopen.bmj.com/ on April 10, 2024 by guest. Protected by copyright	Frequently considering the possibility of finding an ADR when attending a patient with symptoms
		om/ on Apri	Forgetting to report
		ii 10, 2024	Education for ADR reporting
		by guest. Protect	Awareness of the importance of reporting system
		ted by copyri	It is necessary to be sure that the reaction is
		ght.	

			9	
	1 0,		27 December 2017. Downloaded	causally related to the use of a particular drug Basic knowledge about ADR reporting
Jeffe et al., 2004	Focus groups 109 United States of America	Errors that pose little risk to the patient Errors that do not end up harming the patient Not knowing how to report Fear of disciplinary repercussions (nurse and physicians) Fear of legal repercussions (nurse and physicians) Fear of repercussions from doctors (nurses) Link between reporting and performance reviews (nurses)	Serverity of the situation (nurses) Likelihood of resoccurrence (nurses) Servere events reported as the erfor would be 'found' out anyway Servere events reported as the erfor would be 'found' out anyway Servere events reported as the erfor would be 'found' out anyway Servere events reported as the erfor would be 'found' out anyway Servere events reported as the erfor would be 'found' out anyway Afficient portance of reporting errors for educational perposes Agonymous (physician and	
	I	<u>l</u>	ngrses)	

			0
		Protecting colleagues from	27
		disciplinary action(nurses)	Simple (physician
		Lack of confidentiality	and nurses)
			Fast reporting
		Name, blame, shame culture	procedures(physici
			argand nurses)
	10/A	Fear of public exposure	w ni
			Receipt of critical
		Staff shortages	feadback about the
			ergors
		Lack of time	http://www.new.new.new.new.new.new.new.new.new.
		The last of sixuals are and or for	Affonymous, phone
		The lack of simple procedure for	insystem
		reporting errors	(physicians)
		Lack of feedback	Educational rather
			than punitive
		181.	system
			(paysicians)
			≕ S ÿs tem that was
			'lawyer proof'
			4 5
			Blame free
			reporting (nurses)
Jennings et al.,	Focus groups, interviews and	Burden of reporting in terms of time	Carity of indemnity
2011 ^[27]	questionnaire based study	3 3 3 3 a	frem prosecution
	Sample size not stated	Lack of accessibility of reporting	_ _
	Australia	forms	by соруг ⁱ ght
) yrig
			yht.

			On the second se
		Time elapsed following incident	27
		Priority of reporting over other work tasks	December
		Forgetting to report	2017. [
	10 ₁ 0 ₀	Workload	Downloa
		Fear of disciplinary action	aded fro
	~0,	Fear of potential litigation	om http:
		Fear of breaches of confidentiality/anonymity	://bmjopen
		Fear of embarrassment within peer group	December 2017. Downloaded from http://bmjopen.bmj.com/ on April 10, 2024 by guest.
		Fear that incidents many impact on their likelihood of promotion	April 10, 2
		Concern that nothing would change even if the incident was reported	:024 by gue
		Lack of familiarity with process	est. Prot
Johnstone et al., 2008 ^[84]	Focus groups, semi- structured interviews and questionnaire-based study 35	Frequency of incident-more frequent less likely to report	Seniority of graduate nurses

	Australia		27	
Joolaee et al., 2011 ^[113]	Questionnaire-based study 286 Iran		7 Decembe	Perceived work conditions
Kagan et al., 2008 ^[110]	Questionnaire-based study 201 Israel	The practice of ward nurse managers to cover up error, that is dealing with the error themselves without reporting to a higher authority	How the ward's and hospital's dealt with medication error How their ward handles error reporting	
Kagan et al., 2013	Questionnaire-based study 247 Israel	Medical error incidence	Patient safety culture index PSC at organisational level PSC at departmental level PSC at respondents personal performance level Nerses' place of bigh and their perfessional status (æademic or non- academic	

			9
			registered nurse)
Kaldjian et al., 2009 ^[41]	Questionnaire-based study 338 United States of America		Peedback Feedback 20
Karsh et al., 2006	Focus group 14 United States of America	Length of report Punishment	Feedback Mandatory system
	<i>b</i>	Reporting near misses	Figancial incentives
	, 66		Other incentives (protection from malpractice and
		COL.	disciplinary action) Support in using
		Te View	system Education in using
		0,	system
Kennedy et al., 2004 [34]	Questionnaire-based study 113	Not their responsibility to report	4 by gı
	United States of America	Never thought to report/not required to do so	uest. Prof
		Handle errors internally i.e. no corporate system	2024 by guest. Protected by copyright
		No errors worth reporting	соруг

		No time to report	27 Dec
		Forms not available or convenient	ember 2
Khan, 2013 ^[105]	Questionnaire-based study	Unavailability of professional	20
	50 Saudi Arabia	environment to discuss ADR	Dow
	Gaddi Arabia	Reporting forms are not available	nloadec
	100	I do not know how to report	I from I
		Reporting forms are too complicated	http://bi
		Reporting is time consuming	mjopen
		I am not motivated to report	.bmj.co
		I fear legal liability of the reported ADR	om/ on Apr
		I am not confident whether it is an ADR	ii 10, 2024
		Insufficient knowledge of pharmacotherapy in detecting ADR	by guest.
		Belief that only safe drugs are marketed-not cause of reaction	December 2017. Downloaded from http://bmjopen.bmj.com/ on April 10, 2024 by guest. Protected by copyright
King et al., 2006 ^[56]	Questionnaire-based study 39	Time constraints	у сору

	United States of America	Difficulty locating forms	on 27
		Lack of closure/feedback	, Decemp
		Not important	per 2017
	1 0 ₄	Fear of disclosure to risk management	27 December 2017. Downloa
Kingston et al., 2004 ^[9]	Focus groups 33 Australia	Lack of knowledge about the reporting process and	Effective and efficient IRS
	Australia	Lack of knowledge about what constitutes an incident	IRS with threat or blame
		"Nursing form" by association (not identified as being part of doctors role)	Prompt, relevant feedback
		Time constraint	IRS that drive insprovements
		Complexity of reporting form	Monetary payment
		Lack of feedback	Simplification
		Lack of legal privileges afforded to the reporting process	Less time consuming
		Culture of blame	Clear definitions of
		No value	weat constitutes an adverse event/near-miss

NECNELELAL. QUESTIONIALE-DASED STUDY LATITION DUSY TO THE FOURT X		of Reporting process to be made more refevant to doctors Reporting process less threatening by remaining the form Increased awareness and knowledge of IR process Protection from liability System that deesn't require input from doctors (norses) Equation at orientation (nurses) Affonymous reporting
---	--	---

ICOL			9
2009 ^[69]	137		27
	United Kingdom	The form takes too long to complete	Dec
			oe
		I am worried about litigation	ber
			20
		I do not want the case discussed in	7.1
		meetings	Ow
		I nover get ony foodbook	/nlo
	10/0 100/	I never get any feedback	ade
		It makes little contribution to the	d fre
		quality of care	om _
		quality of care	nttp:
		I am not sure what incidents to report	December 2017. Downloaded from http://bmjopen.bmj.com/ on
			qo _{(r}
		The incident was too trivial	en.l
			<u> </u>
		The incident did not result in any	con
		harm	7 01
[407]			>
Li et al., 2004 [127]	Questionnaire-based study	Address of reporting agency not	Inereasing
	1653	available	awareness among
	China	B 46 311	a@ministrators,
		Report forms unavailable	doctors & nurses
		Departing presses unknown	Cetablishing ADD
		Reporting process unknown	Eষ্ট্রtablishing ADR institutes
		Unaware of a national ADR reporting	0 0
		system	Eaucation and
			training in ADR
		Patient confidentiality	krowledge and
		 	related topics
			<u> </u>

			On Control of the Con
		Too busy to report ADR	27 [
		ADR sufficiently well documented)ecemb
		Reluctant to admit that they have caused a patient harm	December 2017. Downloaded from http://bmjop
	^O _A	Worried about feeling foolish	Downloa
	10/ ₀ / ₀₀	Reluctant to admit they may have made a medical error	aded from
	700	Personal ambition to publish a case	n http://b
		study	mjop
Martowirono et al.,	Focus group	Negatively valued	Reporting process-
2012 [100]	22		ability to report
	Netherlands	Costs time	over the phone or send an email
		Derecived as another administrative	Ď
		Perceived as another administrative	Aponymous
		task that they have to complete	
			reporting
		Priority	202
			Provide the
		Do not always agree with the	possibility to report
		definition of incident	without identifying
			the person involved
		Incidents that had no major patient	rote
		consequence	Provide feedback
		Incidents that have happened before	Provide feedback
		and has already been reported	tothe reporter if an
			ght.

	On the second se
	ingident on how the
Incidents that was not preventable	resport will be
	hagndled
The cause of the incident Is already	l be
clear	Feedback-
	communicate the
Incidents is unlikely to happen again	re≅ults in terms of
	systems changes
Was not an incident but a	oac
complication	Create an incident
·	re porting culture
Incident already been discussed with	
the people involved	Create a culture in
	which IR is less
The lack of feedback on a report	emotionally
10	charged e.g. by
Absence of visible system changes	systematically
were also issues	discussing IR
40)	within a ward and
Disloyal to colleagues	stimulating role of
,	supervisors
Not their responsibility	10
	Steplify the
legal liability	procedure
	- oy ç
Unpleasant working conditions	Design a procedure
	in vitis
Lack of encouragement from	possible to only
superiors to report incidents.	report the
	essentials of an
Incident reporting is emotionally	ingident, e.g. by
charged	making a call or
· · · · · · · · · · · · · · · · · · ·	<u> </u>
	

			9
		Some residents stated that they did	filing out a card or cਯੂnpact form with
			standard incidents.
		not complete IR because they did	I
		not think of it whereas others said	If ត្តecessary, the
			resident can be
		Did not know what to report.	contacted for more
			ingormation
		Did not know how to report	v _{nla}
			Make it easy for a
	10 ₁ 0 ₀	IRS complicated	resident to find out
			if an incident has
		Workload	aleeady been
			reported
			/bm
			Carification what to
		Tellien.	report
			<u> </u>
			Carification about
			and how to report
			Ď.
			Execite residents to
			report
			22
			Deaw attention to
			IR e.g. putting up
			posters with a
			cर्ब्युchy slogan
/ava at al 0004	Overting pains be and at all	Afreid of managers as attack	otected by copyright
Mayo et al., 2004	Questionnaire-based study	Afraid of manager reaction	ted.
·~1	983		by
	United States of America	Afraid of co-workers' reactions	c
			y ₁
			ght.

McArdle et al., 2003 [78] Semi-structured interviews 15 United Kingdom Lack of feedback received Lack on incentive Cumbersome Non-anonymous Fear of blame Description of medication did not fall into IRS formats-scope of reporting Merchant et al., 2005 [85] Questionnaire-based study 207 Canada I think of reporting too late Don't know where CIRS forms are Fear of lawyers getting information I don't know what sort of incident to report I'm too busy Fear of record of problem				97	
2003 [78] 15 United Kingdom Lack of feedback received Lack on incentive Cumbersome Non-anonymous Fear of blame Description of medication did not fall into IRS formats-scope of reporting Merchant et al., 2005 [93] Questionnaire-based study 2007 Unnecessary as anesthesia				27	
2003 [78] 15 United Kingdom Lack of feedback received Lack on incentive Cumbersome Non-anonymous Fear of blame Description of medication did not fall into IRS formats-scope of reporting Merchant et al., 2005 [93] Questionnaire-based study 2007 Unnecessary as anesthesia			enough	Dec	
2003 [78] 15 United Kingdom Lack of feedback received Lack on incentive Cumbersome Non-anonymous Fear of blame Description of medication did not fall into IRS formats-scope of reporting Merchant et al., 2005 [93] Questionnaire-based study 2007 Unnecessary as anesthesia			Face of Wastelland and Can	ëm	
2003 [78] 15 United Kingdom Lack of feedback received Lack on incentive Cumbersome Non-anonymous Fear of blame Description of medication did not fall into IRS formats-scope of reporting Merchant et al., 2005 [93] Questionnaire-based study 2007 Unnecessary as anesthesia			Fear of disciplinary action	oer :	
2003 [78] 15 United Kingdom Lack of feedback received Lack on incentive Cumbersome Non-anonymous Fear of blame Description of medication did not fall into IRS formats-scope of reporting Merchant et al., 2005 [93] Questionnaire-based study 2007 Unnecessary as anesthesia	McArdle et al	Semi-structured interviews	It takes too long	2017	
United Kingdom Lack of feedback received Lack on incentive Cumbersome Non-anonymous Fear of blame Description of medication did not fall into IRS formats-scope of reporting Merchant et al., Questionnaire-based study 2005 [93] United Kingdom Lack of feedback received Lack on incentive Cumbersome Non-anonymous Fear of blame Description of medication did not fall into IRS formats-scope of reporting Unnecessary as anesthesia			it takes too long	7 D	
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Merchant et al., 2005 [93] Questionnaire-based study 207 Canada Don't know where CIRS forms are Fear of lawyers getting information I don't know what sort of incident to report I'm too busy Fear of record of problem Non-anonymous Fear of blame Description of medication did not fall into IRS formats-scope of reporting I think of reporting too late Don't know where CIRS forms are Fear of lawyers getting information I don't know what sort of incident to report I'm too busy Fear of record of problem			Cumbersome	htt	
Merchant et al., 2005 [93] Merchant et al., 2005 [93] Questionnaire-based study 207 Canada Don't know where CIRS forms are Fear of lawyers getting information I don't know what sort of incident to report I'm too busy Fear of record of problem				φ://t	
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Merchant et al., 2005 [93] Questionnaire-based study 207				m/ c	
Merchant et al., 2005 [93] Questionnaire-based study 207 Canada I think of reporting too late Don't know where CIRS forms are Fear of lawyers getting information I don't know what sort of incident to report I'm too busy Fear of record of problem Unnecessary as anesthesia is safe futile as anesthesia is safe futile as anesthesia is safe				n >	
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Canada Don't know where CIRS forms are Fear of lawyers getting information I don't know what sort of incident to report I'm too busy Fear of record of problem is safe futile as anesthesia is safe futile as anesthesia is safe	2005 ^[93]	1		10, :	
Fear of lawyers getting information I don't know what sort of incident to report I'm too busy Fear of record of problem futile as anesthesia is safe		Canada	Don't know where CIRS forms are	2024	is safe
Fear of lawyers getting information Guest Fear of lawyers getting information Fear of lawyers gettin				4 by	6 (1)
I don't know what sort of incident to report I'm too busy Fear of record of problem			Fear of lawyers getting information	gue	
report I'm too busy Fear of record of problem			I don't know what sort of incident to	tst.	
I'm too busy Fear of record of problem				Prot	Saic
I'm too busy Fear of record of problem				ecte	
Fear of record of problem			I'm too busy	<u>δ</u>	
Fear of record of problem				CO	
ght.			Fear of record of problem	руп	
				ght.	

			9
		Don't have CIRS forms	27 December 2017. Downloaded from http://bmjopen.bmj.com/ on April 10, 2024 by guest. Protected by copyright
		My incidents are too minor	ember
		Too long	2017.
		No value will come of this	Downk
	10 ₀	Too much writing	paded 1
	100	Incidents I see are other's problem	rom htt
		Too many tick boxes	tp://bm
		Unsure what 'critical incident' is	jopen.b
		Effort is doomed to failure	mj.com
		Too difficult	v on A
		Form is confusing	pril 10,
		Unimportant to me	2024 b
		Nothing can be learned from me	y gues
		CIRS asks wrong questions	t. Prote
Manager 1 - 1	Overskiemensing begandert.		ected .
Mrayyan et al., 2007 ^[126]	Questionnaire-based study 779	Fear of disciplinary action/lose job	by co
	Jordan	Errors not serious to warrant	рууг

	T	1 4	On	T
		reporting	27 [
		Fear of reaction from co-workers	Decemb	
		Fear of reaction from nurse managers	27 December 2017. Do	
			Dc	
Mustafa et al.,	Questionnaire-based study	Uncertain association	Seriousness of	
2013 [124]	136		AਊRs	
	Pakistan	Awareness	ed	
		O	Uฐusual reaction	
		Concern about legal liability	Reaction to a new	
			product	
			pi y duct	
		10.	Cenfidence in the	
			diagnosis of ADR	
			con	
Naveh et al., 2006	Questionnaire-based study	Perceived safety procedures	Perceived safety	Perceived
[112]	632		ingormation flow	priority of
	Israel		<u> </u>	safety
			0, 2	Unit type
			2024	Unit type
Okuyama et al.,	Questionnaire-based study		Safety	Safety
2010 ^[115]	430		management at	management
	Japan		waard level	at the hospital
			otec	level
			ted	Attitudes of
			by c	Attitudes of ward safety
			tected by copyright	managers
				managers

Ochorno et al	Ougationnaira based study	Error pot corious	27 [Doroontions
Osborne et al., 1999 ^[54]	Questionnaire-based study	Error not serious	December 2017. Dow	Perceptions of
1999 1	57		em em	medication
	United States of America	Afraid of repercussions	ber	errors
			20`	
		Afraid of reactions from	17.	
		managers/co-workers	Do	
	· · ·		무	
Parvizi et al., 2014	Questionnaire-based study	Did not know they were expected to	Better education of	
70]	119	do this	the means of	
	United Kingdom		aďverse IR	
		Did not know how to report to MHRA	h ht	
			Introvements in	
		I do not see the purpose of reporting	th € feedback sent	
			tothe reporter on	
		Lack of time	the outcomes of	
			the adverse	
		Blame	ingidents	
		181.	0	
		Direct reporting to the manufacturer	Insprovements in	
			the guidance on	
		Not reporting if the types of device	the type of adverse	
		failure were considered to be	device related	
		common knowledge	ingidents to report	
		S .	9 6	
		Reporting only those that were	Insprovements in	
		unexpected failures or failures that	the electronic	
		may affect the patient or user	means of adverse	
		may amost and patient of door		
		Reported by either a nurse or other		
		doctor	্ত Improvements in	
		400(0)	the clinical and	
				1

			<u> </u>
			adverse incidence
			g&vernance
			cen
Patrician et al.,	Questionnaire-based study	Perceptions that the administration	hber
2009 [43]	43	focuses on the individual and not the	r 20
	United States of America	system)17.
			Dc
		Nurses are blamed when something	lnwi
		bad happened to patients	l oac
			ye d
		Fear adverse consequences for	froi
	100	reporting errors	
			ttp:/
		Nurses believe that their peers will	//bm
		think them incompetent	jop
		10 ,	en.
		Nurses do not think the error was	<u> </u>
		important enough to report	
			n/ c
		Fear of administrative response	2017. Downloaded from http://bmjopen.bmj.com/ on April 10,
			ρrii
		Disagreement over error	10,
			20
		Reporting effort	24
		Lack of agreement about definition of	oy s
		error	l lues
			¥
		Lack of error recognition	2024 by guest. Protected by co
		Excessive length of time for	ecte
		contacting physician	<u>ä</u>
		Seeming projection.	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \
Rasmussen et al.,	Questionnaire-based study		Safety climate
		1	<u> </u>
			

2014 ^[122]	124		27	
	Denmark		T g am climate	
			cem	
			Inter-departmental	
			working	
			retationships	
			Ingreased cognitive	
	O _A		demands	
			ed	
Rogers et al., 1988	Questionnaire-based study	Reporting forms not available	fron	Age
[51]	1121		ր htt	
	United States of America	Event already documented	p://b	Time in direc
		Did not get to it/got busy	omjo	patient care
		Did not get to logot busy	pen	
		Did not believe it was important	.bmj	
			.con	
		Forms were too much trouble	n∕ or	
			1 Ар	
		Minor or expected side effect	rii 1	
		Did not like interacting with the	0, 20	
		government	024	
		government	by s	
		Liability concerns	jues	
			t. Pr	
		Did not know how to report	otec	
		Undetermined as ADE	πed	
		Ondetermined as ADE	by c	
		Not primary physician	from http://bmjopen.bmj.com/ on April 10, 2024 by guest. Protected by copyright	

			<u>. 9</u>	
			27	
Rowin et al., 2008	Descriptive study		Mare likely to	Temporary
[28]	Sample size not stated		report no harm	harm
	United States of America		(ngurses)	
			, 5L ,	Near miss
			More likely to	
			report permanent	
			harm, near death,	
	10 ₁ 0 ₀		death and unsafe	
			environment	
			(doctors)	
			(4201013)	
			Type of incident:	
			falls and	
			medication (nurse)	
			Trans of incidents	
			Type of incident:	
		10.	agverse clinical	
			event (doctors)	
0 1 1 - 1	Occasional and interests	Not be to a second of a second of a	<u> </u>	
Sanghera et al.,	Semi-structured interviews	Not being aware that an error had	_ 3	
2007 ^[79]	13	occurred	, N	
	United Kingdom		022	
		Detailed paperwork	b	
) gu	
		Time constraints	lest	
			P	
		Not understanding incident reporting	ote	
		process	cte	
			April 10, 2024 by guest. Protected by copyright	
		No benefit (perception that nothing is	, co	
		done with the data)	ρ́y	

			9	
		No encouragement by management	27 Dece	
		Fear of loss of professional registration	27 December 2017. Downloaded from http://bmjoper	
		Fear of being in trouble	7. Dow	
	0	Fear of looking incompetent	nloade	
	10 ₁ 0 ₀	Feeling upset	ed from	
		Fear will be blamed	http://b	
		Not wanting to report colleagues' errors	omjopen.l	
Sarvadikar et al.,	Questionnaire-based study		Dectors more likely	Nurses and
2010 [71]	56		togreport errors with	pharmacists
	United Kingdom	18 1.	wersening patient	likely to report
	-		outcome	error
			pril 1	regardless of
			,	patient
			2024 5	outcome
Schectman et al., 2006 [44]	Questionnaire-based study 120	Unsure of reporting mechanism	Allow electronic reporting of	
	United States of America	No actual harm came to the patient	adverse events and	
		Reporting too difficult and time	ngai illisses g	
		consuming	Cerify reporting	
			mæchanism	
		Unsure of what is considered AE/NM	mechanism	
		•	<u> </u>	1

			og .
		Inadequate MD participation in scheme	Charify what constitutes an AB/NM
		Concern about consequences of reporting others' error	Allow anonymous reporting
	10/DO	Reporting makes no difference (nothing will change)	Ingrease physician ingolvement in QI
	Per	Concern about being blamed or judged less competent	Provide feedback on QI projects arising from reports
		Weaknesses in the reporting system	Peovide individual
		Professional behaviours	feedback following report
		Fear of retribution	Provide summary
		Lack of feedback and the perception that change would not result from	feedback on a regular basis
		reports.	Make reporting mandatory
0.1.1		N.C.	~
Schulmeister et al., 1999 ^[45]	Questionnaire-based study 160	Minor error	guest. F
	United States of America	Fear of disciplinary action	Protecte
Sharma et al., 2008 ^[74]	Questionnaire-based study 81	Does not achieve anything	A gonymous system
	United Kingdom	Not in physicians culture	Easily accessible

			9
		Do not wish to incriminate others	forms Figrms not held by
		Do not know how to access forms	ng sing staff
		Not bothered	7
		Do not wish to ask nurse staff	ownlo:
	10, De	Lack of time	aded fro
	7006	Do not know which incidents need to be reported	m http://b
		Lack of anonymity	omjopen.
		Not in habit of considering it	bmj.cc
		Discouraged by senior nurses	om/ on A
Soberberg et al., 2009 [118]	Questionnaire-based study 317	I did not have enough time	April 10
2000	Sweden	I am concerned about possible consequences	2017. Downloaded from http://bmjopen.bmj.com/ on April 10, 2024 by guest. Protected by copyright.
		Someone else did it	guest.
		It is too complicated	Protect
		No one else files incident reports	ted by c
		It would not make any difference	хоруг

			or
		Insufficient routines for reporting	27 Dece
Soleimani., 2006	Questionnaire-based study 128	Threat of public outcry	December 2017. Downloaded from http://bmjopen.bmj.com/ on April 10, 2024 by guest. Protected by copyright
	New Zealand	Professional	2017. [
		consequences/discipline	Jown!
		Embarrassment in front of colleagues	oadec
			i from
Stratton et al., 2004 [59]	Questionnaire-based study 284	No positive feedback is given for passing medications correctly	http://
	United States of America	Nurse administration focuses on the	lomjop
		person rather than looking at the	oen.br
		system	nj. con
		Too much emphasis is placed on medication errors as a measure of	\ no \r
		the quality of care	April 1
		Responses by nursing administration	0, 202
		do not match the severity of the error	24 by 0
		Individual/personal reasons	guest.
		Nurses could be blamed if something happened to the patient	Prote
		Nurse believe other nurses will think	cted b
		they are incompetent	ý copy
			/r/ght.

			On .	
		Nurses fear adverse consequences	27	
		from reporting	December 2017. Downloaded from http://bmjop	
			e m	
		Patient might develop a negative	ber	
		attitude	201	
		N for a second for a	17. [
		Nurses fear reprimand from	Oow	
		physician	nloa	
		Nurses fear losing their license	ade	
		Indises lear losing their license	d fro	
	10/ ₀	Nurses want to avoid potential) H	
		publicity of medication errors in the	http:	
		media	//bn	
			njop	
Sweis et al., 2000	Questionnaire-based study	Busy	Serious ADR rather	Training in
[77]	280		than trivial	reporting
	United Kingdom	Legal liability	Com	
		101	Rarely occurring	Gender
		Fear of breaching patient	ABR rather than	
		confidentiality	common ADR	Type of
			ON CHARAC	hospital
			Confidence in	٨ ٥٠٥
			recognising an	Age
			L C	
			ADR to an	
			established drug	
			ræher than new	
			dig	
			00	
			Agtive support of	
			ght	



			or
			Simplify reporting
			system
			Ser .
			AਊR reporting
			tegm
			17.
			F § edback
			¥ n
Tariq et al., 2012	Semi structured interviews	Lack of time	n paded
[83]	23		e d
	Australia		fron
Taylor et al., 2004	Questionnaire-based study	Not important to report error that did	Make reporting of
[46]	140	not harm patient	erors mandatory
	United States of America		<u> </u>
			Different format for
		Reporting errors does not make any	IR
		difference	mj.
			Use of electronic
		Unsure about what is considered	fogmat for reports
		medical	Ap
			Reward for
		Incident report form too complicated	reporting medical
			eigors
		Concerned about being blamed or	5
		judged incompetent	Better education
			algout what is
		Concerned about implicating others	considered a
			medical error that
		Unsure whose responsibility it is to	should be reported
		report errors	by
			Egidence that
			reporting of errors
			yht.

			9
	10000000000000000000000000000000000000		let to system changes Feedback on regular basis and frequencies of reported errors Feedback regular outcome of a specific error that has been reported
Throckmorton et al., 2007 [47]	Questionnaire-based study 435 United States of America	Level of harm: no harm	Level of harm Working closely to the patient Higher scores on the Wakefield's scale Fewer years since initial license
Tobaiqy et al., 2013 ^[106]	Questionnaire-based study 61 Saudi Arabia	Lack of awareness Workload/time constraints Unavailability of reporting form	Centinuing education events Aprinternet/web based reporting facility

			9	
		Reporting system complexity	27	
		Franto e trivial	Training focused	
		Error too trivial	ongerror prevention	
		Lack of anonymity	Agonymity of reporting	
		Fear of blame	A <u>f</u> non-punitive	
	10 ₁ 0 ₀	Concerns over penalisation	reporting culture	
	100	Difficulty in recognising errors	Figancial incentives	
		Senior staff advised not to report	₹	
		Lack of feedback from authority	://bmjopen.k	
Turner et al.,	Semi-structured interviews	Value-not convinced that the	j.	
(2013) ^[63]	32	reporting system would deliver	.cor	
,	United Kingdom	improvements in clinical care	on on	
Unibootal 2002	Overetion pains beared attack.	Time in table d in decrease with a con-	<u> </u>	This lains at the at
Uribe et al., 2002	Questionnaire-based study	Time involved in documenting an	≅ 2	Thinking that
1	122 United States of America	error	0, 2	reporting has
		Extra work involved in reporting	mj.com/ on April 10, 2024 by guest. Protected by copyrght	contribution for improvement o
		Hesitancy regarding 'telling' on somebody else	guest. P	quality care
			rote	Not knowing
		Thinking that it is unnecessary to	ecte :	the usefulness
		report error because it had no	Ö Ö	of the report
		negative outcome	y 00	'
			Тру	Lack of

	or	
Not being able to report	27	knowledge of
anonymously	De	what should be
	cem	reported
Fear of lawsuits	1be	
	r 20	Lack of
	17.	recognition that
	Do	a medical error
	wn <u>l</u>	has occurred
	oac	
	<u>е</u>	Fear of being
	fron	blamed
	n ht	
	ф://	Fear of
	bm)	disciplinary
	jope	action/ losing
70	95.b	job
	<u>ä</u> .	
	com	Lack of
· C//	v or	information in
	≯ _E	how to report
	orii 2	
	0,	Lack of interest
	202	or motivation
	4 by	for reporting
) gu	_
	est.	Forms or
	Pro	computer
	otec	locations not
	ted.	available to
	by	report medical
	December 2017. Downloaded from http://bmjopen.bmj.com/ on April 10, 2024 by guest. Protected by copyright.	errors
	<u> </u>	
	jh t.	

			9	Mat les accides
			27 December 20	Not knowing
			De	who is
			Cer	responsible for
			nbe	reporting erro
			9r 2	
Vessal et al., 2009	Questionnaire-based study	Uncertain association	The reaction is of a	
114]	110	Officertain association	serious nature	
•		To a fail tiel to me ment	Segious nature	
	Iran	Too trivial to report		
			Tge reaction is	
		Too well known to report	un <u>u</u> usual	
			fror	
		Yellow card not available	The reaction is to a	
			new product	
		Not enough information from the	br	
		patient	Reaction not	
		patient	reported before for	
		Not and Children	I •	
		Not enough time	a particular drug	
		Unaware of the existence of a	Reaction is well	
		national ADR reporting system	resognised for a	
		Hational Abit reporting system	pærticular drug	
		Too burgoueratio		
		Too bureaucratic	0, 2, 1;	
			A y reaction	
		Did not know how to report	, p	
			y gu	
		Fear of legal liability	ses	
		_	D	
		Unaware of the need to report and	rote	
		ADR	ecte	
			<u> </u>	
Vincent et al., 1998	Questionnaire-based study	Unnecessary	4 by guest. Protected by copyright.	Unsupported
72]	198	- Office Coopers	Öp	
· -	190		1 3.	colleagues

			9	
	United Kingdom	Increased workload	27	
			December 2017. Downloaded from http://bmjopen.bmj.com/ on April 10, 2024	Not knowing
		Blame	cem	which incidents
			nbei	to report
		Worry litigation	20	
			117.	As long as staff
		Busy/forgot	D	learn from
			<u>×</u>	incident it is
			oac	unnecessary to
			e d	discuss/report
	70,00		fror	
			<u> </u>	Fear
			dp://	disciplinary
			/bm	
			jop	Not wanting
		10	en.k	incident to be
			<u> </u>	discussed
		review of	CON	
		70 1.	n/ o	Who's
)	responsibility
			prii	,
			10,	Little
			20	contribution
			24 5	
Vogus et al., 2007	Questionnaire-based study	Safety organising	Trust in managers	Care pathways
[49]	1033		ues	
	United States of America	Unit type (emergency)	RÑ experience	% of RNs with
			rote	BSN
		Safety organising and trust	Ugit type (IC)	
			_	Unit type
		Safety organising and pathways	੍ਰ Ngmber of beds	(surgery)
			ppyright.	
	•		ghi	
			• *	

		Detient to DN retie	9	
		Patient-to-RN ratio	27 [
			De	
Walji et al., 2011	Semi- structured interviews	Lack of knowledge about natural	Pgarmacists who	
[09]	12	health products	saw themselves as	
	Canada		'kgowledge	
		Lack of time/priorities	generators' rather	
			than just	
		Complexity of reporting process	'kaowledge users'	
			were more likely to	
	A		report and less	
			likė̃ly to allow	
			werkplace	
			challenges to	
			prevent their taking	
			an extra step	
		10	en. .	
Walker et al., 1998	Focus groups and	Minor incidents (documentation and	More likely to	Fear of
[85]	questionnaire-based study	minor variation from the prescription)	report an incident if	possible
	43		patient safety	punishment
	Australia	Negative past experience of	compromised	senior staff
		reporting	prii	
			Cਕੌpacity to	
		Fear of getting into trouble	feedback and	
			inprove the	
		Fear they will somehow stand out	situation	
		from the crowd in the eyes of those	ues	
		in authority	Reporting might	
			help raise people's	
		Feelings of discomfort or uncertainty	awareness of	
		about being required to report an	problems that could	
		incident that involved a colleague	be occurring	
		morasin that involved a concagac	pg occurring pyr ght.	
	1		1 7	

		On the second se
	This is more difficult if the colleague	27
	is a more experienced nurse	W _g ong drug
		ěm.
	Others expressed with view that they	Wଞ୍ଝong route
	wouldn't report a friend, perhaps	20:
	perceiving that the friend would be in	Wittong person
	trouble if the incident was reported	Do.
		Wkong dose
	Did not always want to admit their)ade
	mistake	H a rm to the patient
		on
	Might not even realise that an error	A desire to target
	had occurred	and individual or
		professional group
	Incident might be highly incriminating	togimprove practice
	If the patient actually came to harm	Legal obligation of
	as a result of the error	the nurse to report
	as a result of the error	, ή
	If the departure from the prescribed	on /
	therapy seemed reasonable	Apri.
	andrapy deciment reasonable	110
	If the problem could be sorted out	, 20
	in the presion scale so contact out	24
	Concern about the time taken to fill	by g
	in the incident report form	Jues
		st. F
	Inadequate understanding of what	rot
	constituted an error	ecte 9
		් ල ල
	A lack of feedback on the number of	y cc
	medication errors was a problem	on April 10, 2024 by guest. Protected by copyright
·		ght
		**

		<u> </u>	9
		Perceived inaction on reported errors incidents	27 Decembe
Waring, 2004 ^[64]	Semi- structured interviews 37 United Kingdom	Acute medicine and rehab: IR system was regarded as nurse led, dealing with ward issues and the work of non-medical groups Anaesthesia: Physicians remained sceptical about the hospital wide reporting system and were generally	er 2017. Downloaded from http://bmjopen.bmj.com/ on April 10, 2024 by guest. Protected by copyright
400		disinclined to participate in this approach	o://bmjope
Waring, 2005 ^[10]	Semi-structured interviews 28 United Kingdom	Fear of blame Blame culture	n.bmj.com/
		Peer of punishment	on April
		Fear of blame from pubic	10, 202
		Fear of litigation	4 by gu
		Fear of professional competence being questioned	est. Pro
		Fear of poor references	lected b
		Reprimands from a senior colleague	у соруг
			ght.

			<u>. 9</u>	
		Fear of use of reports-could be used at a later date in the event in medicolegal disputes	27 Decembe	
Waters et al., 2012	Focus groups	Time	Previous	Risk of
[90]	16 Canada	Fatigue	exiperience of litigation	litigation
	0,	High workload	Protection against future litigation	
	Po	Relevance of reporting form	Professional	
	2.6	Complexity of reporting-gathering many pieces of information.	responsibility	
		Unit culture	IR perceived as learning	
		Fear of blame	opportunity	
		Close knit team	Desire for practice improvement	
		Other methods of reporting-verbal reporting and team debrief	ril 10, 2024 by gue	
		Lack of feedback	4 by gues	
Weissman et al., 2005 [50]	Questionnaire-based study 203	Mandatory	Sérious harm	
	United States of America	Non-confidential system	otected by copyright	
		State run	у сс	

			9
		Less harm	271
Williams et al., 2013 ^[65]	Focus groups 17 United Kingdom	Severity (more likely to report if serious harm	Simpler reporting system
	10 ₁ 0 ₀		Targeted report Feedback Drug-specific error reporting forms
			Electronic forms/systems (easier than paper)
			Anonymous reporting
Winchester et al., 2012 ^[73]	Questionnaire-based study 120	Concerned about confidentiality	Education
	United Kingdom	Did not know the procedure for reporting	Adverts/posters No. 2022 Training
		Did not think anything could be done	Campulsory
		Did not feel incident was important enough to report	reporting
		Believed source to be low risk	Signple reporting system
		Reporting was inconvenient	Ag electronic

			reporting system
ong et al., 2003	Questionnaire-based study	Time constraints	Total anonymity
17]	136		and confidentiality
	New Zealand	Laziness and forgetfulness	r 20
			Protection against
		Dislike form filling	p⊮nitive action
			· w
		A lot of work for little practical benefit	Simplify forms and
		·	brang up to date
		Forms too complicated	fron
	7-(2)		Easy access to
		Do not believe the system is working	forms
			m
		Many incidents not worth reporting	E c ctronic data
		70	entry
		Many other tools exist for correcting	<u>a</u> ;
		errors and improving standards	Ingorporating IR
		· C//.	fogm filling at
		Dislike the published interpretation of	regular M&M
		results with diagnostic views by	m e etings
		some anaesthetists	10, ;
			Mandatory
		Qualitative result not acceptable	b
			Local analysis
		Feel that the main benefit of IR is	ragher than
		local analysis and that very rare	Australasian wide
		events distilled by multi-site	oteç .
		monitoring are less important	Mare aggressive
		Diff. It defines the first	fo∰ow up and
		Difficulty defining what constitutes	regriewing
		incident	ppyright.

			9	
		Inadequate feedback	Publication of problems	
		Medico-legal implications	Agns and purpose should be clarified	
		Forms not available/hard to locate	explicitly	
	10/0 100/00	Lack of appropriate culture within department	Select a few ingidents to monitor frequency	
	Per	Not accepted as part of private practice culture		
		Use of local IR system, hospital based audit	ı://bmjope	
		Incidents are discussed at department level confidentially	from http://bmjopen.bmj.com/ o	
Zwart et al., 2011	Prospective cohort study 66		Expertise	Communicator
	Netherlands		10, 20	Collaborator
)24 by	Manager
			ertis epril 10, 2024 by guest. Protected by copyright.	Health advocate
			rected	Scientist
			by соруг	Professional
			ight.	

Register Nurse (RN)

.eaction (ADIA),
.e in Nursing (BSN),
.epartment of Inspections A_F.
.inistration Error (MAE); Medicatic.
.ind Mortality (M&M); Near Miss (NM); Pa.. Adverse Drug Event (ADE); Adverse Drug Reaction (ADR); Adverse Event (AE); Australia and New Zealand College of Anesthetists (ANZCA); Bachelor of Science in Nursing (BSN); Critical Incident Reporting Service (CIRS); Drug related problems (DRP); Incident Reporting (IR); Iowa Department of Inspections Appeals (IDIA); Incident Information Management System (IIMS); Intensive Care (IC); Medication Administration Error (MAE); Medication and Healthcare Products Regulatory Agency (MHRA); Medical Doctor (MD); Morbidity and Mortality (M&M); Near Miss (NM); Patient Safety Culture (PSC); Quality Improvement (QI);

eTable 2: Frequency of factors influencing engagement in incident reporting

		Impact on	Reporting En	gagement
Factor		Barrier Frequency Count (%)	Facilitator Frequency Count (%)	Negative Case (no impact) Frequency Count (%)
	Adverse consequences	51 (31.68%) [8, 10, 11, 27, 30, 32, 33, 35-37, 42-45, 53-56, 58, 59, 61, 68, 75, 78, 79, 85, 87, 88, 92, 97, 99, 100, 104, 106, 109, 118, 120, 121]	-	3 (25.00%) ^[72, 85, 96]
	Litigation	30 (18.63%) [8-11, 24, 27, 32, 35, 48, 51, 52, 61, 69, 72, 77, 80, 81, 85, 87, 88, 93, 100, 101, 103, 105, 107, 114, 117, 124, 128]	8 (61.54%) ^{[9, 11,} 27, 33, 82, 88, 90]	4 (33.33%) ^[24, 40, 48, 90]
	Blame	24 (14.91%) ^[8, 10, 32, 35, 43, 44, 46, 58-61, 68, 70, 72, 78, 79, 82, 87, 90, 92, 99, 106]	4 (30.77%) ^[9, 11, 87, 88]	1 (8.33%) ^[48]
Fear of Adverse	Judgment	22 (13.66%) [10, 24, 35, 43, 53, 59, 67, 79, 80, 88, 92, 99, 104, 107, 109, 116, 126]		1 (8.33%) [101]
Consequences	Relationships	12 (7.45%) ^[10, 11, 36, 44, 46, 48, 54, 59, 92, 104, 116, 120]	-	-
	Impact on career	10 (6.21%) ^[10, 11, 27, 58, 59, 79, 86, 92, 93, 126]	-	1 (8.33%) ^[125]
	Protection of self	7 (4.35%) ^[24, 76, 80, 107, 122, 127]	-	-
	Avoid discussion in meetings	4 (2.48%) ^{[8, 69, 87,} 117]	_	1 (8.33%) [72]
	Apprehension about sending inappropriate form	1 (0.62%) ^[75]		-
	Non-punitive	-	1 (7.69%) ^[117]	1 (8.33%) [123]
	Total	161 (100%)	13 (100%)	12 (100%)
Process and Systems of	Time	29 (26.36%) [8, 11, 27, 38, 43, 48, 57, 69, 74, 78, 79, 81, 85, 87, 88, 90, 92, 93, 99-101, 105-107, 114, 118, 121]	5 (6.67%) ^[9, 11, 25, 40]	-
Reporting	Complexity/simplification of reporting	28 (25.45%) ^{[8, 9,} 11, 31, 33, 35, 38, 44, 46,	15 (20.00%) ^{[9,} 11, 30, 38, 65, 68, 73,	1 (14.29%) [68]

Anonymity and/or confidentiality		51, 73, 78, 79, 88-90, 93,	77, 81, 100, 101, 117]	
Reporting format 10 (9.09%) 101.44 (12) 12 (12) (13) (14) (14) (14) (15) (15) (16) (17) (17) 17 (14) (15) (16) (17) (17) 17 (17) (17) 17 (17) (17) (17) 17 (17) (17) (17) 17 (17) (17) (17) (17) 17 (17) (17) (17) (17) 17 (17) (17) (17) (17) (17) (17) (17) 17 (17) (17) (17) (17) (17) (17) (17) (100, 101, 105-107, 117,		
Reporting format		74, 76-78, 80, 87, 101,	68, 74, 87, 100, 106,	1 (14.29%) [18]
Unknown destination of report 4 (3.84%)	Reporting format	10 (9.09%) ^[31, 44, 82, 85, 90, 93, 100, 117]	61, 65, 68, 70, 75, 87,	3 (42.86%) [24]
Not enough information to complete report 3 (2.73%) [84, 107, 178] - - -	Type of reporting system	5 (4.55%) ^{[38, 50, 92,} 117]		-
Sharing/access of reports 3 (2.73%) [51,75,87] - - -	Unknown destination of report	4 (3.64%) ^{[24, 70,} 101, 107]	-	-
Insufficient routines for reporting 1 (0.91%) (118) - - -		3 (2.73%) ^{[94, 107,} 114]	1 (1.33%) ^[76]	-
Lack of reporting system	Sharing/access of reports	3 (2.73%) [51, 75, 87]	-	-
Administrative task		1 (0.91%) ^[118]	-	-
Relevant to different HCPs	Lack of reporting system	1 (0.91%) [36]	-	-
Reporting focus	Administrative task	1 (0.91%) [100]	-	1 (14.29%) ^[97]
Information not readily available Not specified When/where to report Doesn't require input from doctors Total 10 (100%) 40 (43.48%) [8, 11, 24, 31, 35, 42-46, 50, 51, 53, 34, 46, 42, 47, 50, 58, 66, 69, 70, 72, 73, 80, 85, 87, 88, 82, 100, 103, 105, 106, 109, 114, 126, 128, 129] Level of harm Prequency of incident 18 (19.57%) [31, 51, 66, 77, 71, 25] 18 (19.57%) [31, 51, 66, 77, 71, 14, 119, 124, 124, 121, 124, 121, 124, 121, 124, 123, 129] 18 (19.57%) [31, 51, 66, 77, 77, 71, 14, 121, 121	Relevant to different HCPs	1 (0.91%) [64]	2 (2.67%) [9, 75]	-
Not specified - - 1 (14.29%) [97]	Reporting focus	1 (0.91%) ^[78]	2 (2.67%) [68]	-
When/where to report		1 (0.91%) ^[31]	-	-
Doesn't require input from doctors	Not specified		-	1 (14.29%) ^[97]
Total 110 (100%) 75 (100%) 7 (100%)	When/where to report	-	1 (1.33%) [117]	-
Level of harm		-	1 (1.33%) ^[9]	-
Level of harm 53, 54, 58, 65, 66, 69, 70, 72, 73, 80, 85, 87, 88, 92, 100, 103, 105, 106, 109, 114, 126, 128, 129]	Total	110 (100%)	75 (100%)	7 (100%)
Characteristics Cause of incident 103, 107, 114, 119, 124, 128, 129] 18 (19.57%) [31, 51, 66, 76, 77, 125] 18 (19.57%) [31, 51, 66, 70, 75, 76, 84, 100, 101, 103, 114, 119, 121, 127-129] 19 (100%) [125, 129] 2 (100%) [125, 129] 2 (100%) [125, 129]	Level of harm	53, 54, 58, 65, 66, 69, 70, 72, 73, 80, 85, 87, 88, 92, 100, 103, 105, 106, 109,	66, 75, 77, 82, 85, 88, 95, 114, 121, 124,	-
Frequency of incident 66, 70, 75, 76, 84, 100, 101, 103, 114, 119, 121, 127-129 13 (23.64%) 66, 75, 77, 114, 121, 124 - 124 124 124 124	Cause of incident	103, 107, 114, 119, 124,	6 (10.91%) ^{[40,} 66, 76, 77, 125]	2 (100%) [125, 129]
Type of incident 13 (14.13%) [8, 33, 8 (14.55%) [82, -	Frequency of incident	66, 70, 75, 76, 84, 100, 101, 103, 114, 119, 121,		-
	Type of incident	13 (14.13%) [8, 33,	8 (14.55%) [82,	-

		34, 52, 69, 81, 85, 92, 93, 100, 107, 117, 121]	85, 121]	
	Level of risk	2 (2.17%) [11, 58]	1 (1.82%) ^[58]	-
	Patient characteristics	-	1 (1.82%) [82]	-
	Total	92 (100%)	55 (100%)	2 (100%)
	Value/attitude towards reporting	53 (59.55%) [8, 9, 35, 44, 46, 56, 61, 63, 64, 66, 68, 70, 73, 74, 76, 79, 81, 86-88, 92, 93, 99-101, 103, 105, 107, 109, 117, 118, 120, 121, 128]	21 (51.22%) ^{[9,} 11, 40, 58, 68, 82, 88, 90, 93, 95, 97, 98, 107, 111, 125]	12 (27.91%) ^[37, 48, 54, 72, 79, 96, 129]
	Forgetfulness	9 (10.11%) ^[8, 27, 31, 72, 87, 93, 117, 119, 129]	-	1 (2.33%) ^[129]
	Perception of self	9 (10.11%) ^{[24,} 36, 55, 80, 87, 107, 127]	2 (4.88%) ^{[89,}	6 (13.95%) [24, 102]
	Emotional response	6 (6.74%) ^{[24, 36,} 55, 80, 87, 107, 127]	5 (12.20%) ^{[31,} _{58, 100]}	-
Individual HCD	Previous reporting behaviors	5 (5.62%) ^[34, 37, 32, 32]	1 (2.44%) [29]	1 (2.33%) [129]
Individual HCP Characteristics	Exposure to errors	2 (2.25%) [38, 97]	1 (2.44%) [90]	-
	Length of time in employment	2 (2.25%)[37]	-	1 (2.33%)[37]
	Seniority	1 (1.12%)[37]	3 (7.32%) [49, 77, 84]	4 (9.30%) ^{[37, 52,} 125, 129]
	Data required for own purposes	1 (1.12%)[101]	-	-
	Work hours	1 (1.12%) ^[52]	1 (2.44%) [52]	1 (2.33%) ^[26]
	Demographics	-	2 (4.88%) [37, 98]	12 (27.91%) [37, 49, 51, 52, 77, 96, 97, 125, 129]
	Profession	-	5 (12.20%) ^{[28,} 71]	5 (11.63%) ^{[28, 71,}
	Total	89 (100%)	41 (100%)	43 (100%)
Knowledge and Skills	Clarify reporting mechanism	36 (42.86%) ^[9, 11, 24, 27, 31, 35, 38, 44, 46, 51, 52, 70, 73, 76, 79, 80, 87, 88, 100, 101, 103, 105, 107, 114, 119, 121, 127, 128]	2 (5.56%) ^{[44,}	5 (33.33%) ^{[29, 48,} 72, 129]
	Adverse event/near miss clarity	31 (36.90%) ^[9, 11, 31, 35, 43, 44, 46, 51, 69, 74, 82, 85, 87, 88, 92, 93, 95, 99, 100, 105, 117, 121]	7 (19.44%) ^[9, 30, 44, 46, 70, 87, 100]	2 (13.33%) [48, 72]
	Ability in error recognition	7 (8.33%) [35, 75, 79, 92, 99, 106, 124]	4 (11.11%) ^{[75-} 77, 124]	1 (6.67%) [48]
	Training	5 (5.95%) [68, 76, 82,	21 (58.33%) [9,	7 (46.67%) [25, 77,

		86, 97]	25, 33, 70, 73, 75, 76, 87, 101, 106, 117, 127]	86, 129]
	Awareness	4 (4.76%) [35, 43, 106, 114]	2 (5.56%) [75, 85]	-
	Not enough information about product being reported	1 (1.19%) [89]	-	-
	Total	84 (100%)	36 (100%)	15 (100%)
	Workload/priority	50 (62.50%) [9, 11, 24, 27, 31, 34, 35, 43, 48, 49, 51, 55-58, 61, 68-70, 72, 75-77, 80, 82, 83, 88-90, 92, 93, 100, 103, 117, 119, 120, 125, 127-129]	6 (33.33%) ^{[31,} 75-77, 122]	3 (30.00%) ^{[51, 123,} 125]
Work	Accessibility	27 (33.75%) [24, 27, 31, 34, 35, 51, 52, 56, 74, 75, 80, 82, 86, 93, 101, 105-107, 114, 117, 119, 121, 127]	11 (61.11%) ^{[30} , 68, 73-75, 87, 100, 101, 117]	1 (10.00%) [48]
Environment	Not specified	2 (2.50%) [61, 105]	-	-
	Unit type	1 (1.25%) [49]	1 (5.56%) ^[49]	3 (30.00%) [49, 112]
	Physical working conditions	-	-	1 (10.00%) ^[26]
	Satisfaction with work environment	-	-	1 (10.00%) [113]
	Care pathways	Z :	-	1 (10.00%) ^[49]
	Total	80 (100%)	18 (100%)	10 (100%)
	Feedback/communication	26 (34.21%) [8, 9, 11, 35, 37, 43, 44, 56, 58, 59, 61, 62, 69, 78, 85-87, 90, 92, 99, 100, 106, 108, 117, 123]	29 (29.90%) ^{[9,} 11, 30, 33, 41, 44, 46, 61, 65, 68, 70, 75-77, 87, 100, 101, 107, 112, 117]	2 (9.09%) [25, 125]
Organization	Reporting culture	17 (22.37%) [9, 10, 34, 35, 49, 66, 70, 81, 86, 90, 92, 114, 117, 118, 123]	16 (16.49%) ^{[29,} 33, 39, 66, 75, 96, 100, 106, 110-112, 121, 122]	1 <i>(4.54%)</i> ^[96]
	Learning/improvement	7 (9.21%) [20, 59, 76, 90, 94, 102, 103]	13 (13.40%) ^{[9,} 31, 40, 61, 68, 70, 85, 90, 100, 110]	2 (9.09%) [29, 123]
o.gamzadon	Use of data	7 (9.21%) [43, 59, 61, 92, 99]	2 (2.06%) ^{[65,}	-
	Policy	6 (7.89%) ^[11, 68, 75, 78, 104, 128]	22 (22.68%) ^{[9,} 11, 29, 30, 32, 33, 40, 46, 58, 68, 75-77, 81, 87, 101, 106, 107]	2 (9.09%) [25, 125]
	Management response	5 (6.58%) ^[55, 68, 79, 92, 112]	2 (2.06%) [58, 115]	4 (18.18%) ^{[29, 97,} 115]
	Outcomes of analysis	4 (5.26%) ^{[10, 88,}	1 (1.03%) [100]	-

	Resource	2 (2.63%) [55, 68]	3 (3.09%) ^{[25, 75,}	1 (4.54%) [25]
	Ownership	1 (1.32%) [40]	4 (4.12%) ^{[25, 52,} 125]	6 (27.27%) [25, 77]
	Hierarchy	1 (1.32%) ^[36]	-	-
	Size	-	3 (3.09%) ^{[25, 26,}	1 (4.54%) [26]
	Nursing quality	-	1 (1.03%) ^[97]	-
	Awareness	-	1 (1.03%) [100]	-
	Location	-	-	1 (4.54%) [26]
	Elapsed time of IRS integration	-	-	1 (4.54%) [25]
	Ward rounds	-	-	1 (4.54%) [25]
	Total	76 (100%)	97 (100%)	22 (100%)
	Relationships	13 (39.39%) [11, 27, 32, 55, 58, 66, 74, 87, 88, 90, 100]	2 (10.00%) ^{[49,}	-
	Influence of Seniors	7 (21.21%) ^{[37, 42,} 74, 82, 106, 110]	1 (5.00%) [87]	-
	Peer reporting	5 (15.15%) [79, 85, 103]	3 (15.00%) ^{[97,} 98, 101]	-
Team Factors	Teamwork/communication	3 (9.09%) [11, 36, 75]	7 (35.00%) ^{[39,} 75, 77, 122]	2 (66.67%) [123]
ream raciors	Support/encouragement	3 (9.09%) [8, 87, 100]	1 (5.00%) [87]	1 (33.33%) [72]
	Medical doctor involvement	1 (3.03%) [44]	1 (5.00%) [44]	-
	Error committed by junior staff	1 (3.03%) [58]	1 (5.00%) [42]	-
	Team culture	-	4 (20.00%) [98, 107, 111, 122]	-
	Total	33 (100%)	20 (100%)	3 (100%)
	Concealment	5 (21.74%) [85, 87, 120]	1 (5.88%) [11]	-
	Duty	1 (4.35%) [81]	8 (47.06%) [75, 85, 88, 95, 101, 107]	1 (25.00%) [125]
Professional Ethics	Accountability	-	2 (11.76%) ^{[88,}	-
	Responsibility	15 (65.22%) [8, 9, 34, 35, 44, 52, 70, 93, 94, 100, 104, 118, 121, 128]	5 (29.41%) ^{[77,} 90, 91, 94]	1 (25.00%) [26]
	Culture	2 (8.70%) [74, 87]	-	-
	Legal	-	1 (5.88%) ^[37]	2 (50.00%) [37]
	Total	23 (100%)	17 (100%)	4 (100%)

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PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
INTRODUCTION			
'Rationale	3	Describe the rationale for the review in the context of what is already known.	4
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	4
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	N/A
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	5-6
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	5
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	5
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	5-6
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	6-7
B Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	6-7
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	7
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	7-8
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I²) for each meta-analysis. Հգ բշոշ - ԵՐ ընդանի ԱԵԴ ԿԱԳ ԱԱԳ ԱԱԳ ԱԱԳ ԱԵՐ ԱԻՐ ԱԵՐ ԱԻՐ ԱԵՐ ԱԵՐ ԱԵՐ ԱԵՐ ԱԵՐ ԱԵՐ ԱԵՐ ԱԵՐ ԱԵՐ ԱԵ	7-9



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PRISMA 2009 Checklist

Page 1 of 2 Report				
Section/topic	#	Checklist item	Reported on page #	
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	N/A	
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A	
RESULTS				
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	9-10	
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	9-10	
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	N/A	
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	10	
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	12-21	
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	N/A	
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A	
DISCUSSION				
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	22-25	
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	25-26	
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	26-27	
FUNDING				
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	27-28	
		*		

42 From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. 43 doi:10.1371/journal.pmed1000097

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