



# Prevalence, severity, and nature of preventable patient harm across medical care settings: systematic review and meta-analysis

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Additional material is published online only. To view please visit the journal online.

Cite this as: *BMJ* 2019;366:l4185  
<http://dx.doi.org/10.1136/bmj.l4185>

Accepted: 30 May 2019

## ABSTRACT

### OBJECTIVE

To systematically quantify the prevalence, severity, and nature of preventable patient harm across a range of medical settings globally.

### DESIGN

Systematic review and meta-analysis.

### DATA SOURCES

Medline, PubMed, PsycINFO, Cinahl and Embase, WHOLIS, Google Scholar, and SIGLE from January 2000 to January 2019. The reference lists of eligible studies and other relevant systematic reviews were also searched.

### REVIEW METHODS

Observational studies reporting preventable patient harm in medical care. The core outcomes were the prevalence, severity, and types of preventable patient harm reported as percentages and their 95% confidence intervals. Data extraction and critical appraisal were undertaken by two reviewers working independently. Random effects meta-analysis was employed followed by univariable and multivariable meta regression. Heterogeneity was quantified by using the  $I^2$  statistic, and publication bias was evaluated.

### RESULTS

Of the 7313 records identified, 70 studies involving 337 025 patients were included in the meta-analysis. The pooled prevalence for preventable patient harm was 6% (95% confidence interval 5% to 7%). A pooled proportion of 12% (9% to 15%) of preventable patient harm was severe or led to death. Incidents related to

drugs (25%, 95% confidence interval 16% to 34%) and other treatments (24%, 21% to 30%) accounted for the largest proportion of preventable patient harm. Compared with general hospitals (where most evidence originated), preventable patient harm was more prevalent in advanced specialties (intensive care or surgery; regression coefficient  $b=0.07$ , 95% confidence interval 0.04 to 0.10).

### CONCLUSIONS

Around one in 20 patients are exposed to preventable harm in medical care. Although a focus on preventable patient harm has been encouraged by the international patient safety policy agenda, there are limited quality improvement practices specifically targeting incidents of preventable patient harm rather than overall patient harm (preventable and non-preventable). Developing and implementing evidence-based mitigation strategies specifically targeting preventable patient harm could lead to major service quality improvements in medical care which could also be more cost effective.

### Introduction

Patient harm during healthcare is a leading cause of morbidity and mortality internationally.<sup>1 2</sup> The World Health Organization defines patient harm as “an incident that results in harm to a patient such as impairment of structure or function of the body and/or any deleterious effect arising there from or associated with plans or actions taken during the provision of healthcare, rather than an underlying disease or injury, and may be physical, social or psychological (eg, disease, injury, suffering, disability and death).”<sup>3</sup> The health burden and patient experiencing healthcare-related patient harm has been reported to be comparable to chronic diseases such as multiple sclerosis and cervical cancer in developed countries, and tuberculosis and malaria in developing countries.<sup>4 5</sup> Harmful patient incidents are also a major financial burden for healthcare systems across the globe. It is estimated that 10-15% of healthcare expenditure is consumed by the direct sequelae of healthcare-related patient harm.<sup>6 7</sup>

Early detection and prevention of patient harm in healthcare is an international policy priority.<sup>8</sup> In principle, zero harm would be the ideal goal. However, this goal is not feasible because some harms cannot be avoided in clinical practice. For example, some adverse drug reactions which occur in the absence of any error in the prescription process and without the possibility

## WHAT IS ALREADY KNOWN ON THIS TOPIC

A better understanding of the nature of preventable patient harm has the potential to impact on international healthcare policy and practice

The prevalence of overall patient harm has been established by systematic reviews but the prevalence of preventable patient harm has received less attention

## WHAT THIS STUDY ADDS

A meta-analysis that quantifies the prevalence, nature, and severity of preventable patient harm in a range of medical care settings

At least one in 20 patients are affected by preventable patient harm in medical care settings

Approximately 12% of preventable patient harm causes permanent disability or patient death and is mostly related to drug incidents, therapeutic management, and invasive clinical procedures

of detection are less likely to be preventable. In recent years, the recognition that a proportion of patient harm is not preventable has increased attention to the notion of preventable patient harm.<sup>9</sup> Most studies classify patient harm as preventable if it occurs as a result of an identifiable modifiable cause, and its future recurrence can be avoided by reasonable adaptation to a process, or adherence to guidelines, although universal consensus has not been established.<sup>10</sup> Key sources of preventable patient harm could include the actions of healthcare professionals (errors of omission or commission), healthcare system failures, or involve a combination of errors made by individuals, system failures, and patient characteristics.<sup>11-14</sup> Strengthening the focus on preventable patient harm has the potential to lead to greater tangible clinical benefits and improved translation of patient safety research findings into clinical practice. Patient safety improvement strategies underpinned by better understanding of the nature of preventable patient harm have greater prospects of efficiency (because they are more specific) and implementation (because clinicians can readily recognise their value).<sup>10</sup>

There are several systematic reviews on overall patient harm across different medical settings, but none of these have focused on preventable patient harm.<sup>15-17</sup> We undertook a systematic review and meta-analysis to estimate the prevalence of preventable patient harm across medical settings including hospitals, various specialties, and in primary care. We also examined the severity and most commonly occurring types of preventable patient harm.

## Methods

This systematic review was conducted and reported in accordance with the Reporting Checklist for Meta-analyses of Observational Studies (MOOSE).<sup>18</sup> The completed MOOSE checklist is available in eTable 1.

## Eligibility criteria

We included quantitative observational studies such as cohort (prospective or retrospective) and cross sectional studies in any geographical area in any medical care setting (primary, secondary, and tertiary care) published from January 2000 onwards. We selected this start date because it coincides with when the published patient safety research began to increase in volume after the publication of the landmark report *To Err is Human: Building a Safer Health System* in 1999.<sup>15-19</sup>

The primary outcome was the prevalence of preventable patient harm. Patient harm (which is synonymous with adverse events in healthcare) is defined as unanticipated, unforeseen accidents (eg, patient injuries, care complications, or death) which are a direct result of the care dispensed rather than the patient's underlying disease. Patient harm is preventable firstly, when occurring as a result of an identifiable and modifiable cause and secondly, when the prevention of future recurrence of the patient harm is possible with reasonable adaptation to a process and adherence to guidelines.<sup>10</sup>

The secondary outcomes were the severity and types of preventable patient harm. In accordance to the reporting format of the eligible studies, severity of preventable patient harm was classified into mild, moderate, and severe. Key types of preventable harm were drug-related, diagnostic, medical procedure-related, and healthcare-acquired infections (definitions are presented in eTable 1).

We excluded the following: studies reporting data on harm but not on preventable patient harm; studies with an exclusive focus on a specific type of harm only (only drug-related harm) or a specific severity level of harm only (incidents which only resulted in readmissions or extended length of stay) because such estimates would differ from estimates based on any type or any severity level of preventable patient harm; and studies focused on specific patient populations (eg, patients with a particular disease) because such estimates could differ from estimates in the general population.

## Searches

We searched five electronic bibliographic databases from January 2000 to 27 January 2019: Medline, Cinahl, Embase, Pubmed, and PsycINFO. We supplemented these searches by screening grey literature sources including three databases (WHOLIS, Google Scholar, SIGLE), relevant reports, and conference abstracts. We also screened existing systematic reviews and checked the reference lists of eligible studies. The search strategy is available in eTable 3.

## Study selection and extraction

We exported the results of the searches to Endnote X8 and removed duplicates. We completed screening in two stages. Initially, the titles and abstracts of the studies were screened for eligibility. Afterwards, the full texts of studies initially assessed as relevant for the review were retrieved and checked against our inclusion or exclusion criteria. We devised a data extraction spreadsheet, after being piloted, to extract descriptive data on key study characteristics (eg, number and age of participants, research design, data collection, assessment of preventability) and quantitative outcomes (prevalence, types, and severity of preventable patient harm). Two independent researchers (KK and MP) performed the screening and data extraction with disagreements resolved by discussion within the wider team (AA, DA, RH, RK). The inter-rater reliability was excellent (kappa=0.88 and 0.90).

## Risk of bias assessment

We evaluated the risk of bias in the studies by using an adapted form of the Newcastle Ottawa scale for cross sectional and cohort studies.<sup>20</sup> This assessed the representativeness of the sample, sample size, response rate, ascertainment of the exposure, control of confounding variables, assessment of preventability, and appropriate statistical analysis, which provided a score ranging from 0 (lowest grade) to 9 (highest grade). A higher grade indicated a lower risk of bias.

For our analyses, studies scoring 7 or above were considered as low risk, whereas studies scoring below 7 were considered as high risk.

### Analyses

Our primary outcome was the prevalence of preventable patient harm expressed as the proportion of patients with at least one preventable patient harmful incident and stratified according to different medical services. We also calculated and reported the median prevalence of preventable patient harm and interquartile ranges across all medical care settings. Our secondary outcomes were the severity and types of preventable patient harm expressed as proportions of the total number of preventable patient harmful incidents. We pooled all data in Stata 15 by using the `metaprop` command.<sup>21</sup> To improve the meaning and interpretation of our findings in relation to the prevalence, severity, and common types of preventable patient harm, we also present data on the prevalence, severity, and common types of overall harm (preventable and non-preventable) by using the same pool of studies in all analyses.

We conducted univariable and multivariable meta regression to test the influence of study level moderators on the prevalence of preventable patient harm using the `metareg` command.<sup>22</sup> Consistent with the recommendations of Thompson and Higgins,<sup>23</sup> eight prespecified study level moderators were hypothesised to have an effect on the prevalence of preventable patient harm (medical setting, population, research design, assessment method of harm, assessment of preventability, sample size, risk of bias, WHO region). Moderators were selected and coded following consensus procedures and each moderator value was based on a minimum of eight studies.<sup>23</sup> Covariates meeting our significance criterion ( $P < 0.10$ ) were entered into a multivariable meta regression model. The  $P < 0.10$  threshold was conservative, to avoid prematurely discounting potentially important explanatory variables. Because proportions were often expected to be small, we used Freeman-Tukey Double Arcsine transformation to stabilise the variances and then performed a random effects meta-analysis implementing the DerSimonian-Laird method.<sup>24,25</sup>

Random effects models were used in all analyses because they are more conservative and have better properties in the presence of heterogeneity.<sup>26,27</sup> Heterogeneity was quantified by using the  $I^2$  statistic. Conventionally,  $I^2$  values of 25%, 50%, and 75% indicate low, moderate, and high heterogeneity, respectively.<sup>28</sup> We inspected the symmetry of the funnel plots and used Egger's test to examine for publication bias.<sup>29</sup> Funnel plots were constructed using the `metafunnel` command,<sup>30</sup> and the Egger test was computed using the `metabias` command.<sup>31</sup>

### Patient and public involvement

Two patient partners, who were members of our research advisory panel, were involved in the

development of our research questions and in selecting the outcome measures of this study. The two patients also provided critical feedback to the protocol of the systematic review and advised on the interpretation and dissemination of results.

### Results

The searches yielded 7313 citations. After we removed duplicates and reviewed the titles and abstracts, 6522 articles were excluded. Of the remaining 307 studies, 241 were excluded after reviewing the full article. A total of 66 studies reporting 70 independent samples were included in the review.<sup>17,32-98</sup> Figure 1 shows the study flow for the selection process.

### Descriptive characteristics

This review is based on a pooled sample of 337 025 patients, 28 150 of who experienced harmful incidents and 15 419 experienced preventable harmful incidents. A total of 47 148 harmful incidents were identified in the pooled sample, 25 977 (55%) of which were preventable. The sample sizes ranged widely across studies (median 1440 patients, range 128-96 047). Thirty three studies (47%) were conducted in the US, 27 (39%) in Europe, and 10 (14%) elsewhere. The most common study design was retrospective or cross-sectional ( $n=50$ ; 71%) followed by prospective (20; 29%). Fifty three studies (76%) reviewed the medical charts of patients to detect harm, whereas 17 studies (24%) monitored patients over time or were based on self reports (eg, interviews with patients). All included studies assess the preventability of patient harm by using consensus procedures between two or more trained reviewers (physicians or teams of physicians and nurses). Fifty studies (71%) used a standardised Likert scale to facilitate the consensus decisions for the preventability of patient harm among the reviewers (harmful incidents assigned a score of four out of six and over were considered preventable).<sup>99</sup> The remaining 20 studies (29%) used implicit agreed criteria to reach consensus regarding the preventability of patient harm among the reviewers. Most studies were conducted in general hospitals involving patients from a range of specialties (45 studies; 64%). Twelve studies (17%) were conducted in advanced care specialties (intensive care 6 studies; surgery 6 studies), six studies (8%) in emergency department, four in obstetrics (6%), and three in primary care (4%). Except for six studies (9%), which were based on children and adolescents, and five studies on older adults (7%), the remaining 59 studies (84%) were mainly based on adults. Further details of the descriptive characteristics of the included studies are available in eTable 2.

All 70 studies reported data on the prevalence of preventable patient harm and overall patient harm. One third of the studies (20 studies, 29%) reported data on the severity of preventable patient harm. Forty three studies (60%) reported proportions of at least two of the following six types of preventable patient harm: drug management, non-drug therapeutic management, diagnosis, invasive medical procedures,

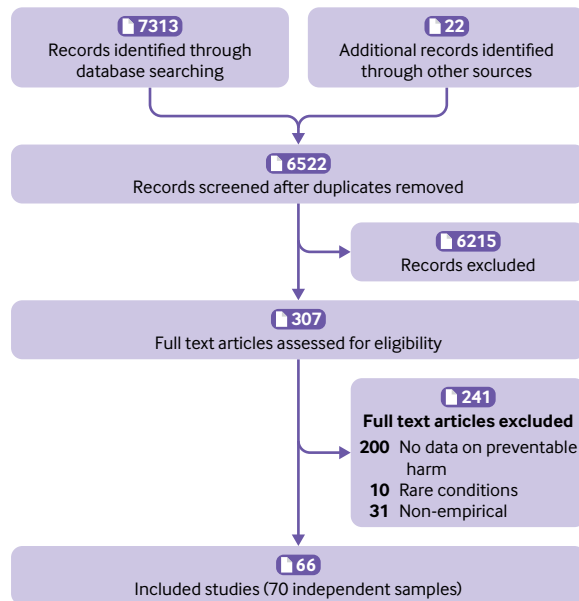


Fig 1 | Flowchart of the inclusion of studies in the review

surgical procedures, and infections acquired during healthcare.

#### Risk of bias results

The Newcastle Ottawa scores for the studies ranged from three to nine (maximum 9, a higher score indicating a lower risk of bias). Twenty nine studies (41%) scored eight or above and were considered to be at low risk of bias (see full assessment in eTable 3).

#### Meta-analysis of the prevalence of preventable patient harm stratified by medical settings

Table 1 shows that the pooled prevalence of preventable patient harm was 6% (95% confidence

interval 5% to 7%,  $I^2=99%$ ) and the median prevalence was 5% (interquartile range 3-9%). In comparison, the pooled prevalence of overall harm (preventable and non-preventable) was 12% (95% confidence interval 9% to 14%,  $I^2=99%$ ; table 1) and the median was 10% (interquartile range 7-15%). The highest pooled prevalence estimate of preventable patient harm was reported in intensive care (18%, 95% confidence interval 12% to 26%,  $I^2=96%$ ) and surgery (10%, 7% to 13%,  $I^2=97%$ ) and the lowest in obstetrics (2%, 0% to 4%,  $I^2=95%$ ). Figure 2 presents the forest plot of the prevalence of preventable patient harm across medical care settings.

#### Meta-analysis of the severity and types of preventable patient harm

Table 1 shows the pooled proportions of the severity and types of preventable patient harm. The pooled proportion of mild harm was 49% (95% confidence interval 43% to 56%,  $I^2=97%$ ), moderate harm was 36% (31% to 42%,  $I^2=96%$ ), and severe harm was 12% (9% to 15%,  $I^2=94%$ ).

Drug management incidents (25%, 95% confidence interval 16% to 34%,  $I^2=98%$ ), and other therapeutic management incidents (24%, 21% to 30%,  $I^2=98%$ ), accounted for the highest proportion of preventable patient harm followed by incidents related to surgical procedures (23%, 9% to 38%,  $I^2=98%$ ), healthcare infections (16%, 11% to 22%,  $I^2=98%$ ), and diagnosis (16%, 11% to 21%,  $I^2=98%$ ).

#### Meta-regressions exploring the variance in the prevalence of preventable patient harm

Table 2 shows the results of the univariable and multivariable analyses. The univariable analyses showed that the prevalence of preventable patient harm was higher across studies based in advanced

Table 1 | Proportions of types of preventable patient harm and overall patient harm

Outcome	No	Preventable harm			Overall harm		
		% (95% CI)	$I^2$	Median (IQR)	% (95% CI)	$I^2$	Median (IQR)
Prevalence							
Overall	70	6 (5 to 7)	99	5 (3-9)	12 (9 to 14)	99	10 (7-15)
Emergency department	6	3 (2 to 4)	78	3 (3-4)	5 (3 to 6)	84	5 (4-6)
Hospitals	45	5 (4 to 6)	99	5 (3-7)	10 (9 to 12)	99	10 (7-12)
Intensive care	6	18 (12 to 26)	96	14 (10-28)	34 (19 to 50)	99	29 (20-59)
Obstetrics	4	2 (0 to 4)	95	NA	4 (2 to 6)	92	NA
Primary care	3	3 (0 to 9)	0	NA	7 (3 to 10)	0	NA
Surgery	6	10 (7 to 13)	97	9 (9-10)	20 (14 to 27)	99	22 (15-30)
Severity of patient harm							
Mild	20	49 (43 to 56)	97	45 (40-55)	50 (41 to 59)	98	49 (43-58)
Moderate	20	36 (31 to 42)	96	38 (30-50)	36 (28 to 44)	98	36 (27-47)
Severe	20	12 (9 to 15)	94	10 (8-19)	12 (8 to 15)	95	13 (6-17)
Types of patient harm							
Drugs	25	25 (16 to 34)	98	20 (9-35)	26 (19 to 34)	99	21 (17-30)
Other therapeutic	17	24 (21 to 30)	98	22 (16-30)	20 (9 to 31)	98	21 (12-32)
Procedure	20	23 (13 to 33)	98	18 (6-28)	24 (17 to 31)	98	19 (14-32)
Surgical procedure	18	23 (9 to 38)	98	21 (8-36)	31 (20 to 42)	98	27 (16-41)
Diagnosis	20	16 (11 to 21)	98	12 (5-22)	9 (6 to 12)	98	10 (6-11)
Healthcare infections	14	16 (11 to 22)	98	NA	21 (15 to 28)	98	NA

The proportions for types of preventable or overall harm do not add to 100% because each figure in the table is the pooled proportion which has been calculated by combining (after assigning appropriate weights) proportions extracted from several independent studies using meta-analysis. Moreover, not all studies reported all types of preventable or overall harm and therefore it is not appropriate to assume they add up to 100%. NA=not applicable.

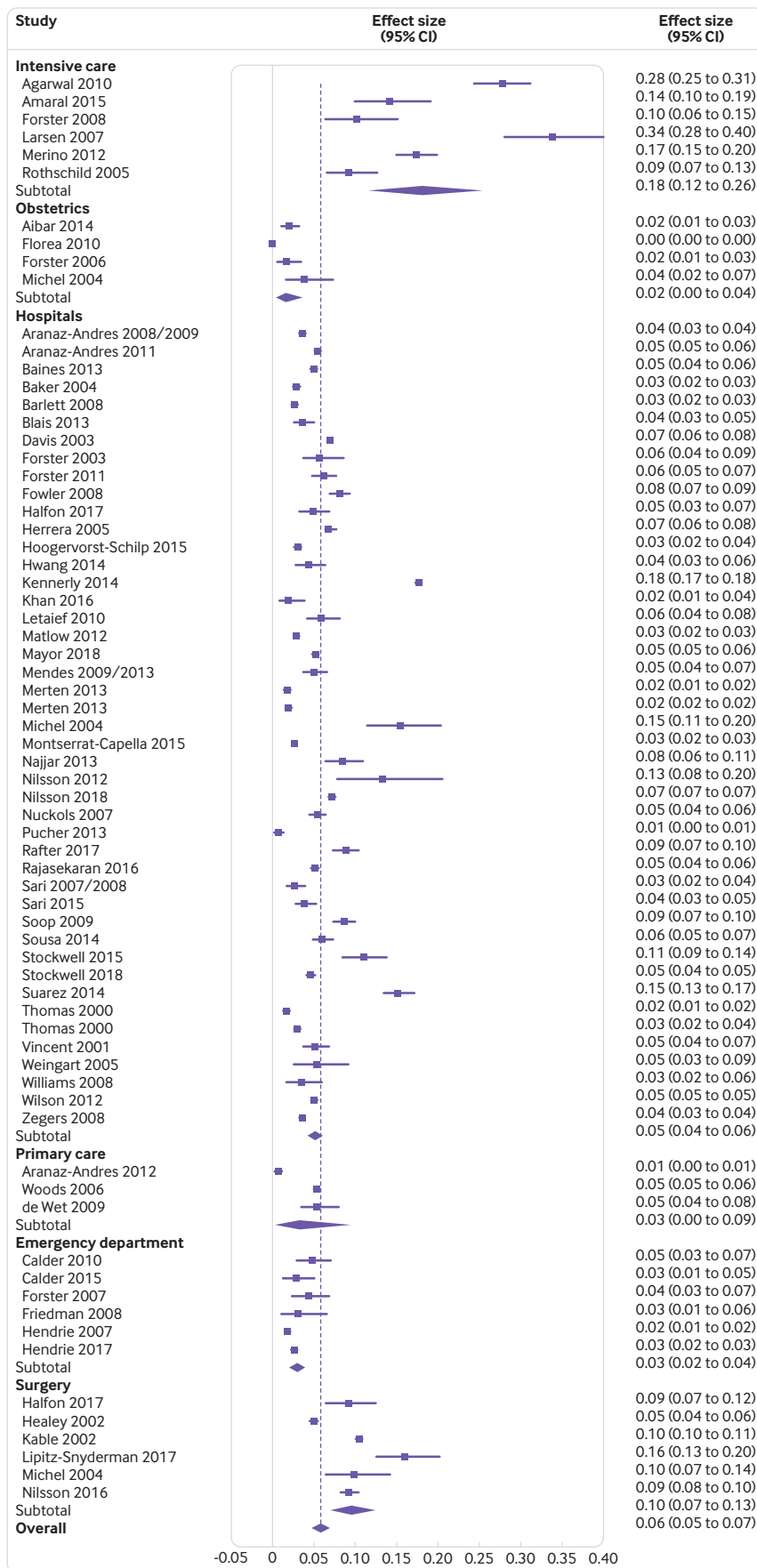


Fig 2 | Forest plot of the pooled prevalence of preventable patient harm across medical care settings

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specialties such as surgery and intensive care ( $b=0.08$ , 95% confidence interval 0.05 to 0.11), in studies with relatively small sample sizes ( $b=0.03$ , 0.01 to 0.06), and in studies on children and older adults ( $b=0.03$ ,  $-0.01$  to 0.05). These three variables (medical care setting, population group, and sample size) were therefore eligible for inclusion in the multivariable regression analysis. All the other variables (research design, assessment method of harm, assessment of preventability, risk of bias, and WHO region) were ineligible for inclusion in multivariable analyses because none of them influenced the prevalence of preventable patient harm in univariable analyses ( $P>0.10$ ).

The overall multivariable model was statistically significant ( $\chi^2(4)=33.98$ ,  $P<0.001$ ) and reduced the  $I^2$  statistic from 79% to 31%. Only the medical care setting ( $b=0.07$ , 95% confidence interval 0.04 to 0.10) remained a significant predictor of the prevalence of preventable patient harm in multivariable analyses suggesting that the prevalence of preventable patient harm is higher in advanced medical specialties (surgery and primary care) compared with studies in general hospitals. The population group and sample size were not significantly associated with the prevalence of preventable patient harm after controlling for the medical care setting in the multivariable analyses.

### Small study bias

Figure 3 shows some evidence of publication bias as indicated by visual inspections of the funnel plots and by the Egger test for small study effects for the primary

outcome (bias coefficient for the main analysis 1.20, 95% confidence interval 0.24 to 2.15,  $P=0.02$ ).

### Discussion

Understanding and mitigating preventable patient harm is a major public health challenge across the globe. We conducted a systematic review and meta-analysis to understand the prevalence, severity, and common types of preventable patient harm across medical care settings. We pooled data from 70 studies and we found that preventable patient harm occurs in 6% of patients across medical care settings. Considering that a pooled prevalence of 12% for overall harm was found, we conclude that half of patient harm is preventable. The proportion of severe preventable patient harm causing prolonged, permanent disability or death was 12%. The most common types of preventable patient harm were related to drugs, other therapeutic management, and invasive medical and surgical procedures. The most extensive evidence on preventable patient harm comes from hospitals (45 studies) but less evidence is available for specific medical specialties. Preventable patient harm was more prevalent in patients treated in surgical and intensive care units compared with patients treated within across general hospitals. None of the other method variations which we examined across the studies influenced the pooled prevalence of preventable patient harm (population group, research design, assessment method of harm, assessment of preventability, sample size, risk of bias, or WHO region).

**Table 2 | Univariable and multivariable predictors of the prevalence of preventable patient harm (n=70)**

Variable	No	Univariable			Multivariable		
		Regression coefficient (95% CI)	SE	P value	Regression coefficient (95% CI)	SE	P value
WHO region:							
US	33	1	—	—	—	—	—
Europe	27	-0.01 (-0.03 to 0.01)	0.01	0.59	NA	NA	NA
Asia or other	10	-0.01 (-0.02 to 0.04)	0.02	0.54	NA	NA	NA
Medical setting:							
General hospitals and obstetrics	49	1	—	—	1	—	—
Primary care and emergency department	9	-0.02 (-0.05 to 0.01)	0.02	0.18	-0.03 (-0.06 to 0.01)	0.02	0.12
Advanced hospital specialties	12	0.08 (0.05 to 0.11)	0.02	<0.001	0.07 (0.04 to 0.10)	0.01	<0.001
Research design:							
Retrospective or cross sectional	50	1	—	—	—	—	—
Prospective	20	0.01 (-0.01 to 0.04)	0.01	0.31	NA	NA	NA
Sample size:							
Large (n>1000)	43	1	—	—	1	—	—
Small (n<1000)	27	0.03 (0.01 to 0.06)	0.01	0.02	0.02 (-0.01 to 0.04)	0.01	0.12
Population:							
Adults	59	1	—	—	—	—	—
Children or older adults	11	0.03 (-0.01 to 0.05)	0.02	0.09	0.02 (-0.01 to 0.05)	0.01	0.09
Assessment method:							
Medical record review	53	1	—	—	—	—	—
Surveys with patients and health providers	17	-0.01 (-0.04 to 0.02)	0.01	0.58	NA	NA	NA
Preventability by consensus among reviewers using:							
Standardised Likert scale	43	1	—	—	1	—	—
Implicit criteria	27	0.01 (-0.01 to 0.04)	0.01	0.36	NA	NA	NA
Risk of bias:							
High (<7 score)	41	1	—	—	—	—	—
Low (>7 score)	29	-0.01 (-0.03 to 0.02)	0.01	0.89	NA	NA	NA

SE=standard error; NA=not applicable.

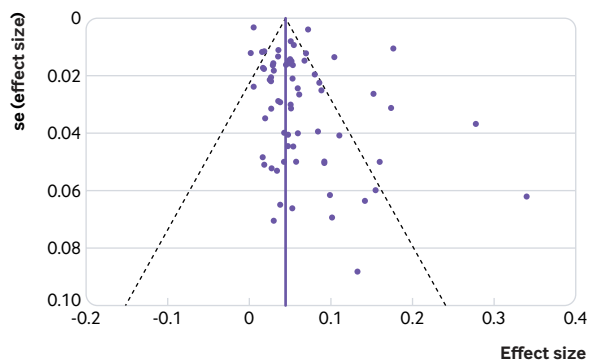


Fig 3 | Funnel plot of studies included in analysis with pseudo 95% confidence intervals (se=standard error)

### Strengths and limitations of the study

Despite the unique focus on preventable patient harm and several method strengths, this review has also limitations. Firstly, the prevalence of preventable patient harm varied considerably across studies and this variation was only partly explained in meta regression analyses. Other relevant factors likely accounted for the unexplained heterogeneity. For example, variations in the timeframe used to detect harm might be important when interpreting the differences in the prevalence estimates,<sup>1</sup> alongside variations in the implementation of quality assurance programmes and the quality of the documentation used for detecting preventable patient harm. For example, quality assurance programmes have possibly been implemented in parallel with some of the reviewed studies which might account for some proportion of the heterogeneity that we observed in this meta-analysis.

Secondly, a critical eligibility criterion to ensure feasibility of this review was that data on preventable patient harm were available in the published reports of the studies. Studies which did not report data on preventable patient harm were excluded from the analyses. However, most studies focused primarily on overall patient harm, reported preventable patient harm as a secondary outcome, and only one third of the studies provided an analysis of severity and types of preventable patient harm.<sup>100</sup>

Thirdly, preventability rankings are likely to evolve over time especially after new technological advancements in healthcare. Consequently, some patient harms which are now considered non-preventable might be preventable in the future.<sup>10</sup> However, the studies we reviewed consistently found that about 50% of patient harm was preventable and we did not observe any different patterns over the past 19 years.

Fourthly, over half of the reviewed studies employed retrospective case record reviews to investigate the prevalence, nature, and severity of preventable patient harm. Although case record reviews are the most universally used method for assessing patient harm to date, patients and healthcare providers have repeatedly expressed concerns that data contained in case records do not capture the full range of harms that they

experience during their healthcare encounters.<sup>101 102</sup> On the other hand, self reporting of patient harms (either by patients or healthcare providers) relies on recall and has its own limitations. Combining methods (such as prospective case record reviews with surveys with patients and healthcare providers)<sup>103</sup> with the parallel engagement of patients as partners in identifying medical errors and mitigating preventable patient harm are promising approaches for enhancing patient safety.<sup>104 105</sup>

### Comparison with other studies

Our headline finding is that preventable patient harm is a highly prevalent international healthcare challenge which causes unnecessary patient suffering and can result in several avoidable deaths. As this review is specifically designed to understand patterns of preventable patient harm, comparisons with existing reviews focused on overall harm is problematic.<sup>115 106-108</sup> Although we concur that examining the nature of overall harm is important, increasing the emphasis on preventable patient harm (which is the most amenable form of patient harm) is critical in terms of designing efficient patient safety strategies.

There is also evidence that preventable patient harm is not only a public health concern but incurs a considerable opportunity cost. The excess length of hospital stays attributable to medical errors is estimated to be 2.4 million hospital days, which accounts for \$9.3 billion (£7.3bn; €8.2bn) excess charges in the US.<sup>7</sup> Similarly, only six selected types of preventable patient harms in English hospitals result in 934 excell bed days per 100 000 population, which is equivalent to over 3500 salaried hospital nurses each year.<sup>109</sup> Thus, investments in developing and evaluating mitigation strategies for preventable patient harm are urgently needed and are strongly supported by our findings.

### Policy implications

Our findings provide a useful agenda of priority areas for mitigating preventable patient harm. When exploring the nature of preventable patient harm, drug related and therapeutic incidents comprise the majority. This finding echoes recommendations from international patient safety policy initiatives in the past decade including the recent WHO's third global patient safety challenge "medication without harm."<sup>106 110</sup> Thus, it would be logical to prioritise efforts on developing and testing evidence-based mitigation strategies for these specific types of preventable patient harm. As this study establishes the scale of preventable patient harm in medical care settings, the need to gain better insight about the systemic and cultural circumstances under which preventable patient harm occurs is highlighted as a priority area. Several studies have sought to explain patient harms by reference to their sociotechnical context. For example, Vincent and colleagues proposes that patient harm occur because of contributory factors (which include "active" and "latent" failures) in the healthcare system.<sup>111</sup> These failures correspond to

characteristics of the system such as the tasks that are undertaken, the people, technology, and tools that are involved, and the organisational values and structures in which the system operates.<sup>112</sup> The studies included in our review, however, did not provide much insight into the way in which such factors might have contributed to the instances of preventable harm identified. Retrospective examination of patient harm often does not capture the myriad ways in which contributory factors could combine to produce—or avert—a preventable incident of patient harm.<sup>113</sup> Mixed method approaches, which connect the occurrence of patient harm to the presence of specific contributory factors and engage patients as partners in establishing these connections, have excellent prospects to achieve an in depth understanding of possible pathways to patient harm.<sup>114-118</sup>

A thorough understanding of the nature of preventable patient harm and its determinants could offer useful, evidence-based directions for designing efficient mitigation strategies. A combination of individual-level measures (eg, educational interventions for practitioners), system-level measures (eg, human-centred design of healthcare tasks and work environments), and organisational-level measures (eg, introducing quality monitoring and improvement processes) are likely to be a promising strategy for mitigating preventable patient harm,<sup>119-120</sup> but scalable evaluations of these interventions are needed to support wider implementation. Furthermore, the interventions depend on the presence of an organisational context that supports their implementation.<sup>121-122</sup>

Another important finding is that preventable patient harm appears to be a serious concern in advanced medical specialties including intensive care and surgical units. Patients treated in these specialties were more likely to experience preventable patient harm compared with patients treated in general hospitals. Surgical harm is a sizeable part of the overall in-hospital harm,<sup>15-123</sup> but our estimates are higher than anticipated. The underlying causes of these figures warrant further investigation because current safety standards could “be failing to rescue” many high risk patients treated in advanced specialties.<sup>124</sup> Moreover, clinicians in these specialties are often exposed to work pressures and are expected to deliver life-changing decisions quickly which might negatively impact on their personal wellbeing, a well known risk factor for preventable medical incidents.<sup>125</sup> On the other hand, surgery and intensive care units deal with high risk patients to whom complex medical procedures are implemented. Patient harm therefore might be more detectable in these settings because of its immediate, serious, or cumulative impact on patients’ health or because better surveillance systems for detecting patient harm are implemented in these settings. Additionally, it is not always clear from the study designs that some proportion of the preventable patient harm has not occurred in the transition between general hospital care and advanced specialty care.<sup>108</sup>

Another major contribution of our synthesis is that it highlights key gaps in the literature on preventable

patient harm. Only two studies were based in primary care, where over 80% of healthcare service is delivered internationally,<sup>8-126</sup> and no evidence was identified in psychiatry. Certain types of preventable harms which tend to occur in primary care and psychiatry might remain undetected or untargeted by quality and safety improvement programmes. For example, we found that diagnostic harm is a common preventable type of harm but our understanding of its nature needs to be improved. A likely explanation is that diagnostic harm is directly or indirectly linked with the provision of services in primary care where research on preventable patient harm is sparse.<sup>127-128</sup> Obtaining more precise estimates of the types and sources of preventable diagnostic harm occurring in primary care or in transitions from primary care to hospital care could lay the foundation for implementing efficient interventions for diagnostic harm. Systemic interventions, enhanced patient involvement in decision making for diagnoses, use of electronic tools, and emotion-cognitive interventions for boosting practitioners’ confidence or certainty in making diagnoses are potentially fruitful intervention areas for reducing diagnostic harm but have not been systematically evaluated or implemented in practice.<sup>104-127-130</sup>

Less than a handful of studies focused on children and older adults, groups increasingly viewed as vulnerable to low quality or unsafe care. Furthermore, only a fraction of the included studies were conducted in developing countries, as many studies from developing countries failed to provide data on preventability of harm which rendered them ineligible. Thus, despite the evidence showing that the prevalence of overall harm is higher in developing countries compared with developed countries, we did not find such difference for preventable patient harm.

Commissioning research to understand the prevalence, nature, and impact of preventable patient harm in primary care and psychiatry, among vulnerable patient groups (eg, young children, older adults, or marginalised groups of the society such as prison healthcare) and in developing countries has the potential to advance policy guidance and practice for mitigating preventable patient harm.

## Conclusion

Our findings affirm that preventable patient harm is a serious problem across medical care settings. Priority areas are the mitigation of major sources of preventable patient harm (such as drug incidents) and greater focus on advanced medical specialties. It is equally imperative to build evidence across specialties such as primary care and psychiatry, vulnerable patient groups, and developing countries. Improving the assessment and reporting standards of preventability in future studies is critical for reducing patient harm in medical care settings.

**Contributors:** The original idea for the research was developed by MP, DMA, RNK, DP, PB, AJA. MP conducted the analysis with input from KK, EK, DMA, RNK, DP, AA, PB, and AJA. MP and KK conducted the searches, study selection, quality assessments, and other data



extraction. MP, KK, and DMA wrote the paper. All authors interpreted the findings and contributed to critical revision of the manuscript. All authors had full access to the data in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis. MP is the guarantor. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

**Funding:** This study was funded by the UK General Medical Council (RMS 113361). The NIHR Greater Manchester Patient Safety Translational Research Centre (GMPSTRC-2012-1) funded the corresponding author's time spent in this project. MP, EK, and PB are also co-investigators in the Evidence Synthesis Working Group (project 390), which is supported by the NIHR School for Primary Care Research. The research team members were independent from the funding agencies. The views expressed in this manuscript are those of the authors and not necessarily those of the General Medical Council, the National Health Service, the NIHR, or the Department of Health. The funders had no role in the design and conduct of the study; the collection, management, analysis, and interpretation of the data; and the preparation, review, or approval of the manuscript.

**Competing interests:** All authors have completed the ICMJE uniform disclosure form at [www.icmje.org/doi\\_disclosure.pdf](http://www.icmje.org/doi_disclosure.pdf) and all other authors declare no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; and no other relationships or activities that could appear to have influenced the submitted work.

**Ethical approval:** Not required.

**Data sharing:** No additional data are available.

The manuscript's guarantor (MP) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; and that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained.

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Supplementary materials: Searches and eTable 1-4