The Health Foundation
Inspiring Improvement

Evidence scan:

Levels of harm

January 2011, amended November 2011

Identify Innovate Demonstrate Encourage

Contents

Health Foundation evidence scans provide information to help those involved in improving the quality of healthcare understand what research is available on particular topics.

Evidence scans provide a rapid collation of empirical research about a topic relevant to the Health Foundation's work. Although all of the evidence is sourced and compiled systematically, they are not systematic reviews. They do not seek to summarise theoretical literature or to explore in any depth the concepts covered by the scan or those arising from it.

This evidence scan was prepared by The Evidence Centre on behalf of the Health Foundation.

Minor amendments were made to this research scan in November 2011.
Originally published as *Research scan: Levels of harm*

Key messages

It is commonly stated that one in 10 patients is harmed through healthcare, but this is based on evidence from more than a decade ago, much of it from outside the UK. Reviewing more recent research suggests that levels of harm range from 3 – 25% in acute care.

The simplest definition of harm in healthcare is a negative effect, whether or not it is evident to the patient. This research scan explores what is known about levels of harm in acute care and primary care. It also briefly examines the main causes of harm and whether harm is avoidable or not.

Levels of harm

This research scan includes more than 100 studies and reviews, predominantly from the US, Australasia, Europe and the UK. The proportion of admissions to hospital which experience an adverse event ranges between 3 – 36%. The upper limit of recent studies is around 25%. Half to one third of these events are thought to be preventable.

In primary care, evidence is sparser but about 9% of primary care records indicate an error in either primary or secondary care, equivalent to 1 in 48 consultations (2%). Studies in community hospitals have suggested adverse event rates of around 15%.

In addition, studies suggest that people receive only half of the appropriate care for their condition. The figures are similar for adults and children. Older people and those requiring a longer hospital stay are more likely to experience an adverse event.

Healthcare levels of harm are higher than for air, road and rail transport and people in high risk occupations such as construction.

Contributing factors

Factors thought to contribute to adverse events in healthcare include human factors such as teamwork, communication, stress and burnout; structural factors such as reporting systems, infrastructure, workforce loads and the environment; and clinical factors such as complexity of care and length of stay.

Overall, there is a large amount of research available about levels of harm in acute care and a lesser amount in primary care. However this research uses different methods (record review versus observation) and varying definitions of what counts as an adverse event so it is difficult to draw firm conclusions. The most recent research from the USA suggests that more than one in 10 people admitted to hospital may suffer an adverse event and rates of misdiagnosis, harm in primary care and medication errors are also high.

Relevance of topic to the Health Foundation	
Relevance to priorities across the UK	
Potential to have real patient and cost outcomes	
Quantity of evidence available	
Quality of evidence available	

1 Scope

The Health Foundation and others commonly state that about one in 10 patients is harmed through healthcare. This statistic is based on evidence collated more than a decade ago, much of it from outside the UK. This research scan seeks to understand whether this statistic is still valid and accurate for use.

The scan summarises readily available research about levels of patient harm in acute and primary care and the potential causes of such harm.

1.1 Purpose

Everyday, about 1 million people use NHS services. Most are satisfied with their care and do not experience any harm or threats to their safety. Yet there is scope for improvement, with a great deal of variation in systems and processes across the NHS. Addressing this variation and improving the reliability, quality and safety of care is a major challenge.

The simplest definition of a healthcare adverse event is a negative effect of care, whether or not it is evident or harmful to the patient. This is the broad definition used throughout the scan, though individual studies each used their own definitions.

1.2 Methods

The scan addresses the following questions:

- What do we know about levels of harm in a variety of settings including acute care and primary care?
- What are the main causes of harm?
- What does the literature say about whether harm is avoidable or not?
- How do these levels of harm compare with other high risk industries such as air, road and rail travel?
- Are there unpublished material or media stories about this and are other people researching this topic?

This section outlines the methods used to collate information. The following sections address the questions briefly in turn.

To collate evidence, one reviewer searched bibliographic databases, reference lists of identified articles and the websites of relevant agencies for information available as at early January 2010.

The databases included MEDLINE, Ovid, Embase, the Cochrane Library and Controlled Trials Register, PsychLit, Google Scholar, the WHO library and the Health Management Information Consortium. All databases were searched from inception until present.

To be eligible for inclusion, studies had to:

- refer to primary research or reviews
- be readily available online, in print or from relevant organisations
- be available in abstract, journal article, or full report form
- address one or more of the core questions listed
- be available in English or readily available for translation.

We scanned more than 50,000 pieces of potentially relevant research, selecting the most relevant to summarise here. No formal quality weighting was undertaken within the scan, apart from the selection process outlined above. Over 100 studies and descriptive overviews were synthesised.

Data were extracted from all publications using a structured template and studies were grouped according to key questions and outcomes to provide a narrative summary of trends.

1.3 Caveats

When interpreting the findings it is important to bear in mind several caveats.

First, the research scan is not exhaustive. It presents examples of studies and interventions but does not purport to represent every study about levels of harm in healthcare. The purpose is to give a flavour of available research rather than to summarise every existing study in detail.

Second, it is difficult to make comparisons between studies because the research uses various definitions of adverse events and harms.[1] In US studies, adverse events were more likely to be defined as things with the potential to cause serious physical harm, whereas studies from the UK, Australia and Europe tended to use broader definitions and include psychological distress, wound infections and 'lesser' harms.

Furthermore, there are differences in the healthcare context in which studies took place. It may not be useful to compare US primary care with primary care in the UK for example, because the systems and processes used are quite distinct.

Even where comparable definitions are used and geographic contexts can be compared, the level of detail reported is sometimes insufficient to provide a meaningful summary. Therefore it is important that the information presented is not used for comparative purposes.

Meta-analysis was outside the scope of scan but may be possible as a great deal of numerical material exists, although it is heterogeneous in nature.

Third, it is important to emphasise questions about the quality of the included studies. Most studies drew on retrospective record review, which means that the researchers looked at patient notes well after people had received care and tried to deduce potential harms. There is potential for significant bias because not all events may be recorded in patient notes, the events likely to be reported may be more significant or harmful and researchers may perceive something as an event even if it was not for the clinical team and the patient themselves.

A small number of studies use observational methods, such as watching hospital care or attending team meetings to record perceived errors. These studies tend to have limited sample sizes and provide higher estimates of harm than those based on chart review.

There is a lack of evidence about harm in some settings such as the independent sector and in primary care. This lack of evidence does not mean that harm is more frequent in the hospital setting, just that more research is available in this arena.

These caveats are all important when considering the synthesis of material overleaf.

2 Levels of harm in acute care

It has been said that medicine used to be simple, ineffective and relatively safe. Now it is complex, effective and potentially dangerous.[2] Over the past 50 years there has been an increasing acknowledgement that healthcare can inflict harm as well as benefit and that these harms can be prevented.[3-8]

Judgements about what constitutes harm are not straightforward. This section provides an overview of research into the level of harm in hospitals. It is important to recognise the way definitions vary between studies.

2.1 Early research

During the 1960s, seminal research was conducted into rates of harm in US hospitals. Although the need to ensure the safety and wellbeing of patients was acknowledged historically, including in the time of Hippocrates, this research marked one of the first studies to explicitly quantify levels of harm. Over eight months, 20% of patients admitted to medical wards at a US hospital experienced an adverse patient safety event and 10% had a prolonged or unresolved episode. Economic loss and emotional disturbance to patients were not included in the study.[9]

Around 15 years later, researchers sought to examine whether there had been any changes, by exploring error rates at a US tertiary hospital. They found that the complexity of medical practice had increased, along with the number of medication related errors. In fact around 36% of patients suffered a medication related or safety incident, with 9% being judged serious enough to threaten life or lead to disability.[10] This is one of the highest reported rates of harm in the literature. At this time, researchers, practitioners and policy makers began to believe that safety incidents may be preventable and should be monitored and acted upon.

In the 1980s and 1990s a number of official reviews came to the conclusion that around 10% of patients in hospital experience significant patient safety events. For instance, the US Institute of Medicine's report, *To Err is Human* (1999), has influenced a greater awareness of patient safety internationally. This report reviewed a number of studies of medical error and harm and extrapolated the impact on the total population. The figure that caught the headlines was that between 44,000 and 98,000 people die in US hospitals every year as a result of medical errors.[11]

The Institute of Medicine report drew heavily on research conducted in 1984 in New York which found that 3.7% of admissions encountered adverse events.[12]

They also drew on a study of events in Utah and Colorado based on 1992 data. The proportion of admissions that suffered an adverse event was 2.9%.[13] Here adverse events were defined as those that caused significant noticeable harm such as extended illness, disability or death. Psychological and emotional wellbeing were not considered.

There have been a number of critiques of the methods used by the Institute of Medicine and others, mainly focused on the methods used to extrapolate from small studies to rates of harm in the wider population.[14-17] Numerous studies support the conclusions of the Institute of Medicine regarding rates of harm, including reports from leading healthcare ratings organisations, the Commonwealth Fund and universities.[18-20] Researchers also explored longitudinal data, suggesting that adverse event rates were increasing over time.[21]

The UK equivalent to the US report, An Organisation with a Memory, was released by the Department of Health in 2000. This document identified weaknesses within NHS processes and the underlying causes of adverse events. It also drew parallels between healthcare and other industries and sought to learn lessons from these industries, though some authors believe this is erroneous because of the specificities of healthcare.[22,23]

Around the same time, work was also underway in other countries. For example researchers in Australia drew on data from 1992 to estimate that 16.6% of people admitted to hospital suffered an adverse event.[24] This rate is considerably higher than those of many US studies during the same period and this may be because the Australian research used a broader definition of harm. The research methods used are also important.

Most studies estimate levels of harm by reviewing patient notes. However, it is thought to be even more rigorous to estimate harm by observing encounters with patients and team meetings directly. In 1997, researchers in the US found an 18% rate of serious adverse events in a surgical unit. The likelihood of experiencing an adverse event increased about 6% for each day in hospital. This higher than usual finding was attributed to using a wider definition of adverse events than that usually applied in the US (incorporating more than serious disability and death) and using direct observation rather than relying solely on reviewing records.[25] That the study focused on a surgical unit rather than general medical wards may also have a bearing.

2.2 Recent research

More recent research is available from a variety of countries. Estimated levels of harm vary widely, with some estimates as high as 25% and others as low as around 6% of admissions experiencing an adverse event. It is important to note that the date of publication does not necessarily mean that the most up-to-date data are included. Some studies draw on fieldwork that is five to 10 years old. Examples of research published over the past 10 years are provided here, even when the data included is older.

In the UK, Vincent and colleagues used patient records from 1999 and found an adverse event rate of 10.8%, or 11.7% of all people admitted once multiple adverse events were accounted for.[26]

More recently, Sari and colleagues studied 1,006 hospital admissions between January and May 2004 using case note review and a routine reporting system. Patient safety incidents were identified in 22.9% of cases and the authors estimated that around 10.9% of people admitted suffered one or more harms.[27] This distinction is important because it illustrates differences in how levels of harm are measured. In this context, adverse event rates were seen as broader, covering any possible event that was 'off track' and problematic whether or not it hurt the patient. On the other hand, 'harm' focused on events that impacted negatively and seriously on the patient. Other studies use these terms interchangeably and sometimes without clear definition, which makes it difficult to compare levels of harm between studies.

Other researchers in England have examined patient safety events of selected types or in specific hospital contexts. For instance, rates of adverse events in surgical emergency departments have been investigated. A review of patient notes found an adverse event rate of 11.9%, with potential adverse events or 'near misses' making up another 13.8% of admissions.[28]

Others have focused on the rate of falls in UK hospitals and concluded that falls accounted for 32% of all reported patient safety incidents. Average standardised rates of falls per 1,000 bed days were 4.8 in acute hospitals, 2.1 in mental health units and 8.4 in community hospitals.[29]

Safety events in prescribing have also been investigated. At one hospital in England, the rate of erroneous orders at discharge was 8% and the rate of patients with error was 20.4%. The incidence of prescribing errors was 8.4%.[30]

In 2009, the House of Commons Health Committee considered patient safety in detail, including rates of error and harm. Data from the National Reporting and Learning System for England and Wales suggests that of the 850,000 or so incidents reported annually, over 65% are 'no harm' incidents, including near misses or prevented incidents, about 25% are 'low harm' incidents, around 5% involve moderate harm, less than 1% involve serious harm and less than 0.5% (around 3,500) involve death. However, there is significant under-reporting of safety incidents.

The Committee concluded that in international studies the rate of adverse events in acute care is between around 3% to 17%.[31]

In the USA, a number of recent studies have investigated levels of patient harm in hospital.[32] Many of these investigate the incidence or extent of harm in incidents reported voluntarily to a monitoring system.[33] These studies do not give a good picture of the overall level of harm because the focus is on events that have been reported rather than all potential events.

Some have found that the rate of adverse events differs depending on the speciality and condition.[34] For instance, one study based on more than two million patient records found that event rates per 10,000 discharges varied from 1.1 for foreign bodies left inside people during procedures to 84.7 for birth traumas.[35]

Another study in an A&E department used 656 hours of direct surveillance and 1,180 interviews with professionals about any part of care they thought was not ideal. Of all visits to A&E, 32% had at least one non ideal care event, most commonly during diagnostic testing, evaluation and treatment. Seven per cent of the non ideal reported events were associated with patient harm.[36]

In November 2010, research by Landrigan and colleagues gained media attention when it was suggested there had been little improvement in levels of harm over time. The researchers conducted a retrospective study using data drawn from 10 hospitals in North Carolina. 100 admissions per quarter were analysed from January 2002 to December 2007, using the Institute for Healthcare Improvement's Global Trigger Tool for Measuring Adverse Events.

Among 2,341 admissions, the reviewers identified 588 harms which equates to 25.1 harms per 100 admissions. There was no significant improvement in harms in 2007 compared to 2002.[37] This is one of the highest rates of harm ever reported in a US study.

In the same month the US Department of Health and Human Services estimated that 13.5% of medicare beneficiaries experienced adverse events during their hospital stays. They reported that of the nearly 1 million medicare beneficiaries discharged from hospitals in October 2008, about one in seven experienced an adverse event. An estimated 1.5% experienced an event that contributed to their deaths. An additional 13.5% experienced events during their hospital stays that resulted in temporary harm.[38]

Recent research from other countries is also available. For instance, researchers in New Zealand assessed the occurrence and impact of adverse events in public hospitals. Medical records (6,579) from 13 acute hospitals were reviewed. An adverse event was experienced in 12.9% of admissions. Fewer than 15% of adverse events were associated with permanent disability or death.[39]

Interestingly, nearly one fifth of adverse events documented in patient notes occurred outside a hospital such as at GP clinics, the patient's home, rest homes or private hospitals. These events may not be routinely captured in other studies of hospital adverse events so this study is important in demonstrating that safety incidents in hospital can have far reaching consequences and may not just be evident in the hospital context itself.

Researchers in France estimated the incidence of adverse events in medical and surgical wards in public and private hospitals. Altogether, 8,754 patients were observed in 292 wards in 71 hospitals. The incidence of adverse events was 6.6 per 1,000 days of hospitalisation. Invasive procedures were the source of half of the adverse events.[40]

Others in Canada found that 39% of patients undergoing surgery experienced complications and adverse effects.[41]

Researchers in Sweden also estimated the incidence and nature of adverse events in hospitals. A total of 1,967 records from 28 hospitals were examined covering admissions over a one-year period ending in 2004. An adverse event was experienced in12.3% of admissions.[42]

In Spain, analysis of data from 2005 found an adverse event rate of 8.4%. The incidence density was 1.2 adverse events per 100 patient days. The most frequent adverse events related to medication (37%), hospital infections (25%) and technical problems during a procedure (25%). In common with other studies, one third of people with an adverse event had a longer hospital stay, an average of six extra days.[43]

A number of studies have been conducted in the Netherlands, with varying findings. For example, a review of almost 8,000 patient notes estimated the adverse event rate at 5.7%.[44] However, another study looking specifically at surgical units estimated that adverse events occur in around 20% of admissions.[45]

Furthermore, researchers examining diagnostic adverse events across all medical specialties in 21 hospitals in the Netherlands found that such events occurred in 0.4% of hospital admissions and represented 6.4% of all adverse events. Diagnostic adverse events had a higher mortality rate than for other adverse events (29.1% versus 7.4%).[46]

Medication related adverse events are associated with considerable preventable harm but detailed information about harm from drugs administered in hospital is relatively scarce. Researchers in the Netherlands examined medication related adverse events through chart review of patients admitted to 21 hospitals in 2004. For each hospital, records of 200 discharged and 200 deceased patients were randomly selected and reviewed. A total of 148 medication related adverse events occurred in 140 hospital admissions, an incidence of 0.9%. The incidence of preventable medication related adverse events was 0.2% per hospital admission; in other words, one out of every five people admitted to hospital suffered an adverse drug event.[47]

In Denmark, researchers examined 1,097 acute hospital admissions from 17 hospitals using a national register. Adverse events were identified in 9% of all admissions. Most adverse events resulted in minor, transient disabilities. Permanent disability or death was recorded in 30 admissions (2.7%).[48] This smaller proportion is similar to the overall event rates recorded in older US studies, and may reflect differences in how adverse events are defined in various studies.

In the US, the focus tends to be on very serious adverse events, such as death, disability or significant complications. Other studies, such as those conducted in Australia, Europe and the UK, tend to have a broader definition and include things such as wound infections which would not necessarily be counted as an adverse event in many US studies, especially those conducted in the 1980s and 1990s.

2.3 Research on cases involving children

Most studies of levels of patient harm in hospital focus on all admissions or adult admissions but there are also some studies specifically about children. For instance, researchers in the USA analysed a database to identify medical errors among children in hospital over the period 1988-97. The national rate of hospital reported medical errors in children ranged from 1.81 to 2.96 per 100 discharges. Children with special medical needs or dependence on a medical technology had higher rates of reported medical errors. Hospital size was not linked to the rate of medical errors, but private for profit hospitals reported lower rates.[49]

Researchers in New Zealand focused on adverse drug events in babies in a neonatal intensive care unit and postnatal wards in one hospital. Chart review, attendance at meetings and interviews with carers and staff were used to collect data for children admitted to these wards for more than 24 hours over a 12 week period in 2002. The rate of adverse drug events was 2.1 per 100 prescription episodes, 12.9 per 100 admissions, and 22.1 per 1,000 patient days.[50]

Other studies have focused on particular types of error and harm.[51] For example, research suggests that medication related harm for children in hospital occurs at a rate of 11.1 per 100 admissions, and hospital related harm occurs in high risk neonatal ICUs at rates as high as 74 per 100 admissions.[52]

More than 1,000 doctors in the USA were surveyed about their perceptions of the frequency, contributing factors, and potential system and provider based solutions to diagnostic errors for children. Fifty four per cent reported that they made a diagnostic error at least once or twice per month and 45% reported diagnostic errors that harmed patients at least once or twice per year. Failure to gather information through history, physical examination or chart review was the most commonly reported process issue and inadequate care coordination and teamwork was the most commonly reported system factor.[53]

2.4 Summary

Table 1 summarises the levels of harm in hospital found in various important studies. The overall trends in literature are:

Table 1: levels of harm in hospital

Research	Context	Country	Approximate harm rate	% preventable
Schimmel (1964)	Hospital medical wards	USA	20% suffer an adverse event; 10% prolonged episode	Unknown
Steel et al (1981)	Hospital medical ward	USA	36% had a safety incident; 9% serious disability or death	Unknown
Brennan et al (1991)	Hospital	USA	4%	Unknown
Andrews et al (1997)	Hospital surgical unit	USA	18%	
US Institute of Medicine (1999)	Hospital	USA	Reviews two estimates of around 3% and 4%	Significant portion
Thomas et al (2000)	Hospital	USA	3%	Unknown
Department of Health (2000)	Mainly hospital	UK	Reviews various estimates	Significant portion
Vincent et al (2001)	Hospital	UK	11% or 12% when multiple adverse events were accounted for	About half
Schioler et al (2001)	Hospital	Denmark	9%	40%
Miller et al (2001)	Hospital	USA	Event rates per 10,000 discharges: one for foreign bodies left during procedures, 85 for birth traumas	Unknown
Davis et al (2002)	Hospital	NZ	12.9%	Unknown
Davis et al (2003)	Hospital	NZ	Unknown	About 5%
Slonim et al (2003)	Children in hospital	USA	two to three per 100 discharges	Unknown
Sharek and Classen (2006)	Children in hospital	USA	11 per 100 admissions for medication related harm; hospital related harm in high risk neonatal ICUs at a rate of 74 per 100 admissions	Unknown
Szekendi et al (2006)	Hospital	USA	74% errors; 49% experienced an error that caused harm	Unknown
Sari etc al (2007)	Hospital	UK	23% experienced an incident; 10.9% suffered harm	Unknown
Sari et al (2007)	Hospital	UK	9%	31%
Michel et al (2007)	Medical and surgical hospital wards	France	6.6 per 1,000 days of hospitalisation	20%
Aranaz-Andres et al (2008)	Hospital	Spain	8%	43%

Research	Context	Country	Approximate harm rate	% preventable
Healey et al (2008)	Falls in hospitals and other units	UK	Rates of falls per 1000 bed days were five in acute hospitals, two in mental health units and eight in community hospitals	Unknown
Ferranti et al (2008)	Hospital medication errors in children	USA	Around two adverse drug events per 1,000 patient days	Unknown
Kreckler et al (2009)	Emergency surgical unit	UK	12% adverse events and 14% potential adverse events	Unknown
Zegers et al (2009)	Hospital	The Netherlands	6%	About 40%
Soop et al (2009)	Hospital	Sweden	12%	70%
Kunac et al (2009)	Postnatal and neonatal wards in hospital	NZ	13% adverse drug events	56.7% adverse drug events
Abdel-Qader et al (2010)	Medication errors at hospital discharge	UK	8% erroneous medication orders; 20% patients had an error; incidence of prescribing errors was 8.4%	Unknown
van Wagtendonk et al (2010)	Surgical hospital unit	The Netherlands	20%	Unknown
Hoonhout et al (2010)	Hospital medication errors	The Netherlands	0.9 adverse drug events per admission	0.2 per admission
Zwaan et al (2010)	Hospital diagnostic errors	The Netherlands	0.4% diagnostic errors	83.3% diagnostic errors
Landrigan et al (2010)	Hospital	USA	25%	Unknown
Hall et al (2010)	Emergency department	USA	34% non ideal events; 7% harmed patients	Unknown
Levinson (2010)	Hospital – Medicare beneficiaries	USA	14%	44%
Kunac and Tatley (2011)	Medication errors in all settings	NZ	Unknown	4.3% adverse drug events

Note: the date of publication does not reflect when data were collected, which could be up to 10 years earlier. The harm rate is usually a proportion of admissions and is rounded to whole figures.

3 Levels of harm in community care

The available evidence suggests that harm rates in primary care might be around 9%. In community hospitals rates of 15% are suggested, although the rates vary between studies.

3.1 Primary care

There is a lack of research about levels of harm in primary care.

The House of Commons Health Select Committee concluded that there was a lot of unknown harm in primary care, which is indicated by available data but not yet fully researched.

About one in 25 patients admitted to hospital in some studies are shown to have been admitted because of a medication problem. This implies that there are clearly issues around medication safety in primary care that could be addressed. Surveys of patients by the Commonwealth Fund have suggested that maybe as many as six in 100 report that they have experienced some sort of error in medication over the last two years.[54]

Some explicit studies about primary care are also available. For instance, researchers examined the value of a trigger tool for identifying safety events in primary care using audits of 100 randomly selected electronic patient records in each of five urban general practices in Scotland. An adverse event was found in 9.4% of records suggesting that harm occurred at a rate of one event per 48 consultations (2%). Severity was low to moderate for most patients (82.9%). Harm rates were higher in older people and most harms were related to medication (59%).[55] It is important to note that whilst this clinical audit examined primary care records, harms in both primary and secondary care were included. This means the figure of one event per 48 consultations may also include harms ultimately experienced in hospital.

Significant event analysis is a team-based approach to enhancing patient safety through reflective learning. It is required for appraisal and contractual purposes in UK general practice.

An analysis of significant event reports submitted in Scotland over an 18-month period between 2005 and 2007 found that 25% described patient harm and 57% of reports outlined circumstances that had the potential to cause patient harm.

Individual error was the most commonly stated reason, in about one third of cases.[56]

In England, researchers tested the value of screening for adverse events using computerised medical record systems. Data extracted from the clinical information management systems in one area were analysed for 2007. The data related to 69,682 registered patients from 25 primary care practices, consisting of 680,866 consultations. Adverse events could be detected using the Read code system including injuries due to surgical and medical care (0.72 cases per 1,000 consultations) and adverse drug reactions (1.26 reactions per 1,000 consultations).[57]

The 'harms' outlined in most studies of primary care include medication events, process errors and knowledge and skills issues.[58,59]

If 'harm' includes not being given appropriate care, the rates may be even higher. For instance, researchers reviewed the medical records of 6,712 adults in the US and interviewed people about their care. They found that patients received only 55% of recommended care overall, meaning that there is a significant gap which could be constituted as harm.[60] Similar studies with children are also available.[61] These estimates of harm due to lack of appropriate care include preventative, community and hospital care.

3.2 Out of hours care

There has been limited research about levels of harm in out of hours primary care. One study examined 1,145 medical records in the Netherlands. Reviewers identified records with a potential patient safety incident and a panel of doctors determined whether a patient safety incident had occurred. The incident rate was 2.4% and half of all incidents related to treatment. Most did not result in patient harm (70%). Older people were more likely to experience adverse events, but this may be because older people are also more likely to engage with primary care frequently than other age groups.[62]

3.3 Community hospitals

In Canada, researchers randomly selected one teaching hospital, one large community hospital and two small community hospitals in each of five provinces for a random chart review in 2000. Although an acute hospital was included, the figures are included here because the majority of data came from community hospitals. The adverse event rate was 7.5 per 100 hospital admissions. Death resulted in 21% of adverse events.[63]

Another study examined the incidence of adverse drug events in six community hospitals in the USA. The records of a random sample of 1,200 patients hospitalised between January 2005 and August 2006 were reviewed using the global trigger tool. Adverse drug events occurred in 141 patients, at a rate of 15 per 100 admissions. Adverse drug events were rated as serious in 49% of cases and life threatening in 11.7%. People with adverse drug events were more likely to be older.[64]

3.4 Nursing homes

There are few studies about levels of harm in the independent sector or in nursing homes. Whilst studies have examined various ways to improve rates of falls, medication errors and other safety incidents, they tend not to provide overall estimates of levels of harm.

For instance, recent research in the US assessed factors that contribute to repeat medication errors in nursing homes and the association between repeat medication errors and patient harm. Routinely submitted data were analysed. Of the 15,037 errors reported, about one third were repeated one or more times by the same nursing home. Wrong dosage and wrong administration were the most frequently repeated issues. Patient harm was reported in 1.2% of repeat errors.[65]

3.5 Summary

Key trends from the literature include:

- There is very little published evidence from which to draw conclusions about levels of patient harm in primary care.
- The available evidence suggests that harm might be evident in 9% of primary care records or around one in 48 consultations (2%). This may include harms in both primary and secondary care. In community hospitals rates of 15% have been proposed, although the rates vary between studies.
- The most common types of errors reported are medication errors, administrative errors and diagnosis errors.
- Most harm encountered is not severe.
- Older people are most likely to be affected.

Table 2, on the following page, summarises the level of harm found in various studies of primary care.

Table 2: estimated levels of harm in the community

Research	Context	Country	Approximate harm rate	% preventable
McGlynn (2003)	All healthcare for adults	USA	Adults only receive 55% of appropriate or indicated care for their conditions	Unknown
Baker et al (2004)	Community and acute hospital	Canada	8%	37%
Mangione-Smith (2007)	All healthcare for children	USA	Children only receive 47% of recommended care	Unknown
de Wet and Bowie (2009)	General practice	UK	9% of records or 2% of consultations list harm experienced in primary care or hospital	42%
Tsang et al (2009)	General practice	UK	Injuries due to surgical and medical care: 0.7 cases of per 1,000 consultations; adverse drug reactions: 1.3 reactions per 1,000 consultations	Unknown
Smits et al (2010)	Out of hours	The Netherlands	3%	Unknown
Hug et al (2010)	Medication in community hospitals	USA	15% adverse drug events	75% adverse drug events
Vincent et al (2001)	Hospital	UK	11% or 12% when multiple adverse events were accounted for	About half

Note: the date of publication does not reflect when data were collected, which could be five-10 years earlier. The harm rate is rounded to whole figures.

4 Preventability

The research scan suggests that a significant proportion of people experience harm from healthcare. Over the past few decades there has been increasing recognition that it is possible to reduce harm by implementing quality improvement initiatives such as teamwork, care bundles, better hygiene and education.

4.1 Level of preventability

Though the most effective interventions remain a matter of debate, it is estimated that up to half of all adverse events are avoidable if good professional practice and evidence-based care is followed.

Over the last ten years there has been a deluge of statistics on medical error and harm to patients, a series of truly tragic cases of healthcare failure and a growing number of major government and professional reports on the need to make healthcare safer. There is now widespread acceptance and awareness of the problem of medical harm and a determination, in some quarters at least, to tackle it. It seems that we are only now waking up to the full scale of medical error and harm to patients. Yet awareness of medical harm and efforts to reduce it are as old as medicine itself.[66]

There are an increasing number of publications about ways to reduce levels of harm in healthcare and surveys of clinicians have found that teams acknowledge the potential to improve care in this way.[67-70] Although there are debates about which incidents are predictable, it is commonly assumed that some harms are avoidable. Research has sought to quantify the degree to which adverse events are preventable.

Research about preventability has methodological problems. It can be difficult to decide whether or not an adverse event was avoidable and looking back at patient notes can result in 'hindsight bias.' The criteria used to determine preventability also varies between studies and it can be difficult to tell whether very ill people would have died or deteriorated anyway, regardless of the care provided.

Studies tend not to spend time describing harms that were not preventable. However, in the majority of cases these relate to side effects from medicines due to physiological impacts or worsening of medical conditions, where there is nothing that the clinical team could have done differently to avoid the harm.

Almost all of the estimates about preventability focus on hospital care. This section summarises some of the key findings.

In 2009, the House of Commons Health Committee suggested that between a third and half of adverse events were preventable.[71]

This was based on consideration of research and verbal evidence.

A chart review of 1,014 medical and nursing records from two acute hospitals in Greater London judged about half of the adverse events as preventable.[72] Another study of 1,006 patient charts in a large NHS hospital found that 31% of adverse events were preventable.[73]

More recently, in November 2010, the US Department of Health and Human Services estimated that 44% of adverse events were preventable in a study of hospital admissions among Medicare patients.[74]

Research from other countries is also available. For instance, a review of more than 1,000 records from 17 Danish hospitals estimated that 40% of adverse events were preventable.[75]

In Canada, a review of admissions in large teaching hospitals and community hospitals found that 37% of adverse events were potentially preventable.[76]

In France, analysis of data from 8,754 patients suggested that 20% of events were preventable, particularly psychological issues and pain.[77]

In Spain, a similar analysis proposed that 43% of adverse events were preventable.[78]

Researchers in Sweden estimated that 70% of adverse events in hospital were preventable. In a study involving 28 hospitals, 55% of the preventable events led to impairment or disability which was resolved during the admission or within one month of discharge, 33% were resolved within one year, 9% led to permanent disability and 3% contributed to patient death.[79]

In the Netherlands, a review of almost 8,000 patient notes estimated that around 40% of adverse events were preventable - or that 2.3% of all people admitted suffer a preventable adverse event.[80]

Other researchers in the Netherlands found that 83.3% of diagnostic adverse events in hospital were preventable.[81]

Researchers in New Zealand examined the local Pharmacovigilance database for 2007. Events deemed preventable were classified to identify the degree of patient harm, type of error, at what stage in the process the error occurred and the origin of the error. Out of 1,412 reports, 4.3% were deemed preventable errors. Not all errors resulted in patient harm: 29.5% were 'no harm' errors but 65.5% of errors were deemed to have been associated with some degree of patient harm. Most adverse drug events occurred in over 65 year olds. The majority of errors related to incorrect dose and monitoring problems, consisting of failures to detect significant drug interactions, past allergies or lack of necessary clinical monitoring. Eighty-two per cent of errors originated in the community setting.[82]

Other researchers reviewed more than 6,579 medical records of patients admitted to 13 randomly selected hospitals in New Zealand. More than 5% of admissions were associated with a preventable in-hospital event. Systems failure was a cause in around half of the events. Adverse events were greater among the elderly, ethnic minority groups and those treated in particular clinical areas.[83]

Also in New Zealand, a study of adverse drug events in neonatal intensive care and postnatal wards found that 56.7% of events were classified as preventable.[84]

Much less information is available about levels of harm in primary care overall, and there is a corresponding lack of information about the preventability of adverse events. One study in Scotland found that 42% of adverse events in primary care were preventable.[85] Research into community hospitals in the USA found that 75% of adverse drug events were likely preventable.[86]

4.2 Ways to avoid harm

A number of studies have tested ways to lessen or prevent patient harm in a variety of settings. This illustrates that teams do believe that some adverse events are preventable and want to take steps to reduce harm.

For instance, a systematic review of different strategies to improve quality and safety found that clinician and patient driven quality improvement strategies had stronger evidence of efficacy and larger effect sizes than manager or policy maker driven initiatives. The most effective strategies included clinician directed audit and feedback cycles, clinical decision support systems, specialty outreach programmes, chronic disease management programmes, continuing professional education with small group discussions, and patient mediated clinician reminders.[87]

The value of systems which allow for regular reporting and analysis of safety incidents has been emphasised.[88-90] A systematic review of the effectiveness of automated inpatient harm detection methods included 43 articles. Compared with gold standard chart review, the sensitivity of automated harm detection methods ranged from 0.10 to 0.94 and specificity ranged from 0.23 to 0.98. The authors concluded that automated methods of harm detection are feasible but effectiveness varies widely, and most studies have methodological weaknesses.[91]

Interventions have been tested to address specific types of harm, such as medication errors.[92] For example, having pharmacists on ICU wards has been found to reduce adverse drug events in US hospitals and in Europe.

In one study, a pharmacist reviewed medication orders for people admitted to a hospital ICU in the Netherlands, and noted issues related to prescribing and discussed recommendations during patient review meetings with the attending ICU doctors. The incidence of prescribing errors during the intervention period (62.5 per 1,000 patient days) was significantly lower than during the baseline period (190.5 per 1,000 patient days). Significant preventable adverse drug events were reduced from four per 1,000 patient days to one per 1,000 patient days. The intervention cost €3.00 per patient day but might have saved €26 to €40 per patient day by preventing adverse drug events.[93]

A recent study in Scotland tested ways to reduce prescribing errors for people admitted to hospital via A&E. Data were analysed for 50 people before the intervention and 50 people afterwards. The intervention involved a pharmacist prescriber completing a systematic medicine reconciliation in A&E before patient transfer. The prescribing error rate reduced from 3.3 errors to 0.04 errors per patient.[94]

In the USA, adverse medication events were reduced in hospitals using a pharmacist managed anticoagulant therapy service. The rate of thrombotic events decreased from 4.6% in 2004 to 3.9% in 2006. There were no events for patients managed collaboratively by doctors and pharmacists.[95]

Some interventions have not been successful. For example, researchers in the USA examined whether having IT applications influenced a hospital's risk adjusted incidence rate per 1,000 hospitalisations for various patient safety indicators. There were 66 hospitals surveyed, each provided routinely collected data. Having access to IT applications did not seem to make a difference.[96]

In this study, many different types of IT systems were examined, including electronic prescribing systems, electronic medical records, electronic handover forms, and systems for sharing information between departments and groups. This does not suggest that these interventions have not been successful elsewhere, but provides an example of how not all interventions successfully reduce levels of harm.

The number of studies about initiatives to improve safety and reduce harm is large. Only a few examples are presented here to give a flavour of the range of topics people have focused on.

4.3 Summary

Key trends in the literature are:

- It is widely accepted among the research community that a proportion of adverse events in hospital and in primary care are preventable if standard or enhanced procedures are implemented.
- Studies of the attitudes of clinicians suggest that teams believe that a proportion of adverse events are preventable too.
- The estimated proportion of adverse events that are thought to be preventable varies, but generally ranges between one third and half of all events.
- Events that are not preventable include involuntary physiological side effects from medications (where there is no prescribing error) or worsening of a disease or condition that was not brought by healthcare.
- A number of studies have tested ways to improve patient safety, including computerised systems, team work and communication skills training, pharmacist intervention, standardised processes, handover templates and proformas.

5 Contributing factors

This section briefly outlines some of the factors that are thought to contribute to levels of harm in healthcare. Many of these factors have been targeted for preventive interventions.

5.1 Common factors

The three most common factors thought to contribute to adverse events are system failures, human factors and medical complexity.[97]

Human factors include:

- variations in healthcare provider training and experience[98,99]
- fatigue, depression and burnout thatimpact on how team members cope with diverse patients, unfamiliar settings and time pressures[100-104]
- inadequate training[105]
- failure to acknowledge the prevalence and seriousness of harm and take steps to do something about it.[106,107]

Clinical complexity factors include:

- using complex technologies and multiple medications[108]
- high risk environments such as intensive care
- prolonged hospital stay
- complex conditions and frailty.

System failures include:

- poor communication and unclear lines of authority between physicians, nurses and other healthcare professionals [109,110]
- reliance on automated systems to prevent error[111]
- inadequate systems to share information about errors which hampers analysis of causes and improvement strategies[112]
- increasing complications due to higher patient to nurse staffing ratios[113]
- cost cutting measures[114]
- fragmented reporting systems within hospitals
- too many handovers, resulting in lack of coordination and errors
- ineffective sharing of information during handovers
- thinking that action is being taken by other groups within the organisation
- drug names that look alike or sound alike
- environment and design factors[115]
- infrastructure failure.[116]

A study of nursing errors focused on the care process, communication, administrative process, and knowledge and skills. Contributing factors included patient clinical and social conditions (27%); resources (22%); environment and workload (18%); other professionals (15%); communication (13%); and nurse's knowledge and experience (5%).[117]

In the USA it has been estimated that inadequate communication between healthcare providers, or between providers and the patient and family members, was the root cause of over half the serious adverse events in hospitals. Other leading causes included inadequate assessment of the patient's condition and poor leadership or training.[118]

Other US researchers directly observed discussion of adverse events during routine clinical meetings in three units of a large, urban teaching hospital. The meetings included day shift, weekday, regularly scheduled rounds, residents' work rounds, nursing shift changes, case conferences, and other scheduled meetings as well as departmental and section meetings. Adverse events were caused by an individual in 38% of cases, 16% had interactive causes and 10% were due to administrative decisions.[119]

Another study in the USA reviewed 30,121 records from 51 randomly selected acute hospitals. Twenty-eight per cent of the adverse events were due to negligence.[120]

Researchers in the Netherlands also found that human error was the main cause of diagnostic errors in hospital (96.3%) but organisational (25%) and patient related factors contributed too (30%).[121]

Research about the contributing factors to patient harm in primary care is scarce but generally mirrors the trends seen in hospital research. For example, researchers in England examined patient safety events from five primary care practices obtained via a confidential but not anonymous reporting system. Reports were followed up with interviews, if needed, and events were analysed for contributing factors. Seventy-eight reports relevant to patient safety were analysed including 21 (27%) adverse events and 50 (64%) near misses. Serious patient consequences occurred in 16.7%, including a death, and 75.7% had the potential for serious patient harm. Most reports related to administrative errors (25.6%). The most frequent contributing factor was work organisation, including excessive task demands (47%) and fragmentation (28%).[122]

In the US error reports were analysed from eight GP offices. Twenty-one per cent of reports of errors included efforts to mitigate. Mitigated events had lower odds of patient harm and negative consequences.[123]

5.2 Summary

The literature suggests that individual and team factors, systems issues and clinical issues all play a part in causing harm in healthcare. Whilst studies vary in their focus and the weight that they place on each of these factors, it is broadly acknowledged that these factors all impact in some way on safety incidents and that efforts to prevent harm should consider these factors and their interactions.

6 Ongoing and unpublished work

This section is not meant to provide an exhaustive overview of unpublished and ongoing work, merely to signal that this is seen as an important topic by the national and international research community and the media.

6.1 Unpublished and ongoing work

As well as the published literature described overleaf, there is also unpublished and ongoing work about harm in healthcare, particularly in terms of efforts to reduce harm. Material is available on various websites, such as patient safety campaigns in England, Wales and Scotland; the US Institute for Healthcare Improvement; and universities and think tanks.

The main organisations currently undertaking unpublished work on levels of patient harm include WHO, IHI, the US Institute of Medicine and NPSA. This ongoing work tends to focus on collecting statistics about levels of harm and making suggestions about how to alleviate harm.

For instance, in Wales, the 1000 Lives Campaign calculated a baseline of 42.21 adverse events per 1,000 patient days based on the six month period of October 2007 to March 2008.[124]

The National Patient Safety Agency prepares quarterly summaries of patient safety incidents reported by NHS organisations in England and Wales to the National Reporting and Learning System. The most recent update was released in October 2010.[125] The Office for National Statistics also produces statistics regarding deaths in which Methicillin-resistant *Staphylococcus aureus* (MRSA) and *Clostridium difficile* are recorded causes.

The US Institute for Healthcare Improvement continues to undertake work into rates of patient safety errors and ways to prevent these. For instance, a Medicare 'innovation centre' has been launched to develop and test ways to improve quality of care and lower costs.

Numerous studies exploring the causes and ways to improve harm are also registered on the international clinical trials register, the US research register and UK equivalents.

6.2 Media stories

There have been a number of stories in the media about levels of patient harm. When the US Institute of Medicine's report, *To Err is Human*, was released more than a decade ago, there were numerous stories about the number of people who were thought to be dying in US hospitals. This gained media attention in the US, UK and other parts of Europe.

When update reports or other studies linked to the Institute of Medicine report are released, further media coverage ensues.

The Department of Health's similar report focusing on patient safety in 2000 did not receive the same level of media attention, though there were stories in some newspapers.

More recently, the USA and international media has picked up a study published in the New England Journal of Medicine in November 2010. The media articles focus on the suggestion that one in four or five people admitted to hospitals in industrialised countries suffer an adverse event such as inappropriate medications, falls or infections. Most media reports focused on the reported rate of errors, the challenges of improving safety and the lack of improvement over time. [126,127]

Other recent news reports have focused on a study from the US Department of Health and Human Services that suggests that one in seven Medicare patients are harmed during their hospital stay and 44% of the adverse events were preventable.[128,129]

In the UK, there have been media reports that one in six NHS patients is misdiagnosed. Research by Imperial College London, which is ongoing, suggests that doctors make mistakes in up to 15% of cases because they are too quick to judge patients' symptoms or reluctant to ask more senior colleagues for help.[130]

There are also frequent reports in the media about particular cases of harm and the Patient Safety First campaigns in England, Scotland and Wales issue regular press releases highlighting success stories.

Previously there have been television documentaries exploring the dangers of healthcare in both the USA and the UK.[131]

7 Estimates from other industries

Literature compiled for the scan suggests that between one in five and one in 10 people admitted to hospital, and a similar proportion of people in primary care, may experience an adverse event. Not all of these events are serious or harmful.

It is problematic to compare these rates with levels of harm in other industries because the way harm is defined differs markedly. Most studies of harm outside healthcare focus on death or serious disability only. The way harm is measured also varies in other industries and there is a lot of reliance on self-reported information. It is important to bear these caveats in mind throughout this section.

Statistics on rates of fatal injury and serious harm in various occupations tend to be expressed as figures per 100,000 population. This is because the size of the workforce or population will impact on the number of harms in any one year and using this statistic allows comparisons over time and between countries. This is different from the proportions used in estimates of healthcare harms.

The UK Health and Safety Executive suggests that the rate of fatal injuries for all sectors in 2009-2010 was about 0.5 per 100,000 workers. In agriculture the figure was as high as eight whereas manufacturing, services and construction had rates of about one to two fatalities per 100,000 workers.[132]

Construction is thought to be one of the most dangerous industries in Europe, after the fishing industry. There are various estimates of accident rates and occupational harm. For instance, in the EU, the fatal accident rate for construction is nearly 13 workers per 100,000 compared to the all sector average of five per 100,000.[133]

The Construction Institute in the USA estimates that in 2009, the total recordable injury rate was 0.57, based on almost 2.1 billion work hours reported by 55 companies.[134]

Information is also available from the transport industry. According to the World Health Organisation, motor vehicle collisions are the sixth most common cause of death in developed nations, with an average rate of 20.8 per 100,000 people in the year 2000 (30.8 for males, 11.0 for females).[135,136]

The Office for National Statistics suggests that the rate of fatal and serious accidents on roads in 2000 was 76 per 100,000 people in London and 61 per 100,000 population in other parts of the UK.[137] This compares with 14.3 per 100,000 people in the US, 7.8 per 100,000 people in Australia and 5.7 per 100,000 population in Japan.[138,139]

Regarding air travel, the fatal event rate varies depending on the airline but ranges between zero and 3.6 per million flights. [140,141]

Whilst trends in transport safety incidents vary among different types of transport and countries, the general pattern in developed countries is a decreasing rate of fatalities and serious injuries from cars, large trucks, ships and trains.[142]

To summarise, it is difficult to gain value from comparing healthcare harms to safety incidents in other industries. The broad pattern is that healthcare harm may be greater than those in other industries and whereas rates of transport harms are declining over time, the same is not necessarily true of healthcare.[143]

8 Conclusion

It would be easy to focus on the numbers and proportions presented in this research scan, while losing sight of what they really mean. Even 'small' estimated proportions of adverse events equate to hundreds of thousands of people potentially harmed through healthcare every year.

In 2009, the House of Commons Health Committee concluded that there was insufficient data about patient safety events in England and that more rigorous data collection was needed.

International studies suggest that about 10% of all patients who are admitted to hospital suffer some form of harm. Judging how far patient safety policy has been successful requires more reliable data regarding how much harm is done to patients. Unfortunately, neither the NPSA nor the DH was able to provide us with that. Government estimates of avoidable harm and the attendant financial costs are extrapolations from old, very limited, data; and no attempt has been made to produce reliable up-to-date figures.[144]

Much UK promotional and informational material uses the figure that one in 10 people are harmed by healthcare. This may be based on reported incidents from hospital care so does not take into account primary care and may suffer from under reporting biases. Rates are likely to vary by country, with recent high profile US studies suggesting the harm rate is between one in four and one in seven admissions.

One of the reasons for varying statistics about levels of harm may be because this concept can be defined in many different ways, from the most severe physical harm or death through to psychological harm and lower level stress and annoyance.

The most common conceptions of harm in developed countries currently combine physical harm from surgery and treatment, medication error and hospital acquired infections. The 'best estimates' range anywhere between 3% and 36% of admissions and the range in primary care is similarly wide.

The Health Foundation and other organisations use the figure of about one in 10 people being harmed, but recent research suggests that the rates could be even higher. It may be more accurate to suggest that 10-20% of people might be harmed or that up to one in five people in hospital and primary care are harmed in minor or major ways. However, a number of older studies, especially those from the USA, have much smaller levels of reported harm.

It is difficult to compare healthcare harm rates with those of other industries such as air, road or rail travel or occupational safety. This is because healthcare harm is more broadly defined and includes smaller or less serious incidents as well as larger events and fatalities. In contrast, occupational and transport safety figures tend to focus on mortality or larger incidents of harm. Episodes of road rage or anxiety while flying are not recorded, for instance, yet these are still types of harm.

Recognising these caveats, it is perhaps unsurprising that based on the information available, healthcare has a greater rate of reported harms than air, rail or road transport or occupational injury.

The factors contributing to levels of harm in healthcare are multifaceted. Most research focuses on human factors, systems issues and clinical complexity. There is increasing recognition that a proportion of adverse events in healthcare are preventable, with estimates of the proportion of avoidable harms usually ranging from one third to a half of all adverse events.

There has been a corresponding increase in research into how to reduce levels of harm most effectively, with much research focusing on error reporting systems, team work and communications training, and specific initiatives to improve handover, medication prescribing and infection control. There is no consensus about the best ways to reduce harm, but there is consensus that this is an important issue requiring further investigation.

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