

Evidence scan:

Levels of harm in primary care

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Contents

Key messages	3
1 Scope	4
2 Measuring harm	7
3 Levels of harm	13
4 Sources of harm	19
5 Ongoing and unpublished work	22
6 Summary	24
References	26

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.

Key messages

A great deal of research is available about patient harm in hospital, but less is known about errors in primary care. This research scan found that about 1–2% of primary care consultations may include adverse events, with the most common errors relating to medication and communication.

Errors or harm in healthcare involve a negative effect, whether or not it is evident to patients. Sometimes researchers make a distinction between ‘error’, which involves some sort of mistake, and ‘harm’, which involves a negative impact. Other researchers use the terms interchangeably.

This research scan explores how levels of error and harm are measured in primary care, the estimated rates of harm, and the main causes of harm. Primary care was defined as the first point of contact with healthcare, focused on ongoing and day-to-day care. Examples include general practice and community pharmacy.

Ten databases were searched and 72 studies were included, predominantly from North America.

Measuring harm

The main methods used to measure harm in primary care include, in order of prevalence:

- incidents self-reported by staff
- review of individual patient records
- automated review of electronic records
- examination of registries or databases
- patient interviews and surveys
- staff surveys and interviews
- direct observation.

Levels of harm

Research suggests that around one in ten people experience harm from hospital care. In primary care, however, the evidence is much more sparse. Studies have widely varying estimates of harm, from less than 1% to 24%. The most robust studies suggest that 1–2% of consultations are associated with an adverse event in primary care. In out-of-hours care, the rate is about 2%. Too few studies are available to draw conclusions in community pharmacy. The majority of events do not impact significantly on patients.

The reason for the variation in estimates is that studies define and measure harm differently and the research is undertaken in different geographical and clinical contexts. The research is observational, sometimes with small sample sizes and methodological biases.

Sources of harm

There is more agreement about the sources of harm in primary care. Factors thought to contribute to adverse events include:

- human factors such as teamwork, communication, stress and burnout
- structural factors such as reporting systems, processes and the environment
- clinical factors such as medication.

1 Scope

More than one million people use NHS services every day, the majority of which use primary care. This research scan explores what proportion of primary care interactions encounter adverse events, errors or harm.

1.1 Purpose

Most people using primary care services do not experience any harm or threats to their safety, but there is always room for improvement. Identifying current levels of harm is a crucial component of the improvement journey.

A great deal has been written about harm in hospital.¹ Some suggest that rates of adverse events in hospital are as low as 3% of all admissions or as high as 25%.²⁻⁹ Most frequently, an average of 10% is used.¹⁰⁻¹² This is a significant proportion, with one in ten people admitted to hospital thought to suffer some form of adverse event, half of which may be preventable with changes to behaviour, systems or processes.¹³⁻¹⁶

Many initiatives have been tested or are underway to reduce adverse events in hospital,¹⁷⁻¹⁹ but far less is known about error and harm in primary care. It is acknowledged that errors occur in primary care but this has received far less priority, perhaps because the incidence of adverse events has not been well quantified.

This research scan seeks to address this gap in knowledge by summarising readily available research about levels of patient harm in primary care and the potential causes of such harm.

The scan addresses the following questions:

- How is harm measured in primary care?
- What are the levels of harm in primary care?
- What are the main causes or sources of harm in primary care?
- Is there unpublished or ongoing work or media stories about this topic?

The scan provides a rapid collation of empirical research about levels of harm in primary care. All of the evidence has been sourced and compiled systematically, but the scan is not a systematic review and does not seek to summarise every study on this topic.

This section outlines the definitions used to guide the scan and the methods used to collate information. The following sections address the questions above in turn.

1.2 Definitions

Primary care

Primary care is the first point of contact for people using health services. It involves generalist one-off or ongoing care, rather than care from a specialist. About 90% of all contact with health services in the UK involves primary care.²⁰

Different organisations run primary care services in each country in the UK, such as community health partnerships in Scotland,²¹ health boards in Wales,²² a joint health and social care board in Northern Ireland, and primary care trusts (PCTs) and developing GP consortia in England.²³ However, regardless of how primary care is managed and funded, the types of services remain similar. Examples include GPs, practice nurses, walk-in centres, dentists, community pharmacists, community midwives and district nursing or general home care.

The NHS is funded through taxation, so visits to GP surgeries and most other primary care services are free but there are charges for dentists. Medicine costs vary. England has a set prescription charge per item, whereas Wales and Northern Ireland have abolished all charges and Scotland is phasing out charges.

In other countries primary care is organised differently. For instance, in countries such as the USA, Australia and New Zealand, people pay to visit primary care or 'family practice' services. In the USA this is mainly covered by medical insurance, with co-payment by patients.

In the USA, some health systems focus on 'integrated care' whereby the organisations offer both primary and secondary care with more seamless service. These organisational differences are important because when studies mention 'primary care' they are not necessarily describing the same thing.

For this research scan, the focus is largely on general practice, community pharmacy and out-of-hours services.

Error and harm

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

Some studies differentiate between errors (mistakes or unintentional actions) and adverse events or harms (actions with some form of negative impact for processes, staff or patients). Some use these terms interchangeably and other studies have very specific definitions of what they are measuring in terms of error or harm.

The scan uses the terms listed within individual studies. Where multiple terms are used interchangeably, the term 'harm' has been used to denote adverse events, errors and harm.

1.3 Methods

The scan focused on attempts to quantify errors, adverse events or harm to patients. The emphasis was on avoiding discrete and direct harms rather than the broader definition of patients being harmed by not receiving all of the care they are entitled to or would benefit from.^{24,25} Omissions of care were included in terms of whether professionals were adhering to guidelines, but it was not possible to measure whether patients were not getting all the care that might benefit them or 'best care' in subjective terms. Thus, the focus was on the extent to which primary care systems and professionals do things that may harm patients or any omissions in guideline-based care that may cause harm.

As well as errors that had the potential to cause physical or mental harm to patients and their families, the scan also incorporated any studies about wrong, missed or delayed diagnoses.

To collate evidence about quantifying harms and safety issues, two reviewers independently searched bibliographic databases, reference lists of identified articles and the websites of relevant agencies.

The databases included MEDLINE, Ovid, Embase, the Cochrane Library and Controlled Trials Register, PsychLit, Google Scholar, Web of Science, ScienceDirect, the World Health Organization (WHO) library and the Health Management Information Consortium. All databases were searched from 2000 until August 2011.

Search terms included combinations of primary care, primary healthcare, family practice, pharmacy, walk-in centre, district nursing, home care, general practice, GP, practice nurse, midwife, patient safety, harm, risk, adverse events, incidents, error, medication errors, significant event and other similes.

To be eligible for inclusion, studies had to:

- be 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 of interest
- be available in English or readily available for translation.

We scanned more than 5,000 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.

72 studies 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.

2 Measuring harm

Patient harm has been measured in a variety of ways in primary care, including self-reports from professionals, feedback from patients and reviewing patient notes. This section describes common approaches.

The main methods used to measure harm in primary care include, in order of prevalence:²⁶

- incidents self reported by staff
- manual review of individual patient records
- automated review of electronic records
- examination of registries or databases
- patient surveys and interviews
- staff surveys and interviews
- direct observation.

Examples of some of these approaches are described in turn.

2.1 Formal incident reporting

Self-report by health professionals

Incident reporting by health professionals and support staff can be either voluntary or compulsory. Some studies have asked staff to report errors specifically as part of research. Others have examined the value of routinely used error reporting systems.²⁷

A number of reports describe how certain organisations have developed systems to track medical errors in primary and ambulatory care. For instance, one US family medicine centre implemented a voluntary reporting system and found that processes improved as a result.²⁸

Another study described the development of an incident reporting system for general practice in Germany. The web-based system received incident reports from anonymous users. Reports were fed into a database, classified and analysed before being disseminated in journals and online. In the first 17 months, the system received 199 reports.²⁹

A team in the USA examined the feasibility of detecting medication errors by self-observation of office transactions related to medication management. 14 primary care doctors and 18 office staff reported all their medication management transactions during a four-hour period. A researcher abstracted additional information from patients' charts. Participants documented 440 medication management transactions for 246 encounters. Errors were identified in 34% of cases. Errors included medication not being listed, incorrectly written prescriptions, incorrect dose, failure to implement medication across care settings, and contraindicated medication prescribed. None of these errors would have been detected by chart review alone. The authors concluded that self-reporting followed by chart review is feasible in primary care practices and discovers medication errors that might not have been detected by either method alone.³⁰

Studies have also investigated the value of reporting by different types of staff. Researchers in the USA implemented a voluntary prescribing error reporting system in seven primary care offices. The system was used by 103 prescribers, managers, nurses and office staff. All practices submitted reports to the system, but usage declined over time. The authors concluded that nurses and office staff are a valuable resource for reporting prescribing errors, but without ongoing reminders, such reporting systems may not be sustainable.³¹

To address issues of sustainability, researchers have tested ways to engage staff with using incident reporting systems. For example, researchers in the Netherlands tested the feasibility of an incident reporting procedure in five primary care centres with 117 GPs, nurses, physiotherapists, pharmacists, pharmacist assistants and trainees. Staff were encouraged to report all incidents. Dedicated 'reporting weeks' were introduced that emphasised reporting of minor incidents and near misses. A committee at each centre analysed the reported incidents and initiated improvements. 476 incidents were reported during a nine-month reporting period. 62% of incidents were reported in a 'reporting week'. Most incidents were process related and in 87% of cases potential harm for patients was small.³²

Researchers in England assessed the feasibility and acceptability of a method for recording staff-reported errors in general practice. Staff at 10 general practices used an anonymous self-report form and were surveyed about the acceptability of the process. The method of error reporting was found to be acceptable by 68% of staff: 8% found the process threatening.³³

Different approaches for recording self-reported incidents have been tested. For instance, in the USA a tool was developed for use with handheld interfaces such as personal digital assistants (PDAs).³⁴

Drug databases have been placed on PDAs so that adverse drug interactions can be detected at the point of care. Researchers in Switzerland tested a drug interaction database for identifying significant adverse drug interactions. 1,801 drug prescriptions from a walk-in clinic were reviewed independently by a clinical pharmacologist using standard methods and by a general internist using the drug interaction database. The drug interaction database correctly identified 81% of clinically relevant adverse drug interactions.³⁵

Some studies suggest that anonymous reporting is more likely to elicit honest feedback from professionals. For instance, an Australian study collected 648 anonymous reports about threats to patient safety from a random sample of general practitioners. The errors focused on both diagnosis and treatment. The researchers suggested that reports would not have been so numerous or detailed if they were identifiable.³⁶

However, there is a trade-off between anonymous feedback and levels of detail in error reports. The Applied Strategies for Improving Patient Safety (ASIPS) study in the USA is a widely written about multi-institutional project that collected data about medical errors in primary care. The voluntary reporting system captured some anonymous reports and some confidential reports of medical errors. The project found that confidential reports provide better detail than anonymous reports, but there were legal concerns regarding how the data might be used, especially in the case of malpractice claims.³⁷

Significant event analysis

In England, Wales and Scotland, primary care practices need to demonstrate evidence of taking part in significant event analysis as part of their quality assessment and monitoring requirements. Some research has drawn on these significant event analyses or invited practices to take part in such analyses voluntarily. For instance, researchers in England examined 337 significant event analyses submitted by general practices in one area. 27% of all significant events were classified as patient safety incidents. Of these, 7% were serious or life threatening and 20% were potentially serious. 29% of the significant events related to medicines management issues.³⁸ This approach does not quantify the amount of harm in primary care, but does provide insight into potential sources and severity of harm.

Similar examples are available regarding community pharmacy. Researchers in Scotland examined 43 significant event analyses undertaken by 37 pharmacists in various sectors. All events were classified as having a negative impact on the quality and safety of patient care. Most events related to prescribing, dispensing, administration, communication and patient- or family-centred issues. Patients were reportedly harmed in 13% of cases.³⁹ Again, this does not provide insight into the scale of harm, but gives some indication of scope and severity.

2.2 Review of patient notes

Manual reviews

Research suggests that it is difficult to encourage clinicians to report errors voluntarily.⁴⁰ Therefore, approaches with non-voluntary reporting methods are becoming more popular. These often involve using ‘triggers’ to identify adverse events in either a manual chart review or electronic format. Trigger tools involve reviewing a random sample of patient records using a series of ‘triggers’ that alert reviewers to potential errors and previously undetected adverse events.

For example, in Scotland a trigger tool has been developed specifically to assess errors in primary care. The approach involves a rapid audit to screen electronic patient records to detect patient harm. This has been found to be a feasible part of routine primary care practice.⁴¹

In one study, this trigger tool was applied by pairs of reviewers who conducted focused audits of 100 randomly selected electronic patient records in each of five urban general practices. Review of 500 records revealed 730 triggers in 2,251 consultations.⁴²

In the USA, another trigger tool was used to identify adverse drug events in older adults in primary care. The authors found that the tool could be shortened considerably by reducing the number of triggers and still remain valid.⁴³

In England, the NHS Institute for Innovation and Improvement came to similar conclusions when developing its primary care trigger tool. The tool was launched in late 2009 and is freely available to the NHS through the NHS Institute’s website.⁴⁴ The tool uses structured review of clinical records to identify the most common areas of harm and calculates an adverse event rate for the time in primary care. It focuses on 24 triggers and takes about four minutes per patient to complete (see box on page 10). It is recommended that practices use the tool to review a three-month period within randomly selected patient records, and that the focus is on patients aged 75 years or older, as this group is particularly vulnerable to harm.

The tool was developed over an 18-month period with the help of 32 GP practices across England. Nearly 4,500 patient records were reviewed by clinicians, providing data about 1,400 adverse events in primary care. It has a sensitivity of 81% for detecting adverse events.⁴⁵

Practices can use the NHS Institute’s online portal to enter casenote review data and the portal then automatically analyses the results on an ongoing basis and provides easy-to-interpret charts and statistics. There are currently 194 practices registered to use the tool and a total of 12,894 casenote reviews have been entered since the public launch of the portal in December 2009.

24 triggers included in the NHS Institute's primary care trigger tool⁴⁶

Medication

- Repeat medication discontinued
- Prescribing of opioid analgesia
- Prescribing oral NSAID/COX2
- Prescribing warfarin
- Prescribing insulin
- Prescribing methotrexate
- Prescribing amiodarone

General care

- Fall if age >75
- Fracture if age > 75
- Pressure sore or ulcer
- Urinary catheter in situ

DVT/PE

- Proven DVT or PE

Patient transfer

- Readmission to hospital within 2 weeks of discharge

Laboratory

- Na+ <130 or > 150 mmol/l
- K+ <3.5 or > 5.5 mmol/l
- INR <2 or >5
- Haemoglobin <9g/dl
- MRSA positive
- C.diff positive
- Positive wound/skin swab culture
- eGFR <= 20

End of life

- Death

Key diagnosis

- New diagnosis of CVA/TIA
- New diagnosis of acute confusional state

There are currently no published evaluations of the tool, but it has been described at a number of national and international conferences, and publications about other NHS Institute trigger tools are underway. During development, the tool was tested in general practice and a qualitative evaluation was undertaken by an independent team. The evaluation found that GPs had positive views of the results provided by the tool and that their interest in patient safety improvement grew as a result of using the tool. The importance of good training to use the tool, clear definitions of adverse effects, and providing simple and prompt feedback of results was highlighted.⁴⁷

Automated analysis

Computerised analysis of information can make the process of identifying errors easier than incident reporting or manual chart reviews.

A team in England explored the potential for building adverse event screening tools using computerised medical record systems in primary care. One year's worth of data were extracted from a clinical information management system at one NHS primary care trust. Adverse events could be detected using terms in the Read code system.⁴⁸

Researchers in the USA developed a computerised adverse drug event monitor using electronic medical records from outpatient practices. The system looked for various diagnostic and laboratory abnormalities caused by a broad range of medications commonly used in primary care. Four months' worth of data from two sites were used to test the system. Possible adverse drug events were identified and validated by chart review. The system was found to be feasible for use with various information systems.⁴⁹

2.3 Existing datasets

A number of studies have used existing databases, registries or datasets to quantify errors or adverse events.⁵⁰⁻⁵² The data may be submitted by healthcare teams via incident reports or significant event analyses, or it may take the form of summary-level patient notes or high-level datasets.⁵³ This type of analysis is most common in the USA, where state-administered databases are sometimes available or large databases have been set up as part of wider research programmes. But examples from other areas are also available.

For instance, a Spanish team investigated which drugs were most implicated in severe interactions in primary care. A computerised medical records database containing records from 362,271 patients was analysed. The authors constructed a severe interaction hazard scale based on the probability that a patient may be taking a particular drug and the probability that a drug may produce a severe interaction. 23% of patients were at risk, and in 6% of cases there were severe interactions.⁵⁴

In England, researchers examined whether primary care teams could use mortality data to help them review policies, identify errors and improve safety. Staff from ten general practices were interviewed. A presentation was important in helping teams to understand the data. Staff thought comparisons should be between practices with similar patient populations and information should be provided on deaths from diseases potentially amenable to change.⁵⁵

2.4 Surveys and interviews

Patients

Another technique that has been used to quantify harm in primary care involves interviews or surveys with patients. With this approach, patients are asked to recall errors or events over a set timeframe.

This is an extremely subjective approach which relies on recall. Patients may not have the same definition of harm as researchers. Studies have found that some types of patients are also more likely to report errors and harms. It is uncertain whether this is because harm is more prevalent in these groups, or whether there is some form of bias.

For example, 1,697 patients from seven primary care practices in the USA were surveyed about their perceptions of medical mistakes. Those with chronic back pain, higher educational attainment and poor physical health were more likely to perceive mistakes. African American patients were less likely to perceive mistakes.⁵⁶

Telephone support is increasingly being provided for people with long-term conditions. One novel study examined whether an automated telephone self-management programme for people with diabetes could be used as a tool to monitor patient safety. Adverse events and potential adverse events were identified via weekly automated interactions augmented by targeted nurse follow-up and medical record review. Among 111 patients, 111 adverse events and 153 potential adverse events were identified. Events were detected in 11% of calls. Events were most commonly detected through health IT facilitated triggers (59%), nurse elicitation (30%) or patient requests for call backs (11%). Most events (93%) were preventable or ameliorable.⁵⁷

Reviewers from Canada examined the best methods to elicit patient reports of adverse events in primary and secondary care. 17 articles were included, which covered a wide range of methods in diverse settings. The review found that patient reporting is reliable. Higher incident rates were observed when open-ended questions were used and when respondents were asked about personal experiences in hospital and primary care. The authors suggest that future patient reporting systems will need a balance of closed questions for root cause analysis and classification, and open-ended questions to allow for patients' limited understanding of terminology about harm.⁵⁸

Staff

Another approach is to ask staff to recall or comment on safety events. This is different from incident reporting because the focus is not on reporting events at the time they occur.

A US team tested an approach to prioritising safety issues in rural primary care based on the method of failure modes and effects analysis (FMEA). Staff at two primary care practices were surveyed and responses were converted to quantitative hazard scores. There was good concordance within sites, but not between sites. The authors concluded that FMEA can be used to estimate the greatest threats to patient safety in rural primary care.⁵⁹

A US study exploring how primary care doctors define the term 'error' underlined the subjectivity of asking clinicians to reflect on errors. The researchers systematically reviewed literature about definitions of error and conducted a survey of 285 clinicians. Participants were asked to judge whether an error occurred in five clinical scenarios. 100% felt that overlooking an abnormal result was an error, but there was less agreement about other scenarios such as performing the wrong test, not following up an abnormal test, scan results not being available during a patient visit, and breaking a blood tube. The study concluded that three aspects may affect how doctors make decisions about error: the process that occurred versus the outcome, rare versus common occurrences, and system versus individual responsibility.⁶⁰

Sometimes staff interviews are used as part of a broader approach to identify errors and harm. For example, researchers in the USA examined the most common errors in primary care. The approach included developing an initial conceptual framework for depicting specific clinical processes at risk of error, validating the framework through consultation with practice staff and concurrent analysis of malpractice insurance data, and implementing practice-specific quality improvement interventions to reduce medical errors. Laboratory errors and prescription errors were two important areas of intervention.⁶¹

2.5 Other approaches

A small number of studies have described other approaches to investigating levels of harm in primary care.

For instance, a team in England used prospective hazard analysis methods to assess patient safety in a care pathway spanning primary and secondary care. These methods take into account the views of staff and patients to understand where potential hazards may lie. A process map of the care pathway was developed for people using a chronic obstructive pulmonary disease (COPD) supported discharge programme. Staff and patients were interviewed. Quality and safety concerns were mostly raised in relation to communication, difficulties in accessing hospital records, information transfer to primary care, and failure to communicate medication changes to primary care.⁶²

A very small number of studies have used direct observation to quantify patient harm, but this is usually as part of a broader range of methods or to validate other methods.

2.6 Summary

- The most common approaches for measuring harm in primary care include self-reporting by staff, analysis of existing databases, reviewing patient records manually or using automation, and asking professionals or patients to recall errors.
- Most of these methods suffer from potential bias. Staff incident reports and patient and staff surveys are all affected by recall bias and potential social desirability bias. Non-voluntary methods such as chart reviews are time consuming and may be influenced by sampling.
- Trigger tools are commonly used to identify events in hospital care but only a few studies have tested this approach in primary care.

3 Levels of harm

Compared with information about hospital services, there is a paucity of research about levels of harm in primary care. This section describes the emerging literature in this area.

There is an increasing awareness of a gap in knowledge regarding harm in primary care. A House of Commons Health Select Committee concluded that there is a lot of unknown harm in primary care which is not yet fully researched.⁶³

Studies are beginning to emerge to address this gap. Most focus on general practice. There are also a smaller number of studies about out-of-hours care, community pharmacies and care homes. Research about these different settings is explored in turn.

3.1 General practice

Level of harm

A review published ten years ago explored harm rates in general practice. Included studies had widely varying estimates of harm, ranging from 5 to 80 per 100,000 consultations or less than 1%.⁶⁴ The reviewers found that the majority of errors did not result in harm to patients and most occur in the very young or old. Errors are most common during diagnosis and treatment.⁶⁵

More recent studies add to this review. 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 Scottish general practices. The study found that harm occurred at a rate of one event per 48 consultations or 2%. Severity was low to moderate for most patients (83%). Harm rates were higher in older people and most harms were related to medication (59%).⁶⁶ While this audit examined primary care records, harms that occurred in either primary or secondary care were counted.

Another team from England collected anonymous self-report data from staff at 10 general practices. 940 errors were recorded in a two-week period. The overall error rate was 76 per 1,000 appointments or 8%. 42% of errors were related to prescriptions, but only 6% of these were medication errors. 30% of all errors were communication errors and 3% were clinical errors.⁶⁷

Also 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. The data related to 69,682 registered patients from 25 primary care practices, consisting of 680,866 consultations. Injuries due to surgical and medical care were detected in 0.72 cases per 1,000 consultations, and adverse drug reactions were detected at a rate of 1.26 reactions per 1,000 consultations.⁶⁸ Overall, this equates to less than 1%.

More subjective approaches tend to find higher harm rates. Researchers in the USA described errors identified by GPs. After each of 351 patient visits, 15 doctors from seven practices were asked to identify process errors and preventable adverse events. Follow-up interviews were conducted. GPs said they had made an error in 24% of visits. However, it is important to note that doctors may not have been aware that they had made an error so would find this type of reporting difficult. Individual doctors also defined errors and harm differently. For example, there was disagreement about whether to include emotional discomfort and wasted time as patient harm.⁶⁹

Another subjective approach involves questioning patients. In a survey of 1,697 patients from seven primary care practices in the USA, 16% said that a doctor had made a mistake. 13% reported a wrong diagnosis and 13% reported a wrong treatment. 14% said they had changed doctors because of a mistake.⁷⁰

As detailed in the next section, the ‘harms’ outlined in most studies include medication events, process errors, and knowledge and skills issues.^{71,72} 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.⁷³ Similar studies with children are also available.⁷⁴ These estimates of harm due to lack of appropriate care include preventative, community, primary and hospital care, so the rates are not strictly relevant for estimating harm in primary care. However, these studies highlight an important point about the potentially diverse ways of defining harm.

Severity of harm

There are also studies of the extent to which events in primary care are harmful. An analysis of significant event reports submitted in Scotland over an 18-month period found that 25% described patient harm and 57% of reports outlined circumstances that had the potential to cause patient harm.⁷⁵

Researchers in England assessed harm in five primary care practices based on adverse event reports. 17% of reports had serious patient consequences, including one death. 76% had the potential for serious patient harm.⁷⁶

Similarly, a study in the Netherlands examined harm caused by adverse events in primary care. Two general practices took part. GPs reported adverse events and a retrospective audit of medical records was undertaken. Adverse events were wide ranging. About half did not have health consequences, but one-third led to worsening symptoms. Potential negative health consequences were likely in three-quarters of the events.⁷⁷

A voluntary prescribing error reporting system in seven primary care offices in the USA found that nearly 90% of errors did not reach the patient. 12% reached the patient without causing harm and 2% caused temporary harm requiring intervention.⁷⁸

Other US researchers found that clinical harm to the patient was reported in around 10% of the medical error reports analysed. Prescription-related errors were most frequently associated with clinical harm.⁷⁹

Another US study that asked doctors to report on whether they made errors after each consultation found that harm was believed to have occurred as a result of 24% of errors, and potential harm was apparent in another 70%. Most harm was believed to be minor.⁸⁰

The overall trend is for research to find that the majority of events or errors in primary care are not associated with patient harm – though there is potential for harm.

However, there are some discordant findings, suggesting the impacts could be more serious. Researchers in the USA used population-based data to examine adverse events occurring in ambulatory care that led to hospital admission. 14,700 hospital discharge records were reviewed. When weighted to the general population, 44% of discharges had an ambulatory care adverse event. Most occurred in GP offices (43%). 10% resulted in serious permanent injury or death.⁸¹

In another study, GPs in Australia, Canada, England, the Netherlands, New Zealand, and the USA anonymously reported errors in their practices over a seven-month period. Specific patient harm occurred in around 29% of errors.⁸²

An observational study found that GPs in the USA reported health, time and financial consequences in nearly 85% of their error reports. Care consequences included delayed diagnosis and treatment.⁸³

Prescribing errors

Studies about general adverse events or harms in primary care have often identified medication errors as a source of concern. In addition, several studies have specifically investigated adverse drug events in primary care.

The rate of prescribing errors in primary care has been estimated to be 11%,⁸⁴ though there is wide variation, with estimates ranging from less than 1% to almost 100%.⁸⁵ This variation may be partly because each study uses slightly different methods and definitions.

Researchers in the USA examined the frequency, types and causes of errors associated with outpatient computer-generated prescriptions. 3,850 computer-generated prescriptions received by a commercial pharmacy chain across three US states were analysed. 12% of prescriptions contained errors, of which 35% were considered potential adverse drug events. The most common error was omitted information (61% of all errors).⁸⁶

Other investigators in the USA examined medication errors reported by family doctors and their office staff. 194 medication errors were voluntarily reported by 440 primary care clinicians and staff from 52 practices. 70% of the medication errors were prescribing errors, 10% were documentation errors, 7% were dispensing errors and 3% were monitoring errors. Adverse drug events resulted from 16% of reported medication errors. Most did not harm patients.⁸⁷

Researchers in Spain investigated the prevalence and types of potential drug interactions in primary care patients. 430,525 electronic medical records were analysed. On a randomly chosen day, 29% of the population were taking medication. Of these, 74% were at risk of suffering interactions. Drug interactions were found in 21% of cases. People with long-term conditions, older people, women and people taking multiple medications were at greater risk.⁸⁸

Doctors and pharmacists in the Sudan were surveyed about medication errors and 2,000 prescriptions were reviewed. Only one prescription (0.1%) was considered ideal with no error encountered. 12% of prescriptions contained errors that might be serious to patients, 18% had errors of major importance, 7% had errors of minor importance and 10% contained trivial errors. 53% of prescriptions were free from errors but were incomplete, which could also lead to patient harm. 14% of prescriptions contained potential drug interactions.⁸⁹

Communication of prescribing information between primary and secondary care has also been found to be less than ideal. One study estimated that 50% of patients were failing to take the correct medicine one month after discharge, perhaps due to lack of partnership working between primary and secondary care.⁹⁰

3.2 Community pharmacy

In addition to studies about prescribing in primary care, some research is also available about rates of errors in community pharmacy.

Researchers in Denmark examined the frequency and seriousness of errors in 40 community pharmacies. The error rate was 23 per 10,000 prescriptions for prescription corrections, 1 per 10,000 for dispensing errors, and 2 per 10,000 for near misses. Most errors occurred in the transcription stage of the dispensing process. Most errors had no direct impact on patients.⁹¹

3.3 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%, 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 likely to engage with primary care more frequently than other age groups.⁹²

Another review of outcomes from after-hours care delivered by primary care cooperatives in the Netherlands found that the rate of patient safety incidents was 2% of all contacts, most of which did not result in harm to patients.⁹³

Researchers in the USA examined an after hours telephone family medicine service. 64 patients were interviewed. There were four instances (6%) of temporary physical harm. 3% of calls involved medical errors with potentially serious consequences to patient safety (wrong dose, serious illness not ruled out). 22% involved events that could have threatened patient safety. The authors concluded that situations that threaten patient safety occur frequently in after-hours telephone support services.⁹⁴

3.4 Other contexts

Studies from other contexts are also available. For example, in Switzerland, data from a walk-in clinic suggested that the prevalence of potential adverse drug interactions was 23%.⁹⁵

Care provided at home and in nursing homes has also been the subject of analysis.^{96,97} This type of care spans the bounds of community and primary care. While not strictly the 'first point of contact', care homes and domiciliary care fall under the remit of family practice teams in some countries, so examples of selected studies are included here.

Investigators in England examined the prevalence and potential harm of prescribing, monitoring, dispensing and administration errors in care homes. Errors from 55 care homes were identified by patient interview, note review, observation and examination of dispensed items. 70% of residents had one or more errors, with an average of two errors per resident. Most errors were not significantly harmful.⁹⁸

Researchers in the USA studied the incidence and preventability of adverse drug events and potential adverse drug events in 18 nursing homes over a one-year period. Potential drug-related incidents were detected by self-reports from nursing home staff and periodic review of records.

The adverse event rate was 1.89 per 100 resident months. The potential adverse drug event rate was 0.65 per 100 resident months. 51% of the adverse drug events were judged to be preventable, including 72% of the fatal, life-threatening or serious events.⁹⁹

Another US study assessed the incidence of, and risk factors for, adverse drug events in long-term care. Records for all residents of two long-term care facilities were analysed over a nine-month period. The overall rate of adverse drug events was 9.8 per 100 resident months. 42% were judged preventable, so the rate of preventable adverse drug events was 4.1 per 100 resident months. Preventable errors happened most often at the stages of ordering and monitoring. Those taking medications in several drug categories were at increased risk, as were those taking antipsychotic agents and anticoagulants.¹⁰⁰

Other researchers from the USA 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.¹⁰¹

Much further research has been undertaken in care homes but is not strictly 'primary care', so only a small sample of studies are described here.

3.5 Summary

- There is very little published evidence from which to draw conclusions about levels of patient harm in primary care.
- Estimates of harm in general practice range from less than 1% of consultations up to 24%. Taking a broad average across studies using the most robust methods, 1–2% of all consultations may include some form of adverse event.
- Around 11% of prescriptions written in primary care may contain an error. Variation is wide, with estimates from less than 1% to almost

100% – though the research has been conducted in widely varying contexts and using different definitions.

- In out-of-hours care, estimated error rates range from 2% to 6%.
- Most harm encountered is not severe.
- Older people are most likely to be affected by errors in primary care.

Tables 1 and 2 summarise seminal studies about harm in primary care.

Table 1: Estimated levels of overall harm in primary care

Research	Method	Country	Estimated harm rate
General practice			
Sandars and Esmail (2001) ¹⁰²	Systematic review	UK and international	Between 5 and 80 per 100,000 consultations; less than 1%
Rubin et al (2003) ¹⁰³	Staff self-report	England	76 per 1,000 consultations (or 7,600 per 100,000); 8%
Elder et al (2004) ¹⁰⁴	GP survey and interviews	USA	24% of consultations
de Wet and Bowie (2009) ¹⁰⁵	Trigger tool	Scotland	1 per 48 consultations (or 2,083 per 100,000 consultations); 2%
Tsang et al (2010) ¹⁰⁶	Computerised record review	England	0.72 cases of injury per 1,000 consultations 1.26 adverse drug reactions per 1,000 consultations; added together this comes to 198 per 100,000 or less than 1%
Walter et al (2010) ¹⁰⁷	Patient survey	USA	16% of patients
Out-of-hours care			
Killip et al (2007) ¹⁰⁸	Patient survey	USA	6% suffered temporary physical harm and 3% of calls involved potentially serious consequences
Smits et al (2010) ¹⁰⁹	Record review	The Netherlands	2% of consultations
Giesen et al (2011) ¹¹⁰	Record review	The Netherlands	2% of consultations

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

Table 2: Estimated levels of medication errors in primary care

Research	Method	Country	Adverse drug event rate
General practice			
Williams (2007) ¹¹¹	Review	Scotland	11% of prescriptions
Lopez-Picazo (2010) ¹¹²	Database analysis	Spain	21% of people taking medication
Nanji et al (2011) ¹¹³	Analysis of prescriptions	USA	12% of prescriptions
Yousif et al (2011) ¹¹⁴	Analysis of prescriptions	Sudan	47% of prescriptions
Community pharmacy			
Knudsen et al (2007) ¹¹⁵	Record review	USA	Up to 23 errors per 10,000 prescriptions (less than 1%)
Other contexts			
Gurwitz et al (2000) ¹¹⁶	Incident reporting and record review	USA	Adverse drug event rate of 1.89 per 100 resident months in nursing homes
Gurwitz et al (2005) ¹¹⁷	Record review	USA	9.8 adverse drug events per 100 resident months in long-term care
Dallenbach et al (2007) ¹¹⁸	Incident reports	Switzerland	23% of patients had potential adverse drug reactions in a walk-in clinic
Barber et al (2009) ¹¹⁹	Record review	England	70% of care home residents had at least one medication error

4 Sources of harm

Human factors, medication or care complexity and systems issues all contribute to harm in primary care. This section summarises research about the key sources of harm in primary care.

Research about the contributing factors to patient harm in primary care is scarce but generally mirrors the trends seen in hospital research. The research scan suggests that the three most common factors thought to contribute to adverse events are clinical complexity, system failures and human factors.¹²⁰

More complex taxonomies have also been developed. For instance, researchers in England developed a framework of patient safety in general practice using fieldwork and confidential reporting of patient safety events in five West Midlands practices. The taxonomy includes three classification levels. At level one, an information processing model of cognition is used to classify errors. At level two, immediate causes are identified, internal and external to the individual. At level three, more remote causal factors are classified, such as ‘work organisation’ and ‘technical’ aspects.¹²¹

An international study using data from GPs in Australia, Canada, the Netherlands, New Zealand, the UK and the USA also developed a taxonomy of errors in primary care. The final taxonomy was a five-level system encompassing 171 error types, including process errors and knowledge and skills errors.¹²²

4.1 Clinical issues

Issues related to clinical complexity that may impact on patient harm in primary care include:^{123–126}

- multiple medications
- complex conditions
- multiple conditions
- frailty.

A review mapped out the medication system in UK primary care. The map demonstrated that error rates are high. Several stages of the process had error rates of 50% or more: repeat prescribing reviews, interface prescribing, and communication and patient adherence. Only between 4% and 21% of patients achieved the optimum benefit from their medication.¹²⁷

Researchers in Bahrain examined prescribing errors related to cardiovascular and antidiabetic medications. An audit of 2,773 prescriptions issued by 194 GPs from 20 health centres was undertaken. About one-quarter of prescriptions contained errors. The most common error was prescribing beta blockers or diuretics to people on lipid-lowering drugs. There were a number of prescriptions for drugs that did the same thing.¹²⁸

A larger analysis in the USA described the types of errors that led to adverse drug events in more than 30,000 patients followed over a year-long period. Most errors leading to adverse events occurred when administering the medication (32%), modifying the medication regimen (42%), or not following clinical advice about medication use (22%). Errors most often involved hypoglycaemic medications (29%), cardiovascular medications (22%), anticoagulants (19%) or diuretics (10%).¹²⁹

4.2 Systems issues

A number of studies suggest that systems or organisational issues are major contributors to harm in primary care.¹³⁰⁻¹⁴¹

System failures and process issues which may contribute to patient harm include:

- poor communication between professionals
- poor communication with patients
- unclear lines of authority
- reliance on automated systems to prevent error
- inadequate systems to share information about errors, which hampers analysis of causes and improvement strategies
- increasing complications due to increasing patient demand
- cost-cutting measures
- fragmented reporting systems
- lack of coordination, including with secondary care
- thinking that action is being taken by other groups within the organisation
- drug names that look alike or sound alike
- environment and design factors
- infrastructure failure.

For instance, 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. 78 reports relevant to patient safety were analysed, including 21 (27%) adverse events and 50 (64%) near misses. Most reports related to administrative errors (26%). The most frequent contributing factor was work organisation, including excessive task demands (47%) and fragmentation (28%).¹⁴²

A web-based incident reporting system in Germany found that 73% of anonymous reports received were process errors and 26% were errors in knowledge or skills. The most frequently reported process errors were treatment errors (32%), communication errors (13%) and investigation errors (9%). 41% of errors were associated with harm to the patient.¹⁴³

Another study described the types, predictors and outcomes of testing errors reported in US primary care. Eight family practices reported events anonymously. Errors occurred in general administration (18%), ordering tests (13%), implementing tests (18%), reporting results to clinicians (25%), clinicians responding to results (7%), notifying patient of results (7%), communication (6%) and other categories (8%). Charting or filing errors accounted for 15% of errors.¹⁴⁴

Another US study examined reports to a primary care patient safety reporting system. Over a two-year period, 33 practices with a total of 475 staff participated. Of the reports analysed, 71% identified communication problems.¹⁴⁵

Researchers in the USA examined the link between organisational climate and errors in primary care. Feedback from 420 doctors found that a lack of emphasis on quality was associated with past errors, and a lack of emphasis on information and communication was associated with a higher likelihood of future errors.¹⁴⁶

Elsewhere in the USA, error reports were analysed from eight GP offices. 21% of reports of errors included efforts to mitigate. Mitigated events had lower odds of patient harm and negative consequences.¹⁴⁷ This suggests that the outcomes are better when there are systems in place to identify and address potential harm.

As well as sources of harm within primary care itself, links and interfaces with other services may be important. A systematic review with 55 observational studies and 18 controlled studies examined the prevalence of deficits in communication and information transfer at hospital discharge. There was little direct communication between hospital and primary care doctors (3% to 20%). Discharge summaries were not usually provided immediately or up to one month later. This affected the quality of care in approximately 25% of primary care follow up visits. When provided, discharge summaries often omitted important information for primary care teams.¹⁴⁸

4.3 Human factors

Human factors that may impact on harm in primary care include.^{149–152}

- variations in the training and experience of health professionals
- fatigue
- depression and burnout, which impact on how team members cope with diverse patients, unfamiliar settings and time pressures
- inadequate training
- failure to acknowledge the prevalence and seriousness of harm and take steps to do something about it.

For example, researchers in Scotland examined 191 significant event analysis reports submitted by general practices over an 18-month period. Individual error was the most commonly cited reason for events (33%).¹⁵³

Researchers in New Zealand assessed how patients and primary care professionals perceive the relative importance of different patient errors. Interviews were conducted with 83 patients and primary care professionals. There was considerable variation regarding the perceived relative importance of different errors. Patients wanted professionals to grow relationships, enable patients and professionals to recognise and manage patient error, acknowledge shared capacity for change, and motivate patients to act together for patient safety.¹⁵⁴

In the USA, 38 patients were interviewed to help develop patient-focused typologies of medical errors and harms in primary care settings. Patients described 221 problematic incidents that mainly involved breakdowns in the clinician-patient relationship (37%) and access to clinicians (29%). The incidents were linked to 170 reported harms, 70% of which were psychological, including anger, frustration, belittlement, and loss of doctor-patient relationship and trust. Physical harms accounted for 23% and included pain, bruising, worsening medical condition and adverse drug reactions.¹⁵⁵

Other US investigators tested the value of the Dimensions of Medical Outcomes taxonomy to describe medical errors in primary care. 34 primary care practices reported medical errors to an incident reporting system. Four individual issues were most associated with harm, including language barriers and errors of judgment. Harm was also associated with communication from another office, mistimed procedures, medication errors and involvement of the treating clinician. Harm was generally not associated with incorrectly performed procedures, failure to perform procedures or general information flow within, into or out of the office.¹⁵⁶

Finally, a study of medication errors in care homes in England found that contributing factors included: doctors who were not accessible, did not know the residents and lacked information when prescribing; high workload and lack of medicines training among care home staff; drug round interruptions; lack of teamwork between the care home, practice and pharmacy; inefficient ordering systems; inaccurate medicine records and prevalence of verbal communication; and difficult to fill (and check) medication administration systems.¹⁵⁷

4.4 Summary

The literature suggests that individual and team factors, systems issues and clinical issues all play a part in causing harm in primary care. Studies vary in the weight that they place on each of these factors.

Key areas with heightened risk include communication within primary care teams, the interface between primary and secondary care, diagnostic tests and prescribing and medicines management.

5 Ongoing and unpublished work

As well as the published evidence base, there are also some ongoing studies and media stories about levels of harm in primary care.

5.1 Unpublished and ongoing work

The World Health Organization (WHO) has stated that quantifying errors in primary care is a priority as part of its broader safety initiatives.¹⁵⁸ Organisations such as the US Agency for Healthcare Research and Quality, Institute for Healthcare Improvement, Institute for Safe Medication Practices, Institute of Medicine, Veterans Affairs health system, WHO, NHS Scotland, Canadian Patient Safety Institute and the Australian Patient Safety Foundation all acknowledge the importance of improving safety in primary care, but few have ongoing research programmes in this area.

Most ongoing research or evaluation about error rates and patient safety at organisations such as the National Patient Safety Agency (NPSA), The King's Fund, the Nuffield Trust and the Department of Health focuses on secondary care. Ways to improve safety in primary care are being explored by a number of researchers, but few are focused on quantifying levels of harm in primary care or ways to measure errors.

An exception is the NHS Institute for Innovation and Improvement's primary care trigger tool. This is available online, but research evidence about its use or effectiveness is not publicly available.¹⁵⁹

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) regarding ideas about reducing harm in primary care, but concrete descriptions of ongoing or unpublished research are rare.

However, a number of researchers have published research protocols outlining plans for further research in this area. For example, the LINNAEUS collaboration is an international group of researchers investigating medical error in general practice in Australia, Canada, England, the Netherlands, New Zealand and the USA. The group has published some of its findings but further research and analysis is underway.¹⁶⁰

A team from the Netherlands is examining patient safety issues in general practices, out-of-hours primary care centres, dental practices, midwifery practices and allied healthcare practices. The focus is on determining the frequency, type, impact and causes of incidents found in the records of 1,000 primary care patients and the type, impact and causes of incidents reported by healthcare professionals.¹⁶¹

Another example comes from the Veterans Affairs health system in the USA, where researchers are examining the use of electronic communication, including for error reporting.¹⁶²

A team from the Bradford Royal Infirmary in England is undertaking a randomised trial of patient led training of junior doctors regarding patient safety. Although the focus is on the hospital context in the first instance, the researchers acknowledge that education of trainees spans the boundaries of primary and secondary care. Patients who have experienced a safety incident in the NHS are being recruited to receive training and then talk to small groups of junior doctors and medical trainees about their experiences. The aims are to increase awareness of patient safety issues among doctors, enhance reporting of errors, and improve practice.¹⁶³

Researchers in Spain have just launched an initiative studying whether adverse events analysis can be used as an educational tool to improve patient safety and culture in primary care. A randomised trial is underway with junior doctors.¹⁶⁴

These examples provide a flavour of the range of studies underway. They also emphasise the lack of research explicitly aiming to measure or quantify levels of harm in primary care. Although numerous authors and organisations suggest this is important, there seem to be few studies underway to address gaps in the knowledge base.

5.2 Media stories

A search of online news archives suggested that there was quite a bit of reporting about errors in primary care between 1995 and 2005, with a real peak in the early 2000s. After this time, stories reduced substantially. Most of the media coverage is US based, but available to UK readers online.

A number of articles have reported on the findings of various research studies into error rates in primary care,¹⁶⁵⁻¹⁷⁵ or ways to measure error in primary care.¹⁷⁶⁻¹⁷⁹

Some of the health-related press has featured stories about potential ways to reduce error in primary care.¹⁸⁰⁻¹⁸⁵

In the USA, some articles also focus on malpractice claims or the financial impact of errors on practitioners.^{186,187}

Few media reports in the UK have focused on specific medical errors in primary care or rates of error in primary care more generally. Stories are more commonly about medical error in hospital or in the transition between hospital and community care.

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 press.

6 Summary

6.1 Key points

Research about levels of harm in primary care is limited, but suggests an adverse event rate of around 1–2%. The prescribing error rate is thought to be about 11%.^{188–192}

This is a lower level of harm compared with that reported in hospital care. However, the number of people seen in primary care is much greater, so the absolute number of people harmed may be just as large or greater than in secondary care.

Around 90% of all healthcare appointments relate to primary care, so if 1% of these consultations encounters an error, that could have significant implications. However, the literature also suggests that most errors will not directly affect patients or cause harm.

It is difficult to state figures with any certainty given the wide variation in research findings. One of the reasons for varying estimates may be because the concepts of error and harm 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, or process issues that do not affect patients directly. A recent systematic review of definitions of adverse events used in primary care included 51 articles, eight reports and two books. The authors identified eight distinct commonly used definitions of medical error.¹⁹³ Another review found 25 different definitions of medical error.¹⁹⁴

It is also important to note that missed or delayed diagnoses and errors of omission may be difficult to spot, and little research focuses on these areas.

The most common way of measuring harm in primary care is self-report by clinicians, which has numerous potential biases. Record review using trigger tools or automated approaches is less common, as is asking patients about their experiences. The measurement methods used are likely to influence the varying results gained.

Although there is no consensus about the exact level of harm in primary care, there is more agreement about the sources of such harm. Most research focuses on systems issues, clinical and medication complexity, and human factors. It is thought that poor communication, within primary care and at the interface with secondary care, is a major contributor.

Given the potential quantity of harm and the lack of studies in this area, it is perhaps surprising that more research is not underway. Although a small number of trials and observational studies are currently being implemented, identifying harm in primary care seems to be less of a priority compared with hospital care for large-scale national and international research programmes. Seminal organisations state that reducing harm in primary care is a key priority, but there are few large-scale programmes being implemented to address this priority.

6.2 Caveats

When interpreting the findings of this research scan, it is important to bear in mind several caveats.

First, the research scan is not exhaustive. It presents examples of studies but does not purport to represent every study about levels of harm in primary care. 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.¹⁹⁵ As a generalisation, US studies were more likely to define adverse events 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, process issues 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 or to extrapolate harm rates.

There are some concerns over the quality of the studies included. A number of 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 bias because not all events may be recorded in patient notes, and the events most likely to be listed may be more significant or harmful. Researchers may perceive something as an event even if it was not seen as such by the clinical team or the patient themselves.

Feedback from professionals and patients suffers from potential recall bias and social desirability bias.

A small number of studies use observational methods, such as watching care provision 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 primary care settings such as dentistry and out-of-hours services. This means that the research scan focused primarily on general practice care. A lack of evidence about other settings does not mean that harm is more frequent in general practice, just that more research is available in this arena.

Despite these caveats, it is clear that while there is no consensus about the best ways to identify harm in primary care, there is agreement that this is an important issue requiring further investigation.

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We are here to inspire and create the space for people, teams, organisations and systems to make lasting improvements to health services.

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