

# The frequency and nature of medical error in primary care: understanding the diversity across studies

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**Background.** The identification and reduction of medical error has become a major priority for all health care providers, including primary care. Understanding the frequency and nature of medical error in primary care is a first step in developing a policy to reduce harm and improve patient safety. There has been scant research into this area.

**Objectives.** This review had two objectives; first, to identify the frequency and nature of error in primary care, and, secondly, to consider the possible causes for the diversity in the stated rates and nature of error in primary care.

**Methods.** Literature searches of English language studies identified in the National Patient Safety Foundation bibliography database, in Medline and in Embase were carried out. Studies that were relevant to the purpose of the study were included. Additional information was obtained from a specialist medico-legal database.

**Results.** Studies identified that medical error occurs between five and 80 times per 100 000 consultations, mainly related to the processes involved in diagnosis and treatment. Prescribing and prescription errors have been identified to occur in up to 11% of all prescriptions, mainly related to errors in dose. There are a wide variety of definitions and methods used to identify the frequency and nature of medical error. Incident reporting, systematic identification and medico-legal databases reveal differing aspects, and there are additional perspectives obtained from GPs, primary health care workers and patients.

**Conclusion.** An understanding of the true frequency and nature of medical error is complicated by the different definitions and methods used in the studies. Further research is warranted to understand the complex nature and causes of such errors that occur in primary care so that appropriate policy decisions to improve patient safety can be made.

**Keywords.** Family medicine, medical errors, primary health care.

## Introduction

The majority of people who have contact with health care providers will receive high quality care but, unfortunately, for some people, this care will actually harm them or be potentially harmful to them. The identification and reduction of harm has become a major priority for all health care providers, including the National Health Service, and although the main impetus has come from highly publicized adverse events in the secondary sector, there is now an increased focus on safety in primary care.<sup>1,2</sup>

In the UK, the Department of Health has started to implement a process to improve patient safety, a major component of which is a system to identify both the extent and nature of medical error in both primary and secondary care.<sup>3</sup> This process is expected to improve quality of health care by rectifying common and important causes of medical error.

Most experience of medical error has been gained from the secondary care environment, but little is known about the situation in primary care, where the majority of patient contacts with health care providers will occur.

This review had two aims: first, to identify the frequency and nature of error in primary care, and, secondly, to consider the possible causes of the diversity in the rates of error and types of error in primary care reported in different studies. Future policy to reduce error is dependent on fully understanding all of these factors. This

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should allow the development of appropriate methods to reduce error.

The review was conducted as part of a larger, and more comprehensive, review into the methods used to measure the frequency and nature of errors in primary care, which was commissioned by the Department of Health.

## Method

Information gathering was performed in July/August 2001 and included a variety of methods to ensure a comprehensive review. No limit was placed on year of publication but the search was limited to English language publications.

The National Patient Safety Foundation Bibliography (1939–2001) ([www.npsf.org](http://www.npsf.org)) was accessed and hand searched. This is a comprehensive database on patient safety that contains listings of articles and book chapters that have been abstracted from 503 journals, including specialist journals on error in non-health care industries. Medline (Ovid, 1966–2001) and Embase (Ovid, 1988–2001) were searched using the MeSH term Medical Errors and the text words adverse events, medical error, error, significant event, delayed diagnosis, sentinel event, root cause analysis and drug reaction. Each term was searched in combination with the MeSH terms Primary Health Care, Family Practice, Pharmacy and the text words general practice and practice nurse. These two additional text words were chosen to reflect the particular context of primary care in the UK.

The above database searches were combined and cross-referenced. A total of 452 separate references were identified, and 280 articles and book chapters were selected jointly by the authors on the basis of applicability to the objectives of the research. Articles were rejected if their main focus was on medical audit or quality of care rather than the identification and description of error. The authors made the decision to exclude these articles in an attempt to limit the number of studies, especially since the association between error, as described in error literature, and audit and quality is not clearly defined. No systematic review of medical error in primary care was identified. To ensure the reliability of the article selection process, the list of chosen articles was discussed with several relevant experts in the area of error in primary care, who agreed that no important studies had been omitted (full details in Acknowledgements).

In addition, the Medical Protection Society provided a non-published study from their primary care specialist medico-legal database. This article was also included in the review.

## Results

Eleven studies related to medical error in primary care were identified. A book chapter describing a further

four studies in The Netherlands was also identified: the four studies described in the book chapter were published originally in Dutch and therefore the original studies were not consulted; however, the authors of the studies had written the chapter, which was in English. A further relevant study was supplied from the Medical Protection Society's internal unpublished report.

The main features of the setting, definition and method to identify error are described in detail in Table 1.

### *Variables between the studies*

A large number of variables between the studies was noted. The variables that were identified included the following.

- (i) *Purpose of data collection in the study.* Studies were performed for a variety of purposes, ranging from those with the primary aim of identifying the frequency and nature of error, to that of medico-legal databases which identify only those errors that result in medico-legal action.
- (ii) *Settings.* The studies were performed in a variety of countries, mainly the USA, Australia and The Netherlands, with differing primary health care systems.
- (iii) *Definitions of error.* There were no consistent definitions of what constituted an 'error'. Some studies used a wider definition that encompassed actual and potential harm to patients, but others only considered those that caused actual harm, including those resulting in medico-legal action. The classification of harm was made by a variety of people, ranging from individual primary care doctors to community pharmacists.
- (iv) *Method of collecting data.* Most studies were opportunistic, relying on the identification of incidents by a variety of methods. These methods varied from critical incident reporting systems, both voluntary and mandatory, to recall of critical incidents. The incident rate was often extrapolated by the authors of the study. The only studies that attempted to be systematic were those using prescribing review, allowing an incident rate to be calculated.
- (v) *Classification of errors.* The classification of error varied between the studies. Several used predetermined categories, but others developed categories by an iterative process.

### *Frequency and nature of error*

Overall, the studies reported wide differences in rates of errors in primary care, varying from five to 80 per 100 000 consultations.<sup>4,5</sup> Errors related to diagnosis were consistently noted to be the most common category across all studies, varying from 26 to 78% of identified errors.<sup>4–12</sup> Errors associated with diagnosis, either delayed or missed, were most likely to result in major harm to the

TABLE 1 *The identified studies of error in primary care*

Setting	Definition of error	Method
Australian general practice <sup>4,6</sup>	“an unintended event, no matter how seemingly trivial or commonplace, that could have harmed or did harm a patient”	Non-random sample of 325 GPs Voluntary contemporaneous incident self-reporting on purpose-designed incident report form with free and fixed responses
US primary care clinics at an academic medical centre <sup>5</sup>	“incidents resulting in, or having a potential for, physical, emotional or financial liability to the patient”	Number of doctors not stated Anonymous mandatory reporting by all personnel. Events identified by a variety of methods, including patient complaints, medico-legal enquiries, observations by risk department and case conferences
US family physicians <sup>7</sup>	“an act or omission for which the physician felt responsible and which had serious or potentially serious consequences for the patient”	Random sample of 53 family physicians Qualitative semi-structured interviews
Netherlands general practice <sup>8</sup>	Not clearly defined Several studies described in book chapter, based on studies published by the authors in Dutch	Study 1: diagnosis compared with necropsy findings Study 2: qualitative open-ended interviews Study 3: analysis of coded morbidity data Study 4: self-reporting of one error per month
US family practice <sup>9</sup>	“that was something that should not happen in my practice, and I don’t want it to happen again”	50 doctors Self-report of incidents using paper cards and computer
Swedish primary care <sup>10</sup>	“neglect that lies within his or her line of responsibility”	187 district physicians Database of complaints, either from patient, relatives or Health Board
UK general practice <sup>11</sup>	“claims recently registered against General Medical Practitioners”	1000 consecutive registered claims on medical negligence insurance claims database
UK general practice <sup>12</sup>	“an event that is thought to be important in the life of the practice and which may offer some insight into the general care of the patient”	Case study of one primary health care team using significant event audit Qualitative interviews of core participants and observation of six significant event audit meetings
UK general practice and community pharmacists <sup>13</sup>	Opinion of community pharmacist and identification of “items which did not conform to the criteria for prescription writing stated in <i>British National Formulary</i> ”	Review of 15 916 prescriptions Identification by community pharmacist at dispensing and duplicate prescriptions written by eight GPs
UK community pharmacists <sup>14</sup>	1. “All potential adverse drug reactions” 2. Prescribing error “a change in the dose, strength or type of medication which was probably not intended by the prescribing doctor”	1. 64 406 dispensed items, community pharmacist review 2. 5906 prescribed items, community pharmacist review
UK community pharmacists <sup>15</sup>	“when a community pharmacist had to contact the prescriber during the dispensing process”	201 000 items dispensed, 14 community pharmacists Frequency recording
Netherlands community pharmacists <sup>16</sup>	“prescription modifications by community pharmacists”	47 374 prescriptions, 141 community pharmacists Frequency recording with validation by original prescription

patient or precipitate hospital admission, and were noted to be less preventable than those associated with other causes. The second most common category of error type related to treatment, either delayed or inappropriate, varying from 11 to 42% of identified errors. These errors were less likely to result in major harm to the patient and were noted to be more preventable.

Studies that tried to develop an understanding of the causes of error noted that the cause was often multiple and that in up to 50% no cause was identified.<sup>4–6,8</sup> Poor communication and co-ordination of care between health care professionals, both within primary care and between primary and secondary care, were identified

as being important in one large study.<sup>4,6</sup> Several studies noted difficulties in doctor–patient communication as an important cause of error.<sup>7,8</sup> The nature of these difficulties was not discussed. The physician as a contributory factor in the cause of error was noted in two studies. For example, tiredness or rushing by the physician was self-reported as a cause in 10% of errors.<sup>4</sup> In-depth qualitative interviews revealed a complex mix of up to eight causes per case, with identified errors stated to be related to an interaction between various factors in the physician and the patient, including stress in the physician, lack of appropriate management plan, not accepting limitations in expertise and respecting patient wishes, even when contrary to

their professional judgement.<sup>7</sup> The contribution of the patient to medical error was noted in three studies and was related to a poor doctor–patient relationship and demanding behaviour from the patient.<sup>7,8,11</sup> Overall, the studies included in the review noted that between 60 and 83% of all identified errors could be considered to be preventable.<sup>4,5,8</sup>

Systematic identification of prescription and prescribing errors has identified rates between <1 and 11% of all prescriptions.<sup>13–16</sup> All of the studies noted that most errors do not cause actual harm but are a potential threat to patient safety. All studies revealed that the most common errors are those concerning dose of medication, with the second most common concerning potential adverse drug interactions.

## Discussion

Research into the frequency and nature of error in primary care shows a marked diversity in the findings. Although a formal systematic review was not performed, the authors undertook a comprehensive literature search, and the findings were discussed with several relevant experts in the area of error in primary care to ensure that no significant studies were missed. Furthermore, a comprehensive review of patient safety in primary care, published after completion of the literature search, did not identify additional significant studies.<sup>17</sup>

Identification of possible reasons for diversity in the reported frequency and nature of errors is an essential step in developing an understanding of both the causation and prevention of error in primary care. This is a major current area of interest for policy makers. The frequency and nature of error in primary care appear to be closely inter-related; however, due to differences in the definition of the term ‘error’ and the methods used to identify error, research to date has revealed varying findings.

Most studies into error in primary care have relied on opportunistic incident reporting rather than a systematic approach that attempts to identify all episodes of error, similar to a screening process.<sup>4–6,8,9</sup> Incident reporting has the potential to identify errors that can cause, or potentially cause, harm to patients, and this approach has been used extensively in secondary care and non-health care settings.<sup>18</sup> However, all incident reporting can produce underestimates of the frequency of error. Indeed, in one study of US hospitalized patients, only 30% of adverse events in patients were reported.<sup>2,19</sup> Factors that contribute to under-reporting include the definition of an incident (whether producing actual or potential harm) and the system for reporting (documentation procedure, preservation of anonymity and degree of voluntary control).<sup>20</sup> None of the identified studies of incident reporting in primary care give an indication of the degree of under-reporting but, on the basis of similar research in secondary care and non-health care, it is likely that the

quoted frequency and incidence rates in primary care, both overall and for specific categories, are underestimates. In addition, the categorization of the types, causes and consequences of error obtained from incident reporting may not be a true reflection of the nature of error. There is wide variation across studies in the categorization procedure, e.g. some studies utilized predetermined categories whilst others used an iterative process developed after the reported incidents had been collected. Differences in categorization may have affected incident reporting as well, since reporters may have been uncertain as to which error type category incidents should be placed in.<sup>21</sup> Several studies showed that for up to 50% of identified errors, no cause was found. A possible explanation is that the reported event could not be easily placed into an error cause and/or error type category.

The only studies included in the review that used a systematic approach to the identification of the frequency and error in primary care were those that investigated error related to prescribing.<sup>12,14,16</sup> All of these studies identified higher rates of error than in the non-systematic incident reporting studies. As outlined above, this difference is likely to be due to the lower occurrence of reporting when a more opportunistic approach is used.

Error in primary care may be identified through medico-legal databases in which complaints and litigation are recorded.<sup>10,11</sup> However, errors that lead only to potential rather than actual patient harm are recorded on the databases. In particular, the events that are recorded are more likely to be those errors that produce major patient harm, such as death through highly inappropriate treatment. Finally, many complaints and malpractice claims are unrelated to medical error, meaning that, whilst medico-legal databases can provide useful and detailed information on medical error, they may produce unreliable estimates of the frequency and nature of error in primary care.

Further understanding of the nature of error may be assisted by considering a conceptual model of error developed following research into accident causation.<sup>22</sup> Errors that produce, or have the potential to produce, harm can be classified as ‘active’ or ‘latent’. Latent errors do not have a direct temporal relationship with an actual accident, but contribute or ‘shape’ intended plans or actions. In a medical context, a major latent component is the organizational characteristics of any primary care system, which will differ between countries. Differences in organizational characteristics may therefore contribute to creating differing reported frequencies and nature of error between different countries. Active errors usually are a direct precursor to the incident producing harm, or potential harm, and research into accident causation in aviation has highlighted the importance of ‘human factors’, such as fatigue, stress and over work.<sup>23</sup> Two studies used qualitative approaches to identify physician-reported factors that were associated with errors that produced harm, or potential harm, to patients.<sup>4,7</sup> The

findings of these self-report physician studies tended to support previous research in other fields in that fatigue and stress were again found to be important active causes of error.

Most of the studies included in the review relied on identification by physicians alone, yet the findings of these studies may be unreliable due to under-recognition of errors.<sup>24,25</sup> Only the studies considering prescription and prescribing errors used another health care professional (a community pharmacist) to identify error in primary care. Patient identification of error can be implied from medico-legal databases, but no specific studies were identified in which patients identified and reported errors. To maximize reliability of error reporting, it is beneficial to obtain data from a second reporter rather than relying on the physician alone.

This review highlights the major difficulties in attempting to understand the frequency and nature of error in primary care. The conceptual models of error suggest that a complete picture can only be obtained by taking a combination of approaches. Incident reporting, systematic identification and medico-legal databases will reveal differing aspects, and there will be additional perspectives obtained from GPs, primary health care workers and patients.

The setting up of a national database of medical error in primary care that can provide an estimate of the frequency and nature of error is being developed currently in the UK by the National Safety Patient Agency.<sup>3</sup> The purpose of this database is to identify and reduce error, but this incident reporting approach is very unlikely to identify the various 'human factors' and complex doctor-patient interactions that are associated with error. Another proposal suggests that there should be local reporting systems in an attempt to increase reporting, but again this approach is likely to result in significant under-reporting.<sup>26</sup> It is unknown whether implementing either national or local databases will actually improve patient safety in primary care.

The ultimate aim of research into the frequency and nature of error in primary care is to reduce harm and improve patient safety. This review identifies similar frequencies and aspects of the nature of error in primary care to those reported in a comprehensive review of safety in primary care published after this search was carried out.<sup>17</sup> However, this review discusses additional studies that emphasize the importance of 'human factors' and the complexity of doctor-patient interactions in the causation of error in primary care. These aspects require recognition if patient safety is to be improved. They are an integral part of the overall attempt to reduce error in primary care and are essential for the development of any policy in patient safety. The authors suggest that further research is warranted in order to fully understand the nature of error before we develop systems that may not actually reduce harm and improve patient safety in primary care. This call for further research is supported

by recent reviews of patient safety in both primary and secondary care.<sup>1,17</sup>

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