

# **THREATS TO PATIENT SAFETY IN PRIMARY CARE**

**A review of the research into the frequency  
and nature of error in primary care**

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# 1 SUMMARY

Research into the frequency and nature of threats to patient safety has received scant attention in primary care, especially in the UK. Existing studies have identified that such threats occur between 5 and 80 times per 100,000 consultations, mainly related to the processes involved in diagnosis and treatment but this is likely to be an underestimate. Prescribing and prescription errors have been identified to occur in up to 11 per cent of all prescriptions, mainly related to errors in dose. Most errors do not cause actual patient harm but have the potential to do so.

Opportunistic incident reporting is the most widely used method to identify error in both primary and secondary care. The main limitation is under-reporting but this can be maximised by ensuring that the system is voluntary, confidential, user friendly and gives feedback promptly. Regular prompting to report and the use of computers also increases reporting.

Case note review improves the data about frequency but is highly resource dependent and has not been studied in primary care. Experience in secondary care has also identified difficulties related to data retrieval and coding.

Understanding the nature of error is complex. This can be helped by investigating error in a systematic way, often using root cause analysis techniques. Quantitative methods, using databases of collected data, provides a useful, but superficial, approach to understanding why errors occur. Deeper understanding of the complexity of professional practice in primary care requires a qualitative approach but there has been little research.

The aim of all studies into medical error is to improve patient safety. Existing research has identified the importance of latent errors that are related to the underlying organisational structure and culture. Understanding and changing these factors has been little researched in primary care.

Short term priorities to improve patient safety include evaluating the pilot incident reporting scheme of the National Patient Safety Agency and to develop the use of existing mechanisms, such as significant event audit and index conditions from audit and quality improvement data. The role of community pharmacists is an important area to be researched in the medium term. Long term research is required to answer more fundamental questions on the frequency and nature of threats to patient safety in primary care, including why errors occur and how they can be minimised in the future.

## 2 BACKGROUND

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 the NHS and although the main impetus has come from highly publicised adverse events in the secondary sector there is now an increased focus on primary care<sup>1</sup>.

In the benchmark Harvard study of medical practice an adverse event occurred in 3.7% of admissions and subsequent analysis found that 69% of injuries were caused by errors<sup>2</sup>. Subsequent epidemiological studies in Australia and Utah have confirmed these findings in secondary care<sup>3,4</sup>. The consequences of such adverse events are enormous, with increased patient mortality and morbidity, health care costs and effects on health care staff.

The Department of Health has recently reviewed the extent and nature of adverse events in the NHS, with particular reference to how it may learn from such events to improve the quality of care that it provides. Most experience has been gained from secondary care where it can be expected that adverse events are more likely to occur in a complex organisational and technical environment. However, little is known about the situation in primary care where the majority of contacts with health care providers will occur. Learning from adverse events is a component of clinical governance and Primary Care Organisations will need to respond to this challenge<sup>5</sup>.

In response to the report by the expert group on learning from adverse events in the NHS, 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 adverse events in both primary and secondary care<sup>6</sup>.

### **3 PURPOSE AND SCOPE OF THE PROJECT**

This review on threats to patient safety in primary care was commissioned as a project by the Department of Health<sup>1</sup>.

The project had the following aims

- Identify the methods for measuring the frequency and nature of errors in primary care
- Summarise the error rates in primary care
- Provide recommendations for future research

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<sup>1</sup> Dr John Sandars reviewed the available literature and drafted the report. Dr Aneez Esmail negotiated with the DOH in commissioning the project, commented on the review and contributed to the final draft.

Competing interests: Dr Aneez Esmail is the Medical Adviser to The Shipman Inquiry and is the UK Chief Investigator of a multi-national study into threats to patient safety in Primary Care.

## 4 INFORMATION GATHERING

A systematic review of all the available literature was not performed due to the time constraints . However, an extensive and systematic approach was undertaken to review the literature.

The following databases were accessed in July/August 2001

Medline (Ovid – BMA library ) 1966 - 2001  
EMBASE (Ovid – BMA library) 1988 - 2001  
Aditus – NorthWest Knowledge Portal ([www.aditus.manchester.nhs.uk](http://www.aditus.manchester.nhs.uk))  
CINAHL  
British Nursing Index  
Nursing Standard  
HMIC  
PsychLit  
Yahoo – [www.yahoo.com](http://www.yahoo.com).

Key words used: adverse events, error, medical error, critical incident, significant event, drug reaction, delayed diagnosis, reflective practice, sentinel event, root cause analysis

Searched in combination with: primary care, general practice, family medicine, family practice, practice nurse, pharmacy

No limit was placed on year of publication but was limited to English language

Patient safety bibliography resource of National Patient Safety Foundation (NPSF - USA), 1939-2001 [www.npsf.org/](http://www.npsf.org/)

Patient safety bibliography resource of Agency for Healthcare Research and Quality (AHRQ -USA) Making Health Care Safer: A Critical Analysis of Patient Safety Practices Evidence Report No 43 1999 [www.ahrq.gov/clinic/ptsafety/](http://www.ahrq.gov/clinic/ptsafety/)

452 articles were identified and 280 articles and book chapters were read on the basis of applicability to the purpose and scope of the project

In addition, discussion with relevant experts was undertaken

Keith Haynes, Head of Risk Management Services, Medical Protection Society, Leeds

Professor Nick Boreham, Institute of Education, University of Stirling

Professor Alison Blenkinsopp, Professor of the Practice of Pharmacy, Department of Medicines, Keele University

Dr Gill Hawksworth, Community Pharmacist, Old Bank Chemist, Mirfield

Stuart Emslie, Head of Controls Assurance, Department of Health, London

#### Acknowledgements

Professor Martin Roland, Director of National Primary Care Research and Development Centre, University of Manchester, for his helpful comments

Steve Glover and Jane Russell, Medical Librarians, The Christie Hospital, Manchester for obtaining the references

## 5 INTRODUCTION

A search of the relevant literature identified two closely interrelated concepts that must be understood if there is to be a thorough appreciation of error in primary care.

- **The frequency of errors** Identification of the true frequency requires a systematic process, similar to a mass screening programme for disease identification. Surveys have tried to capture the frequency in a hospital population, often by targeting specific groups, such as those receiving medication. However, such surveys are highly resource dependent and opportunistic programmes have been widely introduced, including primary care. Incident reporting, a type of opportunistic screening, does not give a true population frequency since it is limited to those incidents that are reported.
- **The nature of error** The definition of an “error” will determine what is identified and what constitutes an error varies considerably across various studies. To fully understand why errors occur, which is essential for preventing such errors in the future, requires some form of classification but this again varies considerably.

Overall, the studies that describe the frequency and nature of error have been performed for specific purposes and audiences. There are few studies that have been performed in primary care but experience in secondary health care and other disciplines can provide valuable insights.

## **6 REVIEW OF STUDIES IN PRIMARY CARE**

### **6.1 Introduction**

Only a small number of studies were identified that had researched threats to patient safety in a primary care setting. These studies are described in detail since they not only provide information about the frequency and nature of error but illustrate the various methodological approaches used to produce this information.

### **6.2 Summary of studies**

The studies have demonstrated that threats to patient safety occur in a primary care setting, ranging from 5 to 80 per 100,000 consultations. Most threats do not result in actual patient harm and the threats mainly occur in the young and old. These rates are likely to be an underestimate since they have been identified opportunistically. The cause of these threats was often due to multiple inter-related factors but the commonest factors appear to be related to diagnosis (range 26-78%) and treatment (11-42%). Contributory factors are often related to lack of coordination or communication between the various health care providers and difficulties in making professional judgements. The important contribution of the patient and practice staff to error is also noted

Individual doctors tend to recall more significant threats to patient safety, especially those that have a contributory cause that is related to significant human factors in the doctor, such as fatigue.

Systematic identification of prescription and prescribing errors has identified rates between less than one to 11 per cent of all prescriptions. Most errors do not cause actual harm but are a potential threat to patient safety. The most common error concerns dose of medication. The important role of the community pharmacist in the identification and rectification of error is noted.

### 6.3 Threats to patient safety during care

<b>Setting</b>	<b>Australian General Practice</b> 1993-1995 <sup>7</sup>
<b>Definition of event producing harm or potential harm</b>	“an unintended event, no matter how seemingly trivial or com harm a patient”
<b>Method</b>	<p>Non-random sample of 325 GPs</p> <p>Voluntary, anonymous and contemporaneous self-report of inc report form</p> <p>Form records free text descriptions of the incident, its consequ the outcome and GP’s opinion on its preventability. Also fixed contributing and mitigating factors, potential for harm, immedi outcomes</p>
<b>Main findings</b>	<p>805 incidents received Quantitative analysis for all incidents:</p> <p><b>Patients</b> Higher rates of incidents in women older than 75 years and inf</p> <p><b>Incidents</b></p> <ul style="list-style-type: none"> <li>• Pharmacological eg drug inappropriate or prescribing e</li> <li>• Non-pharmacological eg treatment omitted/delayed</li> <li>• Diagnostic eg missed or delayed</li> <li>• Equipment eg malfunction/ineffective</li> </ul> <p>Overlap between non-pharmacological and diagnostic in 79 in</p> <p>GPs considered that 76% preventable and 11% unpreventable</p> <p>Pharmacological incidents were largely considered preventable long term. However, diagnostic incidents were less preventable reported, 30 involved a diagnostic incident</p> <p><b>Mitigating and contributing factors:</b></p> <p>Incident outcomes more frequently mitigated by chance factor: procedures. Frequent contributing factors cited were ineffective healthcare services and actions or involvement of others involv 100 incidents) Another cluster was assessment –related mistak recognise significant signs and symptoms (rates of 15 per 100 GPs reported being tired or rushed in 10% of incidents. No association noted between specific contributing factors and</p> <p><b>Qualitative analysis identified 4 broad groups:</b></p> <ul style="list-style-type: none"> <li>• Communication problems, including doctor-patient cor</li> </ul>

	<p>providers and unclear medical records</p> <ul style="list-style-type: none"> <li>• Procedural problems, especially failure to check medication, inadequate history and examination in order to develop</li> <li>• Clinical problems eg inappropriate drug or treatment choices</li> <li>• External problems eg equipment failure or actions of other factors included patient misunderstanding.</li> </ul>
<p><b>Comment</b></p>	<p>No attempt at “saturation” (until no new incident types were recorded)  No record of number of consultations. However, authors estimate number of incidents performed during the study period, resulting in an approximate 10% incidence.  Relies on voluntary self-reporting by participants; authors acknowledge limitations.</p> <p>A sub group analysis was performed on a subset of 219 GPs and used to identify how diagnostic incidents occur and to consider prevention of such incidents<sup>8</sup>.</p>

<b>Setting</b>	<b>US Primary Care Clinics at an academic medical c</b> Includes family practice and internal medicine, paediatric med 1991-1996 <sup>9</sup>
<b>Definition of event producing harm or potential harm</b>	“incidents resulting in, or having the potential for, physical, en patient”
<b>Method</b>	<p>Number of doctors not stated</p> <p>Reporting of incidents anonymous and mandatory by all perso a variety of other methods, including patient complaints, medi management department and case conferences</p> <p>Identification of incidents entered onto a risk-management dat These include only incidents that resulted in an injury, a poter patient</p> <p>All incidents reviewed independently by two family physician associated with medical management or an environmental haz management categorised into one of four types:</p> <ul style="list-style-type: none"> <li>• Diagnostic</li> <li>• Treatment</li> <li>• Preventive</li> <li>• Other</li> <li>•</li> </ul> <p>Any differences between reviewers were discussed with the tv to case notes and the original investigation findings</p>
<b>Main findings</b>	<p>Total of 51 incidents identified Prevalence of incidents 5.4 per 100,000 clinic visits</p> <p>68.6% of incidents were due to an adverse event and 13.7% att as tripping over in the car park</p> <p>In only 47% of incidents was there an agreement on error class</p> <p>83% of the adverse events were judged to be the result of prev environmental hazard</p> <ul style="list-style-type: none"> <li>• Diagnostic           26%</li> <li>• Treatment           11%</li> <li>• Preventive           0%</li> <li>• others               25.7%</li> </ul> <p>Of the 29 incidents attributed to medical error, there was one c and 6 temporary delays in recovery</p>
<b>Comment</b>	No systematic gathering of incidents - authors state that only the risk-management office were entered on the database

<b>Setting</b>	<b>US Family Physicians</b> 1992-1993 <sup>10</sup> .
<b>Definition of event producing harm or potential harm</b>	“an act or omission for which the physician felt responsible serious consequences for the patient”
<b>Method</b>	Random sample of 53 family physicians  Qualitative interviews – semi structured with open-ended and a sequence of closed-ended items. Interview schedule based on findings from initial focus groups Individual audio-taped interviews performed by one interviewer
<b>Main findings</b>	53 errors identified <ul style="list-style-type: none"> <li>• Delayed or missed diagnosis <ul style="list-style-type: none"> <li>Cancer</li> <li>Myocardial infarction</li> <li>Trauma</li> <li>Bowel obstruction</li> <li>Meningitis</li> </ul> </li> <li>• Surgical mishaps</li> <li>• Obstetric mishaps</li> <li>• Medical treatment mishaps</li> <li>• Contraindicated drugs</li> </ul> <p>Most patients sustained a severe adverse outcome, including disability (6 cases) No adverse outcome was noted in 14 cases</p> <p><b>Causes of errors stated:</b></p> <p>A mean of 8 causes per case</p> <ul style="list-style-type: none"> <li>• Physician stressors <ul style="list-style-type: none"> <li>eg Hurried, sense of being distracted, misled by advice or family, underestimate seriousness of illness</li> </ul> </li> <li>• Process-of-care factors <ul style="list-style-type: none"> <li>eg too focussed on one diagnostic or treatment plan, no lack adequate follow up plan</li> </ul> </li> <li>• Patient-related factors <ul style="list-style-type: none"> <li>eg misled by normal findings, attributed to considering</li> </ul> </li> <li>• Physician characteristics <ul style="list-style-type: none"> <li>eg lack of medical knowledge, not accepting limitations, interaction</li> </ul> </li> </ul>
<b>Comment</b>	The average number of years in practice of the physicians over a professional lifetime per physician was 10.7, with 1 in death

<b>Setting</b>	<b>Netherlands General Practice</b> 1978-1994 <sup>11</sup>
<b>Definition of event producing harm or potential harm</b>	<p><b>Several studies reviewed</b></p> <p>Study 1: Comparison with necropsy findings</p> <p>Study 2: Self categorised statements</p> <p>Study 3: ICPC codes A-85 (adverse effect medical agent p surgery/ medical complications)</p> <p>Study 4: Not stated</p>
<b>Methods used in different studies</b>	<p>Study 1: Necropsy findings considered by group of GPs stated</p> <p>Study 2: Open-ended interviews with 17 GPs to identify the subsequent means of dealing with them</p> <p>Study 3: Analysis of general practice morbidity data regis</p> <p>Study 4: Self reporting of one error per month to identify c</p> <p>Number of cases or participants not stated</p>

<p><b>Main findings of the different studies</b></p>	<p>Study 1: “a portion of deaths (estimates) ranged from just a portion contributed to by physicians”</p> <p>Study 2: 16 GPs provided “over 100 examples” of errors  14 cited errors with fatal or disabling consequences  GPs applied the term “error” if “the patient is affected by a condition that contravened professional regulations”</p> <p>GPs distinguished four types of errors</p> <ul style="list-style-type: none"> <li>iMedical-technical eg practice is contrary to regulations</li> <li>iRelational eg failure of social conduct/ communication</li> <li>iCarelessness eg under influence of alcohol or drugs</li> <li>iIncorrect decisions, apparent only in hindsight</li> </ul> <p>67 cases cited, most with serious consequences</p> <ul style="list-style-type: none"> <li>• Faulty diagnosis in 78 %, especially in elderly and children with fevers</li> <li>• In 43% of the cases the patient died as a consequence of the illness not treated</li> </ul> <p>Study 3: In 2% of diagnoses the categories were associated with “complications”</p> <p>Study 4: 39 errors were identified and most had multiple causes  Most frequent were</p> <ul style="list-style-type: none"> <li>• 25 cases “communication with patient”</li> <li>• 25 cases “attitude of GP” (fatigue/irritability)</li> <li>• 12 cases “failure to use or incorrect use of equipment”</li> </ul>
<p><b>Comment</b></p>	<p>These studies were published in Dutch but were discussed in the original studies</p> <p>Comments by the study GPs emphasise the nature of general practice, such as initial patient contacts, such as advice over the phone, emergency care, etc. During the diagnosis phase the GP relies on probabilities, own experience, and equipment, and this process is dependent on a working doctor. The doctor is often reluctant to refer for specialist advice. The treatment phase may be problematic.</p>

<b>Setting</b>	<b>US Family Practice</b> 2000 <sup>12</sup>
<b>Definition of event producing harm or potential harm</b>	“ that was something that should not have happen in my practice again” Such an error may be small or large, administrative or clinical
<b>Method</b>	Members of National Network for Family Practice and Primary Care 50 doctors Self report of incidents using paper cards and computer Research objectives <ul style="list-style-type: none"> <li>To develop a taxonomy of errors in family practice</li> <li>To determine whether the mode of data transfer will affect error rates</li> </ul>
<b>Main findings</b>	Approximately 5% of avoidable errors directly precipitate : <p><b>Types of errors</b></p> <ul style="list-style-type: none"> <li>Process problem 34%</li> <li>Clinical judgement 32%</li> <li>Interspeciality communication 15%</li> <li>Medication error 13%</li> <li>Ordered care not provided 3%</li> <li>Charting error 3%</li> </ul> <p><b>Actual consequences</b></p> <ul style="list-style-type: none"> <li>None 50%</li> <li>Delayed care 20%</li> <li>Worsening illness 10%</li> <li>Patient upset 10%</li> <li>Other 10%</li> </ul>
<b>Comment</b>	The total number of reported errors not stated

<b>Setting</b>	<b>Sweden Primary Care 1987-1988</b> (Kriisa, I. Swedish <i>Quality Assurance in Health Care</i> 1990; 2, 329-334)
<b>Definition of event producing harm or potential harm</b>	“neglect that lies within his or her line of responsibility”
<b>Method</b>	184 complaints concerning 187 district physicians Review of complaints made to the National Board of Health
<b>Main findings</b>	Majority of complaints made by patient (59%) , occasional remainder from patient relatives <p><b>Reason for complaint</b></p> <ul style="list-style-type: none"> <li>Erroneous diagnosis or treatment, 58%</li> <li>Including delay 12%</li> <li>Administrative error/certification 11%</li> <li>Wrong medicine 14%</li> <li>Treated impolitely</li> </ul> <p><b>Reprimands included:</b></p> <ul style="list-style-type: none"> <li>Undiagnosed epiglottitis in adult 3 cases</li> <li>Pneumothorax from shoulder injection 2 cases</li> </ul>

	<p>Vaccination without parental consent          Undiagnosed fracture          Underestimate need for help in elderly          Delay diagnosis – nephritic syndrome, carcinoma of kidney</p> <p>In addition, there were 36 complaints about clinic or district administration of medication (12 cases)</p>
<b>Comments</b>	Database of complaints made to a statutory body

<b>Setting</b>	<b>UK General Practice</b> 1996-2000 <sup>13</sup>
<b>Definition of event producing harm or potential harm</b>	“claims recently registered against General Medical Practitioners”
<b>Method</b>	1000 consecutive formally registered claims from 1 <sup>st</sup> July 1996 Codes assigned according to ICD-10 (International Classification of Diseases) and OPCS-4 (Office of Population Censuses and Surveys)
<b>Main findings</b>	<p>Largest category was Investigation and Treatment (63%), followed by</p> <p><b>In Investigation and Treatment</b></p> <ul style="list-style-type: none"> <li>• Failure/Delay Diagnosis 54%</li> <li>• Wrong Diagnosis 25%</li> </ul> <p>Largest category was malignant neoplasms, followed by dental injuries</p> <p>Subgroup analysis identified consistent trends, for example failure to examine and lack of appropriate examination</p> <p><b>In Prescribing</b></p> <p>Largest category was failure to warn or recognise drug side effects          prescribing errors          The main groups were steroids and antibiotic allergy</p> <p><b>Alleged failures on the part of GPs</b></p> <p>In 449 claims the main categories were related to failure/ delay</p> <ul style="list-style-type: none"> <li>• Hospital admission 118</li> <li>• Referral 116</li> <li>• Examine 69</li> </ul> <p><b>Administration errors</b></p> <ul style="list-style-type: none"> <li>• Present in 4.8% of claims</li> </ul> <p>The main categories were poor records, error in communication, error by other employee</p> <p><b>Practice Nurse error</b></p> <ul style="list-style-type: none"> <li>• Present in 3.2% of claims</li> </ul> <p>The main categories were related to an injection or blood test, failure to give inappropriate advice</p>

<b>Comments</b>	The data is based on a medico-legal database but there are in primary care
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<b>Setting</b>	<b>UK General Practice</b> 2000 <sup>14</sup>																				
<b>Definition of event producing harm or potential for harm</b>	“an event that is thought to be important in the life of the p into the general care of the practice” These events may be																				
<b>Method</b>	<p>Case –study of one primary health care team to observe the audit in a practice</p> <p>Three main types of data collection</p> <ul style="list-style-type: none"> <li>• Preliminary interview with 4 core Participants</li> <li>• Observation of six consecutive SEA meetings</li> <li>• Post –SEA interview and feedback session</li> </ul> <p>Data was analysed by thematic analysis</p>																				
<b>Main findings</b>	<p>The meetings were attended by a variety of primary health receptionists, nurses and physiotherapists Issues were pre:</p> <p>26 separate issues were discussed over 10 months in the si</p> <p><b>Events</b></p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td>Routine administration</td> <td style="text-align: right;">10</td> </tr> <tr> <td>Diagnosis/clinical management</td> <td style="text-align: right;">4</td> </tr> <tr> <td>Patients “hassling staff”</td> <td style="text-align: right;">4</td> </tr> <tr> <td>Clinical emergency management</td> <td style="text-align: right;">3</td> </tr> <tr> <td>Miscommunication</td> <td style="text-align: right;">3</td> </tr> <tr> <td>Patients rude to staff</td> <td style="text-align: right;">1</td> </tr> <tr> <td>Extra patients policy</td> <td style="text-align: right;">1</td> </tr> </table> <p><b>Outcomes</b></p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td>Immediate action</td> <td style="text-align: right;">33</td> </tr> <tr> <td>Conventional audit</td> <td style="text-align: right;">3</td> </tr> <tr> <td>Congratulations</td> <td style="text-align: right;">1</td> </tr> </table>	Routine administration	10	Diagnosis/clinical management	4	Patients “hassling staff”	4	Clinical emergency management	3	Miscommunication	3	Patients rude to staff	1	Extra patients policy	1	Immediate action	33	Conventional audit	3	Congratulations	1
Routine administration	10																				
Diagnosis/clinical management	4																				
Patients “hassling staff”	4																				
Clinical emergency management	3																				
Miscommunication	3																				
Patients rude to staff	1																				
Extra patients policy	1																				
Immediate action	33																				
Conventional audit	3																				
Congratulations	1																				

	Total of 62 separate solutions with agreed action plans
<b>Comments</b>	An opportunistic approach to identifying error

## 6.4 Threats to patient safety associated with medication use

<b>Setting</b>	<b>UK General Practices and Community Pharmacies 1985-1986<sup>15</sup></b>
<b>Definition of event producing harm or potential harm</b>	<ul style="list-style-type: none"> <li>• Opinion of community pharmacist. Not specified</li> <li>• Opinion of community pharmacist . Not specified</li> <li>• “items which did not conform to the criteria for pre National Formulary”</li> </ul>
<b>Method</b>	<ul style="list-style-type: none"> <li>• Frequency observation over 15 days - community prescriber’s intentions</li> <li>• Frequency observation - 3 months of community pharmacist prescription or return incomplete prescriptions</li> <li>• Frequency observation over 3 months – duplicate of prescriptions in three practices</li> </ul> <p>Trained staff identified errors and assessed potential</p>
<b>Main findings</b>	<p>Total 15, 916 prescriptions reviewed</p> <p>504 prescription errors</p> <ul style="list-style-type: none"> <li>• Dose error 42%</li> <li>• Pack quantity error 37%</li> <li>• Drug name error 8 %</li> <li>• Formulation error 11%</li> <li>• Non availability 2%</li> </ul> <p><b>Classification of errors:</b></p> <ul style="list-style-type: none"> <li>• Type A – potentially serious to patient 0</li> <li>• Type B - major nuisance 169</li> <li>• Type C – minor nuisance 273</li> <li>• Type D – trivial 62</li> </ul>
<b>Comment</b>	Prescription error rate 3%

<b>Setting</b>	<b>UK Community Pharmacists</b> 1977 – 1980 <sup>16</sup>
<b>Definition of event producing harm or potential harm</b>	1. “all potential adverse drug reactions – <ul style="list-style-type: none"> <li>• The prescription of a drug to which the patient had enough to warrant being told by a doctor to stop the</li> <li>• The prescription of two or more drugs known to int</li> <li>• Drugs used in certain groups in which they are cont</li> </ul> 2. Prescribing error “ a change in the dose, strength or type intended by the prescribing doctor”
<b>Method</b>	1,366 patients who had a pharmacist-held medication recor multiple drug therapy, long term medication, specific thera corticosteroid, cardiovascular, anti-inflammatory, antocoag  Method 1 <ul style="list-style-type: none"> <li>• Community pharmacist review, supported by literat</li> </ul> Method 2 <ul style="list-style-type: none"> <li>• Community pharmacist review, over first five mont</li> </ul>
<b>Main findings</b>	1. 86 potential ADRs in 64,406 dispensed items 76 prescription errors in 64,406 dispensed items  2. 640 items did not have dosage instructions in 5,906 iter
<b>Comment</b>	Rate of ADR 0.13 % Rate of prescription error 0.12% Rate of prescribing error 11%

<b>Setting</b>	<b>UK Community Pharmacists</b> 1987-1988 <sup>17</sup>
<b>Definition of event producing harm or potential harm</b>	“ when a community pharmacist had to contact the prescri except on issues other than legality or simple clarification c
<b>Method</b>	14 community pharmacists from 5 adjacent localities. Data recorded for one week of each month for a period of c Data recorded on reasons for contacting prescriber Multidisciplinary clinical panel assessed potential of each i patient’s clinical management and to prevent a drug relatec

<b>Main findings</b>	<p>During period covering one week per month over one year, were made out of 201, 000 items dispensed</p> <p>Clinical panel assessment of intervention by community ph</p> <ul style="list-style-type: none"> <li>• Between 19 (0.01% of the total items dispensed) at drug-related hospital admission</li> <li>• Between 71 (0.04 %) and 483 (0.24%) could have p</li> <li>• Between 103 (0.05%) and 364 (0.18%) had the pot intended therapeutic plan</li> <li>• 748 (0.37%) improved the clinical outcome and co</li> </ul>
<b>Comment</b>	Highlights the role of the community pharmacist during the

<b>Setting</b>	<b>Netherlands Community Pharmacists</b> 1999 <sup>18</sup>
<b>Definition of event producing harm or potential harm</b>	<p>“prescription modifications by community pharmacists” Reasons for modification, and inclusion in study, stated in authors)</p> <p>Protocol excluded certain modifications due to lack of pote administrative errors (eg errors with address or insurance d dose; product not in stock; legal requirements (eg for narcc</p>
<b>Method</b>	<p>141 community pharmacies, from a random selection of all ( 9% of total)</p> <p>Included all prescriptions for medicines and other health ce incontinence materials)</p> <p>Collection of data on a predetermined day in a specified p</p> <p>Data recorded in three groups</p> <ul style="list-style-type: none"> <li>• Clarification needed – usually essential administrat</li> <li>• “Correction prescription error” – administratively c consequences if not altered, eg “wrong dose”</li> <li>• Other causes</li> </ul> <p>All completed forms validated with copies of original presc</p>

<p><b>Main findings</b></p>	<p>Characteristics of participating pharmacies comparable to t pharmacies in Netherlands</p> <p>Overall incidence of modifications by the community phar 4.3% ( 2014 cases of 47,374 prescriptions) Mean number of prescription modifications per pharmacy 14.3 (range 0-100)</p> <p>Main therapeutic groups associated with modification: nerv alimentary tract and metabolism and cardiovascular system</p> <p>Pharmacist consulted prescriber in 15.6% of cases, rest bei their representative</p> <p>Main reasons for modification:</p> <ul style="list-style-type: none"> <li>• Clarification needed 71.8%</li> <li>• Correction prescription error 22.2%</li> </ul> <p>Similar rates for modification in young and old patients bu between</p>
<p><b>Comment</b></p>	<p>Specific and selected cases that were identified as an error</p>

## **6.5 Comment on methodology**

A large number of variables between the studies were noted, making comparison difficult. These variables were:

### **1 Purpose of data collection in the study**

Studies were performed for a variety of purposes, ranging from an attempt to identify the nature of medical error to that of an administrative medico-legal database.

### **2 Settings**

The studies were performed in a variety of countries, mainly the USA, Australia and the Netherlands, where different health care systems to the UK are in operation.

### **3 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 by a variety of people, ranging from individual GPs to community pharmacists.

### **4 Method of collecting data**

Most studies were opportunistic, relying on the identification of incidents. The only studies that attempted to be systematic were those using prescribing review, allowing an incident rate to be calculated.

### **5 Classification of errors**

The depth of understanding of the causes of error varied across the studies. Most studies identified simple classifications but more intensive interviews allowed a deeper insight into causation.

Despite these difficulties, the studies provide a valuable overall insight into the frequency and nature of error in primary care.

# **7 UNDERSTANDING THREATS TO PATIENT SAFETY: METHODOLOGICAL CONSIDERATIONS**

## **7.1 Introduction**

An understanding of both the frequency and nature of error requires a method that identifies error and then analyses the frequency and nature. These are separate processes but they are closely inter-related. Some of the available methods have been noted earlier in the studies of error in primary care but an appreciation of the strengths and weaknesses is essential if an understanding is to be developed. These insights can be obtained from consideration of the available methods used in other areas of medicine and industry.

## **7.2 Identification of error**

### **7.2.1 Opportunistic incident reporting**

#### **Background**

The concept of critical incident monitoring and reporting arose from studies in the Aviation Psychology Program of the United States Air Force during and after the Second World War<sup>19</sup>. Since that time the technique has been applied within a variety of industries, ranging from aviation to petrochemical processing<sup>20;21</sup>. It is recognised that there is a continuum of incidents, from apparently trivial incidents to near misses and full blown adverse events. Major adverse events, or sentinel events, rarely occur but “precursor events” or near misses occur more often. Studies of commercial aviation have shown that safety incidents associated with such near misses are very similar to those associated with full-blown disasters.

#### **Experience of Incident Monitoring in Intensive Care Units**

A comprehensive system for the identification and analysis of adverse events in the intensive care environment has been developed in Australia. It is useful to consider this system since the development and evaluation have been extensively researched and there are useful lessons to be learned for primary care.

In 1993 the system was piloted in three intensive care units and was designed to be non-threatening to all staff<sup>22</sup>. An incident was defined as “any event or outcome which could have reduced, or did reduce, the safety margin for the patient”. Information about an incident was gathered anonymously from staff involved in an incident using an Incident Report form. This form was designed to include a narrative section to elicit a description of the incident in the reporter’s own words, and a multiple choice section to elicit contextual details about the incident regarding type of incident, predisposing and limiting factors, staff and patient factors, patient outcome and suggestive corrective strategies. All staff, medical and nursing, was introduced to the concept of incident reporting and there was continuous support from a local coordinator, in addition to a resource manual. The incident forms were freely available and were returned to a locked deposit box. Patient and staff confidentiality was ensured by excluding personal

identification information from the report forms. One hundred and twenty-nine incidents were reported and 90% of participants showed a “positive attitude” to the incident monitoring system.

The Australian Incident Monitoring Study in the intensive care unit (AIMS-ICU) was subsequently established nationally and the first year of reporting was studied<sup>23</sup>. Seven ICUs contributed 536 reports which identified 610 incidents, providing an insight into the nature of incidents. National reporting of data provides information related to wider practices and professional issues but at the heart of the system is a local facilitated group review meeting to suggest preventive strategies and explore national study findings. Ongoing momentum of the project is assisted by regular local staff newsletters and poster displays.

### **Experience with a prototype medical event-reporting system for transfusion medicine**

A prototype system was designed, developed and implemented in six centres in the US<sup>24</sup>. The process was achieved through an interdisciplinary consensus development approach, using a three round Delphi method, in which twenty-three experts in safety from a variety of fields identified the ideal design parameters of a medical event-reporting system. These parameters were:

- Overall

No adverse consequences are attributed to the reporter

All errors reported, including no-harm or near miss events

Input solicited from all those involved in the event

- System input

Ability to track back from the reported error to the root cause

Identify the specific procedures involved

- Data collection

Allow further contact with reporters for data clarification, while maintaining anonymity

Make blank report forms available to all who might wish to report events

Emphasise narrative descriptions of events

Use adaptable on-line computer system for easy reporting

Have a trained system operator with knowledge of domain to receive reports

- Analytical process

Look beyond a single event to the entire system

Categorise events into where they occurred in the process

Categorise events using an accepted error categorisation approach

Identify common problem areas across centres

- Intervention

Find underlying system failures by analysis of all errors

Make recommendations based upon error analysis to decision makers

Target problem areas prone to error for additional study

Track implemented corrective actions to determine their effectiveness

Develop intervention strategies by multidisciplinary groups

An operational prototype of the medical event-reporting system was developed with seven major functional components:

- 1 Detection
- 2 Selection
- 3 Description
- 4 Classification
- 5 Computation
- 6 Interpretation
- 7 Local evaluation

**1 Detection** The individual who discovers an event completes a discovery form, which states where and when an event was discovered, the event's consequences (if known), the reasons for the event and the actions taken to minimise the adverse consequences of the event. The reporting individual need not have been involved in the event. The discovery form is submitted to a "systems operator", as used in the Aviation Safety Reporting System, who reviews and investigates the reported events.

**2 Selection** The system operator determines whether the event is new or in some way unique, in which case an expanded root cause investigation is performed. For routine events a causal code is assigned. All information on the form is scanned directly into the computer

**3 Description and Classification** An important feature of the system is the common classification of all events. The Eindhoven Classification Model, (Medical Version), developed by van der Schaaf was selected. This model uses an error classification that identifies latent (organisational and technical) errors and active (human factors) errors.

**4 Computation** The large amount of multifactorial data would be likely to create difficulties in comparison across centres but was resolved by grouping events into a combination of condition-specific and centre-specific categories.

**5 Interpretation and evaluation** A preliminary classification/action matrix allows interpretation at both national and local levels, resulting in appropriate interventions.

### **Experience from non-medical near miss reporting systems**

The experiences in aviation, aerospace, petrochemical processing, nuclear power and radio pharmaceutical industries have been identified by a literature review and interviews with key individuals and experts involved in reporting systems<sup>25</sup>. Several common themes were identified from the 12 incident reporting systems that were studied:

1. There was a variety of nomenclature in the definitions used to describe adverse events.
2. Seven systems were mandated and implemented by federal government but with voluntary participation
3. Ten systems were confidential, the other two anonymous
4. Some offered legal protection to those reporting incidents
5. Near misses occur 3-300 times more often than adverse events, allowing quantitative analysis

6. Fewer barriers to data collection exist, allowing analysis of interrelations of small failures
7. Hindsight bias was reduced
8. Recovery strategies can be studied

## **Discussion**

The above studies on incident monitoring provide valuable insights into the features associated with successful systems but also some of the dilemmas. Many of these features are closely inter-related:

### **1 Reporting participation: mandatory versus voluntary**

All incident reporting is to an extent voluntary – incidents have to be identified and reported by free-willed individuals and both types of reporting systems are subject to under-reporting. After reviewing the incident reporting systems present in health care in the US, The Institute of Medicine recommended complementary mandatory incident reporting systems and voluntary near miss reporting systems<sup>26</sup>. Mandatory systems are usually related to accountability and receive reports on errors that resulted in serious harm or death, tend to receive reports from organisations and may release information to the public. In contrast, voluntary systems have a focus on safety improvement and may receive reports from organisations or frontline practitioners, are more likely to be confidential and report near misses. Near misses provide an opportunity to identify “cracks” in the system which may lead to major adverse events.

Mandatory systems have not been successful in gaining compliance with reporting requirements and often little action is taken unless significant numbers of harmful events have been reported. There is an implication that an individual is at fault, yet analysis of most serious errors reveals multiple system failures and the involvement of many individuals.

### **2 Provision of anonymity versus confidentiality**

The main objective of any incident reporting system is to gather information about the frequency and nature of adverse events but often a major reason for not reporting adverse events is fear. This fear is multidimensional, including fear of embarrassment, fear of punishment and fear of litigation. Voluntary reporting systems provide an opportunity for frontline practitioners to tell the complete story without retribution but this can only occur if there is an assurance that they will not be blamed or subject to litigation. Confidentiality, where information will not be disclosed outside the system, appears to be a pre-requisite for any system. There is also a strong case for anonymous reporting in which individuals do not have to identify themselves or others<sup>27</sup>. However, experience in Australia with many thousands of anonymous reports shows that many who file anonymous reports are quite happy to own up to them at quality assurance meetings with peers. This concept of anonymity has been challenged as being undesirable<sup>28</sup>. Analysts cannot contact reporters to obtain more information and it may be difficult to guarantee anonymity. A system of anonymous incident reporting also does not confer a special privilege to doctors since it does not replace existing legal or disciplinary procedures.

### **3 Definitions of adverse events**

There is no uniform nomenclature and this can be a major barrier to incident reporting, creating uncertainty on what type of incidents to report but also affecting any data analysis<sup>29</sup>. The detection of incidents that have both produced or have the potential to produce harm requires clear definitions. In An organisation with a memory an adverse health care event and a health care near miss are clearly defined<sup>1</sup>:

“ An adverse health care event is an event or omission arising during clinical care and causing physical or psychological injury to a patient.”

“ A health care near miss is a situation in which an event or omission, or a sequence of events or omissions, arising during clinical care fails to develop further, whether or not as the result of compensating action, thus preventing injury to a patient”.

These definitions have been simplified for the Department of Health pilot studies on incident reporting, yet still recognising the important distinctions<sup>30</sup>.

An adverse patient incident is “any event or circumstance that could have or did lead to unintended or unexpected harm, loss or damage”. If the incident resulted in harm, loss or damage then an “adverse event” has occurred, but if no such consequence occurred it is called a “near miss”.

#### **4 Reporting and documentation of incidents**

The reporting of incidents is an obvious pre-requisite for any incident monitoring system. It is generally accepted that in all systems there is underreporting. In a study of two UK obstetric units less than a quarter of designated incidents were reported<sup>31</sup>. A questionnaire to explore the reasons for low rates of reporting identified that although most staff knew about the incident reporting system, almost 30% did not know how to find a list of reportable incidents and there was considerable variation in their views of when they would report an incident. The main reasons for not reporting were fears that other staff members would be blamed, high workload and the belief that the circumstances or outcome of a particular case did not warrant a report. Similar findings have been described in incident reporting schemes in the US in which 30% of all adverse events in patients were not reported<sup>32</sup>. In Taiwan 82% of needle stick injuries were non reported, especially by medical staff, with the stated explanation that they were too busy or unaware of the reporting requirement or mechanism<sup>33</sup>.

Most incident reporting systems maintain two methods for documenting incident reports, a paper incident report system and a computerised database. A paper incident system can have problems associated with legibility of forms, confidentiality/security, misplacement of forms and delays in resolving the reported incident after it had been reported. A study comparing a point of service computerised system with a paper incident reporting system identified several advantages for the point of service system<sup>34</sup>. The benefits included real-time information and trending of occurrences, reduced liability by securing reports earlier, earlier problem resolution and maintaining a higher level of confidentiality.

#### **5 Classification and analysis of incidents**

Incident analysis ought to uncover what happened in an incident occurrence, how it happened and, most importantly, why it happened. However, most incident analysis approaches only record the “what” and “how” of an incident occurrence.

Research into adverse incidents in other disciplines has shown that incidents are typically not caused by a single, unique factor but by a complex combination of

conditions and events<sup>35</sup>. Any incident occurrence is precipitated by a number of factors that can be organised into a “causal tree”. These causal factors are organised into a hierarchy, with factors immediately preceding the incident (also called “active failures”) and those further removed from the incident (also called “latent failures”). A complete understanding of “how” an incident occurred can only be achieved by identifying both active and latent failures. This deeper understanding can be achieved by incident analysis, provided that there are methods to classify incidents, and this is the first step to develop a corrective strategy to prevent the occurrence of further incidents.

(a) Narrative description of incidents is a feature of most incident reporting systems but requires classification prior to analysis. This can be achieved by using existing classifications such as ICD-9 and the Read system but they have been found to be unsuitable for this purpose<sup>29</sup>. The Australian Incident Monitoring Study (AIMS) identified the salient features of a large number of incidents by placing them into “natural categories”. A “Generic Occurrence Classification” was developed through an iterative process from over 2000 incidents and 800 adverse events<sup>36</sup>.

(b) Categories for classification can be used as a multiple choice section on incident reporting forms. This approach has been used in both the Australian Incident Monitoring Study (AIMS-ICU) and incorporated into the prototype medical-event reporting system in blood transfusion. The AIMS-ICU reporting form has a series of short questions which only require a tick response. The questions cover details about the patient, the personnel involved, when and where the incident happened, the factors contributing to the incident and the factors limiting the effect of the incident. The factors contributing to the incident are further subdivided into system based factors and human factors, with a categorisation devised from psychological research<sup>37</sup>. The prototype medical –event reporting system uses the Eindhoven Classification Model for Medical Domain which was developed from the same research and uses a similar categorisation system<sup>38</sup>. An incident reporting system in a US community hospital has been described that uses context-sensitive coding to allow extensive data to be captured about an incident<sup>39</sup>. The user assigns a category to the incident and then picks applicable subcategories.

There has been a plea that there should be a “consumer (patient)-centeredness” to the development of these categories but no studies adopting this approach were identified<sup>40</sup>.

## **6 Feedback of findings to produce change**

The ultimate aim of any incident reporting system is to learn from the incidents to prevent them happening again, thereby improving quality of patient care. An important factor is the time required for feedback<sup>26</sup>. Increased timeliness to achieve rectification of the incident has been demonstrated in a US community hospital using a computerised incident reporting system<sup>39</sup>. A longitudinal study of incident reporting in an anaesthetic department in Hong Kong revealed no decrease in potentially preventable incidents or the number of reported contributing factors, either latent or active<sup>41</sup>. However, in many high risk fields such as nuclear power technology, aviation and petrochemical processing it has been shown that implementing incident reporting systems for near misses can benefit the organisation and be cost effective<sup>42;43</sup>. The reasons for no apparent benefit are complex and poorly understood.

## **Approaches to maximise incident reporting**

## **1 Prompting by peer group**

An attempt to increase identification and reporting of incidents was studied in 1997 at a US hospital<sup>44</sup>. The hospital had an incident reporting scheme but in addition each doctor was regularly interviewed by a peer group member to identify adverse, and potentially adverse events. The trained interviewer clarified contributory and background factors to the event. During the study period, the hospital incident reporting system identified 58 incidents but the doctors reported to the peer interviewer 100 incidents. Only one of the doctor identified events was reported to the hospital. The most commonly described process of care events were inadequate evaluation of the patient and failure to monitor or follow up. These findings are similar to those in a US anaesthetics department in which 71% of adverse events were identified by the doctors and discussed at a regular peer group meeting and only 9.1% by the hospital incident report system<sup>45</sup>. One different study noted that only 30% of adverse events were reported on hospital incident reports and these were mainly the more serious events<sup>41</sup>. In conclusion, prompted recall of adverse events by a supportive peer group appears to be useful to increase identification and reporting.

## **2 Prompting by computer dialogue**

A computer program was developed in a US hospital that was able to flag admissions that previous research had shown to be associated with an adverse event, such as readmission within 31 days or more than one visit to the operating room<sup>46</sup>. At the time of discharge, the doctor who had cared for the patient in hospital noted whether the incident was expected or unexpected. The study showed that this use of screens was a useful tool for identifying adverse events, with a positive predictive value of 87%. However, in a review of generic adverse event screening, including clinical and administrative events, the authors noted that to be effective it required multiple screens and a sophisticated computer system<sup>47</sup>.

## **Conclusion**

The use of adverse event incident reporting has been used extensively in a variety of medical and non-medical settings but there is little research in a primary care setting. Under-reporting of adverse events appears to be the main problem with incident reporting systems (ranging from 30 to 80%) and this is associated with several interrelated factors. Reporting can be maximised by ensuring that the system becomes part of the organisational culture and that barriers to reporting are minimised. This can be achieved by encouraging all near-misses to be voluntarily reported in an environment which is free from reprisal and that concentrates on identifying underlying system defects rather than individual error. All members of staff can be involved but there is a need for regular prompting to report incidents and a mechanism that is both simple and soon after the event. The importance of local review meetings to plan actions to remedy identified problems is emphasised but there is also a role for national databases that can identify trends and allow policy to be developed.

### **7.2.1.1 Significant event audit**

## **Background**

Traditional medical audit uses quantitative methods to identify shortfalls in quality of care following the setting of acceptable standards. In significant event audit, individual cases in which there has been a significant event are systematically analysed to identify points that provide opportunities from which lessons can be learnt about the overall quality of care<sup>48</sup>. The process of significant event audit can be undertaken in a series of steps :

- 1 Consideration of the events to be audited
- 2 Collect data on these events
- 3 Hold a meeting to discuss the events
- 4 Documentation

This process can be regarded as a “mini incident reporting system” in which adverse incidents are identified, made sense of and then actions taken to prevent similar occurrences in the future.

Significant event audit has been proposed as an important part of clinical governance in any practice<sup>49</sup>. Doctors intuitively appear to be receptive to the use of anecdotes as learning points and significant event audit has been quickly accepted into the culture of general practice, both by individual practices and throughout primary care organisations. It has also been enthusiastically proposed as a method for identifying learning needs in the development of personal development plans, a cornerstone for continuing professional development and accreditation<sup>50</sup>.

### **The process of significant event audit**<sup>48</sup>

The process follows a well described step-wise procedure:

**1 Consideration of significant events** The definition is wide-ranging, “any event thought by anyone in the team to be significant in the care of patients or the conduct of the practice”. All practice members are encouraged to identify significant events, including those that have positive aspects in addition to those that have adverse aspects. It has been suggested that practices begin with a core list of events, including the areas of preventive care, acute care, chronic disease management and practice organisation.

**2 Data collection** Mechanisms for identifying and reporting significant events are developed in the practice. This is usually achieved by the completion of a pre-designed form.

**3 Significant event meetings** It is recognised that the heart of significant event auditing is the meeting held to discuss events. The meeting allows discussion of what happened and why, considers the implications of the event on the quality of care being provided by the practice but, most importantly, there is the development of a clear action plan. The result may be that there is no change required to current practice or procedures, congratulations may be due to the team, a conventional audit may be required to ascertain the extent of the problem or immediate action may be required to prevent the event occurring again. Subsequent follow up is clearly a feature if the process is to be considered as an audit, rectifying identified shortfalls in care.

**4 Documentation** Keeping a record of the salient points and the action plan is considered a key component of significant event audit. This record is usually regarded as being confidential and anonymous. If agencies outside the individual practice require information, such as for clinical governance or continuing professional development, then only minimal information is given.

### **The strengths and weaknesses of significant event audit as a method for the identification of adverse events in primary care**

In a study of 10 practices that had commenced significant event audit, 8 had introduced it as part of regular practice meetings and 9 expressed satisfaction with the process and considered it to be enjoyable and educational<sup>51</sup>. A large variety of events were identified by practices, ranging from failure to early diagnose cancer to non-recording of telephone prescription request. Significant event audit becomes part of the established clinical governance activity of the practice and all primary care team members are actively involved in the process. The identified events are of immediate concern to the individual practice and patients, they are discussed within the primary care team and appropriate changes are instituted in the practice.

A particular strength is the development of an organisational culture in which safety becomes a focus. The perceptions of a range of primary care staff who had been involved in practice-based significant event audit highlighted the difficult balance of factors that both help and hinder this process. These factors were essentially those required for effective multi-disciplinary team work and would equally apply to other situations, such as root cause analysis. The authors emphasised that significant event audit was a powerful team building exercise, an essential requisite for delivering high quality primary health care<sup>52</sup>.

### **Conclusion**

Significant event audit combines identification of adverse events with analysis and rectification in an easily accessible form. A particular strength of the method is that it has already become part of the clinical governance programme in many practices and has been promoted by Primary Care Organisations. It has been well accepted and enables multidisciplinary working. There is little research into the use of the technique.

## **7.2.2 Systematic medical record review**

There is a need to estimate both the frequency and nature of “adverse events” that occur in patients during their contact with health care providers. Incident reporting has been regarded as underestimating the extent and since it is opportunistic there is no indication of the incidence in the population. This dilemma led researchers to develop two large studies that used “chart review” in which medical records were studied to reveal “adverse events”.

The Harvard Medical Practice Study (HMPS) studied 31,429 records from patients discharged from acute care hospitals in New York State in 1984<sup>2;53</sup>. This methodology was replicated in the Utah and Colorado Medical Practice Study (UTCOS) in 1992 with 14,565 patients<sup>4</sup>. In 1994 the Quality in Australian Health Care Study (QAHCS) was performed in New South Wales and South Australia<sup>3</sup>. This was a replica study to the HMPS in which 14,179 admissions were reviewed.

A five-fold difference in adverse event rates was noted between the studies, with 2.9% in UTCOS and 16.6% in QAHCS. The studies were reviewed with a step-by-step comparison of the methodology and five methodological differences have been noted

that accounted for some of the discrepancy between the studies<sup>54</sup>. Both studies used a two-stage chart review process in which a screening nurse review was followed by confirmatory physician review. The main methodological differences were:

- QAHCS nurse reviewers referred records that documented any link to a previous admission, whereas UTCOS imposed age-related time constraints
- QAHCS used a lower confidence threshold for defining medical causation
- QAHCS used two physician reviewers, whereas UTCOS used one
- QAHCS counted all adverse events associated with an index admission whereas UTCOS counted only those determining the annual incidence
- QAHCS included some types of events not included in UTCOS

All of the above methodological considerations are important if similar studies are to be replicated in primary care. Despite the identified methodological differences there is still a three-fold disparity in the rates. This may be due to the use of “generalist” reviewers in UTCOS but “specialist” in QAHCS. However, a study has shown that the reliability and validity of judgements concerning adverse events in medical records is comparable between trained lay-reviewers using explicit criteria and physicians<sup>55</sup>. Differences in what is recorded in the medical record and how it is recorded may also be important. The QAHCS had a quality improvement objective whereas UTCOS was designed to identify the likelihood of malpractice lawsuits.

In a US study of a hospital anaesthetic department which compared various methods of identifying adverse events, 71% of adverse events were identified by the staff themselves, 38% by medical record reviewers and 9.1% by incident reports<sup>45</sup>. Reporting by medical record reviewers appeared to be biased both by the severity of outcome and severity of patient illness, whereas incident reports tend to focus on human factors. Medical record reviewers were less likely to identify transient injuries and incidents in healthy patients.

### **Conclusion**

Review of medical records may provide greater identification of both the frequency and nature of adverse events and this systematic process is the only method that can give a reliable estimate of the true incidence. The resources required to reliably use this method are obviously considerable, both in time, training, staffing and financial costs. This method also assumes that data can easily be extracted from the record systems in primary care but there are over 30 different systems available, with different ease of access, and missing data is common. In a validation exercise, only 85 per cent of patients referred to hospital had their referral noted in the computer record<sup>56</sup>. Despite these difficulties, there is potential to use case note review, either with a sample or with target conditions, for example angina.

No studies were identified that used medical record review in studying error in primary care.

### **7.2.3 The use of medical audit and quality improvement data**

Medical audit has now become established as part of the regulatory and quality improvement systems in health care, both primary and secondary. Medical audit has been defined as “the attempt to improve the quality of medical care by measuring the performance of those providing that care, by considering the performance in relation to desired standards, and by improving on this performance”<sup>57</sup>. The GMC expects all doctors to undertake regular audit of their activities and this will be embodied in the revalidation requirements but it is also the foundation for clinical governance and the NHS framework for quality in health care.

There is already a large amount of audit in primary care but there has been little attention to its use in systematically detecting practitioner and system error. However, there is a huge potential for using existing systems of quality improvement and audit to identify, classify and reduce error in health care. A recent systematic review of quality of clinical care in general practice emphasises that in almost all studies the processes of care did not attain the standards set out in national guidelines or set by the researchers themselves<sup>58,58</sup>. For example, in the highest achieving practices, 49% of diabetic patients had had their fundi examined in the previous year.

Experience of introducing both error analysis and performance improvement into the usual medical audit system of a US hospital has been described<sup>59</sup>. The intervention consisted of expanding the scope of analysis to include both a simplified root cause analysis and a performance improvement discussion on each case. The reviewers were given 2-3 hours of in-house training to enable them to perform the root cause analysis which was focused on identifying any equipment, system or process problems that contributed to the error. Root cause analysis was typically performed using facilitated brain storm techniques, without additional data collection. The detection of system errors and the number of improvement projects per year were significantly improved. Promotion of a culture of patient safety was emphasised by the authors as being an important effect of the project.

The potential for learning through existing channels for medical audit include:

### **1 Identification of critical incidents**

This can include significant event audit but there are variants, such as practice mortality meetings. Some GPs and practices perform regular audits of all deaths, both within primary care but also in other settings. In one study 14 doctors identified 1263 deaths over a 40 month period<sup>60</sup>. Peer review within a supportive group revealed that 5% of the avoidable factors contributing to patient’s death were attributed to factors in the GP, including delayed referral, diagnosis and treatment.

There are certain methodological issues related to such audits. Background information may be difficult to obtain, especially since primary health care extensively interfaces with secondary care and other health care providers in the community. One study that tried to identify factors associated with stillbirths attempted to gather information from several sources, including detailed chart review of the medical records, interviews with the doctors involved and the mother<sup>61</sup>. Medical records were incomplete and there was suspicion, antagonism and defensive behaviour in the staff. It was estimated that about four months and 25 man hours were required to investigate each stillbirth.

### **2 Systematic identification by identifying shortfalls in the process of care**

The last few decades have seen an increasing use of standardised approaches to medical care in response to observed wide variation in clinical practice<sup>62</sup>. The reasons for such variation are complex but include an expanding evidence base for clinical practice and increased fragmentation of care across various health care providers. Standardisation of care ensures that cost-effective care can be consistently provided and that the process and outcomes can be evaluated by audit. This can be achieved by setting standards, such as in guidelines or care pathways.

Care pathways, also known as profiles of care and care protocols, have their origins in the engineering and project management technique of critical path analysis and were first applied in the late 1980's to the development of outcomes-based nursing case management tools<sup>63</sup>. The degree to which there is a formal documentation structure varies considerably and may only be expressed as critical stages contained within a guideline. The latter approach is more typical of that found in primary care.

Audit of care can identify areas of concern, either as actual adverse events or as potential adverse events. For example, in a study of hospital admissions for acute severe asthma it was possible to identify that serious management errors occurred very frequently, mostly being related to patient self-management behaviour<sup>64</sup>. Identified difficulties included a variety of social factors but it was also noted that there was a stated inability to contact GP, lack of medication and inappropriate advice had been given. However, no systematic root cause analysis was performed, precluding any deeper understanding of the phenomenon and development of strategies to avoid the same happening again. Effective change requires clear identification of the problem, especially the deeper latent errors that are embedded in the system.

The analysis of variant care requires an evaluation of both process and outcome. Identified shortfalls in care can be regarded as “critical incidents” which can then be investigated and analysed with available techniques, depending on severity, impact and potential for harm.

### **Example : GP referral for suspected colorectal cancer using care pathways**

In response to the finding that patients with most types of cancer in the UK often have more advanced disease at presentation than in other European countries, the Department of Health has introduced a series of performance indicators that specify standards in both primary and secondary care for the identification and early referral of suspected cancer<sup>65</sup>. Colorectal cancer is responsible for about 10 per cent of all new cases of cancer in the UK population overall, in one-fifth of patients it is treated as an emergency and it accounts for about 12% of all cancer deaths<sup>66</sup>. This example is chosen since it highlights a potential to both identify and understand the complex nature of medical error in primary care.

The care pathway has certain critical points: patient noticing symptoms, patient making decision to see GP, wait to see GP, assessment by GP and referral to specialist. Each point can be recorded, variations from accepted standards identified and causes noted. However, this process is complex and it is important that the numerous factors are appreciated. There is an absence of highly sensitive and predictive system clusters for gastrointestinal cancer which makes clinical diagnosis by the GP difficult<sup>67</sup>. Simply identifying that GPs do not refer patients early will give only a superficial active error

rate, whereas fuller investigation will reveal deeper latent causes. The information from case note audit may be incomplete<sup>68</sup>. This is important if such data is to be accepted and acted upon. A recent study in UK hospitals revealed that clinical outcome indicator data was often not perceived to be credible and feedback was not felt to be timely, in consequence it was not acted upon<sup>69</sup>.

### **Conclusion**

There is enormous potential to identify both the frequency and nature of errors in primary care by the use of existing quality improvement and audit data. This data is routinely collected by both individual practices and Primary Care Organisations and it is possible to investigate shortfalls in care by using a systematic process, such as root cause analysis. Priorities need to be established but certain key time-critical conditions, such as cancer referral, could provide important insights. Errors associated with delayed referral are often cited in the primary care studies of medical error.

No research was identified that described the use of such data in primary care.

### **7.2.4 The use of medicolegal and complaints databases**

Medical error is often highlighted through patient complaints and litigation. There are several problems associated with the use of such data. Most instances of adverse events do not result in complaints or malpractice claims and many complaints and malpractice claims are unrelated to error. However, such data is accessible, contains clinically detailed information and may hold lessons that can be learned. Often the information is about major adverse events, such as reported by the various defence organisations or the GMC.

Much of the data is held on confidential databases held by the various defence organisations and although it is periodically released to non-period members detailed analysis is not usually forthcoming, especially since the legal system encourages identification of negligent individuals rather than defective systems. A large US insurance carrier has analysed extensive claim data over a 13 year period for major high risk hospital specialities<sup>70</sup>. The database recorded detailed coding of patient management problems but also technical performance problems and communication problems between medical and nursing staff. This enabled trends and time comparisons both within and between specialities to be identified. A review of 50 malpractice claims made against optometrists identified important themes, especially misdiagnosis and management<sup>71</sup>. However, there is no record of analysis based on described root cause analysis models used to identify medical error.

A feature of current health care is the increased role of the consumer. Patient satisfaction of medical care is a measure of patient perception of the quality of that care and may be used as a way of opportunistically identifying adverse events, both actual and potential. However, like litigation claims there is no clear relationship between adverse events and complaints. In a content analysis of 342 letters of complaint it was impossible to determine in 29% the nature of the complaint or what action the complainant wanted<sup>72</sup>. Patient complaints do provide important insights into the care provided, especially giving an additional viewpoint. In a patient satisfaction survey of out of hours service there was greater dissatisfaction with deputising doctors and prolonged delays until a visit<sup>73</sup>. The authors acknowledge that satisfaction is related to

patient satisfaction rather than actual service provided but consumer quality is a key feature of any health care quality programme. It would appear that patient complaints offer areas to be targeted for further investigation and analysis.

The impact of litigation and patient complaints on doctors is often not appreciated. A survey of senior hospital clinicians in the UK highlighted the psychological effects experienced, including anger, distress and a feeling of being personally attacked<sup>74</sup>. The doctors also described the impact on clinical practice, but this was not always detrimental. Most had subsequently attempted to improve communication with patients and staff and to keep better records. Adverse consequences included loss of confidence and a desire to withdraw from clinical practice. The authors suggested that doctors should receive adequate support, especially from managers who the doctors often perceive are partly to blame for the incident.

### **Conclusion**

Learning from patient complaints and litigation can be a painful experience for both patients and health care professionals. However, these databases can offer valuable insights into error but there is over emphasis on actual harm, rather than potential harm, and many events are either very rare and dramatic, or trivial and related to compensation claims.

No published studies were identified that considered the impact on improving quality of care.

## **7.2.5 The use of direct observation**

The observation of doctor-patient interaction, and the assessment of quality of care, has utilised standardised patients who anonymously attend a doctor. Several studies have shown that such standardised patients can capture variation in clinical practice and are reproducible over time<sup>75;76</sup>. Objective criteria can be applied to specific tasks, such as history, examination and management plan, and the doctor can be assessed as to whether certain performance criteria are met or not. In a US outpatient primary care clinic it was demonstrated that standardised patients were significantly better than medical record review at identifying performance criteria<sup>77;78</sup>.

### **Conclusion**

There is potential for the use of this technique in identifying both the frequency and nature of error in primary care but it is labour intensive and costly. However, the principles are almost identical to those used in simulation exercises that are a feature in anaesthetics and airline pilot training<sup>21</sup>. The main use could be as a research tool to identify error in specific circumstances where a greater understanding of human factors is required, such as clinical decision making.

No studies were identified that specifically used this technique in error detection in primary care.

## 7.3 Analysis of error

### Background

Once an incident has been identified it is important to identify the cause, or more likely causes, so that action can be taken to avoid it happening again. This is the underpinning principle of the recent Department of Health guidance on learning from adverse events and also at the heart of sentinel event monitoring which is required for the accreditation of health care providers in the US<sup>1;6;79</sup>.

Finding, and eliminating, the root cause of a problem can be helped by a process called “root cause analysis”, a method extensively used in quality improvement processes in various industries<sup>80</sup>. Root cause analysis has been defined as “a structured investigation that aims to identify the true cause of a problem, and the actions necessary to eliminate it”<sup>81</sup>. A problem is often the result of multiple causes and these are at different “levels”. First level causes are those that directly lead to a problem but there are higher level causes that lead to the first level causes. The highest level cause of a problem is called the root cause and is the trigger to the cause-effect chain that creates the problem. Elimination of the root cause should stop similar problems from occurring again in the future.

Root cause analysis is a collective term that describes a wide range of tools and techniques. Several main types have been described, each having a specific role in the analysis and understanding of the problem :

- 1 Problem understanding
- 2 Possible cause generation and consensus reaching
- 3 Problem and cause data collection
- 4 Possible cause analysis
- 5 Cause –effect analysis

The choice will depend on several factors, including the seriousness of the problem, the available resources (mainly time and money) and the urgency required for action. A key determinant is likely to be the requirements of any regulatory body but the success is most likely to be linked to the motivation and skills of the people required to perform the technique.

#### (a) Proposed model by National Patient Safety Agency<sup>30</sup>

All incidents that are reported “in accordance with local arrangements” will be graded through a 3 step process:

**Step 1** The actual impact on patient(s) is identified, either as none, minor, moderate, major or catastrophic

**Step 2** The likelihood of recurrence of a similar incident “within your local organisation”

**Step 3** The most likely consequences of the incident if it does happen again.

Many of the grading assessments are subjective and it is recommended that the process is by consensus and appropriately trained individuals.

The result of this grading process is the identification of four categories: red, orange, yellow and green. Red, orange and yellow categories will be investigated further using full root cause analysis whereas green will be subject to aggregate review.

### **Incident investigation**

The scheme proposed by the National Patient Safety Agency follows the general guidance issued by the Health and Safety Executive. The underpinning principles are that all incident investigations should identify the reasons for substandard performance, identify underlying failures in systems, learn for incidents and make recommendations, implement improvement strategies and satisfy mandatory and reporting requirements. Five components are essential for any investigation:

1. Collect evidence Typically the sources of information and methods include direct observation, documentation and interviews. Each element is distinct but allows a wider overall view to be obtained.
2. Assembling and considering the evidence to determine causation There is an identification of both immediate and underlying causes, including human factors.
3. Comparing findings with relevant standards This stage compares the sequence of events with relevant standards, such as guidelines or protocols.
4. Drawing up an improvement strategy.
5. Implementing the improvement strategy and tracking progress.

The above scheme is recommended to be mandatory for all category red incidents and most orange and yellow incidents.

(b) A systematic process to investigate and analyse clinical incidents as been developed and utilised in UK hospitals<sup>82</sup>. The approach is research based and has a focus less on individuals and more on organisational factors. A particular feature of this model is that it adapts the available research to a health care setting and has produced a framework of factors influence clinical practice: institutional factors, organisational and management factors, work environment factors, team factors, individual (staff) factors, task factors and patient factors.

The investigation model starts by examining the chain of events that led to the adverse event. This process includes the identification of several steps:

- Care management problems These are the actions or omissions by staff in the process of care; care deviated beyond safe limits of practice and this deviation had a direct or indirect effect on the adverse outcome for the patient.
- Clinical context and patient factors
- Specific contributory factors
- General contributory factors

The authors state that model has been tested on over 40 incidents, notably obstetrics, anaesthetics and accident and emergency, and “the aim is to use clinical experience and expertise to the fullest extent”. Particular benefits of the model are described, enabling easier investigation, greater transparency and acceptance by staff. The requirement for formal training of investigators is emphasised.

(c) The requirement for a thorough root cause analysis for JCAHO accreditation standards in the US has seen the development of a variety of approaches, especially the use of software to aid the process<sup>26</sup>. Several authors note that the process to perform a root cause analysis takes several sessions, over several days and involving all members of the team. However, simpler approaches have been described in the literature and applied to health care.

(d) Several approaches used for root cause analysis in a pathology department are described and the authors emphasise that they should be performed as soon as possible after the incident (to avoid recall and hindsight bias) and with all the personnel involved in the incident so that all information is available<sup>83</sup>. The described techniques are:

- “Ask why 5 times” The simplest way to perform a root cause analysis is to ask “why?” five times
- Causal Tree The worst thing that happened, or almost happened, is placed at the top and is followed by the secondary causes until the root causes are identified. It is helpful to assign codes so that tracking and trending can be performed. The Eindhoven classification model for a medical domain, identifying both active and latent errors, provides a useful guide.
- Decision Table The use of this tool helps to prevent knee jerk reactions in response to identified root causes. The decision tree considers the severity levels of events and also the probability of recurrence and detectability of the event.

A difficulty with all root cause analysis is recall and hindsight bias. This psychological phenomenon has two important elements, cognitive factors and motivational factors<sup>84</sup>. Apparent random sequences of events can be forced with enough thought to become a logical, causal chain but there is also an element of preserving self-esteem, with the desire to be correct and competent. One study of nurses responses to severity dependent errors indicated that they responded atypically and tended to take responsibility for their actions<sup>85</sup>.

### **Conclusion**

Some form of analysis of data is essential if any inferences are going to be drawn about the frequency and nature of error. The method chosen will depend on the use being made, balancing breadth of coverage with depth of investigation. There are likely to be different requirements that depend on local and national priorities, with national priorities usually reflecting a regulatory function.

## **7.4 The relationship to professional judgement**

A clear understanding of each notion is essential for the full appreciation of why events that harm, or have the potential to harm patients, occur in the complexity that is

characteristic of primary care. The word “error” is a rather emotionally laden term, implying blame rather than simply representing any aspect of performance which, with hindsight, deviated from the ideal. The psychology of error highlights the inevitability of error within any human performance and that this is often highly “context bound”, in which performance is influenced by the nature of the task and the circumstances and environment in which it is being undertaken<sup>86</sup>.

In carrying out any action there is the setting of goals and intentions that drive performance<sup>87</sup>. An “error” is a flawed plan or action and occurs when the planned sequence fails to result in an intended outcome. Such errors can be divided into two major categories, “active” and “latent”. Research into errors in numerous industrial settings has highlighted the importance of latent errors. Active errors are usually immediate precursors to an incident and can be considered in three broad categories:

- 1. Knowledge-based errors** These are the result of forming the wrong intention, or making the wrong plan, and are due to inadequate knowledge or experience.
- 2. Rule-based errors** These errors involve the failure to apply a rule designed to avoid error or to apply a badly designed rule.
- 3. Skill –based errors (slips and lapses)** These are the result of “absent mindedness” and occur in highly skilled people who have a large repertoire of subconscious responses but who fail to monitor actions. The result is an action that was not intended.

Latent errors contribute or “shape” the intended plans and actions. Examples include the individual’s physiological state, working environmental conditions, training, working policies and procedures and socio-cultural factors.

The reality of professional practice is characterised by its complexity and the inability to apply neutral knowledge to such situations<sup>88</sup>. There are important implications, especially in primary care where undifferentiated problems often present, disease often presents at an early stage, patients often want to make major choices to suggested management plans and there is often the need to juggle the available resources<sup>89</sup>. Professional judgement, which lies at the heart of professional practice, is highly dependent on craft knowledge that has been acquired through professional practice. This is in contrast to technical knowledge that is often not regarded by practitioners as being relevant to the demands that they face.

Research into accident causation, especially in aviation and other high profile industries, has revealed the important contribution of “human factors” as a cause of active error<sup>35</sup>. It has been estimated that 90% of aviation accidents can be attributed to such factors. This does not mean that blame can be placed at individuals but that error is inevitable and systems need to be in place to prevent such errors. In medicine, and especially primary care, decisions are often made with incomplete knowledge of all the available facts, without all of the investigations, respecting patient preferences and little idea of the ultimate outcome. This is the reality of practising general practice.

To begin to understand the nature of error in primary care it is important that these “human factors” are identified. The exemplar studies of identifying adverse incidents show that the deeper aspects, such as practitioner fatigue or running late, can best be identified with a qualitative technique in which practitioners describe the reality of their world. Once such factors have been identified it is important to put changes into place but this is an equally difficult task since often it is not new knowledge that is required but more of a change in attitude. Reflective practice is one such method that combines these approaches.

### **Reflective practice and reflective practitioners**

The principle of reflective practice is the foundation of clinical supervision, a process that has been established as good practice in nursing and health visiting but little adopted within the medical profession<sup>90</sup>. Clinical supervision has been defined as “ a formal process of professional support and learning which enables professional individual practitioners to develop knowledge and competence, assume responsibility for their own practice and enhance consumer protection and the safety of care in complex clinical situations”<sup>91</sup>. Similar approaches have been applied to group peer review in psychiatry in which continuing professional development and quality improvement have been achieved by critical review of patient management<sup>92</sup>.

Important distinctions can be made between “single-loop” and “double-loop” learning<sup>93</sup>. It has been argued that lasting organisational change will only occur if the underlying values and beliefs of the individuals that make up that organisation are changed, otherwise there is perpetuation of practice<sup>94</sup>. This process of transformation is at the heart of organisational learning, a key objective of the proposed plans for learning from adverse events in the NHS<sup>1</sup>. Double loop learning, in which fundamental beliefs are challenged and changed, can only occur if individuals are working in an environment where they can candidly discuss their practice. The existing arrangements for clinical supervision recognise that a confidential and supportive, yet challenging, system is required . This existing process has the potential for identifying adverse events, identifying the root causes and learning from the event .

## **7.5 The use of local and national databases**

A database that logs all medical errors has an intuitive appeal, enabling analyses that can provide information on both the frequency and nature of errors, including trends over a period of time. This process would enable lessons to be learned and reduce medical error in the long term. The Department of Health has recognised the importance of such a process and plans to build on the existing systems used in health care, such as Confidential Enquiries into Maternal Death <sup>1</sup>. Experience in aviation has demonstrated the value of a voluntary incident reporting system that provides regular feedback of aggregated anonymous data <sup>21</sup>. A particular benefit appears to be the discussion of incidents associated with human factors<sup>95</sup>.

Experience in the use of databases that collect and analyse routine information in health care has mainly been gained by clinical epidemiologists and recently their role in medical error has been highlighted<sup>96,97</sup>. Valuable insights into how to organise large

databases, both mandatory and voluntary, have already been gained from other areas of health care.

A recent review of the conceptual and methodological considerations in setting up a database of medical error in primary care has highlighted some important considerations<sup>98</sup>.

- What is the objective of the database ? Incidents range from near-misses to major adverse events, with differing relative frequencies and importance as a threat to patient safety. There are enormous resource implications depending on what is recorded.
- Confidentiality and legal immunity
- Mandatory or voluntary reporting
- Reporting, analysis and feedback within Primary Care Organisations
- Reporting to National Databases

A model has recently been proposed by the National Patient Safety Agency that recognises these dimensions<sup>30</sup>.

### **Conclusion**

The importance of local and national databases of threats to patient safety have been recognised as a valuable tool for the identification of both the frequency and nature of error in primary care. There is possible conflict in the main objective of the database, although there is a large degree of overlap. There is a need for a mandatory database that can be used for local and national accountability purposes but there is also the need for a voluntary database that can be used to initiative change in the people and organisations involved in primary care.

No studies were identified that described or evaluated the experience of using a database on error in primary care.

## **8 THREATS TO PATIENT SAFETY AND MEDICATION USE IN PRIMARY CARE**

### **8.1 Introduction**

The frequency and nature of threats to patient safety associated with medication use has been separately considered because it has been subjected to intensive research in secondary care, especially in the US, and to a lesser extent in primary care. Important areas include the extensive, and often novel, use of information technology and the role of pharmacists. This research has highlighted the advantages and disadvantages of the various methods and there are many lessons that are relevant to the wider study of error in primary care but especially prescribing.

### **8.2 Background**

The number of items dispensed in primary care has steadily risen, reaching in 1996 an average of 9.9 items per person per year<sup>99</sup>. An average of 65% of all prescriptions were “repeats”, issued without a consultation. The potential for problems to occur with the use of medication is vast and in the US adverse drug reactions are estimated to be responsible for between 2.9% and 7.9% of hospital admissions<sup>100</sup>. There is no reason to suspect that the extent is lower in the UK. The Department of Health has recommended targets to reduce serious errors in drug administration, recognising the significant burden of patient morbidity and mortality<sup>6</sup>.

### **8.3 Definitions**

Definitions are important since without generally accepted definitions it is difficult to consistently identify problems and subsequently compare data across settings. There may be disagreement between individuals but individuals themselves may not appropriately regard incidents as being important<sup>101</sup>. The hospital-based Adverse Drug Event Prevention Study used the following consensus derived definitions<sup>100</sup>

- Adverse drug event This has been defined as any injury due to a medication. The event may be preventable or non-preventable, the latter is also called an adverse drug reaction.
- Medication error This is an error at any stage of the medication process, including ordering, dispensing, administering and monitoring.
- Potential adverse drug event This is an incident with potential for injury; all potential adverse drug reactions are medication errors.

Most medication errors do not result in an adverse drug event and in a US hospital study only 1% were found to result in an adverse drug event and 7% in a potential adverse drug event<sup>102</sup>.

## 8.4 Methods of identification

### Incident reporting

Spontaneous reporting of adverse drug events is a common method but it only identifies about 7% of adverse drug events<sup>103</sup>. Similar under-reporting also occurs in medication error incident reporting, ranging from 0.07% to 1%<sup>104</sup>. The reasons for non reporting are complex but the available research has identified certain factors:

- A questionnaire survey of Spanish physicians, both primary and secondary care, identified that the probability of reporting an adverse drug event increased with increasing volume of prescriptions and decreased with increasing patient load<sup>105</sup>. A smaller probability of reporting was associated with a belief that the adverse events are already known about, that it is nearly impossible to determine if the drug was responsible for the particular adverse event and that one case identified will not contribute to medical knowledge. Similar beliefs were obtained in a study of doctors, including GPs, from the Netherlands but they also stated that they were not aware of their obligation to report and did not know how to report adverse drug events<sup>106</sup>.
- An Australian study of hospital nurses identified several themes by self-report questionnaire and focus groups<sup>107</sup>. They were most likely to report medication incidents that were more serious to the patient but did not want identifying information collected about themselves, mainly for fear of repercussions. Similar findings were noted in a study of US hospital nurses in which 15 different potential barriers to reporting medication administration errors were identified<sup>108</sup>. These barriers were combined into 4 subscales: disagreement over what constitutes an error, the effort required to report, fear of reporting and the response by their administration.
- A comparison of an incident reporting system that assured anonymity and one that did not was studied in a Scottish hospital<sup>109</sup>. During the 3 month period 266 medication errors were reported in the anonymity system but only 1 in the other system.
- The importance of “ownership” of the reporting system was demonstrated in a US study in which a six fold increase in incident reporting was achieved by introducing a new system that was based on the ideas generated by a multidisciplinary group brainstorm<sup>110</sup>. Improvements included a change in name from “medication error” to “medication occurrence” and using an anonymously reported pre-categorised report card

Stimulated voluntary reporting has been used in an attempt to increase adverse drug event reporting. Methods include confidential interviews with paid peer-interviewers; over 100 events were reported verbally compared with only one report filed in the hospital incident reporting system<sup>111</sup>.

### **Retrospective medical record / chart review**

This method has been used in US hospital and outpatient settings and requires looking for problems related to medication use in the medical record by trained chart reviewers<sup>101</sup>. This requires extensive training, it is time consuming and costly. Only a very small proportion of events are actually recorded in the patient record and it relies on the ability of the reviewers to adequately perform the review<sup>112</sup>.

### **Prescription monitoring**

Medication prescribing errors can be identified by pharmacists reviewing copies of all prescriptions. Any queries are investigated by contact between the reviewer and the prescriber. This method has been used in a US hospital and a review of their experience over 9 years gives valuable insights into the extent and nature of medication errors<sup>113</sup>. There was an average of 2.87 errors per 1000 prescriptions, with 1 in 5 leading to severe and serious errors.

### **Computer monitoring**

An integrated US hospital information system has been used to identify potential adverse drug events by using multiple sources<sup>104</sup>. In addition to voluntary self-reporting there was automated detection by using various signals, such as discontinuation of medications, decreases in dosages, ordering of specific laboratory tests and specific laboratory test abnormalities. Each day a trained pharmacist investigated each incident and made a judgement as to whether there was an adverse, or potential adverse, drug event. This intensive approach identified 731 verified events in 648 patients, the majority of which were serious, but only 92 of these events were self-reported. The research identified the common clinical indicators of adverse drug events and the commonly associated drugs. Similar results were found when using a computerised database of abnormal laboratory tests in a German hospital<sup>114</sup>.

### **Detection by pharmacist review**

Community pharmacists are the usual dispenser of prescriptions issued in primary care and represent the final point at which prescribing errors can be identified and corrected. In a study of 89 community pharmacists across 5 states in the US a prescribing problem was identified in 1.9% of new prescriptions, and 1 in 4 had the potential for causing patient harm if the pharmacist had not intervened<sup>115</sup>. Often the problems are multiple but there are some general trends. Errors of omission, such as non specification of dose or quantity, account for 45% of errors, with errors of commission, such as incorrect dose or drug, in 36% and drug interactions in 7%.

Review of repeat medications by UK community pharmacists using the “brown bag” method, in which patients bring in their medications for review, identified in 12% of reviews problems that could potentially result in a hospital admission<sup>116</sup>. The highest clinical significance was associated with beta-blockers, NSAIDs and verapamil.

### **Patient reporting of prescription filling errors**

A US study of hospital outpatient dispensed prescriptions identified 323 errors over an 18 month period and 89% of prescription filling errors were identified at the time of patient contact rather than after the patient had left the pharmacy<sup>117</sup>.

### **Direct observation of medication errors**

This approach has been used for several years, mainly in the US, and utilises a researcher who accompanies nurses preparing and administering drugs<sup>101</sup>. Error rates varying between 1.6% and 24% have been noted, with the highest rates in nursing homes. A study of the validity and reliability of this method has been shown to be high.

### **The cost-effectiveness of the various methods**

A perceived advantage of incident reporting compared with the observation method is the lower cost. However, it has been noted that the time per patient required for the observation of 20 patients was significantly less than the time required per patient to complete and review an incident report<sup>118</sup>. The cost of completing and analysing one incident report has been estimated at \$ 6.71 (1979 figures.)<sup>119</sup>.

The main disadvantage of incident reporting is that they require error awareness and this results in marked under-reporting. In a study of 30 long term facilities in the US there was simultaneous direct observation, chart review and incident reporting. A mean error rate of 9.6% was noted by observation but chart review and incident reporting only identified a mean error rate of 0.2%<sup>118</sup>.

### **Problems related to medicines in specific settings**

#### **(a) The Elderly**

Adverse drug events are more likely to occur in the elderly. The elderly have a disproportionate level of chronic and degenerative disease morbidity, leading to increased demands for medication, but they are also more susceptible to complex pharmacokinetic interactions. In a cross sectional Norwegian study in primary care, a total of 13.5% of all prescriptions were considered pharmacologically inappropriate<sup>120</sup>. A particular cause for concern has been residents in nursing home settings since medication consumption is among the highest of any patient population. Combining incident reporting and patient record review, 546 adverse drug events and 188 potential adverse drug events were identified<sup>121</sup>. Overall, 51% of the adverse drug events were judged to be preventable and were particularly associated with psychoactive medications and anticoagulants. Errors occurred mainly at the stage of ordering and monitoring medication.

#### **(b) Repeat prescribing**

In 1992/3 it was calculated that repeat prescribing, in which prescriptions are re-authorised by a doctor without a face-to-face consultation, was responsible for 65% of the volume and 75% of the costs of prescribing in computerised UK general practices<sup>122</sup>. Continuing prescribing of inappropriate medication, often with the high potential for adverse drug events, is a feature of repeat prescribing, especially in the elderly<sup>123</sup>.

## **8.5 Methods of Analysis**

Once problems are identified the next step is to analyse the data to gain an understanding of the frequency and nature of errors.

### **Root cause analysis**

A structured process is essential to identify, and subsequently eliminate, root causes. An intensive systems analysis of adverse drug events and potential adverse drug events in US hospitals identified 16 major systems failures as the underlying causes of the errors<sup>124</sup>. The most common systems failure was the dissemination of drug knowledge, followed by inadequate availability of patient information.

### **Benchmarking through collaborative data sharing**

A review of the effectiveness of a hospital medication safety programme highlighted the importance of being able to compare individual performance with that of others<sup>125</sup>. The use of benchmarking has demonstrated improvement in medication event reporting and quality of care but the authors emphasise the need for adequate funding, competent hardware and software, staff training in the system (including incident report completion) and standardisation across the sites. The process may be facilitated by using structured incident report forms.

Comparison data is available through collections of national data, such as death rates from adverse drug events and post-marketing surveillance<sup>126</sup>. However, the numbers of deaths attributed to adverse drug events reported in these data sets varied 34-fold and were up to several 100-fold based on extrapolation of data obtained from surveillance studies.

### **The need for a “deeper” understanding**

To fully understand the nature of the causes of medication error it is essential that the beliefs of individuals are recognised. Many methods of identifying incidents use pre-coded data and although this allows for ease of classification and analysis it is at the expense of understanding how practitioners work in their world. A study of inappropriate prescribing by a small group of GPs in the UK identified that the influence of the original prescriber and the patient’s dependence on the drug helped to explain its continued use<sup>123</sup>. Dispensing errors in Tasmanian pharmacists were attributed to high prescription volumes, pharmacist fatigue, interruptions during dispensing and overwork<sup>127</sup>.

## **8.6 Conclusion**

Threats to patient safety associated with medication use are common and are an important cause of morbidity, and occasionally mortality, in both hospital and primary care settings. High rates are noted in patients who are elderly and on repeat prescriptions. Most errors do not result in harm but have a potential to do so.

Errors can occur at any stage of the process in which patients receive medication. This process begins with the decision to prescribe, followed by writing the prescription, dispensing the prescription, giving the medication to the patient, and finally the patient taking the medication and the healthcare professional monitoring the effect of the medication on the patient. Research has identified the importance of both human and system factors at all of the stages of the process.

Identification of errors associated with the use of medication can be difficult, with errors identified by incident reporting tending to be under-reported. Studies emphasise the useful role of information technology, pharmacists and national databases.

## 9 RECOMMENDATIONS FOR FURTHER RESEARCH

### Introduction

The majority of research into both the frequency and nature of threats to patient safety has been in secondary care but there is a need to develop the same understanding in primary care. The recommendations for further research are based on the review of current understanding and have taken into account the expedient time frame required to implement a process that is useful to all stakeholders.

### Short term priority

- 1 Evaluation of the pilot scheme currently being undertaken by the National Patient Safety Agency. The pilot is based in one Primary Care Trust and features the model proposed in the draft document “Safety First: managing, reporting, analysing and learning from adverse incidents involving NHS patients”.

**Recommendation** – both process and outcome need to be evaluated. The outcome measures should demonstrate how lessons have been learned and how patient care has been improved as a consequence. It is important for the evaluation to consider the various barriers to implementation of the whole process, including staff, information technology and production of a database at both local and national levels.

- 2 Development and evaluation of a model for incident reporting based on Significant Event Audit. There is potential for enhancing the use of Significant Event Audit in identifying and rectifying medical error, especially by making the process more systematic by introducing root cause analysis. This model is likely to be perceived as less threatening than a model introduced from outside since many practices are already using this form of audit and have ownership of the process. Examples of significant events are wide, and can include routine collected information, including deaths in practice, Coroner’s cases, referral sentinel events and quality/audit data.

**Recommendation** – to develop and evaluate a model for making Significant Event Audit more systematic in a pilot selection of Primary Care Organisations

### Longer term priorities

There is much overlap between the categories and future research may combine several categories. Incident reporting, analysis of error and rectification of error are inter-related but for ease of presentation are separated. This research will require a transdisciplinary approach which combines a variety of research methods from a variety of disciplines. Such an approach recognises the complexity of the nature of threats to patient safety in primary care.

### **(a) Identification of error**

- 1 Clear definition of what constitutes an error This is essential for both incident reporting and more systematic identification. Definitions will need to be understood by everyone involved so that there is little or no doubt, including incidents that produce actual and potential harm.

**Recommendation** – definitions to be developed by consensus methods and piloted across various members of the primary care team.

- 2 Development of a user friendly system for incident reporting in primary care. Previous experience in anaesthesia and laboratory medicine have clearly demonstrated that success of an incident reporting system depends on recognition of user concerns and the subsequent development of a system that addresses these concerns.

**Recommendation** - identification of perceived barriers and facilitating factors by all members of primary care teams. Development of incident reporting model and piloting of this model. Consideration needs to be given to widening the reporting system, for example patient feedback and role of other health care professionals eg pharmacists and practice nurses

- 3 Identification of learning needs for various members of primary care team. Successful introduction of an incident reporting system will require training for all members, ranging from clinical to administrative staff.

**Recommendation** – learning needs analysis for incident reporting

- 4 Identification of frequency and nature of error by a systematic process of case note review or standardised patients. Exemplar studies of medical error have adopted a case note review process but this is expensive in time, cost and trained resources.

**Recommendation** – development of a systematic process for a limited number of index areas, such as referral for cancer.

- 5 Identification of threats to patient safety associated with the use of medication. Such errors can be detected by community pharmacists but at the moment there is little feedback to prescribers.

**Recommendation** – development of a systematic process to identify and feedback errors associated with medication use. This will be a model based in community pharmacy.

### **(b) Analysis of error**

- 1 Development of categorisation of error. Categorisation is essential for identifying trends and causation patterns. Research in secondary care has

adopted two approaches: an iterative development of categories and use of fixed, previously designed categories.

**Recommendation** – development of a categorisation system for use in primary care that is iterative.

- 2 Investigation of identified events. Previous research in industry and other medical fields have used root cause analysis models to identify root causes. There are numerous models with differing degrees of rigour and resource implications.

**Recommendation** – development of a root cause analysis model that is appropriate for use in primary care

- 3 Modification of use of existing audit and quality improvement data to identify and analyse error. The investigation of shortfalls in care are usually not performed in a systematic process, resulting in lack of identification and rectification of underlying causes. However, adaptation of root cause analysis is a possibility to enhance error identification, analysis and rectification.

**Recommendation** - development of a root cause analysis model for use with routine audit and quality improvement data

- 4 Development of local databases. Local databases that hold details about the frequency and nature of error have an important function in analysis and subsequent rectification. In primary care this is likely to be at Primary Care Organisation level but there are no existing mechanisms.

**Recommendation** – development of a model for local database development This will require development and evaluation of information technology systems

- 5 Deeper understanding of the nature of error in primary care. Most of the existing, and proposed, models adopt a quantitative approach but a deeper understanding by qualitative methods is essential if a safety culture is to be established.

**Recommendation** – fundamental research to identify the complex determinants of error and professional judgement.

### **(c) Rectification of error**

- 1 Feedback and mechanisms for producing change. The ultimate aim of any system that considers error is to reduce such errors occurring in the future. There are a variety of models that have been used in an attempt to change professional practice, mainly related to feedback of audit and quality data. Little research has considered feedback on threats to patient safety.

**Recommendation** – to develop a model for feedback to primary care teams

- 2 Development of mechanisms in Primary Care Organisations to learn from threats to patient safety. Organisational learning, with resultant change in culture, is essential if a patient safety culture is to be established. A key component is likely to be related to leadership.

**Recommendation** – to identify the barriers to organisational change and develop strategies on how they can be overcome

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