

An overview of patient safety in primary care

Dr. Carl de Wet

November 2012

About this document:

This document aims to summarize a non-systematic scan of the international patient safety literature relating to patient safety in primary care settings in general, and Scottish general medical practice in particular. It may therefore be of interest to a wide range of clinical and non-clinical health care staff, whether new to or more experienced in the nascent discipline of patient safety.

Contents page

Executive Summary	p3
Section 1: An introduction to the discipline of patient safety	p6
➤ Historical background	
➤ Terminology	
➤ Classification systems	
➤ Theoretical and analytical frameworks	
Section 2: The incidence, nature and outcome of healthcare error	p14
➤ Incidence	
➤ Diagnostic errors	
➤ Medication errors	
➤ Investigation errors	
➤ Interface errors	
➤ Out-of-hours errors	
➤ Organisational and system errors	
Section 3: Patient safety improvement measures	p20
➤ The mixed methods approach	
➤ Specific methods:	
• Incident reporting	
• Medical record review	
• Perceptions of patients and health care providers	
• Mortality data and medico-legal claims analysis	
Section 4: Improving patient safety	p24
➤ Improvement initiatives	
➤ Mitigation	
➤ Education	
➤ Patient safety and quality improvement	
➤ Further research	
References	p28
Appendices	p35
➤ Appendix I: A timeline of the recent history of patient safety in the UK	
➤ Appendix II: Additional patient safety theories and frameworks	

Executive Summary

Section 1: An introduction to the discipline of patient safety

Patient safety was highlighted as a problem in the UK by a number of high-profile incidents which received wide media coverage in the last decade of the twentieth century. In response, a number of secondary care patient safety improvement initiatives have since been implemented, for example The Safer Patients Initiative (2004 until 2008) and the Scottish Patient Safety Programme (2008 to present). The Safety Improvement in Primary Care (SIPC) programme started in 2010 in Scotland. It aims to become the first known programme to implement safety improvements in primary care on a national basis by 2013.

Patient safety is a relatively new discipline with its own evolving terminology. As a result the same term often has different definitions,(1) other words are used interchangeably, new terms are constantly being added and the meanings of words evolve.(2) A standardized patient safety vocabulary is an essential requirement for effective patient safety research and improvement and is currently being developed.(3)

There are several primary care patient safety taxonomies, but few that have been validated.(4)(5) A validated taxonomy is a requisite step to prevent and reduce error and harm.(6) More recently, the World Health Organization (WHO) has proposed a universal patient safety classification system.(7)

Section 2: The incidence, nature and outcome of health care error

There has been no large-scale epidemiological study to reliably quantify error and harm rates in primary care. However, a substantial minority of errors results in patient harm and may be preventable.(4) The majority of harm incidents are minor or moderate in severity, but some have serious consequences, including hospital admission and even death.(8)

Investigation errors occur in all stages of the investigation process, but more frequently involves: failure to investigate, test result not relayed to clinician or clinician not acting on results.(9)

Diagnostic error is the most common reason for medico-legal claims, yet is rarely reported and research remains insufficient.(10) The overall diagnostic error rate in patients admitted to hospital from primary care range from 2 to 4%.(11)

Adverse drug events (ADE) affects up to 20% of patients irrespective of country or specific clinical setting.(12) Between 10 and 50% may be preventable.(13) The majority of ADE are of minor or moderate severity, but a substantial minority is serious, with as many as 7.6% associated with a hospital admission.(14) ADE are caused by 'complex and multifaceted' errors that occur in all stages of the medication use system.(15) A handful of medications are associated with the majority of ADE.(16) Reducing ADE will require multiple interventions as well as improved understanding of the causes.(17)

The 'boundaries' of general practice interface with a wide range of other health care services. The risk of health care error is increased by lack of continuity and inadequate communication.(18) A substantial proportion of discharge medication is unjustified or omitted.(19)

Very little is known about the incidence, causes or outcomes of error in the UK out of hours (OOH) setting.(20) Telephone triaging introduces patient safety risk, but may be more dependent on training, previous experience and record keeping than on the type of health care provider.(21)

Discrepancies between recorded and actual medication use and allergies increase risk.(22) Information handling errors may account for up to 29% of primary care errors.(23) Work environment and workplace factors may impact positive or negatively on patient safety.(24)

Section 3: Patient safety research methods

Different methods detect adverse event with different levels of precision and accuracy and little or no 'overlap' between the types of patient safety incidents.(25) Medical record review can detect more harm than any other method. However, the majority of studies using this method are limited by poor to moderate inter-rater reliability.(26) The general consensus is to combine a 'mix of methods' when aiming to quantify patient safety.(25)(27)

Incident reporting systems (IRS) underestimate the true incidence of error and harm.(28) Reported incidents may have important educational benefits, but a number of barriers to clinician engagement have been described in the UK primary care setting.(29)

Mortality data and patient safety intuitively seem linked, but there is no evidence of its use or impact in general practice.(30) There are important reliability concerns about attitudinal surveys and adverse event measurement. (31) Perceptions of GPs does not 'completely match' those presented in published papers and policy documents or by patients'.(32) Patients report access and relationship problems and psychological harm more than physical harm and technical, diagnostic or treatment errors.(33)

Section 4: Improving patient safety

The majority of patient safety research is descriptive, with very few studies focusing on practical improvement interventions. Examples of piloted, formal safety improvement interventions include: pharmacist-led medication reviews, chronic disease nurse-led protocol management, education programmes for GPs and 'complex' interventions.(34) There is no evidence (so far) that any formal primary care intervention effectively reduces harm. However, informal measures such as mitigation may already be present in some systems. Mitigation often goes unrecognized but has been estimated to 'stop' up to a fifth of all errors.(35) Recognizing mitigation may unlock a useful resource, given all health care staff, patients and their families are potential 'mitigators'.

Successful patient safety interventions will likely require a multi-method approach, rigorous evaluation, more research and education. Effective education implies protected time, self-reflection and additional resources.(36) Future research should focus on effective solutions that reduce harm.(37) The main priority is to work 'on the nuts and bolts of how we turn measurement for improvement into tangible change in practice'.(38)

Section 1: An introduction to the discipline of patient safety

The recent history of patient safety improvement in the UK

Patient safety was highlighted as a problem in the UK by a number of high-profile incidents which received wide media coverage in the last decade of the twentieth century. In response, the Department of Health published 'An Organisation with a Memory' in 2000. The report's key messages were that health care should learn lessons from adverse events and system-wide, formal patient safety improvement initiatives were necessary. A list of other influential reports and a timeline summary of improvement initiatives are provided in Appendix 1.

The *Safer Patients Initiative* (SPI) was one of the first organised attempts to improve patient safety in the UK. It was commissioned by the Health Foundation to address the problem of preventable harm in secondary care. Twenty four hospital sites participated during two phases that ran from 2004 until 2008.

The aim of phase one was to reduce the number of adverse events in the first four pilot hospital sites by 50%. The initial four sites were to achieve this aim through a 'change package' designed by the Institute for Healthcare Improvement. This package consisted of change on three levels: implementation of evidence-based interventions in five clinical areas; training staff in quality and safety improvement methodologies; and establishing specific roles for the Chief Executives and senior executive teams. The aims of phase two were to reduce the mortality rate by 15% and to reduce adverse events by 30% in twenty four hospitals over the two year period from 2006 to 2008.

The SPI provided valuable experience and lessons that informed the design and implementation of the national patient safety initiatives of the UK countries. For example: it is necessary to raise awareness of the patient safety problem before implementing improvement programmes; the majority of health care workers require additional training to help them contribute effectively to initiatives; improvement has to be informed by 'front line' staff; and existing reporting systems need improvements to be used effectively.

The *Scottish Patient Safety Programme* was launched in 2008. Its aims were to reduce secondary care mortality by 15% and morbidity by 30% over a five year period.

Secondary aims were to reduce healthcare associated infections, adverse surgical incidents and adverse drug events and to improve critical care outcomes and build a safety and quality culture. Methods include training and support of frontline staff. The focus initially was to implement the programme in every acute hospital in Scotland, with spread to primary and community care from 2011 onwards. Stakeholders include NHS Scotland, the Scottish Government, NHS Quality Improvement Scotland, NHS Education Scotland (NES) the Institute for Healthcare Improvement and the Health Foundation.

The Health Foundation launched the *Safer Patients Network* in June 2009. The vision for the network was to create a self-sustaining, member-driven community of practices to catalyse improvements in patient safety. Eighteen of the original 24 hospital sites from the Safer Patients Initiative joined the network. They continue to help test, develop and export approaches and methods that will make healthcare safer for patients in the UK and beyond.

The *Safety Improvement in Primary Care* (SIPC) programme commenced in May 2010 with recruitment of twenty general practice (GP) teams in three regional health authorities in Scotland. A key aim was to raise awareness of patient safety concepts and provide training in different improvement methods to selected GP team members at organised learning sets. They then return to frontline practice to share and implement this learning during the action period phase with further aims to reduce incidents of harm and improve the reliability of specific aspects of health care delivery. In phase I patients with a diagnosis of heart failure or taking high risk medication (Methotrexate or Warfarin) were selected as the clinical focus for improvement efforts. From March 2013, SIPC has ambitions to become the first known programme to implement targeted safety improvements in primary care on a national basis.

Patient safety terminology

Patient safety has its own vocabulary, just as any other medical discipline. As a relatively new field, the same terms often have different definitions,(1) words are used interchangeably, new terms are constantly being added and the meanings of words evolve.(2) For example, a recent review found 25 different terms related to medication safety and that the terms had 119 different definitions.(1)

Even common terms such as 'error' can be difficult to define. It has been argued that patient safety terms are 'relative concepts' and 'may be difficult to pin down'.⁽³⁶⁾ A survey of general practitioners (GPs) found at least 25 different definitions of error. The lack of consensus was due to their individual consideration and decision-making of at least three sets of factors: process vs. outcome, rare vs. common occurrences and system vs. individual responsibility.⁽²⁾

In addition to a multiplicity of definitions, terms also seem to have different functional meanings. One important implication is that incidence data can be difficult to interpret and compare between studies and settings.⁽¹⁾⁽³⁹⁾ An international standardized patient safety vocabulary is therefore an essential requirement for effective patient safety research and improvement. Such a system is currently being developed through pan-European collaboration and a number of other national and international initiatives.⁽³⁾⁽⁷⁾

A number of common patient safety terms are defined below for the purpose of this review and will be assumed throughout this report unless otherwise specified.

Patient safety

Patient safety is freedom from healthcare associated, preventable harm. A simple explanation is that 'when things go right, nothing bad happens.' To improve patient safety, healthcare error has to be prevented, recovered or at least minimized.

Patient safety incident

A patient safety incident is any healthcare related incident that was unintended, unexpected and undesired and that could have or did cause harm to a patient.⁽⁷⁾ It has become the preferred term when discussing adverse events, near misses and significant events.

Adverse event

An unintended and undesired occurrence in the healthcare process because of the performance or lack of it of a healthcare provider and/or the healthcare system.⁽³⁾ Adverse events are characterized by three key aspects: negativity, patient involvement (impact) and causation. ⁽³¹⁾

Significant event

A significant event is any event thought by anyone in the team to be significant in the care of patients or the conduct of the organization.(40)

Near miss

A 'near miss' is any incident that could have led to harm but did not, either by chance or through timely intervention.(3) It is also sometimes referred to as a 'close call' or 'free lesson'

Harm

Harm occurred if a patient's health or quality of life is negatively affected by any aspect of their interaction with health care. A pragmatic interpretation is 'anything' that you would not want to happen to you or your relatives while receiving care.

Although some incidents of harm are preventable, others are recognized complications of care. The severity of harm ranges from transient inconvenience and self-limiting symptoms, through prolonged admissions, disabling injuries, permanent functional impairment and even death.

Error

The most common definition of error is '...the result of choosing the wrong plan to achieve an aim, or not initiating or completing the right plan as intended...(41) There are at least three different types of errors: slips (incorrectly executed plans), lapses (a plan or part of plan is not executed) and mistakes (choosing or executing the wrong plan).

Adverse event investigations in various industries, including aviation, oil, nuclear power, the military and health care have shown that the same types of errors are made by everyone.

Not all errors will lead to harm, just as not all harm are caused by error.(42) However, an association has been shown between error and harm.(43) Errors are unintentional and should not be confused with violations, negligence or recklessness.

Violations

Violations are deliberate deviations from standard procedure.(44) They are inconsistent with rules or recommended practice familiar to a health care worker. Violations are sometimes adaptive behaviour in response to complex, challenging or demanding situations. It has been argued that violations cannot be eliminated, but that they can be managed.(44)

Safety learning system (SLS)

A safety learning system is a method of monitoring the occurrence of incidents and developing improvement strategies to address the cause of the incidents...'(45)

Classification systems in patient safety

A validated taxonomy is a requisite step to prevent and reduce error and harm. Taxonomies are useful because they promote recognition of diversity and similarity. They also provide explanatory power by defining and identifying contributory factors.(6) In primary care, there are many different patient safety taxonomies, but very few have been validated or lack consensus.(4)(5)

When the different taxonomies were compared, the main source of their difference was attributed to the different approaches taken by taxonomists, rather than their content.(6) For example, taxonomists can be 'lumpers' or 'splitters'. The term succinctly summarizes the approach of some taxonomists to merge categories, while others subdivide themes, sometimes several times over. There are also two main approaches taxonomists can take – phonetic or cladistic. When classifying errors, the phonetic method (classification according to common characteristics) is arguably more appropriate than the cladistic method (classification according to common ancestry).(6)

A suitable error taxonomy should be based on a theory of human performance, mutually exclusive categories and identify influences of the system on the individual.(5) Mutually exclusive categories may have the limitation of artificially lowering the observed frequencies in some error categories. For example, Hickner et al found communication

errors were implicated in many more incidents than the 6% in their classification system.(9)

A suitable taxonomy will also require multiple levels to prevent errors being counted more than once and reduce uncertainty about where to classify them.(5) For example, Kostopoulou proposed a classification with three different but related levels: level 1, cognitive domain and error mechanism; level 2, immediate internal and external causes; and level 3, performance shaping factors.

Classification of patient safety

The World Health Organization (WHO) has recently proposed a universal patient safety classification system.(7) The framework consists of ten 'high level classes' and 48 'key concepts'. The framework appears to have face validity, but has not been adapted for primary care.

Classification of healthcare error

Various classification systems exist for specific types of errors. For example, a classification system for adverse drug events (ADE) include: preventability, ameliorability, disability, severity, stage of process and responsible person/group.(46)

There is recognition that reducing healthcare error requires an understanding of the types of errors that may occur, and the factors that contribute to them. Rubin et al developed a UK primary care taxonomy with six categories of error: prescriptions, communication, appointments, equipment, clinical care and 'other'.(4) In the USA, Dovey et al were among the first to develop a preliminary taxonomy of primary care medical errors in 2002.(23) It consisted of eight categories: administrative failures, investigation failures, treatment delivery lapses, miscommunication, payment system problems, error in execution of a clinical task, wrong treatment decision and wrong diagnosis. This taxonomy has now been superseded by newer, validated instruments, but the categories remain important when considering primary care patient safety.

Makeham et al developed a general practice error taxonomy from international self-reported incidents in 2002.(47) The framework is reasonably complex with five levels and 171 different types of error. They suggest that errors are '...likely to affect patients in

similar ways in countries with similar primary healthcare systems...' Jacobs et al developed and validated a medical error taxonomy for Canadian primary care in 2007.(6) They identified six types of errors: administrative, communication, diagnostic, documentation, medication and surgical/procedural. They also identified ten causal factors: case complexity, discontinuity of care, failure to follow protocol, fatigue, knowledge gap, workload, insufficient information, medication side effects, relationship dynamics and structural problems. They propose that the taxonomy may help facilitate error reporting and aid development of interventions to prevent errors. Buetow et al used nominal group interview with GPs and patients in New Zealand. They developed a three level taxonomy of patient error with 70 potential types of error.(48) They caution against conceptualizing patient, clinician and system error as 'separate categories of errors' and propose research to help explain how they all 'interact to co-create and reduce errors'.

Theoretical and analytical frameworks

The Swiss cheese model

Reason's Swiss cheese model is arguably the best known theoretical model to explain health care error and harm and have underpinned much research.(41) It has been argued that the swiss cheese model has become too 'simplified'.(49) However, even this model can be interpreted in 'considerably' different ways by different quality and safety professionals.(49)

In the latest version of the model, slices of cheese represent the various system defences between hazards and adverse events and the holes in the cheese represent active and latent (system) errors. The slices of cheese are in constant motion. The holes generally do not form a straight line, with at least one slice blocking hazards from reaching patients. Most incidents of harm occur when the holes in the slices of cheese (the active and system errors) temporarily align, allowing hazards to reach patients.

The model's underlying assumptions are that not all errors lead to serious harm and that it usually requires a string of errors to result in harm to patients. It has several important safety implications, for example patient safety improvement requires a systems-approach and errors are potential learning opportunities. From this perspective reliability can be defined as 'a dynamic non-event'.

Human factors

The discipline of human factors has been defined as 'environmental, organisational and job factors and the human and individual characteristics which influence behaviour at work in a way which can affect health and safety' It is especially relevant to patient safety as it includes the study of human limitations, adaptive mechanisms and the main factors that affect behaviour, cognition and decision-making.(2)(5)(50)

Although human skills and abilities vary widely, everyone eventually will reach natural limits if demands keep increasing. As we come closer to or exceed our limits we are increasingly left vulnerable to making errors. Specific examples of human factors that are limited include: attention span, memory, situation awareness and personal resources (ability to process information appropriately as stress and fatigue increase). In addition, there are multiple external factors which can influence our behaviour and predispose to error. These factors can be grouped into three systems: 'job', 'individual' and 'organisational'. The three systems are interlinked and exert a combined influence - positive or negative - on the safety-related behaviour of every health care workers.

Humans have adaptive mechanisms that function as 'short-cuts' by launching pre-programmed actions when confronted with new or complex problems. Although they usually help us, they can lead to error at other times. For example: pattern-matching, previous success, involuntary automaticity, availability heuristic, confirmation bias and frequency gambling. It has recently been proposed that involuntary automaticity may be a legal defense, though this has not yet been put to the test.(51).

Other frameworks

Other frameworks include Howard et al's model,(14) Haddon's matrix, cascade analysis,(52) tempo's, the hourglass model and complexity. These frameworks are summarized in appendix II.

Section 2: The incidence, nature and outcome of healthcare error

Incidence of error and harm

The majority of health care is delivered in primary care. Ongoing changes in UK general practice have increased patient safety risks: patients are discharged from hospital earlier, GPs increasingly prescribe and monitor high-risk medications, time pressures in consultations are increasing and services and continuity of care are fragmenting.(5) Primary care medicine involves 'incremental longitudinal processes and is founded on decisions concerned with managing uncertainty and marginalizing risk'.(36) Yet, in spite of these implicit patient safety risks, there has been no large-scale epidemiological study to reliably quantify the harm rate in primary care.(53)

This challenge has been described as '...sorting out how big an issue safety really is, has been like looking at mountains in the clouds – it is hard to tell where one thing begins and another ends...'(53) However, we do know that errors are relatively common in primary care health care settings and that a substantial minority result in patient harm and may be preventable.(54) The majority of harm incidents are minor or moderate in severity, but some have serious consequences, including hospital admission and even death. (55)

In the USA, Woods et al estimated that as many as 75 000 admissions a year may be as a result of preventable adverse events originating in outpatient settings.(56) Of these, 4 839 will result in serious permanent injuries and 2 587 in death.

Wachter described six 'unique advantages' of primary care over and different to secondary care to help improve patient safety.(57)

Sanders et al were some of the first researchers to review healthcare error in primary care. They found a rate of between 5 and 80 errors per 100 000 consultations and errors in up to 11% of all prescriptions.(58) The paucity of studies and considerable methodological limitations of their evidence suggested this was a gross underestimation. Since then, Rubin et al found a rate of 75.6 errors per 1000 consultations in UK primary care using a voluntary incident reporting system.(4) More recently, a harm rate of 9.4% was found in Scottish general medical practice records, with a substantial proportion preventable and derived from secondary care.(8)

Investigation errors

The investigation process can be divided into three main phases: preanalytic, analytic and postanalytic. Subcategories include ordering tests, implementing tests, reporting results to clinicians, clinicians responding to results, notifying patients of results, general administration, communication and 'other'.

All investigation-related studies are from USA primary care settings and emphasize different aspects of the investigation process. Wahls et al (2007) described the frequency of 'missed' test results and treatment delays.(59) Casalino et al found that 7.1% of clinically significant outpatient test results were not relayed to patients or not documented.(60) Hickner et al found that errors occur throughout the testing process.(9) They found adverse consequences were common but 'physical harm' to patients rare. The most error-prone processes were test implementation (one third of errors), reporting test results to clinicians (one quarter of errors) and administrative errors such as misfiling (one fifth of errors).

Elder et al examined the management of test results in GP offices in the USA using a multimethod approach.(61) They found 'wide variation' which they attributed to two main themes: safety awareness (leadership, communication, teamwork, policies and procedures) and technological adoption (electronic medical records, digital connections, patient communication and forcing functions). Lo et al's aim to improve recommended baseline laboratory test monitoring through non-interruptive electronic 'alerts' were unsuccessful.(62) Sung et al considered the potential of reporting test results directly to patients to 'enhance' patient safety.(63) Surveyed physicians' support for this measure decreased as potential scenarios involved higher risk and more abnormal results.

Diagnostic errors

The overall diagnostic error rate in patients admitted to hospital from primary care range from 2 to 4%.(11) The majority of errors are caused by incomplete history taking and clinical examination. Diagnostic errors is also the most common reason for medico-legal claims against GPs.(64)(65) Yet, in spite of their relative frequency, they are rarely reported and have seldom been studied.(10) Diagnostic errors are especially important in

primary care systems where GPs have a 'gatekeeping' function, for example the UK, Australia and Canada.

Diagnostic errors may be especially difficult to eliminate for at least three reasons. First, diagnostic error often has multiple causes. Second, diagnostic error is not condition specific. It appears that way because certain conditions are more memorable or may lead to litigation more often, for example: cancers, myocardial infarction and infective diseases like meningitis. Third, various cognitive processes such as diagnostic overshadowing, hypothesis generation and satisficing (pattern matching) may predispose to them. Satisficing' is much faster than hypothesis-generation processes. It generally allows for quick diagnoses but risks missing rare conditions. A recent review described five features of 'diagnostic difficulty' atypical presentations, non-specific presentations, very low prevalence, presence of co-morbidity and perceptual features.(10)

Medication errors

Adverse drug events (ADE) affects up to 20% of patients irrespective of country or specific clinical setting.(12)(66)(67) Between 10 and 50% may be preventable.(13)(16) The majority of ADE are of minor or moderate severity, but a substantial minority is serious, with as many as 7.6% associated with a hospital admission.(14)(66)

Medication use processes are often simplified into four stages: prescribing, dispensing, administration and monitoring. Garfield et al were the first to map out the whole UK primary care medicines management system and to systemically review the evidence of cumulative medication errors in it.(15) They found errors in every stage, with error rates in excess of 50% for repeat prescribing reviews, interface prescribing, communication and patient adherence. As a result the minority of patients (4 to 21%) achieved optimum benefit from their medication. They recommend routine monitoring of adherence, clinical effectiveness and related hospital admissions as the first step to improve the quality of the medication system.

ADE are usually caused by 'complex and multifaceted' errors that occur in all stages of the medication use system.(15)(13) Examples include drug-drug interactions, discrepancies between prescribed and administered drugs, communication failures and knowledge gaps. Errors are most commonly associated with the prescribing and

monitoring stages. (16) A handful of medications - cardiovascular drugs, NSAIDs and anticoagulants - are associated with the majority of ADE.(16)(68) Other drug categories frequently associated with ADE are anti-infective agents, diabetogenic medication and analgesia.(17)(69) Conversely, some drugs may cause preventable hospital admissions if they are not prescribed, for example anti-anginals and asthma preventers.(70)

Older patients are at increased risk to suffer an ADE. Barber et al found one or more errors in 69.5% of patients, and 1.9 mean errors per resident in UK nursing homes.(13). Other risk factors that may increase ADE risk include female gender, very young age (< 4years old), multiple prescription items, number of daily doses, multiple co-morbidity and high consultation rates.(66)(71)(69)(72)

There is some evidence emerging that pharmacists, patients and GPs may effectively mitigate some ADE.(67)(73) However, reducing ADE will require multiple interventions as well as improved understanding of the causes.(17)

Interface errors

The 'boundaries' of general practice interface with a wide range of other health care services. The risk of health care error is increased by lack of continuity and inadequate communication between different organisations.(18) Desai et al found that 11% of errors reported by USA nursing home residents related to transition of care and that interface errors were associated with higher odds of harm.(74) A number of contributing factors were identified, including: staff communication problems, order transcriptions, medication availability and pharmacy issues.

Bell et al found that communication could be 'substantially improved' across boundaries.(75) In a survey of primary care providers, 77% were aware that their patient had been admitted and 42% received a discharge summary within a fortnight. During a 30 day follow-up period, 22% of patients died, were readmitted or attended Accident and Emergency.

The peri-discharge period has been identified as a particularly at-risk period.(76) Adverse drug events and procedure-related incidents are common in this period and a substantial proportion of discharge medication may be unjustified or omitted.(19) Drug omissions

have more potential for patient harm than unjustified medication. The number of discrepancies increased linearly with the number of prescribed items.

Out-of-hours (OOH) errors

In the USA setting, 3% to 6% of patients may suffer temporary physical harm as a result of OOH errors, such as not appropriately forwarding calls to a duty physician.(42)(77)(78) In the Netherlands Giesen et al found nurse-led phone triaging efficient but 'possibly not safe'.(21) While telephone triaging introduces patient safety risk, it may be more dependent on training, previous experience and record keeping than on the type of health care provider.(21)

Very little is known about the incidence, causes or outcomes of error in the UK OOH setting.(20) The vast majority of patients access OOH general practice care through telephone consultations and are triaged to receive further assessment or not. Non-GPs are increasingly delivering all aspects of OOH care. Lattimer et al studied the impact of nurse-led telephone consultations and triaging in UK primary care and found that the number of adverse events were unchanged, GP workload decreased and patient access improved.(20) More recently, high-profile OOH patient incidents were widely reported in the UK media. In response, a number of recommendations have been made to improve the safety of OOH care, including '...safety should always take priority over efficiency...'(79)(21)

Organisational and system errors

Medication and medical record discrepancies

Discrepancies between recorded and actual medication use and allergies increase risk.(22) In the USA, up to 97% of patients have at least one discrepancy between their recorded and actual medication use and 32% have an allergy discrepancy.(22) Discrepancies are more likely for female patients, patients with cardiovascular disease and those hospitalized in the previous year. However, only the number of prescribed medications has predictive value for discrepancies. (22) The most common cause for discrepancies are medication discontinued by the patient, but still being prescribed or

listed in the record. The majority of discrepancies are 'system generated' and patients are implicated in 20.2% of cases.(80)

Information technology (IT)

High-quality primary care depends on information that is comprehensible, accessible, timely and correct. Information handling errors may account for up to 29% of primary care errors.(23) Beasley et al considers the association between '*information chaos*', physician workload and patient safety. They describe information chaos as combinations of information overload and 'underload', scatter, conflict and erroneous information. They suggest a conceptual framework to understand the concept and calls for further research to define methods to measure and reduce it.

Environmental factors

Linzer et al found an association between negative working conditions (time pressure, 'chaotic environments', low work control) and adverse effects on USA physicians (stress, burnout).(24) Manwell et al conducted focus groups with USA primary care physicians who clearly identified a number of positive and negative workplace factors which they perceived as related to safety and error.(81) They identified '...systems of care and their dynamic nature...' as priorities for further research.

Physician stress is prevalent in primary care and increases the likelihood of error.(24) However, many health care workers 'seem to deny the effect of stress and fatigue on performance...'(82) Some doctors also find it difficult to express criticism for 'unacceptable conduct' and at least 17% found patient safety incidents 'had a negative impact on their private life'.(83)

Section 3: Patient safety improvement measures

‘Mix of methods’

There are a number of different methods available for assessing the nature and scale of harm caused the health system.(46)(84) Some are more suited to count patient safety incidents (frequency assessment) while others increase our understanding of the causes, contributory factors and consequences.(85) The different methods’ specific advantages and disadvantages are more often properties of the context in which they are applied than of the measures themselves.(53)

Different methods tend to detect adverse event with different levels of precision and accuracy, with very little or no ‘overlap’ between the types of identified patient safety incidents.(25)Christiaans-Dingelhoff (2011) For example, Olsen et al found that incident reporting ‘needs to be supplemented with other more systematic forms of data collection’ and that structured record review ‘provides an important component of an integrated approach’.(86) The general consensus is to combine a ‘mix of methods’ when aiming to quantify patient safety.(25)(27)

There are important reliability concerns about adverse event measurement in general, (31) and attitudinal surveys, incident reporting systems and medical record review in particular.(31) One of the main concerns, which have been recognized since at least 1982, is inter-rater reliability.(87) Inter-rater reliability is ‘highly sensitive to the degree of consensus and confidence’ among researchers and health care workers.(26) There have been many attempts to improve reliability, for example through education and training, standaradized protocols, continuous monitoring and quality improvement feedback mechanism.(88)(46) However, inter-rater reliability for adverse event identification remains ‘average’. Forster et al recently highlighted ‘multiple reviewer agreement’ as essential.

Incident reporting systems (IRS)

Mckay et al found 48/191 (25.1%) of UK general practice significant event reports described harm and 57.1% the potential to cause harm.(89) The most common cause

was 'individual error'. The vast majority identified learning opportunities, which supports the promotion of incident reporting and analysis as an educational and team-based activity.(90)

Incident reporting system data forms the basis of the majority of primary care patient safety incidence research.(28) Clinician engagement has been a major challenge in all health care settings, but especially general practice.(91)(29)(45) As a result, it tends to grossly underestimate the incidence of error and harm.

Analysis of mortality data and medico-legal claims

Mortality data

Wester et al reviewed mortality data in Sweden.(92) They found 3.1% of deaths were caused by ADE. Of these, 8/49 (16.3%) occurred outside a hospital. The most common types of ADE were gastro-intestinal haemorrhage (37%) and central nervous system haemorrhage (29%). The most common drugs were antithrombotic (63%), NSAID (18%), antidepressants and cardiovascular drugs. Mortality data and patient safety intuitively seem linked, but there is no evidence of its use or impact in general practice.(30) However, 'GPs appear interested in the potential of this information'.(30)

Medico-legal claims

A review of settled primary care medico-legal claims in the USA found the minority were negligent.(64) The majority (about a third) involved diagnosis error. No single clinical condition accounted for >5% of claims, but relative to frequency of conditions in primary care there was a significantly disproportionate risk. For example, appendicitis was 25 times more likely to generate a claim than breast cancer.

Perceptions of patients and health care providers

Health care providers

The majority of surveyed doctors indicated they have encountered a peer's medical error in the previous six months.(93) The vast majority had never received training in dealing with this issue. The majority thought the best approach would be to report it to the responsible doctor and to encourage disclosure to patients.(94) In a survey of UK trainee doctors 57% reported they had made an error that caused harm to patients, and 68% informed the patient of the error.(95) The vast majority reported the incident, but only 31% were investigated or analyzed further.

A survey of GPs in the Netherlands found their views did not 'completely match' those presented in published papers and policy documents.(32) GPs perceived poor doctor-patient relationship a serious threat. Other risk factors such as infection prevention, guideline deviation and incident reporting were judged less relevant when compared with perceptions of policy makers. GPs and patients' perceptions were comparable 'to a degree'. GPs perceived care quality more critical than patients and underestimated how positive patients were.(96)

GPs have previously identified and described multiple causes for medical error, including: hurrying, distraction, knowledge gaps, 'premature closure of the diagnostic process' and 'inadequately aggressive patient management'.(97) They have also identified positive and negative workplace factors related to safety and error, a number of mitigating factors and made improvement of 'systems of care' their main safety priority. (24)

Patients

The majority of surveyed patients reported hospital 'mistakes' with little variation between countries.(98) Patients tend to report access and relationship problems rather than technical, diagnostic or treatment errors. They are also more likely to report psychological than physical harm.(33) Patients identified 'deficiencies in care transition' as a major patient safety problem. It has recently been proposed that patients' perceptions of safety may be harnessed to help identify additional safety threats during their interactions with health care.(99)

Medical record review

Medical record review can be automated or manual and full or adapted (like the trigger tool method).(100)(101)(102)(103)

A retrospective record review of 1000 Dutch general practice records detected 211 patient safety incidents, of which 58 affected patients and 7 resulted in admission. None resulted in disability or death.(Gaal 11). An adverse event rate of 9.4% was detected in Scottish general medical practice records.(8) A substantial number of incidents and most severe harm originated in secondary care. Almost half of the patient safety incidents were judged to be preventable.

The utility of medical record review as a routine metric by frontline teams have recently been questioned.(104) Triggered reviews have arguably greater potential as educational and improvement tools and have been described as 'quality improvement processes'(104)(105)

Section 4: Improving patient safety

Formal interventions

The vast majority of primary care patient safety studies are descriptive. They help to improve our understanding of the types and consequences of medical errors and may suggest potential solutions. The implicit assumption is that reducing error will improve safety. (36)(106) However, very little research has focused on interventions to improve safety or mitigate error. There is no evidence (so far) that any formal primary care intervention effectively reduces harm. Evidence for secondary care improvements is also limited.(107)

Patient safety often 'borrows' interventions from quality improvement (QI) programmes. However, QI evidence has limited validity or generalizability due to heterogeneity and methodological flaws.(108) Sturmberg suggests we may need to 'explore how complexity approaches can provide different solutions to the problems in health care than the prevailing Newtonian ones.'(109) Successful interventions will likely require a multi-method approach and rigorous evaluation to ensure there are no 'unintended consequences'.(110)(111)

Examples of piloted, formal safety improvement interventions include: pharmacist-led medication reviews, chronic disease nurse-led protocol management, education programmes for GPs and 'complex' interventions to reduce falls in elderly patients.(34) A meta-analysis of 38 studies (7 in UK primary care settings) found no evidence of effectiveness for any of these interventions, although there was some 'weak evidence to indicate' that pharmacist-led review may reduce medication related hospital admissions. There is emerging evidence that eliciting and addressing patients' medication symptoms may be an effective strategy to help reduce ADE.(112)

During a randomized controlled trial in GP practices in England a pharmacist reviewed patients (>65 years) and their medication records during dedicated consultations.(113) During the twelve month follow up period medication costs rose in both groups, but significantly less in the intervention group. Recommendations for medication changes were made for 21% of patients, most commonly 'stop medicine' and 'technical' (generic switch, removal of redundant item). No statistical differences were detected between

groups for numbers of outpatient consultations, hospital admissions, practice consultations or deaths.

There has recently been a suggestion that a new health care role should be created, namely the 'patient safety professional'.⁽¹¹⁴⁾ This is currently being piloted in secondary care settings. It is unclear how generalizable this would be to primary care.

Mitigation

Mitigation is any process that prevents an error from resulting in harm. Mitigation occurs in the temporary state after an error occurs but before it has resulted in harm. It should be distinguished from 'recovery' which describes the actions after the 'chain of events has played out'.⁽³⁵⁾ All health care staff and patients and their families are potential 'mitigators'. For example, Swinglehurst et al's ethnographic case study of UK GP practices found that receptionists and administrative staff 'make important "hidden contributions" to quality and safety in repeat prescribing'⁽⁷³⁾

Mitigation often goes unrecognized but may 'stop' up to a fifth of all errors.⁽³⁵⁾ Parnes et al reviewed voluntary patient safety incident reports from a USA primary care setting.⁽⁴³⁾ They found 8.0% were 'ameliorated events'. Ameliorators included practice staff, pharmacists, diagnostic laboratory staff and patients and their families. They suggest that 'medical staff and patients who are encouraged to be vigilant, ask questions and seek solutions may correct otherwise inevitable wrongs'. Graham et al found that 21% of testing process errors was mitigated in USA primary care.⁽³⁵⁾ Practice staff (79%) and patients and their families (7%) were important mitigators. Mitigated events resulted in less severe outcomes.

Measurement

There is an important association between measurement and improvement. The challenge is 'getting one to follow the other'.⁽³⁸⁾ To be effective, a performance measure requires certain attributes, including: relevance, validity, reliability, discriminative power, credibility, timeliness, feasibility, acceptability and be actionable.⁽³⁸⁾ Unfortunately no 'ideal' measure with all these attributes exists.

A recent literature review to find effective quality and safety improvement strategies only found studies with limited validity or generalizability due to their heterogeneous nature and methodological flaws.(108) What little evidence there is seems to suggest that clinician and patient driven improvement may be more effective than manager and policy driven initiatives. Unfortunately, there are many challenges in engaging clinicians in quality and safety improvement.(38) Prof. Siriwardena recently proposed how this challenge may be overcome (at least partly). He described a practical and individualized approach for GPs to use QI projects for appraisal and revalidation purposes.(115) Could this be a feasible way to demonstrate patient safety in primary care?

Education

A systematic review of the effectiveness of teaching quality improvement to clinicians found that the vast majority of studies described team-based projects, reported only positive effects and only a small minority evaluated educational and clinical outcomes. (116) While learners' self-reported knowledge and confidence generally improved, there was no evidence that the educational interventions had any impact on clinical outcomes. In a recent evaluation of an online patient safety module for UK healthcare workers, self-reported knowledge increased, but no impact on behavior, attitudes or clinical outcomes were demonstrated.(117)

Inadequate supervision has been identified as an important patient safety risk in secondary care.(118) Although there is currently no evidence, inadequate supervision during general practice training may also be a patient safety threat and will require further consideration.

If education is to be effective, it will be important to provide the necessary resources, protected time and support self-reflection. It has been suggested that one of the best ways to improve patient safety in primary care may be for GPs '...to set aside time and space to conduct the required, appropriate reflection effectively...'(36)

Further research

A recent review of the international patient safety literature concluded: ‘...we know relatively little about harm outside the hospital...’ and ‘...we still need to develop many more effective intervention strategies...’. (37) The next research aims should therefore be to better define the state of patient safety in primary care and to provide effective solutions to help reduce harm in this setting. To achieve this aim, it may be necessary for existing tools to be adapted or applied in different ways. For example, adverse event analysis may be useful as an education tool to help influence primary care safety culture.(119)

Further research is also required to identify ways to better monitor and manage key primary care health care processes, for example dealing with investigation results, prescribing and referrals. We also need to improve our understanding of decision making in clinical and administrative tasks and improve the presentation of information to reduce task demands and fragmentation.(5)

In summary - the main priority is to work ‘on the nuts and bolts of how we turn measurement for improvement into tangible change in practice’.(38)

References

- (1) Yu KH, Nation RL, Dooley MJ. Multiplicity of medication safety terms, definitions and functional meanings: when is enough enough?. *Qual Saf Health Care* 2005 Oct;14(5):358-363.
- (2) Elder NC, Pallerla H, Regan S. What do family physicians consider an error? A comparison of definitions and physician perception. *BMC Fam Pract* 2006;7:73.
- (3) Kristensen S, Mainz J, Bartels P. A patient safety vocabulary: Safety Improvement for patients in Europe. 2007;SimPatIE Work Package 4.
- (4) Rubin G, George A, Chinn DJ, Richardson C. Errors in general practice: development of an error classification and pilot study of a method for detecting errors. *Quality & Safety in Health Care* 2003 Dec;12(6):443-447.
- (5) Kostopoulou O, Delaney B. Confidential reporting of patient safety events in primary care: results from a multilevel classification of cognitive and system factors. *Qual Saf Health Care* 2007 Apr;16(2):95-100.
- (6) Jacobs S, O'Beirne M, Derfiingher LP, Vlach L, Rosser W, Drummond N. Errors and adverse events in family medicine: developing and validating a Canadian taxonomy of errors. *Canadian Family Physician* 2007 270; Feb;53(2):271-276.
- (7) World Health Organization. Conceptual Framework for the International Classification for Patient Safety. 2009;Version 1.1.
- (8) de Wet C, Bowie P. The preliminary development and testing of a global trigger tool to detect error and patient harm in primary-care records. *Postgrad Med J* 2009 Apr;85(1002):176-180.
- (9) Hickner J, Graham DG, Elder NC, Brandt E, Emsermann CB, Dovey S, et al. Testing process errors and their harms and consequences reported from family medicine practices: a study of the American Academy of Family Physicians National Research Network. *Qual Saf Health Care* 2008 Jun;17(3):194-200.
- (10) Kostopoulou O, Delaney BC, Munro CW. Diagnostic difficulty and error in primary care--a systematic review. *Fam Pract* 2008 Dec;25(6):400-413.
- (11) Singh H, Thomas EJ, Khan MM, Petersen LA. Identifying diagnostic errors in primary care using an electronic screening algorithm. *Arch Intern Med* 2007 Feb 12;167(3):302-308.
- (12) Tache SV, Sonnichsen A, Ashcroft DM. Prevalence of adverse drug events in ambulatory care: a systematic review. *Ann Pharmacother* 2011 Jul;45(7-8):977-989.
- (13) Barber ND, Alldred DP, Raynor DK, Dickinson R, Garfield S, Jesson B, et al. Care homes' use of medicines study: prevalence, causes and potential harm of medication errors in care homes for older people. *QSHC* 2009;18:341-346.
- (14) Howard R, Avery A, Bissell P. Causes of preventable drug-related hospital admissions: a qualitative study. *Qual Saf Health Care* 2008 Apr;17(2):109-116.
- (15) Garfield S, Barber N, Walley P, Willson A, Eliasson L. Quality of medication use in primary care--mapping the problem, working to a solution: a systematic review of the literature. *BMC Med* 2009;7:50.
- (16) Gurwitz JH, Field TS, Harrold LR, Rothschild J, Debellis K, Seger AC, et al. Incidence and preventability of adverse drug events among older persons in the ambulatory setting. *JAMA* 2003 Mar 5;289(9):1107-1116.
- (17) Morris CJ, Rodgers S, Hammersley VS, Avery AJ, Cantrill JA. Indicators for preventable drug related morbidity: application in primary care. *Qual Saf Health Care* 2004 Jun;13(3):181-185.

- (18) Makeham MA, Mira M, Kidd MR. Lessons from the TAPS study - communication failures between hospitals and general practices. *Aust Fam Physician* 2008 Sep;37(9):735-736.
- (19) Perren A, Previsdomini M, Cerutti B, Soldini D, Donghi D, Marone C. Omitted and unjustified medications in the discharge summary. *Qual Saf Health Care* 2009 Jun;18(3):205-208.
- (20) Lattimer V, George S, Thompson F, Thomas E, Mullee M, Turnbull J, et al. Safety and effectiveness of nurse telephone consultation in out of hours primary care: randomised controlled trial. The South Wiltshire Out of Hours Project (SWOOP) Group. *BMJ* 1998 Oct 17;317(7165):1054-1059.
- (21) Giesen P, Ferwerda R, Tijssen R, Mokkink H, Drijver R, van den Bosch W, et al. Safety of telephone triage in general practitioner cooperatives: do triage nurses correctly estimate urgency?. *Qual Saf Health Care* 2007 Jun;16(3):181-184.
- (22) Stephens M, Fox B, Kukulka G, Bellamy J. Medication, allergy, and adverse drug event discrepancy in ambulatory care. *Fam Med* 2008;40(2):107-110.
- (23) Dovey SM, Meyers DS, Phillips RL, Jr, Green LA, Fryer GE, Galliher JM, et al. A preliminary taxonomy of medical errors in family practice. *Qual Saf Health Care* 2002 Sep;11(3):233-238.
- (24) Linzer M, Manwell LB, Williams ES, Bobula JA, Brown RL, Varkey AB, et al. Working conditions in primary care: physician reactions and care quality. *Ann Intern Med* 2009 W6-9; Jul 7;151(1):28-36.
- (25) Wetzels R, Wolters R, van Weel C, Wensing M. Mix of methods is needed to identify adverse events in general practice: a prospective observational study. *BMC Fam Pract* 2008;9:35.
- (26) Thomas EJ, Lipsitz SR, Studdert DM, Brennan TA. The reliability of medical record review for estimating adverse event rates.[Erratum appears in *Ann Intern Med* 2002 Jul 16;137(2):147]. *Ann Intern Med* 2002 Jun 4;136(11):812-816.
- (27) Field TS, Gurwitz JH, Harrold LR, Rothschild JM, Debellis K, Seger AC, et al. Strategies for detecting adverse drug events among older persons in the ambulatory setting. *J Am Med Assoc* 2004 Nov-Dec;11(6):492-498.
- (28) Makeham MA, Kidd MR, Saltman DC, Mira M, Bridges-Webb C, Cooper C, et al. The Threats to Australian Patient Safety (TAPS) study: incidence of reported errors in general practice. *Med J Aust* 2006 Jul 17;185(2):95-98.
- (29) McKay J, Bowie P, Murray L, Lough M. Barriers to significant event analysis: an attitudinal survey of principals in general practice. *Quality in Primary Care* 2003;11:189-198.
- (30) Baker R, Sullivan E, Camosso-Stepinovic J, Rashid A, Farooqi A, Blackledge H, et al. Making use of mortality data to improve quality and safety in general practice: a review of current approaches. *Qual Saf Health Care* 2007 Apr;16(2):84-89.
- (31) Walshe K. Adverse events in health care: issues in measurement. *Qual Health Care* 2000 Mar;9(1):47-52.
- (32) Gaal S, Verstappen W, Wensing M. Patient safety in primary care: a survey of general practitioners in The Netherlands. *BMC Health Serv Res* 2010;10:21.
- (33) Kuzel AJ, Woolf SH, Gilchrist VJ, Engel JD, LaVeist TA, Vincent C, et al. Patient reports of preventable problems and harms in primary health care. *Ann Fam Med* 2004 Jul-Aug;2(4):333-340.
- (34) Royal S, Smeaton L, Avery AJ, Hurwitz B, Sheikh A. Interventions in primary care to reduce medication related adverse events and hospital admissions: systematic review and meta-analysis. *Quality & Safety in Health Care* 2006 Feb;15(1):23-31.
- (35) Graham DG, Harris DM, Elder NC, Emsermann CB, Brandt E, Staton EW, et al. Mitigation of patient harm from testing errors in family medicine offices: a report from the American Academy of Family Physicians National Research Network. *Qual Saf Health Care* 2008 Jun;17(3):201-208.

- (36) Jacobson L, Elwyn G, Robling M, Jones RT. Error and safety in primary care: no clear boundaries. *Fam Pract* 2003 Jun;20(3):237-241.
- (37) World Health Organization. Summary of the evidence on patient safety: implications for research. 2008.
- (38) Scott I, Phelps G. Measurement for improvement: getting one to follow the other. *Intern Med J* 2009 Jun;39(6):347-351.
- (39) Grober ED, Bohnen JM. Defining medical error. *Can J Surg* 2005 Feb;48(1):39-44.
- (40) Pringle M, Bradley CP, Carmichael CM, Wallis H, Moore A. Significant event auditing. A study of the feasibility and potential of case-based auditing in primary medical care. *Occas Pap R Coll Gen Pract* 1995;70(March):1-21.
- (41) Reason J. Human error: models and management. *BMJ* 2000 Mar 18;320(7237):768-770.
- (42) Killip S, Ireson CL, Love MM, Fleming ST, Katirai W, Sandford K. Patient safety in after-hours telephone medicine. *Fam Med* 2007 Jun;39(6):404-409.
- (43) Parnes B, Fernald D, Quintela J, Araya-Guerra R, Westfall J, Harris D, et al. Stopping the error cascade: a report on ameliorators from the ASIPS collaborative. *Qual Saf Health Care* 2007 Feb;16(1):12-16.
- (44) Amalberti R, Vincent C, Auroy Y, de Saint Maurice G. Violations and migrations in health care: a framework for understanding and management. *Qual Saf Health Care* 2006 Dec;15(Suppl 1):66-71.
- (45) O'Beirne M, Sterlin PD, Zwicker K, Hebert P, Norton PG. Safety incidents in family medicine. *BMJ Quality and Safety* 2011;Online first:1-6.
- (46) Morimoto T, Gandhi TK, Seger AC, Hsieh TC, Bates DW. Adverse drug events and medication errors: detection and classification methods. *Qual Saf Health Care* 2004 Aug;13(4):306-314.
- (47) Makeham MA, Dovey SM, County M, Kidd MR. An international taxonomy for errors in general practice: a pilot study. *Med J Aust* 2002 Jul 15;177(2):68-72.
- (48) Buetow S, Kiata L, Liew T, Kenealy T, Dovey S, Elwyn G. Patient error: a preliminary taxonomy. *Ann Fam Med* 2009 May-Jun;7(3):223-231.
- (49) Perneger TV. The Swiss cheese model of safety incidents: are there holes in the metaphor?. *BMC Health Serv Res* 2005;5:71.
- (50) Scott IA. Errors in clinical reasoning: causes and remedial strategies. *BMJ* 2009;338:b1860.
- (51) Toft B, Mascie-Taylor H. Involuntary automaticity: a work-system induced risk to safe health care. *Health Services Management Research* 2005 Nov;18(4):211-216.
- (52) Woolf SH, Kuzel AJ, Dovey SM, Phillips RL, Jr. A string of mistakes: the importance of cascade analysis in describing, counting, and preventing medical errors. *Ann Fam Med* 2004 Jul-Aug;2(4):317-326.
- (53) Bates DW. Mountains in the clouds: patient safety research. *Qual Saf Health Care* 2008 Jun;17(3):156-157.
- (54) Rosser W, Dovey S, Bordman R, White D, Crighton E, Drummond N. Medical errors in primary care: results of an international study of family practice. *Can Fam Physician* 2005 Mar;51:386-387.
- (55) Tsang C, Majeed A, Banarsee R, Gnani S, Aylin P. Recording of adverse events in English general practice: analysis of data from electronic patient records. *Inform Prim Care* 2010;18(2):117-124.
- (56) Woods DM, Thomas EJ, Holl JL, Weiss KB, Brennan TA. Ambulatory care adverse events and preventable adverse events leading to a hospital admission. *Qual Saf Health Care* 2007 Apr;16(2):127-131.

- (57) Wachter RM. Is ambulatory patient safety just like hospital safety, only without the "stat"? *Ann Intern Med* 2006 Oct 3;145(7):547-549.
- (58) Sandars J, Esmail A. The frequency and nature of medical error in primary care: understanding the diversity across studies. *Fam Pract* 2003 Jun;20(3):231-236.
- (59) Wahls TL, Cram PM. The frequency of missed test results and associated treatment delays in a highly computerized health system. *BMC Fam Pract* 2007;8:32.
- (60) Casalino LP, Dunham D, Chin MH, Bieland R, Kistner EO, Karrison TG, et al. Frequency of failure to inform patients of clinically significant outpatient test results. *Arch Intern Med* 2009;169(12):1123-1129.
- (61) Elder NC, McEwen TR, Flach JM, Gallimore JJ. Management of test results in family medicine offices. *Ann Fam Med* 2009 Jul-Aug;7(4):343-351.
- (62) Lo HG, Matheny ME, Seger DL, Bates DW, Gandhi TK. Impact of non-interruptive medication laboratory monitoring alerts in ambulatory care. *J Am Med Inform Assoc* 2009 Jan-Feb;16(1):66-71.
- (63) Sung S, Forman-Hoffman V, Wilson MC, Cram P. Direct reporting of laboratory test results to patients by mail to enhance patient safety. *J Gen Intern Med* 2006 Oct;21(10):1075-1078.
- (64) Phillips RL, Jr, Bartholomew LA, Dovey SM, Fryer GE, Jr, Miyoshi TJ, Green LA. Learning from malpractice claims about negligent, adverse events in primary care in the United States. *Qual Saf Health Care* 2004 Apr;13(2):121-126.
- (65) Graber M. Diagnostic errors in medicine: a case of neglect. *Jt Comm J Qual Patient Saf* 2005 Feb;31(2):106-113.
- (66) Miller GC, Britth HC, Valenti L. Adverse drug events in general practice patients in Australia. *Med J Aust* 2006 Apr 3;184(7):321-324.
- (67) Kuo GM, Phillips RL, Graham D, Hickner JM. Medication errors reported by US family physicians and their office staff. *Qual Saf Health Care* 2008 Aug;17(4):286-290.
- (68) Howard RL, Avery AJ, Slavenburg S, Royal S, Pipe G, Lucassen P, et al. Which drugs cause preventable admissions to hospital? A systematic review. *Br J Clin Pharmacol* 2007 Feb;63(2):136-147.
- (69) Tam KW, Kwok KH, Fan YM, Tsui KB, Ng KK, Ho KY, et al. Detection and prevention of medication misadventures in general practice. *Int J Qual Health Care* 2008 Jun;20(3):192-199.
- (70) Howard RL, Avery AJ, Howard PD, Partridge M. Investigation into the reasons for preventable drug related admissions to a medical admissions unit: observational study. *Quality & Safety in Health Care* 2003 Aug;12(4):280-285.
- (71) Doubova Dubova SV, Reyes-Morales H, Torres-Arreola Ldel P, Suarez-Ortega M. Potential drug-drug and drug-disease interactions in prescriptions for ambulatory patients over 50 years of age in family medicine clinics in Mexico City. *BMC Health Serv Res* 2007;7:147.
- (72) McCarthy L, Dolovich L, Haq M, Thabane L, Kaczorowski J. Frequency of risk factors that potentially increase harm from medications in older adults receiving primary care. *Can J Clin Pharmacol* 2007;14(3):283-290.
- (73) Swinglehurst D, Greenhalgh T, Russell J, Myall M. Receptionist input to quality and safety in repeat prescribing in UK general practice: ethnographic case study. *BMJ* 2011;343:6788.
- (74) Desai R, Williams CE, Greene SB, Pierson S, Hansen RA. Medication errors during patient transitions into nursing homes: characteristics and association with patient harm. *American Journal of Geriatric Pharmacotherapy* 2011;Online first.

- (75) Bell CM, Schnipper JL, Auerbach AD, Kaboli PJ, Wetterneck TB, Gonzales DV, et al. Association of communication between hospital-based physicians and primary care providers with patient outcomes. *Journal of Internal General Medicine* 2008;24(3):381-386.
- (76) Forster AJ, Murff HJ, Peterson JF, Gandhi TK, Bates DW. The incidence and severity of adverse events affecting patients after discharge from the hospital. *Ann Intern Med* 2003 Feb 4;138(3):161-167.
- (77) Hildebrandt DE, Westfall JM, Fernald DH, Pace WD. Harm resulting from inappropriate telephone triage in primary care. *J Am Board Fam Med* 2006 Sep-Oct;19(5):437-442.
- (78) Hildebrandt DE, Westfall JM, Smith PC. After-hours telephone triage affects patient safety. *J Fam Pract* 2003 Mar;52(3):222-227.
- (79) Cosford PA, Thomas JM. Safer out of hours primary care. *BMJ* 2010;340:3194.
- (80) Orrico KB. Sources and types of discrepancies between electronic medical records and actual outpatient medication use. *J Manage Care Pharm* 2008 Sep;14(7):626-631.
- (81) Manwell LB, Williams ES, Babbott S, Rabatin JS, Linzer M. Physician perspectives on quality and error in the outpatient setting. *WMJ* 2009 May;108(3):139-144.
- (82) Sexton JB, Thomas EJ, Helmreich RL. Error, stress, and teamwork in medicine and aviation: cross sectional surveys. *BMJ* 2000 Mar 18;320(7237):745-749.
- (83) Aasland OG, Forde R. Impact of feeling responsible for adverse events on doctors' personal and professional lives: the importance of being open to criticism from colleagues. *Qual Saf Health Care* 2005 Feb;14(1):13-17.
- (84) Thomas EJ, Petersen LA. Measuring errors and adverse events in health care. *J Gen Intern Med* 2003 Jan;18(1):61-67.
- (85) Michel P. Strengths and weaknesses of available methods for assessing the nature and scale of harm caused by the health system: literature review. 2003.
- (86) Olsen S, Neale G, Schwab K, Psaila B, Patel T, Chapman EJ, et al. Hospital staff should use more than one method to detect adverse events and potential adverse events: incident reporting, pharmacist surveillance and local real-time record review may all have a place. *Quality & Safety in Health Care* 2007 Feb;16(1):40-44.
- (87) Busto U, Naranjo CA, Sellers EM. Comparison of two recently published algorithms for assessing the probability of adverse drug reactions. *Br J Clin Pharmacol* 1982 Feb;13(2):223-227.
- (88) classen DC, Lloyd RC, Provost L, Griffin FA, Resar R. Development and Evaluation of the Institute for Healthcare Improvement Global Trigger Tool. *J Pt Saf* 2008;4(3):169-177.
- (89) McKay J, Bradley N, Lough M, Bowie P. A review of significant events analysed in general practice: implications for the quality and safety of patient care. *BMC Family Practice* 2009;10:61.
- (90) de Wet C, Bradley N, Bowie P. Significant event analysis: a comparative study of knowledge, process and attitudes in primary care. *JECP* 2010:1-9.
- (91) Bowie P, McKay J, Dalgetty E, Lough M. A qualitative study of why general practitioners may participate in significant event analysis and educational peer assessment. *Quality & Safety in Health Care* 2005 Jun;14(3):185-189.
- (92) Wester K, Jonsson AK, Spigset O, Druid H, Hagg S. Incidence of fatal adverse drug reactions: a population based study. *Br J Clin Pharmacol* 2008 Apr;65(4):573-579.
- (93) Asghari F, Fotouhi A, Jafarian A. Doctors' views of attitudes towards peer medical error. *Postgrad Med J* 2010 Feb;86(1012):123-126.

- (94) Gallagher TH, Waterman AD, Ebers AG, Fraser VJ, Levinson W. Patients' and physicians' attitudes regarding the disclosure of medical errors. *JAMA* 2003 Feb 26;289(8):1001-1007.
- (95) White SM, Deacy N, Sudan S. Trainee anaesthetists' attitudes to error, safety and the law. *Eur J Anaesthesiol* 2009 Jun;26(6):463-468.
- (96) Jung HP, Wensing M, Olesen F, Grol R. Comparison of patients' and general practitioners' evaluations of general practice care. *Qual Saf Health Care* 2002 Dec;11(4):315-319.
- (97) Ely JW, Levinson W, Elder NC, Mainous AG, Vinson DC. Perceived causes of family physicians' errors. *Journal of family medicine* 1995.
- (98) Schoen C, Osborn R, Huynh PT, Doty M, Zapert K, Peugh J, et al. Taking the pulse of health care systems: experiences of patients with health problems in six countries. *Health Aff (Millwood)* 2005 Jul-Dec;Suppl Web Exclusives(Suppl Web Exclusives):W5-509-25.
- (99) Scott J, Dawson P, Jones D. Do older patients' perceptions of safety highlight barriers that could make their care safer during organisational care transfers? *BMJ Quality and Safety* 2011;Online first.
- (100) Cantor MN, Feldman HJ, Triola MM. Using trigger phrases to detect adverse drug reactions in ambulatory care notes. *Qual Saf Health Care* 2007 Apr;16(2):132-134.
- (101) Hazlehurst B, Frost HR, Sittig DF, Stevens VJ. MediClass: A system for detecting and classifying encounter-based clinical events in any electronic medical record. *J Am Med Inform Assoc* 2005 Sep-Oct;12(5):517-529.
- (102) Muething SE, Conway PH, Kloppenborg E, Lesko A, Schoettker PJ, Seid M, et al. Identifying causes of adverse events detected by an automated trigger tool through in-depth analysis. *Qual Saf Health Care* 2010 Oct;19(5):435-439.
- (103) Melton GB, Hripcsak G. Automated detection of adverse events using natural language processing of discharge summaries. *J Am Med Inform Assoc* 2005 Jul-Aug;12(4):448-457.
- (104) de Wet C, Bowie P. Screening electronic patient records to detect preventable harm: a trigger tool for primary care. *QPC* 2011;19(2):115-125.
- (105) Durkin N. Using record review as a quality improvement process. *Home Healthc Nurse* 2006 quiz 503-4; Sep;24(8):492-502.
- (106) Wilson T, Sheikh A. Enhancing public safety in primary care. *BMJ* 2002 Mar 9;324(7337):584-587.
- (107) Landrigan CP, Parry GJ, Bones CB, Hackbarth AD, Goldmann DA, Sharek PJ. Temporal trends in rates of patient harm resulting from medical care. *N Engl J Med* 2010 Nov 25;363(22):2124-2134.
- (108) Scott I. What are the most effective strategies for improving quality and safety of health care? *Intern Med J* 2009 Jun;39(6):389-400.
- (109) Sturmberg JP, Martin CM. Complexity and health--yesterday's traditions, tomorrow's future. *J Eval Clin Pract* 2009 Jun;15(3):543-548.
- (110) Lester HE, Hannon KL, Campbell SM. Identifying unintended consequences of quality indicators: a qualitative study. *BMJ Quality and Safety* 2011;20:1057-1061.
- (111) Cohen MM, Kimmel NL, Benage MK, Cox MJ, Sanders N, Spence D, et al. Medication safety program reduces adverse drug events in a community hospital. *Qual Saf Health Care* 2005 Jun;14(3):169-174.
- (112) Weingart SN, Gandhi TK, Seger AC, Seger DL, Borus J, Burdick E, et al. Patient-reported medication symptoms in primary care. *Arch Intern Med* 2005 Jan 24;165(2):234-240.

- (113) Zermansky AG, Petty DR, Raynor DK, Lowe CJ, Freemantle N, Vail A. Clinical medication review by a pharmacist of patients on repeat prescriptions in general practice: a randomised controlled trial. *Health Technology Assessment* 2002;6(20).
- (114) Saint S, Krein SL, Manjlovich M, Kowalski CP, Zawol D, Shojania KG. Introducing the patient safety professional: Why, what, who, how and where? *Journal of Patient Safety* 2011;00(00):1-6.
- (115) Siriwardena AN. Quality improvement projects for appraisal and revalidation of general practitioners. *Quality in Primary Care* 2011;19:205-209.
- (116) Boonyasai RT, Windish DM, Chakraborti C, Feldman LS, Rubin HR, Bass EB. Effectiveness of teaching quality improvement to clinicians: a systematic review. *JAMA* 2007 Sep 5;298(9):1023-1037.
- (117) Patey R, Flin R, Cuthbertson BH, MacDonald L, Mearns K, Cleland J, et al. Patient safety: helping medical students understand error in healthcare. *Qual Saf Health Care* 2007 Aug;16(4):256-259.
- (118) Shojania KG, Fletcher KE, Saint S. Graduate medical education and patient safety: a busy--and occasionally hazardous--intersection. *Ann Intern Med* 2006 Oct 17;145(8):592-598.
- (119) Gonzales-Formoso C, Martin-Miguel MV, Fernandez-Domingues MJ, Rial A, Lago-Deibe FI, Ramil-Hermida L, et al. Adverse events analysis as an educational tool to improve patient safety culture in primary care: a randomized trial. *BMC Family Practice* 2011;12(50).
- (120) Elder NC, Dovey SM. Classification of medical errors and preventable adverse events in primary care: a synthesis of the literature. *J Fam Pract* 2002 Nov;51(11):927-932.
- (121) Miles A. Complexity in medicine and healthcare: people and systems, theory and practice. *J Eval Clin Pract* 2009 Jun;15(3):409-410.
- (122) Parker D, Lawton R. Psychological contribution to the understanding of adverse events in health care. *Qual Saf Health Care* 2003 Dec;12(6):453-457.

Appendix I. A timeline of the recent history of patient safety in the UK

- 1997** ■ The Bristol Royal Infirmary Inquiry commence
- 2000** ■ The Department of Health (DOH England) publish 'An Organisation with a Memory'.
- 2001** ■ The DOH publish 'Building a safer NHS for patients'
 ■ The Bristol inquiry report makes 200 recommendations
 ■ The National Patient Safety Agency (NPSA) is established, with responsibility for England and Wales
- 2002** ■ The DOH publish 'Learning from Bristol'
- 2003** ■ NHS Quality Improvement Scotland (NHS QIS) assumes responsibility for patient safety in Scotland.
 ■ The Scottish Executive Health department publish 'Learning from Experience: How to Improve Safety for Patients in Scotland'
- 2004** ■ The NPSA publish 'Seven steps to patient safety'
 ■ The Health Foundation launch phase one of the Safer Patients Initiative
- 2005** ■ The National Audit Office report finds evidence of improvement in some areas of patient safety and recommends a further series of actions
 ■ The House of Commons Committee of Public Accounts publish 'A Safer Place for Patients: Learning to improve patient safety'
- 2006** ■ NHS QIS publish 'Safe Today, Safer Tomorrow'
 ■ The DOH publish 'Safety First: a report for patients, clinicians and healthcare managers'
 ■ The Health Foundation launch the second and final phase of the Safer Patients Initiative
- 2008** ■ National patient safety improvement initiatives are launched in each UK country
- 2009** ■ The Health Foundation launches the 'Safer Patients Network'
- 2010** ■ The Safety Improvement in Primary Care (SIPC) programme is launched in Scotland

Appendix II. Additional patient safety theories and frameworks

Cascade analysis

The majority of errors are not single acts, but 'a chain of events' with 'complex anatomy'.⁽⁵²⁾ Woolf et al found that 77% of reported incidents had evidence of a 'cascade of events' that constituted errors. A cascade implies that one error leads causally to another. The benefits include: error, rather than incidents, become the unit of analysis; it redirects attention and resources from proximal causes ('actors') to root causes; and it reveals the 'storyline' of errors, clarifying temporal and causal interrelationships.

Tempo's

Amalberti and Bami reviewed French malpractice claims with their 'five time scales framework'.⁽⁴⁴⁾ The time scales required parallel processing by GPs and were called 'tempos'. The five tempos and their relative frequencies were: disease tempo 37.9%, office tempo 13.2%, patient tempo 13.8%, system tempo 22.6% and time to access knowledge 33.2%.

Hourglass model

Elder et al systematically reviewed the literature in 2002.⁽¹²⁰⁾ They describe patient safety by considering 'what went wrong' (diagnostic, treatment or preventative care incidents) and 'why it went wrong' (process errors). Process errors are categorized into four groups: clinician factors, communication factors, administration factors and blunt end factors. They proposed an Hourglass model to incorporate patient factors with medical errors.⁽¹²⁰⁾ The framework incorporates four potential components of preventable adverse events in primary care. Two relate to system factors (process errors and patient safety factors) and two relate to patient factors (patient risk factors for ADE and patient-controlled patient safety factors). In the model patient encounters flow like sand through the health care system.

Complexity

Sturmberg and Martin argue that health care organisations have the same properties as complex systems, including: non-linearity, open to environment, self-organization, emergence and patterns of interaction.⁽¹⁰⁹⁾ They represent complexity with a 'Cynefin framework of sensemaking' which incorporates domains of order and unordered, causal and effect agents and weak and strong relationships.

Clinicians' 'reductionist instinct' is often unsuited to the complexity of modern health care systems and patients.⁽¹²¹⁾

Howard et al's model⁽¹⁴⁾

Howard et al's analytical framework adapted previous versions of Reason's (and Woolf's) model of organizational accidents and cascade analysis.⁽¹⁴⁾ It summarizes contributing factors, proximal causes, active failures and overcome safety barriers.

Cognition and decision-making

Elder et al propose a model of physician decision making when assessing whether an event should be classified as an error. It consists of three questions that helps 'balance' their decision to a yes or no.(2)

Kostopoulou et al discuss cognitive and system factors. They identified 'failures in situation assessment and response selection ...in both clinical and administrative tasks...related to serious harm...' in a small sample of self-reported incidents.(5) The 'information processing model' of human cognition can be used to characterize cognition of individuals involved.(5) Most common cognitive domain involved in patient safety events was found to be 'situation assessment and response selection'.

'Diagnostic overshadowing' is a psychological process explaining many misdiagnoses due to misattribution of presenting symptoms to obvious or readily available explanation

Scott described cognitive psychology of clinical reasoning, sources of cognitive error (reasons for diagnostic and management reasoning errors) and strategies to prevent reasoning errors.(50)

Parker and Lawton summarizes attributional processes, blame and cognitive biases contributing to patient safety (adverse events), including: fundamental attribution error, just world hypothesis, coping strategies, unrealistic optimism and illusion of control.(122) Cognitive biases include heuristics (rules of thumb) that help us understand behaviour.