内の目・外の目 ⑩②

ITで信頼を維持・回復

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●東京大学政策ビジョン研究センター教授　●マサチューセッツ工科大学スローン経営大学院客員教授　●1957年，香川県生まれ　●国立四国がんセンター，国立国際医療センター等の病院で，医師として20年余りの泌尿器外科，腎臓内科の臨床経験後，2005年～マサチューセッツ工科大学スローン経営大学院客員教授　●09年8月より現職，医学博士　●専門は，医療のIT化，医療安全，経営工学，マネジメント　●08年～WHO World Alliance for Patient Safety（Technology for Patient Safety）日本代表委員　●10年よりWHO Joint Classification and Reporting Initiative代表委員　●厚生労働省厚生科学研究事業「医療情報システムによる新しい管理会計と医療の最適化に関する研究」および「情報の構造化による医療事故・ヒヤリハット情報の利活用に関する研究」研究代表者，他。『ITで可能になる患者中心の医療』『デジタルフォレンジック事典』等，著書多数

＜前号よりつづく＞

◎医療の信頼維持・回復

超高齢化を迎えた我が国の医療を考えてみると，国民はますます増大する医療費や崩壊しつつある医療提供体制への不安が増大している。医療提供体制の維持のためには，費用を増やす必要があるが，国家財政は逼迫している。国民も医療費の財源問題は深刻と考えているので，医療費の増額は理解できるが，その額を最小限にしたいと考えている。医療の効率化とはいっても，簡単な話ではなく，大幅な制度変更が必要になってくる。そこで，医療制度の見直し，それも国家レベルでの仕組みの変更が必要になる。

しかし，「本当に医師は足りないのか？」「必要最小限の医療費はいくらか？」など，医療費の問題や医療事故の問題では，患者・国民側と医療従事者側の視点は，180度違うように思われる。前回述べたように，仕組みを変える際には「正しい情報」が大きな力を持つ。正しい情報に基づいたデータを見せることにより，初めて合意形成が可能となる。この過程で，国民から医療提供側に求めるものは，「透明化」いわゆる「見える化」である。そこで，「見える化」による「信頼維持・回復」が求められる。

ここで，信頼回復にあたり，Transparency（透明度を上げること）やAccountability（説明責任）は必須のことである。ただ，患者や国民は現状で医療側にそれらがかなり不足していると考えているようである。不足の程度の認識が，両者間で乖離しているというのは，「情報」の流通不足と考えられるだろう。すなわち，「患者のための医療」を考える場合に，患者が求めているのは「信頼」であり，その継続により，それは「信用」とか「ブランド」というもの（Trust）に変わっていくと考えられる。

その「ブランド」を維持することが，医療機関の目的にもなる。そのためのキーワードが，前述したTransparencyとAccountabilityと考えるが，医療従事者から見ると，患者の側にも考えてほしいことがある。それはResponsibilityということである。

Responsibilityという語を日本語で訳した場合，責任とか責任感となるが，欧米ではそれと

は少し語感の違う「自己責任」（自分の力で決めて，自分がその結果責任まで負う）というニュアンスが入っている。その意味では，病気に向かって，医療従事者と患者や家族たちが一体となって戦う仕組みが，本当の患者本位の医療体制ということになる。したがって，そこで担保されるべきものは相互の信頼関係（Trust）になる。

◎情報の偏在

その信頼関係を考えたときに，それを阻害している大きな要因は，「医療の閉鎖性」とか「ブラックボックス」という言葉で表現されている。つまり，患者サイドから見たときに，いかに医療機関内部が見えないかということであり，その閉鎖性を払拭しようとする場合に，ITが役に立つ。即ち，情報の重心，すなわち情報の偏在性というものを解消することに，ITが有用である。現在は，診療情報の重心が医療機関側に偏っており，情報の偏在性が指摘されている。そこで，この情報の重心を患者と医療機関とのちょうど中心に持って行くことを，医療機関が目指すべきであり，情報公開という言葉はこのことを指している（図）。

しかし，単に情報の重心を中心に移すのみでは不十分である。情報の重心を移動させても，例えば，カルテ開示をする，カルテを見せるという行為だけで，単純に信頼を回復できるとは思えない。例えば一度事故が起こってしまうと，単に情報公開しただけでは，また重心が戻ってしまうのではないか，一部のみで全体像ではないのではないか，最悪の場合，当初まで戻ってしまうのではないかという危惧が，患者側にあると思われる。いわゆるカルテの改ざん等である。また，事故が起こった場合，そもそも「最初からカルテに記載しない」という例もあるだろう。この場合は，いくら開示をしても無意味である。

したがって，信頼回復時には，ただ単に見せるのみではなく，その情報が如何に正しいか，情報の正確性ということが担保されなければ，どんなにカルテを見せても，いくら看護記録を閲覧させても，何の信頼感も得られない，言い換えればブランドは維持できなのではないだろうか。即ち，「正確に記録をする」ということは，簡単なようで意外に難しい。

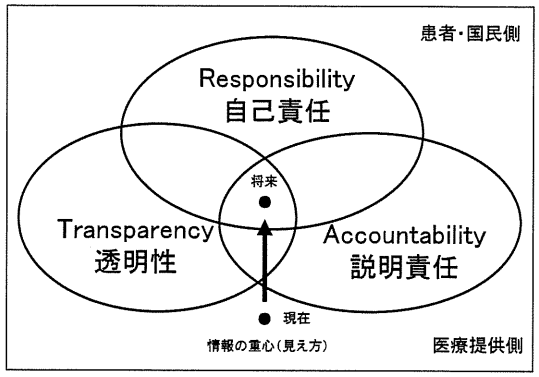

図　医療における信頼回復のために

周知のように医療現場は大変忙しい。医師・歯科医師のみならず看護師も大変である。諸外国に比べ職員の数が少ないという大変な激務の中で，如何に正確な記録を行うかを追求すると，さらに多忙になる可能性がある。その正確な記録を取る時間をかけつつ，医療の質を下げないようにするという難しい問題を孕んでいる。さらに，診療情報をただ単に見せるだけで，医療側の説明責任は十分に達成されるわけでなく，患者や家族に理解されるように丁寧な説明を行う必要があることはいうまでもない。結果として，超過勤務が増えるようでは，良い解決とはいえない。

◎ITは正確な記録作りに有用

それでは実際にITは何を実現するのであろうか。診療に関わる指示だけでなく，指示受け，実施を含む医療行為の経過や実績が記録されるシステムであることが望ましい。

具体的には，オーダリングシステムや電子カルテシステム等において，医師による指示の発行，内容の変更，指示の中止の記録以外に，看護師による医師指示の確認，診療や医療行為の実施記録，薬局，検査部門などの診療部門における指示の確認，指示に基づく行為の実施記録は必須であろう。もちろん，診療行為の実施者によって作成された実施記録やレポートについて指示・実施内容と更新履歴，またそれぞれの時刻，操作者が一元的に記録できるシステムであることも必要である。

次号では，信頼回復を実現するためのITの将来像を考えてみる。

（次号へつづく）

Information technology for patient safety

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Information technology for patient safety

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ABSTRACT

Background Research on patient care has identified substantial variations in the quality and safety of healthcare and the considerable risks of iatrogenic harm as significant issues. These failings contribute to the high rates of potentially avoidable morbidity and mortality and to the rising levels of healthcare expenditure seen in many health systems. There have been substantial developments in information technology in recent decades and there is now real potential to apply these technological developments to improve the provision of healthcare universally. Of particular international interest is the use of eHealth applications. There is, however, a large gap between the theoretical and empirically demonstrated benefits of eHealth applications. While these applications typically have the technical capability to help professionals in the delivery of healthcare, inadequate attention to the socio-technical dimensions of their use can result in new avoidable risks to patients.

Results and discussion Given the current lack of evidence on quality and safety improvements and on the cost–benefits associated with the introduction of eHealth applications, there should be a focus on implementing more mature technologies; it is also important that eHealth applications should be evaluated against a comprehensive and rigorous set of measures, ideally at all stages of their application life cycle.

INTRODUCTION

World Health Organization (WHO) Patient Safety established the Information Technology for Patient Safety Expert Working Group to examine the role of Information Technology (IT) in improving patient safety in healthcare. The Working Group included representatives from high-, middle- and low-income countries with expertise from clinical medicine, academia, government, health services management and industry. This report by the Working Group provides an overview of the interplay between IT and issues of patient safety in healthcare, maps out the boundaries of knowledge in this area and makes recommendations for future research and development. It builds on a recent systematic literature review commissioned by the English National Health Service (NHS) Connecting for Health Evaluation Programme, which included a review of research papers from across the world.

We identified priority areas through a consultation process involving all members of the Working Group. Although there are concerns about the variable methodological quality and completeness of the evidence base in the field—particularly in the evaluation of the impact of new technology in healthcare on patient safety—there is a specific lack of information on the experience in developing countries. The majority of published research has been carried out in high-income countries such as the UK and USA. This paper is therefore most applicable to economically developed countries; however, where possible, we have also drawn lessons for economically developing countries and illustrated the key points from the paper with a number of case studies.

INFORMATION TECHNOLOGY IN HEALTHCARE

The US government has defined IT as '...any equipment or interconnected system or subsystem of equipment that is used in the creation, conversion or duplication of data or information.'[1] This paper focuses on the information transacting role, considering those applications where there is a transformative or integrative element involving information. The focus is on the role of software and platforms that integrate information from these and other sources (eg, electronic patient records). We consider the requirements that might be made at a software–hardware-systems level to address issues of patient safety, but in-depth exploration of issues around technical implementations of software and hardware lay outside the scope of this paper. Reflecting this higher level view, we consider issues of patient safety relating to the key applications for information tools in healthcare delivery rather than considering each component separately.

The rationale for this selective approach reflects the priorities identified by the Working Group and the focus of IT implementation in healthcare internationally. There is significant interest in the potential for IT to address some of the current challenges facing healthcare systems, specifically:

- the resource and cost implications of serving populations with increasing life expectancy and improved survival in chronic illness;
- continuing deficiencies in the provision of healthcare that result in iatrogenic harm;
- opportunities to use IT to improve access to information by healthcare workers in developing countries to enable them to deliver safe, effective care.

New technologies have the capacity to both extend and replace existing clinical and administrative processes in health. The term eHealth is increasingly used to acknowledge that technological innovation is simply a component of a larger process of change, which ideally represents 'a new way of working, an attitude and a commitment for networked, global thinking to improve healthcare locally, regionally and worldwide....'[2] The conceptual map of eHealth (figure 1) developed recently by Pagliari *et al* identifies three top-level domains:

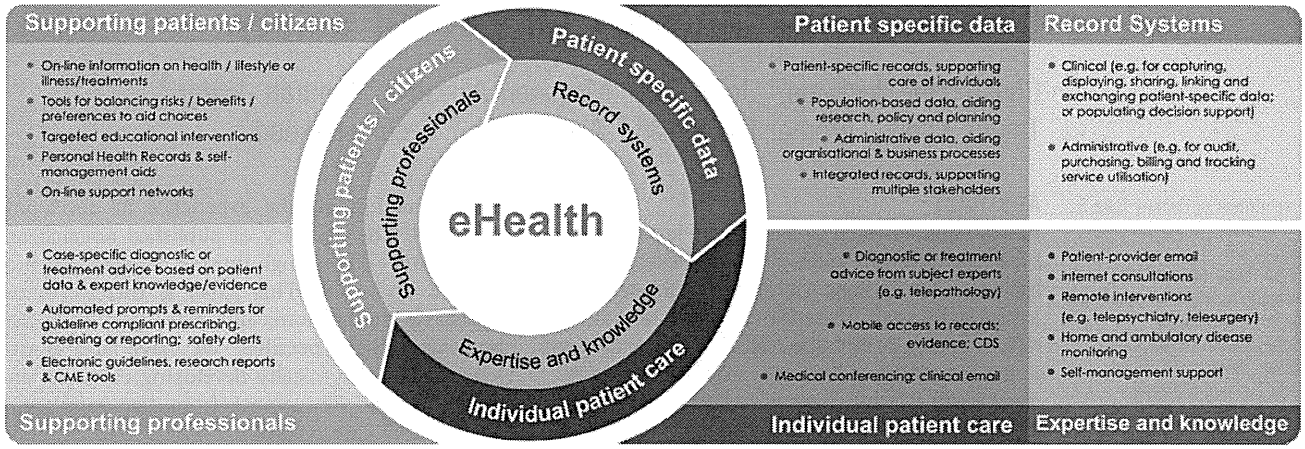

Figure 1 Conceptual map of eHealth showing how the different domains integrate to support professionals, patients and the public.

storing and managing data; informing and supporting decisions; and delivering expertise and care at a distance.

Information technology may reinforce existing barriers and introduce new barriers to error; for example, by preventing specific unsafe actions (active failures). Similarly, in ensuring that certain information is uniformly available or in reducing the time required to complete certain tasks, tools can actively address latent failures. Conversely, the introduction of a tool can disrupt an existing process in a way that introduces a new source of risk, perform incorrectly under certain conditions or facilitate unsafe behaviours by workers.

IT AND PATIENT SAFETY AT THE POINT OF CARE

Supporting care decisions

Every patient journey involves multiple decisions made by the team of healthcare professionals responsible for the patient's care. Each team member has the potential for active error, as well as contributing to an environment in which the scope for future errors might be enhanced. IT should therefore be used to ensure that optimal choices are made at every step of a patient's care pathway. IT must also be used to limit decisions that are clearly wrong and where there is a significant risk of iatrogenic harm. Although the scope for harm varies by decision type, deciding not to do something can be as harmful as an incorrect active treatment intervention.

Computerised Decision Support Systems (CDSS) are '...active knowledge systems which use... patient data to generate case-specific advice.'[3] These systems aim—with varying degrees of sophistication—to support the care decision process. There are good theoretical reasons to believe that CDSS can contribute to patient safety. First, they can guarantee consistency of decision-making; thus, the risk of violation or omission is mitigated. Second, by incorporating specific contingencies for unusual presentations conferring specific risks, errors associated with cognitive lapses or bias can be controlled.

These aims can only be achieved if the outputs of such tools are themselves correct and applied in clinical practice. Concerns about the former stem partly from the lack of regulation in this area and because the evidence on which such tools are based has significant gaps in some areas of practice, while expanding rapidly in others. There is a risk that increasing sophistication (eg, in tools that use dynamic inference) abstracts the decision-making process in a way that such gaps are not made visible. New risks also accrue from the information requirements that such tools introduce: parameters must be supplied accurately and for the right patient and relevant cofactors accurately specified. In one series, for example, omitted data resulted in 77% (95% CI 71 to 83%) of recommendations made by a CDSS being rated as potentially inappropriate and unsafe.[4]

The impact of incorrect clinical recommendations by CDSS extends beyond the risk of iatrogenic harm. Negative perceptions about IT tools are an important determinant of their continued use: if CDSS are perceived to produce unreliable outputs, they may not find use in routine clinical practice, and all the potential benefits are therefore negated. To combat this, an active approach to quality assurance is advocated that explicitly aims to mitigate the risks of covert error associated with problems in the underlying knowledge base—for example, by including algorithmic validation of consistency and completeness.[5] Effective user interface design and active validation of input can serve to limit the scope for user-related error; for example, user interfaces that are confusing or illogical can induce errors even by the most skilled users. Good user interface design requires a detailed understanding of how a technology will be used and of the work environment to gauge the types of errors that could arise in use and thereby eliminate or mitigate their impact.

Data completeness is an important safety issue in its own right. A given care decision might be inappropriate only in specific contexts. Although redundancy is desirable, opportunities to capture the information that defines these contexts are typically discrete; for example, a relevant medical history might only be captured during the initial assessment of a patient. Accurate medication history, details of any allergies and significant comorbidities are obvious examples that have the potential to have a recurring effect on future care decisions. Such information, once captured, should be accessible for all future healthcare encounters and, where care involves multiple providers, should be shared efficiently and securely between providers.

Electronic Patient Records (EPR) underpin CDSS and many other eHealth applications. One of the aims of the EPR is to tackle issues of data completeness. Structured inputs can mandate information recording, while the electronic format minimises the risk that information is subsequently mislaid. For example, in the UK, the EPRs used in primary care include recording templates for many chronic diseases (eg, diabetes, hypertension, coronary heart disease, etc) to ensure that key

demographic, clinical, physiological, biochemical and pharmaceutical variables are collected systematically and in a standardised manner for all patients. However, a current issue in many health systems, particularly in developing countries, is the low level of uptake of EPR systems.

An electronic system can be self-diagnosing in terms of measures of accuracy and completeness, and can motivate specific remedial actions. Where interfaces are poorly designed, however, or system reliability and performance effects clinical practice and workload, such systems can introduce new clinical risks. Empirical evidence for benefit is currently limited and compromised by poor methodological design: for example, there is currently no strong evidence for a reduction in adverse drug events with EPR implementation.[6]

Combating medication error

Mistakes in prescribing are one of the most common types of medical error and can be potentially serious, sometimes leading to death or disability for the patient.[7 8] The initial prescription order (decision-calculation) typically carries the greatest risk of serious harm, but mistakes can occur at each stage of the prescribing process:

- decision errors: failure to account for relevant comorbidities, polypharmacy, previous reactions, incorrect decision;
- calculation errors: failure to calculate the appropriate dosage;
- communication errors: dosage written incorrectly, illegible handwriting, wrong patient, ambiguous information on prescription, medication not given in a timely fashion;
- monitoring error or incorrect length of treatment: failure to track drugs with risk of accumulation of toxicity or where time-limited treatment is desirable;
- slips: incorrect drugs or dose packaged at dispensation, drugs given to wrong patient.

Electronic systems to support prescribing (ePrescribing solutions) typically combine structured capture of prescription requests with a varying degree of CDSS support. ePrescribing is one facet of Computerised Provider Order Entry (CPOE), which uses computer-based tools to record and communicate specific clinical actions (eg, prescriptions, tests, interventions). The potential impact on safety in terms of decision and calculation error is similar to CDSS: aggregation and presentation of relevant details at the point of decision-making reduces the scope for such mistakes. With increasing sophistication, tools can integrate relevant history (including recent laboratory results) and specific medication-related risks. Interaction with the ordering clinician can range from flagging up potential errors to placing more active constraints on what may be requested. Well-designed software can tackle issues of interpretation by ensuring that prescription information is presented unambiguously and is rapidly transmissible. The integration of patient and pharmaceutical identification schemes using barcode and radio frequency identification (RFID) technology with electronic prescriptions holds the potential to reduce slips around patient identification and physical dispensation of drugs (box 1). Automated flagging-up of missed prescriptions and monitoring tests is also possible with ePrescribing systems.

Interpretation of evidence for the efficacy of such tools is limited by the variety of outcome measures and construction of what represents a medication error (objective errors versus events that result in actual harm).[10] Where empirical benefits, measured in terms of reductions in preventable adverse events, have been shown with in-patient care, these studies have generally been carried out in centres of excellence using home-grown applications.[11 12] A 2000 Cochrane review suggested that dosage advice can be effective in preventing adverse drug reactions, as well as improving performance in situations where drug levels must be monitored to prevent toxicity.[13] The efficacy of interaction and allergy flagging is also unclear.[14] CDSS that include drug-management systems appear to improve clinical performance, but without concomitant benefits in terms of patient outcomes.[15] Where flagging systems are optional, they appear to be used infrequently, while routine flagging may come to be viewed as an unwelcome distraction. In a 2002 survey of UK general practitioners, 28% admitted to frequently or very frequently dismissing medication alerts without reading them.[16] Dismissing flags without consideration clearly defeats the purpose of such tools. Consequently, a synergistic role for the various components of medication-error-reducing solutions (information to support decision-making, CPOE, integrated pharmacy management and automated dispensation) has been suggested.[17]

Electronic prescribing tools can introduce new sources of risk that fall into two broad categories. First, there is information-related risk, where failure to integrate information sources means that the expected benefits from ensuring relevant information is presented are not realised. Second, there are failures of human–machine interaction. Such failures relate to both the way information is presented and requested and, more generally, the way the tool fits into clinical work patterns.[18] Structuring input can have unintended consequences: for example, the use of lists for medication dosages could facilitate slips that would not have happened had the user entered information manually.[19]

Because of the integration at critical points of care, and because introducing CPOE is typically with the intention to supplant existing mechanisms for decision capture, a safety

Box 1 Application of retail point-of-sale and back-office technologies to improve patient safety in Japan

Integrated point-of-sale and back-office operations that hinge on common identification and tracking technologies (typically barcodes) are pervasive in commercial settings, but their possible benefits in healthcare have only recently begun to be realised. Tackling patient identification error through the use of bar-coded or RFID chipped tags worn by the patient is increasingly advocated as an easy way to address the first of the 'five rights' of medication safety (right patient, drug, dose, administration route and time). Pilot programmes at the International Medical Centre in Tokyo and Red Cross Hospital in Morioka combine these technologies with a 'Point of Act' system that tracks both patient activity and consumable use. Every clinical contact represents a discrete event triggered—like the checking out of goods at a cashier till—by the scanning or entry of an identifier tag and captured by the system with relevant contextual information. This information details what was done at what time and where, to whom, why and by what means. This event-driven approach provides a robust method of exploring process flows, as well as inherently providing stock management capabilities. Safer care is anticipated from the constraints that are placed on patient and medication selection (the universal use of barcodes should guarantee the identity of both), the traceable provenance of the latter (managing the risk of counterfeiting and batch quality issues). In addition, the automatic capture of care data—and the unambiguous nature of the associated contextual information—makes this a useful resource that can be mined prospectively for unreported adverse events and as a forensic tool to reconstruct the care journey before any incident.[9]

impact at the organisational level is inevitable. The impact may be covert; for example, users may make unreasonable assumptions about the capacity of the tool to control certain types of error. Explicit understanding of the limitations of tools is necessary at the level of process design to avoid this problem. There is also an onus on software designers to ensure consistency: for example, in ensuring that prompts for a given type of medication error are displayed against all relevant drugs, rather than as a subset. Other organisational impacts with safety implications include occupying clinical time that would previously have been spent on other activities and duplication of work.[20]

Specific types of error could increase where the negative effect of process change is not fully appreciated. Spencer *et al* demonstrated an increase in dispensation duplication and inappropriate dose-related error associated with the use of a new CPOE system: the system failed to accommodate the need to transmit updated prescription information to the dispensary whenever a clinical decision was made to amend the dose, instead requiring that a new prescription be issued each time.[21] Concern at this level is further supported by the observation that mortality can increase after the implementation of an ePrescribing system and that organisational factors seem to have a significant role.[22] As with CDSS, there is a current lack of regulatory oversight. For example, ePrescribing systems are exempted from federal oversight in the USA and UK. There is also a need to develop systems to identify potential adverse drug reactions prospectively (box 2), rather than relying on manual reporting systems that have very low reporting rates.[23]

Delivering patient-centred care

An emerging theme in healthcare in countries like the UK and USA is that patients should have greater involvement in the care that they receive and be more informed about their own health and the treatments available to them. Technological developments are facilitating the sharing of information between patients and clinicians through online services, and such online access to medical records (figure 2) results in new opportunities for self-monitoring and for convenient care delivery (eg, email consultations).[24] Each of these developments can be designed with safety issues explicitly in mind (eg, patient validation of information in an electronic record could contribute to reduced error) while also conferring new risks.

Health systems across the world are now focussing on health promotion, disease prevention and optimising the management of chronic diseases. To help achieve this, there is considerable scope for collecting and utilising information from patients about lifestyle (eg, exercise, diet, smoking, alcohol consumption, etc) without the involvement of clinicians. These systems can be used to collect information directly from the patient, for example, at a preconsultation interview (remotely via the internet or in the clinic waiting room). Computerised history-taking systems can be used in many clinical settings and, when eliciting data directly from patients, could prove particularly useful in identifying potentially sensitive information such as alcohol consumption, sexual health and mental health, which patients might be otherwise reluctant to divulge.[25 26] Computer-based questionnaires are also useful for gathering important background data before the consultation, which can then allow more time for focussing on key aspects of the health problems within the consultation. As well as improving patient safety, these systems can also reduce administrative costs, thus releasing funds for other areas of healthcare.

Box 2 Prospective identification of adverse drug reactions using electronic health records, data mining and signal detection

Current systems for the detection of Adverse Drug Reactions (ADRs) have serious limitations. For example, the associations between Cyclo-Oxygenase Type 2 (COX-2) inhibitors used in the treatment of arthritis and increased risk for myocardial infarction and stroke were only discovered after these drugs had been used for 7 years by hundreds of thousands of users. Even where an association has been described, underestimation of the magnitude of risk could delay withdrawal of a drug; for instance, with the eventual withdrawal of thioridazine in June 2005, many years after the association with long QT syndrome had been described. Using information from electronic health records, it is now possible to consider identifying ADRs prospectively using data mining and signal detection. This raises a number of technical challenges, including the large size of the data sets (sometimes including records from millions of patients) and the difficulty in sifting out false-positive signals from true positives. However, successful developments in this area could radically transform the speed with which ADRs are detected, thus leading to the opportunity to withdraw a drug or limit its prescribing and hence improve patient safety.

Mobile telephones have also gained recent attention as a way of delivering care in developing countries. Mobile phone use is widespread in both developing and developed nations, and offers potential benefits over other forms of communication that rely on infrastructure (eg, postal systems, land-line telephones); people carry their phone wherever they go and, importantly, consider it an acceptable route through which to receive private information. Tailored alerts and prompts facilitate medication and condition monitoring, thus offering an avenue by which potential problems can be detected and acted upon early.[27] For patients in remote areas, mobile telephony offers a route to access care advice when no local clinical staff are available (box 3).[28] Future developments include the ability to perform simple laboratory tests using chip technology, the results of which are transmitted to clinicians using mobile connectivity. However, many of the programmable features on which more advanced systems depend are not available in the first- or second-generation handsets that are commonly in use in developing countries. There is also a current lack of guidance around how to ensure that healthcare interaction conducted using mobile telephony is safe.[29]

IT AND PATIENT SAFETY AT THE ORGANISATIONAL AND SYSTEM LEVEL

Capturing adverse events

Adverse events are important in healthcare because of the scope for significant harm to patients. Worryingly, they appear to be extremely common.[30] In the UK, around 850 000 errors occur annually in hospitals, contributing towards 40 000 deaths.[31] Most events have a mixture of latent and active contributory causes. This complicates their analysis and can make it hard for responsible organisations to identify the most effective strategy for their prevention. Each 'fix' has a cost–benefit profile and also represents a potential process change that has its own safety implications.

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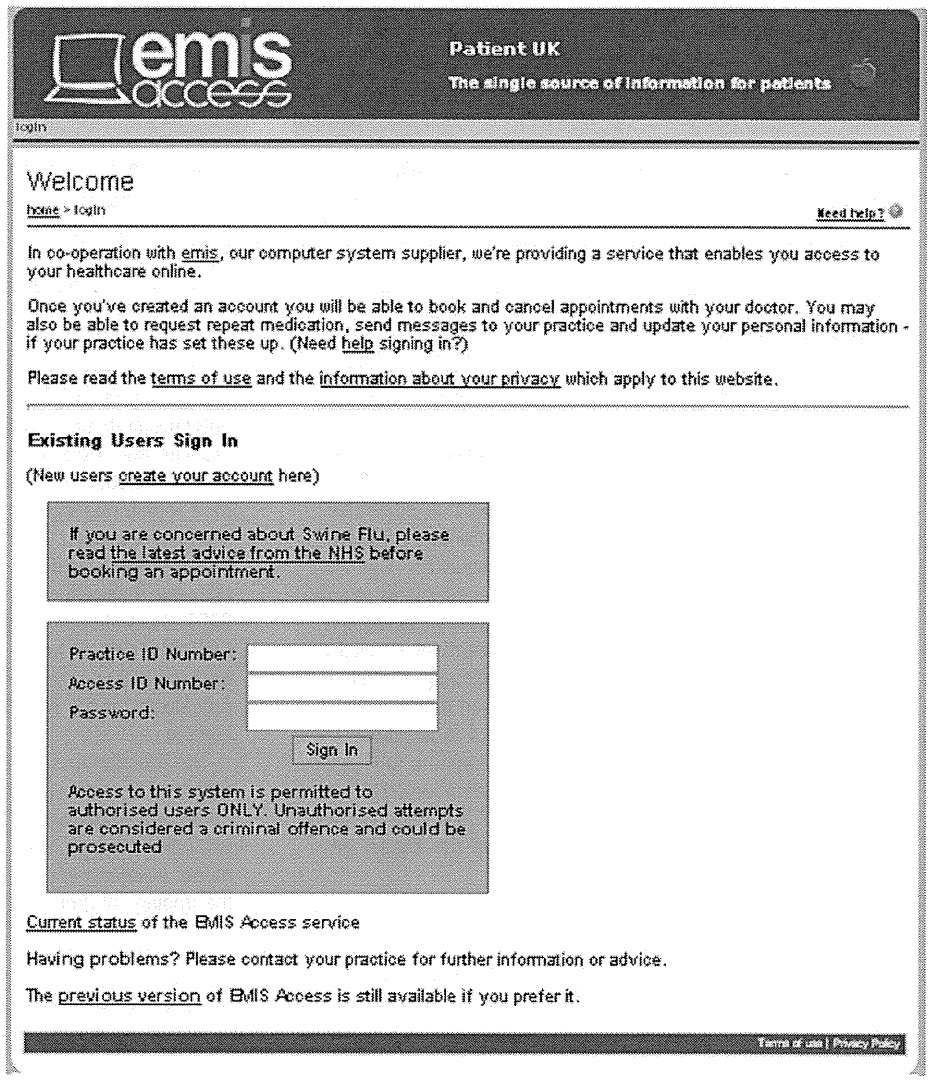

Figure 2 Online patient access to electronic patient records in the UK.

Currently, the capture of adverse event in healthcare is generally through voluntary reporting. Although high rates of reporting have been successful in reducing serious events in some industries (eg, aviation), there is significant under-reporting in healthcare. For example, fewer than 10% of adverse drug reactions are reported to regulatory authorities by clinicians. The reasons for this are complex and include fear of blame, organisational culture, lack of reminders and time effects.

Automated post-hoc identification of adverse events holds significant scope to address under-reporting issues; for example, deaths due to substandard care (box 4). A key requirement for event identification is synthesis of information from disparate sources in searching for the 'fingerprint' of an incident. Interoperability is therefore an important requirement for progression in this area. Specific prospective monitoring strategies for new-to-market products that would be amenable to IT-based tools have also been suggested. Signal detection and data-mining techniques can also be used to identify other threats to patient safety, such as clusters of adverse events or deaths following healthcare interventions.

Aggregation of incidents at organisational and national levels is also desirable, because the rarity of many events makes it hard to identify underlying systematic causes. Many countries now operate central collections (eg, the National Patient Safety Agency in England) to which events are submitted.[32] Automated analysis of these submissions poses significant technical challenges concerning semantic interpretation of event reports. Techniques that are likely to yield greater benefits in the near future are those that facilitate human operators in matching events and aggregating evidence in ways that can then be shared. Specific software tools already exist for certain types of safety exploration (eg, root cause analysis).

Standards

The current scope for standards in health informatics focuses on two main areas: data capture and data exchange. From a safety perspective, both hold the potential to address a number of issues. Data completeness is essential for many of the tools with potential safety gains, such as CDSS and ePrescribing.[33] Facilitating information exchange has direct safety implications: systematic transfer reduces the scope for transcription errors and physical loss of data, and can help to ensure that information is available when needed. Furthermore, when patients are receiving care from many different providers, ensuring that relevant parts of their clinical record are available, particularly in emergencies, has clear safety benefits.

Disease and intervention taxonomies are now common, driven partly by their role in remuneration in many health

Box 3 A consolidated care architecture can help to deliver safer care in inaccessible locations: the Malaysian example

Healthcare agencies in developing and newly industrialised nations face common challenges in providing high-quality, safe healthcare. These challenges include: variable coverage and quality of transport, utility and healthcare specific infrastructures that affect their ability to provide care, particularly outside urban settings; infrastructural and income-related constraints that limit the ability of patients to access services; and resource-related constraints affecting both staffing and equipment. A particular challenge for the Malaysian Ministry of Health is the limited access to remote areas and the reliance on boat travel that can incur significant delays in transferring patients who need urgent care to secondary centres. One solution, developed from 2003 onwards, is the TelePrimary Care (TPC) project that combines elements of electronic patient records, Computerised Provider Order Entry (CPOE), teleconsultation and data-quality-improvement programmes in a single system. Patients in remote locations benefit from their clinicians having access to expert advice to guide diagnosis and initiate early treatment as well as gaining case-specific feedback as part of Continuing Medical Education conducted through the system. When patients are transferred between centres, their entire record is available through a common system. Medication errors relating to illegible handwriting and drug interactions and contraindication have been reduced. A formal programme of evaluation of TPC was initiated in 2008 and is planned to include evaluation of the impact on patient safety.

Box 4 Auditing safety at a national level; applying signal detection to routine outcome statistics to identify failing care

In March 2009, the UK's Care Quality Commission (CQC), which is responsible for monitoring the quality of care in England's National Health Service (NHS), completed its report into standards of care at the accident and emergency department of a small acute urban hospital. The CQC believed that poor-quality care directly resulted in over 400 excess deaths over the period 2005–2008. Service availability, ward configuration and staffing levels were ultimately identified as key contributory factors to this critical failure, but it was notable that routine monitoring of outcome statistics played a role in highlighting the potential problem and triggering the subsequent investigation. Between 2007 and 2008, six 'outlier' alerts were generated for this hospital by a monitoring system that compares condition-specific mortalities against national figures. Although the hospital had already been alerted to a possible problem by an elevated all-cause standardised mortality generated by the same system in 2007, the outlier alerts acted as the trigger for involvement by the CQC. The data required to calculate these metrics are collated automatically as anonymised care-episode statistics and processed for the NHS by the Dr Foster Unit at Imperial College London.

The monitoring solution adopted in the UK combines automated routine reporting with national coverage, with a statistical methodology that is robust to false alerts; for example, the increased uncertainty associated with measurements involving very small numbers of patients. Prerequisite for the implementation of this kind of solution is reliable capture of event data in electronic form and an infrastructure for aggregation of these data nationally. In the UK, this is achieved in secondary care by electronically coding the main reason for each admission through a standard form and the use of a common national IT infrastructure to aggregate the data for analysis. Coded data extracted from primary care systems could be used for similar monitoring work. Beyond the IT components of the solution, responsible authorities must have processes in place that guarantee appropriate action when outlying data are generated. The judicious use of specific alerts to highlight salient issues can be advantageous, particularly where the perceived reliability of such alerts is high.

systems but also by the need to collect information required for public health surveillance. Similar work on information exchange has resulted in a number of standards. Syntactic interoperability relates to the ability of systems to exchange information about care and requires both a common message statement and a model of the care process involved. The principal international standard is HL7 (Health Level 7).

Semantic interoperability requires the use of common (or appropriately mapped) terminologies. Terminologies can also be related to classification systems based on an underlying ontology, as an ontology is required to map concepts in different terminologies. However, clinical coding (using a taxonomy to classify relevant parts of a patient's medical history) introduces new risks. The coding must be accurate, especially if the coded data will have clinical uses. Minimising errors of miscoding and—importantly—omission, requires well-designed taxonomies with adequate coverage that are applied systematically. Semantic ambiguities in some coding systems (eg, where a particular diagnosis can be coded in several ways, as in the Read code system used in UK primary care) limit the scope for automated interpretation and introduce a source of risk where systems cannot handle these variations. The shift away from paper-based management also introduces new requirements for system reliability. Systems must be robust to random failure and have contingencies in place to ensure that clinical work is not disrupted.

A recurring theme in eHealth is the lack of regulation for medical software. There is significant scope for regulatory authorities to exact the same demands for reliability that are used in other industries where software tools are mission-critical (eg, aviation). The complexity of medical systems is often cited as a barrier to this regulation; however, simple parameters like system uptime are easily measurable. Organisations such as the European Committee for Standardisation (CEN) could also help to develop international standards.

Implementation issues

The impact of IT tools on clinical processes can be significant but appears to be frequently underestimated both by system designers and implementing organisations. Risks can occur as a result of the explicit changes to existing processes that the tool introduces. Changes in the behaviour of end users can also occur—for example, cultural factors, attitudinal elements including resistance, assumptions (eg, assuming that the tool offers certain functions) and changes in the proportion of time allocated to different tasks. Failure to understand these possible effects carries the risk of patient harm. Introduction of a tool (and reversion where tools subsequently fail) is disruptive and

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itself carries a safety burden. Multidisciplinary working is the hallmark of modern healthcare; this imposes an additional burden on IT platforms in meeting the requirements of a team of users in which each member might have a different set of priorities.

Understanding safety in all contexts, including IT, requires a holistic approach considering elements that partition into those that are specific to IT (reliability, ergonomics, standards compliance, etc) and those relating to any process of organisational change (process redesign, culture, training and competence). A recent review of UK adverse incident reporting specifically identifies training and process integration as specific causes in relation to IT.[34] Adequate monitoring of implementation requires systematic planning and oversight throughout the lifespan of each tool as risks shift from implementation to ongoing training, sustainability and service level issues. Every implementation will have a combination of beneficial and detrimental effects. These may be intended, unintended but predictable or unintended and unpredicted. Discussion in the context of IT tools too often focuses on the beneficial, intended effects. A robust strategy can help identify possible risks (and devise mitigating strategies) and, postimplementation, identify those unpredicted consequences that can then be addressed locally. Captured at an organisational level and beyond, these analyses can be used to feed into the future design of both systems and implementation strategies. Examination of patient safety issues should be a recurring and explicit programme of work throughout the life cycle of every relevant IT tool.

ISSUES SPECIFIC TO DEVELOPING COUNTRIES

In developing countries, issues surrounding the use of IT to improve patient safety are often very different to those in developed countries. Healthcare workers in developing countries often lack access to information that could help them provide safe, effective care to their patients.[35] This often results in substandard medical practice. Improving access to relevant, reliable and up-to-date information has great potential to improve the safety of healthcare in such settings.

The Health InterNetwork Access to Research Initiative (HINARI) Programme, established by WHO in collaboration with major publishers, enables healthcare workers in developing countries to gain access to a large collection of biomedical journals and health literature.[36] With improved access to the internet in many parts of the world, information access initiatives such as HINARI could have a major impact on the safety of healthcare in resource-poor countries. For example, the first undersea cable to bring high-speed Internet access to East Africa went live in 2009, substantially increasing the number of people in the area with access to the internet, while at the same time reducing the cost of access.

A RESEARCH AGENDA FOR IT AND PATIENT SAFETY

Efforts to provide a robust commentary about patient safety in the context of IT are impeded by ongoing issues of methodological quality of research and evaluation in the field.[37] These issues can be summarised as:

- a fragmented theoretical framework that limits the scope for consistency in approach and stepwise evolution of the field—efforts to establish taxonomies for patient safety are an important first step in tackling this;
- parallel fragmentation in primary and secondary methodologies for the evaluation of IT tools, which includes all stages of design and implementation.

The diversity of outcome measures available and the quality with which investigations are reported are often cited as issues in the field. Both impact critically on the ability to perform effective synthesis of the literature. The critical gap between the benefits anticipated from theoretical work and those realised in clinical practice can only be addressed through well-designed evaluation programmes around technology implementation. Lessons can also be drawn from the health informatics literature on human factors research and human factors engineering.

Most evaluations of IT tools are currently described in the context of a single product being implemented in a live environment. This reflects a lack of confidence in developing more complex study designs that combine robust implementation evaluation with process, cost-effectiveness and impact analyses rather than ignorance of the possible organisational and financial consequence of technology implementation. The complexity of organisational impact can only be well explored with ethnographic approaches, but dedicated between-technology comparisons in controlled situations are clearly desirable. Efforts to standardise the approach to evaluation are continuing. Recent progress includes the introduction of guidelines for evaluation and reporting of IT interventions (GEP-HI, STARE-HI).[38] Consideration of harm as a specific outcome measure has also recently been advocated.[39]

Specific current topic areas where further research work is indicated include:

- methods of improving data quality in electronic patient records;
- identification of threats to patient safety using prospective methods and signal detection—for example, pharmacovigilance and postoperative mortality to identify adverse drug reactions;
- the use of mobile-phone technology to provide prompts and reminders to patients and to store key medical information on people with chronic illnesses;
- the use of IT for home-based care delivery and the role of pervasive sensing and remote monitoring;
- evaluation of information access initiatives such as HINARI and their effect on patient safety in developing countries.

CONCLUSIONS

This review outlines the potential of IT solutions to improve patient safety. Although it is developed countries that will benefit from such technological interventions in the short term, the rapidly falling cost of IT means that middle-income and eventually lower-income countries will also eventually benefit. A key lesson from health systems that have been successful in implementing IT in healthcare is that a commitment from the funders of healthcare (whether these are governments, national insurance schemes or third parties) to meet the costs of IT solutions is essential to ensuring their rapid and effective take-up. Countries with health systems where this is not the case, such as the USA, have had a much lower uptake of essential technologies, such as electronic patient records, than countries like the UK and Netherlands, where funders have shown greater commitment.[40 41]

Although IT solutions do have considerable potential to improve patient safety, there is currently a gap between the theoretical and empirically demonstrated benefits. Given the lack of evidence on quality and safety improvements and on cost–benefits, future eHealth applications should be evaluated against a comprehensive and rigorous set of measures, ideally at all stages of the application life cycle. Attention must also be paid to socio-technical factors to maximise the likelihood of

successful implementation and adoption.[42] Finally, most of the research in this area has been carried out in affluent, developed countries. Detailed case studies and rigorous research are also needed from middle- and lower-income countries if eHealth solutions are to be developed that can benefit public health and improve patient safety across the world.

How, then, can funders and providers of healthcare take forward the use of IT to improve patient safety? A key step is introducing the use of electronic patient record systems; these systems lie at the heart of many eHealth technologies, such as electronic prescribing and computerised test ordering, as well as providing data for the identification of potential threats to patient safety. However, the introduction of electronic patient records can bring its own threats to patient safety, particularly in the early stages, when healthcare providers could be using electronic and paper-based records in parallel. One consequence of this dual usage is that the data held in electronic patient record systems can be inaccurate or incomplete, with the potential to compromise patient safety because key data items (eg, drug allergies or important comorbidities) might not be recorded. Other key steps are to ensure the full engagement of clinicians and other professionals, and to provide adequate training to allow them to use eHealth solutions appropriately. It is also important that methods for effective data interchange between IT systems are in place if the full benefits are to be realised, and to limit the workload and errors that can arise from duplicate and unnecessary data entry. Finally, the implementation of IT solutions in healthcare should be linked to an effective research, development and evaluation agenda to allow appropriate lessons to be learnt and to ensure that only systems that have a real impact on patient safety, quality and healthcare efficiency are disseminated more widely.

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Making existing technology safer in healthcare

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Making existing technology safer in healthcare

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ABSTRACT

Background Technology, equipment and medical devices are vital for effective healthcare throughout the world but are associated with risks. These risks include device failure, inappropriate use, insufficient user-training and inadequate inspection and maintenance. Further risks within the developing world include challenging conditions of temperature and humidity, poor infrastructure, poorly trained service providers, limited resources and supervision, and inappropriately complex equipment being supplied without backup training for its use or maintenance.

Methods This document is the product of an expert working group established by WHO Patient Safety to define the measures being taken to reduce these risks. It considers how the provision of safer technology services worldwide is being enhanced in three ways: through non-punitive and open reporting systems of technology-related adverse events and near-misses, with classification and investigation; through healthcare quality assessment, accreditation and certification; and by the investigation of how appropriate design and an understanding of the conditions of use and associated human factors can improve patient safety.

Results and discussion Many aspects of these steps remain aspirational for developing countries, where highly disparate needs and a vast range of technology-related problems exist. Here, much greater emphasis must be placed on failsafe, durable and user-friendly design—examples of which are described.

INTRODUCTION

The ubiquity and usage of equipment and technology within healthcare are growing rapidly, with over US$130 billion spent in the USA alone in 2006 on medical devices.[1] Although essential for advances in modern medicine, many established and associated risks of technology continue.[2] It is therefore paramount to reduce the potential risk using a combination of methods that link human factors, equipment and the healthcare environment, as shown in figure 1.

A WHO Patient Safety working group was established to consider how existing technology can be made safer. The group includes representatives from high-, middle- and low-income countries with expertise in clinical medicine, academia, policy, health services management and industry. It is guided by a panel of international experts and draws on the scientific literature, where available, that is associated with the safety of current technology in the healthcare environment. Educational bodies and health service providers were approached to provide information on the specific technology problems that developing countries face. This report on this work is global in its scope, considering both the developed and developing world.

We have used the definition of 'Health Technology' adopted by the Health Technology Assessment programme in the UK—'a range of methods used to promote health, prevent and treat disease and improve rehabilitation and long-term care, including drugs, devices, procedures, settings of care and screening'—but have avoided any analysis of pharmacovigilance efficacy. One paper within the supplement recommends an agenda for future research within the field, whereas another outlines how new technology can be introduced safely.

We have identified four broad themes:

- The importance of reporting and learning systems to identify areas where technology is unsafe—importantly, these demonstrate that even in equipment-rich environments, such as critical care and anaesthetics, fewer than one in 10 incidents of healthcare-associated harm or death are attributable to actual device failure or faults.[3 4]
- Establishing systems of healthcare accreditation to ensure continuous evaluation and quality improvement.
- Because the majority of adverse incidents are associated with improper use and problems at the interface between equipment, users and patients, greater consideration needs to be given to human factors[5] and intelligent redesign.
- The specific challenges and issues in developing countries.

ADVERSE INCIDENT REPORTING

Reporting systems provide a mechanism for enhancing patient safety through learning from failures reported by healthcare workers. They reflect a measure of progress towards achieving a safety culture. The primary purpose of reporting systems for adverse incidents and near-misses within healthcare is to learn from experience.[6] However, reporting systems do not improve safety directly. It is the analysis of reports and subsequent dissemination and implementation of recommendations (eg, announcing recalls and safety alerts)[4] that leads to changes. Serious incident reports should trigger an extensive investigation to identify underlying systems failures and lead to efforts to redesign the systems to prevent recurrences. Although most incident reporting systems suffer from under-reporting for a variety of reasons,[7 8] and are restricted by a lack of denominator data, there are several ways in which reporting can lead to learning and improved safety.

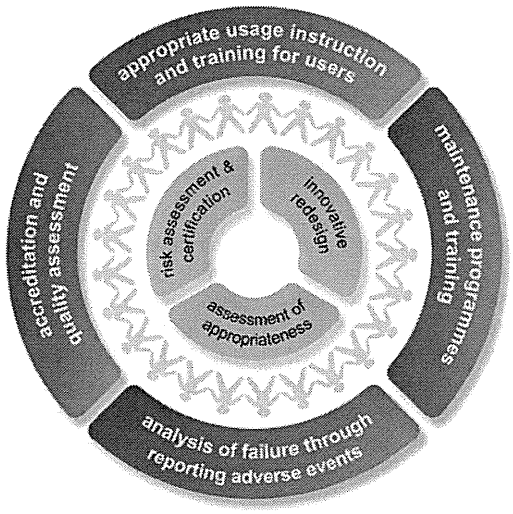

Figure 1 Reducing the risk associated with technology within healthcare. Mechanisms for addressing and reducing risk associated with technology in healthcare.

- Early warning systems for device failure: These can generate alerts regarding new and unsuspected hazards, and 'accidents waiting to happen,' as a means of achieving prevention without the need to learn from an injury.[9] This could result from a few similar incoming reports picked up by human review of previously unrecognised complications associated with the use of a new device. For example, even if only a few people report that free-flow protection on a particular pump model can fail, that might be sufficient for the receivers of the reports to recognise the problem, alert the providers and communicate directly with the pump manufacturer.
- Early warning systems for poor device design: Reporting could identify an important gap in current safety systems, such as devices with designs or interfaces that allow or induce misuse in ways that can produce serious adverse events—even though they still meet the manufacturer's specifications and pass regulatory standards. Conversely, a well-known example of surveillance failure is the software bugs of the Therac-25 linear accelerator for radiation therapy during the mid-1980s.[10] Inadequate reporting mechanisms and communication between hospitals, the Food and Drug Administration (FDA) and manufacturer were partly responsible for ongoing fatal radiation overdoses in six patients over a period of 18 months.
- Detecting problems that occur after several years: Some problems are not highlighted during short premarket studies and take years to become apparent.
- Detecting problems that rarely occur: By summing a large number of reports, it is possible to detect rare problems or complications that would not be detected by premarketing studies of limited size. This is the major thinking behind pharmacovigilance systems.[11]
- Opportunity for analysis: Analysis of many reports by the receiving agency or others can reveal unrecognised trends and hazards requiring attention. Analysis of multiple reports can lead to insights into underlying systems failures or specific patient factors associated with technologically related adverse events.[12 13] This generates both priority areas for remedial efforts and educational recommendations for 'best practices.'

Surveillance/reporting methods

There is no 'gold standard' for the surveillance or identification of Medical Device Related Events (MDREs) or their subsequent reporting.[5] Samore *et al* compared six methods for exclusively highlighting MDREs, in a US tertiary teaching hospital in 2000. Importantly, they found minimal overlap in the events identified by the different methods.[14] During 20 441 inpatient stays, an online incident reporting system voluntarily completed by healthcare professionals highlighted only 80 MDREs, whereas 1359 reports were logged to the hospital's clinical engineering department. During the 9-month study, 1122 International Classification of Diseases, Ninth Revision (ICD-9) MDRE-related codes were ascribed by the hospital's administration at patient discharge, and a postdischarge patient survey found that 7% of patients considered that there had been problems with medical devices during their stay. A voluntary telemetry checklist yielded no MDREs. This study found that automated surveillance of the electronic medical record (previously shown to detect adverse drug events)[15] using seven selected 'flags' had a 7.8% positive predictive value (PPV), with only 552 out of 7059 'flagged' events being actual MDREs.

By using an example of an incident-management system based on a universal classification system, 43 desirable attributes of an integrated framework for safety, quality and risk management have been described previously.[9] Once this classification can be agreed internationally (see below), work could proceed under the auspices of WHO Patient Safety on developing standards, field formats for data collection, aggregation, storage and analysis, and, ultimately, make it easy to allow data sharing and the creation of a universal database, as foreshadowed in 2002.[13]

International classification for patient safety

To date, incident reporting has been compromised by a lack of agreed definitions and preferred terms for the key concepts necessary to describe the attributes, characteristics, limitations and pitfalls of underlying healthcare technologies.[16 17] To promote a common understanding and ease the comparison of international datasets from different reporting systems, WHO Patient Safety commissioned work to develop a framework for an International Classification for Patient Safety (ICPS) (figure 2).[18 19]

Sources of information for the ICPS include incident reports, medicolegal files, coroners' recommendations, complaints and audits. Clinical engineering departments also use failure-related data extracted from computerised medical-equipment management systems for risk-management purposes. Reporting via a call centre equipped with the appropriate software for eliciting the information needed to populate a classification such as the ICPS would be cost-effective and require little infrastructure. Such a system is being used successfully in South Africa (see box 1). The database is populated in English using operators who speak English as well as the language of the reporter.[20]

Collecting information from all available sources into a classification system such as the ICPS can help to identify problems early. Clinicians and regulatory authorities in that jurisdiction, as well as in other countries, can then be alerted.

Importance of transparent non-punitive reporting

To encourage reporting and an appropriate response within the prevalent 'blame culture,' successful patient safety reporting systems must employ a non-punitive 'just culture' approach[21 22] except in the case of significant negligence. Neither reporters nor

Qual Saf Health Care 2010;**19**(Suppl 2):i15—i24. doi:10.1136/qshc.2009.038539

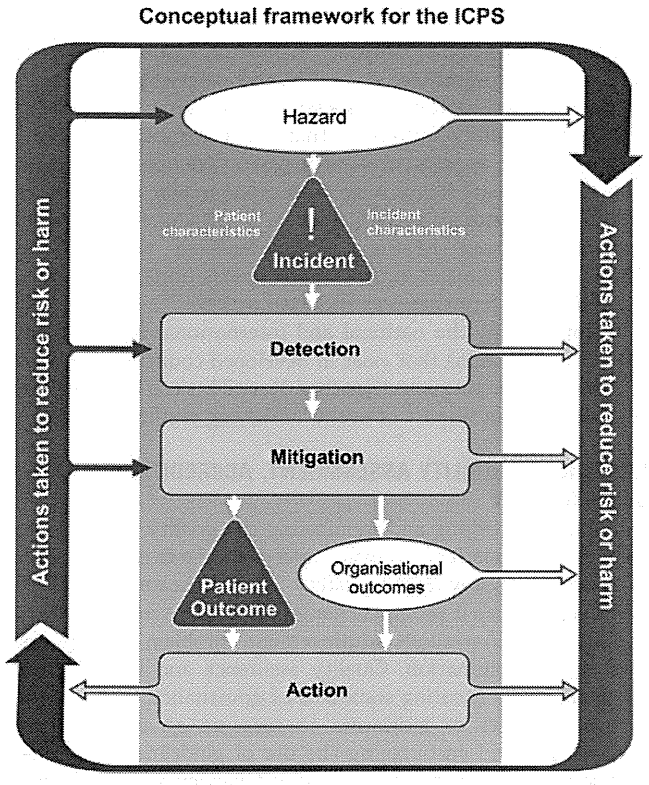

Figure 2 Conceptual framework for the International Classification for Patient Safety (ICPS). Maximum information collected from all adverse events and near misses is grouped into incident types ('medical device/equipment/property' and 'infrastructure/building/fixtures' having direct relevance to technology). During the incident, mitigating factors prevent or moderate harm to the patient. Organisational outcomes refer to the effects on the organisation, such as appropriation of resources to the affected patient. Adapted from Sherman *et al*.[19]

others involved in the incidents should be punished as a result of reporting, with the knowledge that adverse events and errors are symptoms of defective systems, not defects themselves. Figure 3 shows the sharp rise in telephone reporting to the Advanced Incident Management System (AIMS) in South Africa's North West Hospitals with a just culture approach in which staff were given the written assurance that they would not be punished regarding adverse incident reports. This excluded staff that displayed reckless behaviour by ignoring well-known safety protocols but included human error and at-risk behaviour (staff who did not know that they were doing wrong). Many systems offer the option of reporter anonymity, which increases the rate of reporting.[20 23]

Box 1 How the safety of technology in developing world healthcare can benefit from incident reporting systems

Incident reporting in South Africa

In South Africa, COHSASA is piloting the Advanced Incident Management System (AIMS) previously developed in Australia. Healthcare staff report problems via telephone to a call centre where data are recorded onto the AIMS database. These problems are then analysed and a report is quickly sent back to the institution. AIMS also assesses the institution's response to the report. In South Africa, insufficient consumables have been immediately evident as frequent causes of adverse events that are quickly rectifiable. For example, the absence of Yankauer suction tubing led to the death of a patient because it was not possible to perform tracheal suction. Similarly, an unexpected neonatal death occurred because of a failure to recognise the deterioration of simple physiological parameters in a newborn because there were insufficient pulse oximeters. (Case reports provided by COHSASA.)

Types of reporting systems

The most modest reporting systems are local audit. For example, a recent Tanzanian audit suggested that a quarter of perinatal deaths were associated with inadequate maternal and fetal heart monitoring.[24] If the audit cycle is completed, awareness of these deficiencies leads to improved safety.[25]

Generally, reporting systems can be either mandatory or voluntary and either held in complete confidence or reported to the public or to regulatory agencies. Reporting systems are generally internal or external and are open-ended, capturing all adverse events across care delivery, or focus on particular types of events such as predefined serious injuries, epidemiological outcomes such as the emergence of antimicrobial resistance or blood transfusion events. An example of the latter is the UK's Serious Hazards of Transfusion (SHOT) organisation, which was established in 1996 to encourage all hospitals in the UK to participate in haemovigilance to enable the identification and dissemination of solutions to make transfusion safer. Since its inception, SHOT has borne the hallmarks of an effective vigilance system with rising reporting accompanied by a steady decline in transfusion-associated mortality in the UK.[26]

Formats and processes within different reporting systems vary from prescribed forms with defined data elements to free-text reporting. It is imperative that sufficient information is provided for subsequent analysis—for example, the make and model of ventilator.[4] The system might allow for reports to be submitted in various formats including mail or telephone,[5] although electronic submission is arguably easier[27] and becoming more commonplace.

Some systems primarily have learning objectives, for example for device reporting to the FDA,[28 29] whereas others are designed to provide accountability. Rather than ensure a minimum standard of care, learning systems are designed to foster

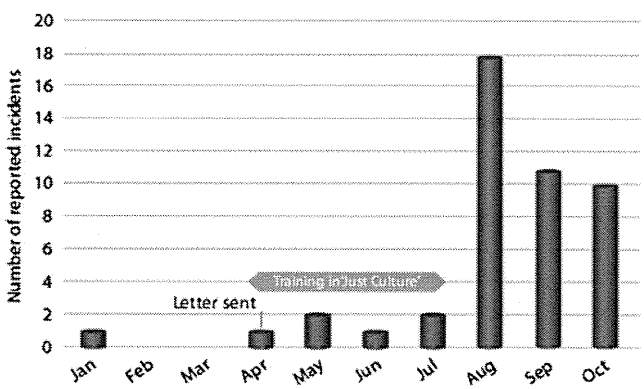

Figure 3 How a 'just culture' improves reporting: the rise in telephone reporting of adverse incidents to the Advanced Incident Management System in South Africa's North West Hospitals after a guarantee to staff of a non-punitive just culture during the first 10 months of 2008. Adapted from data provided by the Council for Health Service Accreditation of Southern Africa.

continuous improvements in care delivery by identifying themes in adverse events and near-misses, reducing variation in their incidence, facilitating the sharing of best practices and stimulating system-wide improvements. Incident reporting within learning systems is usually voluntary, and, via careful expert analysis of the underlying root causes, recommendations are made to redesign and improve the performance of systems in order to reduce errors and injuries. For example, the National Reporting and Learning System (NRLS) in England and Wales receives reports of patient safety incidents from local healthcare organisations. Its annual summary in November 2008 found that 27% of the 656 781 inhospital reports were about problems arising from medical devices or equipment.[30] About 1% of these caused death or severe harm to the patient.[31]

Conversely, reporting in accountability systems is usually mandatory and restricted to a list of defined serious events (also called 'sentinel' events) such as unexpected death, transfusion reaction and surgery on the wrong body part. Accountability systems typically prompt improvements by requiring an investigation and systems analysis ('root cause analysis') of the event. However, few regulatory agencies have the resources to perform external investigations of more than a small fraction of reported events, which limits their capacity to learn. Table 1 gives further examples of both systems.

Most accountability systems hold healthcare organisations accountable by requiring that serious mishaps be reported. Furthermore, they provide disincentives to unsafe care through citations, penalties or sanctions. The effectiveness of these systems depends on the ability of the agency to induce healthcare organisations to report serious events and to conduct thorough investigations.

For any system, the analysis of reports with assessment of risk needs to be prompt, with notification of serious hazards being made without delay. With a large number of reports, estimations of the probability of recurrence of a specific type of adverse event or error can be calculated. Analysis of reported outcomes can also produce an estimate of the average severity of harm caused by the incident or type of incident.[34] Risk analysis should be carried out by the most appropriate committees found within the healthcare facility. Depending on the institution, this might include an advisory committee on healthcare technology, the resuscitation committee, a health and safety committee or a theatre-users committee. Findings from reporting systems inform new safety initiatives that are generated and implemented by the appropriate authority. For example, the suggestion that adequate monitoring with capnography and oximetry would have resulted in the detection of 88% of the first 2000 anaesthesia-related adverse events reported to AIMS in Australia[35] had a major impact on the International Standard for Anaesthesia Safety that was endorsed in 1994.[36]

Unfortunately, the national and international reporting and surveillance systems that exist in developed countries are scarce or new in developing countries (box 1), and little is known about the frequency or impact of events involving medical devices.

HEALTHCARE QUALITY ASSESSMENT, ACCREDITATION AND CERTIFICATION

Evaluating, certifying and monitoring the quality of the provision of healthcare services using agreed standards is an excellent method of improving the safety of healthcare technology, particularly when it prompts change, subsequent reappraisal and a culture of continuous improvement, problem solving and critical self-examination. Quality assurance and improvement are achieved by ensuring standards of governance, using performance measures or indicators to measure an organisation's performance and encouraging the use of guidelines. Accreditation sceptics cite an increased workload, particularly for hospital middle management, a lack of consistency and significant cost. With reference to technology, however, accreditation can encourage training and continued professional development, improve audit and catalyse change to equipment and estates.[37] Examples include the Joint Commission and the Community Health Accreditation Program (CHAP) from the USA, the Trent Accreditation Scheme (TAS) in the UK and the Australian Council on Healthcare Standards.

Quality assurance is possible in the developing world:[38 39] in South Africa, COHSASA uses standards that define the key functions, activities, processes and structures required for the

Table 1 Further examples and descriptions of both learning and accountability types of reporting systems

Learning systems	Description
Advanced Incident Monitoring System	A system developed by the Australia Patient Safety Foundation and used by 200 Australian healthcare organisations for voluntary report submission. It uses the Healthcare Incident Types classification system, which elicits detailed information from the reporter regarding incident types, contributing factors, outcomes, actions and consequences. Statistical analysis of the relationship between the 1 million potential permutations of data describing each incident becomes useful.
Medicines and Healthcare Products Regulatory Agency in the UK	Healthcare professionals, industry and the public relay concerns about medical devices and medicines. In 2007, there were 8634 adverse incidents investigated related to medical devices, including packaging failures compromising sterility, faulty point of care/home tests (eg, those used for glucose monitoring) and pregnancy testing kits displaying false-negative results.[32] Although their investigations suggest that the responsibility lies as often with the healthcare establishment and end user as it does with the manufacturer, Medicines and Healthcare Products Regulatory Agency issued Medical Device Alerts on products such as vascular and dialysis devices, counterfeit condoms and infusion and feeding pumps.
Japan Council for Quality Health Care	Voluntary reporting of adverse events—particularly sentinel events with root cause analysis
National Electronic Injury Surveillance System in the USA	This monitors the safety of medical equipment in the community by recording the details of injuries caused by consumer products that require attendance at an emergency department. Between July 1999 and June 2000, there were 454 383 attendances, mostly caused by physical trauma from wheelchairs, scooters and other walking devices.[33]
Accountability systems	**Description**
Sentinel events in Slovenia	Sentinel events must be notified to the Ministry of Health within 48 h; 45 days later, a satisfactory analysis with corrective actions must be submitted; otherwise a follow-up consultation with the ministry occurs
Health Care Inspectorate of The Netherlands	Hospitals must report adverse events that have led to death or permanent impairment
Some States of the USA	Certain types of serious, usually preventable events must be reported

health facility departments to be in a position to provide quality Healthcare Technology Management services (HTM) that meet the principles set out by the International Society for Quality in Health Care (ISQua).[40] Accreditation is provided if minimum standards are demonstrated across seven areas: medical equipment support, healthcare technology planning, policies and procedures, medical equipment management, staff training, quality improvement and equipment safety. The 'equipment safety' area assesses the institutions' risk management and performance testing services, as well as the safety of the working conditions for the staff and their involvement in electrical safety training. In a typical programme, a baseline survey of an entire hospital is undertaken. Areas of non-compliance are identified, which for COHSASA are more commonly HTM planning, equipment safety and quality improvement. A multidisciplinary, continuous quality improvement approach follows, and external surveys are carried out by peers at various stages during the process. Figure 4 shows how mean levels of compliance across COHSASAs seven areas of HTM can be improved.

A culture of quality and safety has also been encouraged in Ghana with the establishment of a Non-Governmental Organisation (NGO) called the Ghana Quality Organisation collaborating with the Ghana Health Service to launch a series of workshops, seminars and conferences.[41]

Certification of technological products within healthcare

Medical product regulation and certification relies heavily on the use of agreed standards from international NGOs such as the International Organisation for Standardisation[42] (ISO with 163 member countries) and the International Electrotechnical Commission (IEC with 56 member countries). Standards include common safety symbols, common nomenclature and common paths for the validation of the safe usability of medical devices. The standards are nevertheless intended to allow individual manufacturers freedom to design their own solutions. The use of standards has given a strengthened focus on safety issues through safety-oriented standards such as quality-management systems and risk management applied to medical devices.[43–45] However, this certification is more common in industrialised countries with existing regulatory frameworks. Furthermore, certification bodies are usually based in these richer countries, despite commendable efforts from standardisation bodies to increase stakeholder representation from all geographical areas and interest groups. Many advocate a widened stakeholder base in standardisation work. This would not only encompass the medical device industry, but also require more input from healthcare professionals, safety professionals and regulatory agencies—the latter providing invaluable information from adverse event reporting and postmarket surveillance systems.

ERROR, HUMAN FACTORS AND SYSTEMS DESIGN

Human error

An error has been defined by WHO Patient Safety as 'failure to carry out a planned action as intended or application of an incorrect plan.'[18] Within the context of medicine, an adverse event is defined as 'an unintended harm caused by medical management, rather than by a disease process, serious enough to lead to prolonged hospital admission, temporary or permanent disability to the patient.'[46] James Reason has divided the investigation of human error into the person approach or the system approach.[47] The person approach focuses on the errors of individuals, with blame for forgetfulness, inattention or moral weakness. This is rare, and only illustrated by high-profile cases such as those of the family doctor Harold Shipman[48] and nurse Beverley Allit.[49] The system approach focuses upon the work conditions, bringing with it the concept of ergonomics—the science of designing the job, equipment and workplace to fit the worker.

Reason states that latent conditions can provoke error in the workplace, through time pressures or inadequate staffing. Such conditions can lie dormant for long periods before they combine with active failures to produce an adverse event. Reason has famously proposed the 'Swiss cheese model' of error, whereby layers of swiss cheese act as defences to error.[47] However, each layer has holes within it that are under a state of dynamic shift with regard to their presence, size and position. Each hole within a slice does not normally lead to a poor outcome, but when a number of holes in several layers line up, the potential for error production and propagation is great.

Vincent has expanded upon Reason's model to provide a classification of error-producing factors within a framework that can affect clinical practice.[50] These range from task design and use of protocols, through to team communication and organisational structures. The report 'To err is human' was seminal in proposing that events causing or risking harm to patients were more likely to result from systemic failure,[51] rather than the actions of individuals. The report suggested that efforts to improve patient safety should move away from a 'blame culture' and focus on removing 'error-provoking' aspects of care delivery systems. However, the traditional view of blaming and retraining an individual still prevails.[52]

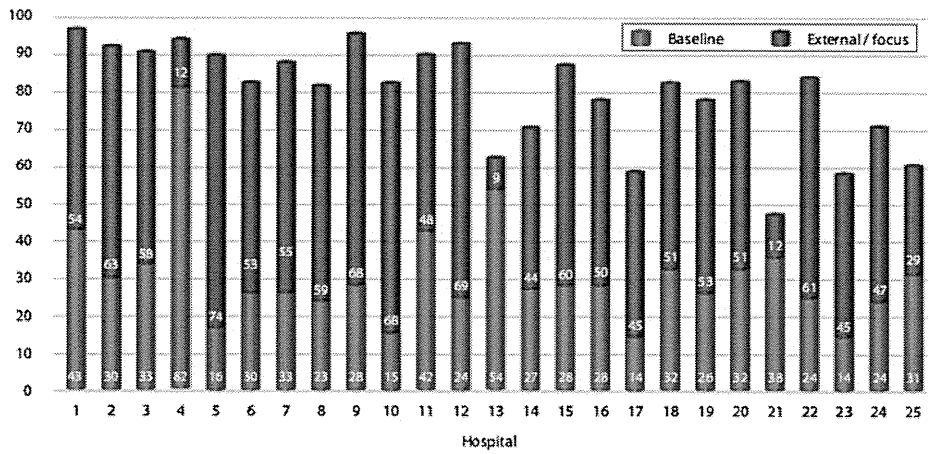

Figure 4 Healthcare Technology Management (HTM) scores for 25 facilities at baseline and after quality improvement. The mean performance indicator scores were measured over 5 years for the seven HTM areas at baseline (green bar) and after quality improvement at least 18 months later (blue bar) in 25 different institutions in South Africa. Scores greater than 80 are acceptable, and scores under 40 are considered highly unsatisfactory. Adapted from Council for Health Service Accreditation of Southern Africa data.

Measurement of error

Measurement of error is difficult. Within the context of intervention, it is possible to produce a protocol that defines the steps in a prescribed order. Any deviation from this is defined as error. This approach, also known as Human Reliability Analysis, was explored by Joice *et al* during observation of laparoscopic surgical procedures.[53] The aim was to define competent performance, although the study also demonstrated tasks that were more prone to error and instruments that were more likely to be associated with an error. The problem with such a tool is that it is quite focused upon the task in hand, and it is very difficult to consider the wider environment of the operating theatre with regards to patient factors, team factors and environmental factors.

Failure Modes and Effects Analysis (FMEA) is a procedure for analysis of potential failure modes within a system for classification by severity or determination of the effect of failures on the system.[54] Failure modes are any errors or defects in a process, design or item, especially those that affect the customer (patient), and can be potential or actual. Effects analysis refers to studying the consequences of those failures. This tool has been hailed as a useful approach to identifying problems within wider healthcare processes, with a focus upon the interaction with technology. For example, FMEA has been used for analysis of processes of care related to medication delivery, infusion pumps, radiation therapy and suicide risk.[54] Although a potentially useful tool, it is a laborious process requiring expert opinion upon the question in hand. Furthermore, its reliability has recently been questioned, with the conclusion that healthcare organisations should not depend solely upon FMEA findings to direct resources towards patient safety.[55]

Human factors

With particular focus on medical technologies, the aim is not only to produce high technology that serves a clinical purpose, such as a mechanical ventilator, but to ensure that the error-producing factors are considered with regards to placing such a device into clinical practice. There is of course a need to advance equipment design, but the importance of team structure and communication, organisational culture and crisis management cannot be understated. In high-reliability organisations such as the nuclear, oil and mining industries, these aspects are collectively known as human factors—a discipline that spans ergonomics, engineering and cognitive psychology. Human factor analysis focuses on performance design, incorporating human strengths and limitations, leading to iterative testing and evaluation. The importance of this concept to medicine is that testing occurs within an already functioning system (ie, in vivo) and could improve or endanger care.

The application of human factor approaches to medicine has been led by the anaesthetic community. In the 1970s, escalating litigation costs resulting from critical errors in anaesthesia led to analysis of near misses and fatal errors. This, in turn, led to the development of technologies to provide early warning of human or equipment error. Safety advances included non-interchangeable screw threads for different pipeline gases with the inlet on the anaesthetic machine, to prevent the delivery of hypoxic gases to the patient. Similarly, there has been work to develop separate 'lock and key' systems for intravenous and intrathecal delivery of medication—see the case study in box 2.

Systems design

To enhance patient safety, it is necessary to concentrate upon the systems approach to error and, in particular, upon latent failures. Solutions to such error and subsequent adverse events have been designed, investigated and implemented within medicine. The most recent and widely known is perhaps the WHO Surgical Safety Checklist project, which identifies three phases of an operation, each corresponding to a specific period in the normal flow of work: before the induction of anaesthesia (sign in); before the incision of the skin (time out); and before the patient leaves the operating room (sign out). In each phase, a checklist coordinator must confirm that the surgical team has completed the listed tasks before it proceeds with the operation. The checklist has been shown to reduce both patient morbidity and mortality in both developed and developing nations.[58] There is now a drive for widespread use of the checklist.

The checklist is a very simple but effective technology that aims to enhance patient safety; however, other technologies that are already in use might be more difficult to redesign. An example of a piece of ongoing work at Imperial College is the redesign of the resuscitation trolley. Traditionally, this is no more than a workman's tool trolley, although absolutely crucial during a cardiac arrest. In the pressurised, time-critical and often crowded environment of a cardiopulmonary arrest, it has been shown that division of team roles with leadership and direction of resuscitation algorithms are often lacking. This is compounded by inaccessible contents and inadequate daily stock checking.[59] Collaborative work between clinicians, nurses, psychologists, human factor specialists and engineers, using footage of real and simulated arrests, has led to a drawer-free open-layout resuscitation station with logical separation of equipment (for airway, breathing and circulation); radio-frequency identity technology has also been employed for instantaneous stock checking.[60] The trolley incorporates an interactive touch screen to prompt the team leader and encourage appropriate role adoption within the team, while the software provides data capture for subsequent audit. Redesign and renewal is not always a financial possibility, however; simply understanding how errors are created is sufficient to

Box 2 Intelligent redesign resulting from a recurring severe adverse event

Vincristine: Wayne Jowett

Wayne Jowett was in remission from acute leukaemia, undergoing the final stages of his treatment. He was being treated with two chemotherapeutic drugs, vincristine given intravenously and cytosine given intrathecally. By mistake he was given vincristine intrathecally.[56] Intrathecal vincristine causes paralysis and death. Wayne died a month after the injection. There have been over 50 cases of intrathecal vincristine reported worldwide.[5] Despite awareness of the problem and repeated warning, this event still occurs. A variety of solutions have been proposed,[57] including restrictions around seniority and training, separation of the intrathecally and intravenous drugs in time and space and technical solutions. Separate 'lock and key' systems for intravenous and intrathecal systems to prevent cross-use have long been viewed as the solution but have proved hard to achieve. More recently, the supply of vincristine in a 'mini-bag' of saline has been used. The volume of saline is such that no doctor or nurse would consider nor could inject the drug into the spinal space. However, owing to the volume of fluid, the mini-bags are not safe in the paediatric setting and so only represent a partial solution. These solutions represent key examples of redesigning technology to make care safer.

change the practice of the end user. For example, heuristic violation assessment can be performed on widely used technologies such as infusion pumps to identify potential usability problems.[61]

The standard process of blood transfusion is an inherently dangerous process prone to human error. Through systematisation and multiple verification steps, much of the error from incorrect blood component transfusion has been removed. Bar coding to verify correct identification at multiple steps in the transfusion, such as a process to match patient and blood product at the bedside, has been introduced at the John Radcliffe Hospital in Oxford, UK.[62] Hand-held computers are used to scan bar codes on the patient's wrist band and the blood product to ensure a match. Early data suggest that use of this system increases checking behaviours; long-term study will establish if there is a reduction in harm to patients.

Similarly, patient wrist band bar codes can be scanned together with medication bar codes to try to avoid human error.[63] This increased complexity can have drawbacks,[64] for many reasons including time constraints and the possibility of staff employing workaround strategies.[65] However, human factor analysis within the sphere of intravenous drug errors in anaesthesia has demonstrated that the solutions need not be complex: there is evidence that prefilled syringes, colour-coding and syringe labelling immediately after drawing up the drug, structured organisation of drug drawers and different packaging and presentation of drugs in different classes help.[66]

It is imperative that all end users appreciate that intelligent redesign and safety systems will never eliminate risks from human factors. Indeed, measures taken to address human factors can increase complexity and, therefore, the propensity for errors due to technical failure. For example, the anaesthetic machine safety pins described in box 3 can be found to be missing or become worn and bent. Therefore, qualified and competent user vigilance is still required, along with continuous professional development to keep abreast of changes in technologies.

Box 3 How technology can be used to prevent human error within anaesthesia

Anaesthetic misconnections

While human error is responsible for most adverse incidents within anaesthesia, equipment inadequacies have been highlighted by the seminal papers on critical incident analysis by Beecher in 1954[67] and Cooper in 1978.[68] In the 1970s, escalating litigation costs resulting from critical errors within anaesthesia catalysed critical incident analysis in a manner that had previously been practised in the airline industry. This analysis of near-misses and actual incidents led to developments in technology that provide early warning of, or prevent, human and equipment error. There was acceptance of national (eg, British Standards Institution) and international standards (International Organisation for Standardisation) for the components of anaesthetic machines. Safety advances include non-interchangeable screw threads between pipeline gases and the inlet on the anaesthetic machine, along with alarms and mechanical devices to prevent the delivery of hypoxic gas mixtures to the patient. Additionally, the pin index safety system offers protection against accidental connection of a pressurised gas cylinder to the wrong yolk. Each air, oxygen, carbon dioxide, heliox and nitrous oxide cylinder top has a unique arrangement of holes into which only the corresponding gas yolk's projecting pins can be inserted.

KEY ISSUES FOR THE DEVELOPING WORLD

Insufficient attention to patient safety in low-resource, developing-world settings has been the result of a lack of awareness and inadequate financial, human and communication resources. In these settings, access to service and supplies is often limited, and there are major infrastructure gaps, such as outdated facilities, overcrowding, inadequate clean water, power and sanitation. There has been a perceived limited market for appropriate health technologies, and sometimes the only available technologies are designed for industrialised markets and are inappropriately complex. This causes both operating difficulty, with inadequately trained healthcare professionals of low literacy, and maintainance difficulties, particularly with extremes of temperature and humidity.[69] Governance within developing-world healthcare is less advanced, and patients less aware of the risks and their rights; there is a power imbalance between patient and healthcare provider with poor reporting structures and legal recourse. Some argue that the increased presence and voice of professional medical bodies with their evidence-based guidelines within the developed world puts pressure on

Box 4 Development of auto-disable hypodermic syringes

Points of safety

Disposable plastic hypodermic syringes were developed in the 1950s, partly solving the problems caused by inadequate sterilisation of reusable syringes and needles. However, inappropriate reuse remains an issue, particularly within the developing world where cost and the reluctance towards single use are important factors. Reuse of syringes can cause transmission of nosocomial bloodborne infections, including HIV and hepatitis B and C, and has threatened the acceptability of immunisation programmes in the developing world. This prompted a 1986 WHO request for auto-disable syringe ideas. Over 400 designs were submitted, involving ideas such as immobilisation of the plunger, blockage of the needle and leakage when a second injection is attempted. Currently available auto-disable systems or syringes with reuse prevention features include the SoloShot, which has an internal metal clip to lock the plunger after injection to prevent refilling; the K1 syringe, which can serve curative injection needs as well as immunisation; and the Uniject, which is a prefilled single-dose non-reusable plastic bubble.[71] All these systems can have integrated needles to prevent needle reuse and are now manufactured in more than 10 developing countries, priced at US $0.1—0.3 more than standard disposable syringes.[72] Uptake has been boosted by Unicef replacing standard disposable syringes for vaccination programmes with autodisable syringes. Safety issues remain concerning the disposal problems inherent with any disposable needle,[73] and a lack of needle protection for the prevention of sharps injuries. However, new low-cost needle protection systems are under development. Significant reuse is still prevalent in the curative sector, even within public health facilities. Reuse will hopefully become unnecessary as the market becomes saturated with K1 and similar devices that can replace all syringe sizes and types used in most procedures.