

## **Chapter M: Human Factors of Reporting Systems**

A number of mechanisms that can be used to elicit epidemiological information about adverse events in healthcare. Morbidity and mortality committees provide a primary means of detecting potential problems in the quality of patient care (Wald and Shojania, 2001). Litigation and malpractice statistics focus attention on incidents and accidents. The publication of clinical studies also helps to ensure that medical practice remains at a high level within particular organisations. However, these epidemiological techniques often provide insights many months and years after the original incidents have occurred. They also are often limited in terms of the insights they provide into mitigation and error reduction strategies. Other techniques such as chart reviews and the use of automated detection systems provide limited information about the causes of adverse events and can provide results that are both partial and biased. This chapter focusses on the role that mandatory and voluntary reporting systems can play in improving patient safety.

### **M.1 Introduction to the Human Factors of Adverse Events**

Human factors play a dual role in healthcare. On the one hand, we rely upon individual and team decision making to guide most aspects of diagnosis and treatment. We rely on the skill and judgment of clinicians to decide when and when not to intervene. We depend upon their vigilance to determine when mistakes have been made or, ideally, to intervene before colleagues make a mistake. On the other hand, as we have seen in previous chapters, human factors issues can trigger accidents and incidents. For example, a physician might make a slip if they write down 10 mg of an appropriate medication when the intention was to prescribe 1 mg. Alternatively, they might make a mistake by giving a medication that was not intended as part of the patient's treatment. They could also lapse by forgetting to deliver an intended drug. Finally, clinicians can commit violations by deliberately ignoring recommended practice. All of these different forms of human 'error' have been noted in a range of hospital and primary care settings (Johnson, 2003).

#### ***M.1.1 Estimating the Costs of Adverse Healthcare Events***

It is difficult to underestimate the significance of human error in healthcare. We are surrounded by newspaper items and television broadcasts that reinforce concern over a succession of incidents and accidents. The products of research in this area inform much of this media interest. For example, a series of studies have argued that almost 100,000 patients die from preventable causes in United States' hospitals. This annual toll exceeds the combined number of deaths and injuries from motor and air crashes, suicides, falls, poisonings and drowning (Barach and Small, 2000). It has been estimated that there are 850,000 adverse incidents every year in the UK National Health Service. The UK National Patient Safety Agency reinforced this concern when they found more than 24,500 adverse incidents in 28 trusts over a six-month period (BBC, 2002). Such statistics are, however, very difficult to validate. National figures rely on interpolation from relatively small samples. The biases within these samples further confound interpretation. For instance, some trusts in the NPSA study reported a high number of minor events, such as the misapplication of a bandage, while others reported virtually nothing. The underreporting of adverse events to national monitoring organisations is estimated to range from 50%-96% annually (IoM, 1999).

The financial costs associated with adverse medical events are slightly easier to determine, although they provide a very indirect measure of the physical and psychological consequences for individual patients. These costs partly stem from the additional treatment that is required in the aftermath of adverse events. They are also associated with litigation. There is a wider perception that rising legal bills are undermining the economic underpinnings of many national and local systems. For instance, the NHS faces a litigation liability in excess of £4.4 billion, a figure that has more than trebled in the last three years (BBC, 2002a). This represents just under one tenth of their annual budget. George W. Bush has responded to these costs in a forthright manner; “there are some costs that are unnecessary as far as I’m concerned. And the problem of those unnecessary costs don't start in the waiting room, or the operating room, they're in the courtroom...And one thing the American people must understand is, even though the lawsuits are junk lawsuits and they have no basis, they're still expensive. They're expensive to fight. It costs money to fight off a junk lawsuit. And oftentimes, in order to avoid litigation, and oftentimes, to cut their costs, docs and, therefore, the companies that insure them just settle. See, so even though there's no merit, in order just to get rid of the thing, they just say, okay, let's just pay you. We'll get you out of the way. Instead of maybe suffering the consequences of a lousy jury and a lousy verdict, just pay them off. That is expensive to the system when it happens time and time and time again, like it's happening in America today” (Office of the Press Secretary, 2003).

### ***M.1.2 Tort Reform and an Introduction to Incident Reporting***

The rising human and financial cost of adverse healthcare events has triggered a number of responses. In particular, several governments have proposed a limit on the damages that may be awarded in medical cases. These caps are justified either in terms of the limiting the financial exposure of national systems, such as the NHS, or in terms of the ‘spiralling’ insurance costs that individual practitioners must meet in order to protect themselves against such litigation. Most of these limits are inspired by the Californian Medical Injury Compensation Reform Act (MICRA). This was part of a wider initiative to address the financial consequences of healthcare litigation and resulted in a limit of approximately \$250,000 being placed on non-economic damages in malpractice suits. One study has argued that malpractice premiums in the state increased 175% between 1975 and 1985, but after the introduction of these measures they dropped 8% between 1988 and 2000.

Other healthcare providers have looked beyond a maximum limit for all healthcare litigation. For instance, Sweden and Norway have moved the burden of insurance from the clinician by developing voluntary insurance schemes for patients. Denmark and Finland rely on mandatory patients' insurance. Other proposals have focussed on fixed tariffs for specific injuries. Structured payouts instead of large one-off lump sums have also been suggested, as well as non-cash compensations, such as home nursing care (Gaine, 2003). Alternative dispute resolution systems have also been proposed. These proposals have been motivated by a number of reports into the inefficiencies that complicate the settlement of claims in the aftermath of adverse incidents. For instance, a

report by the UK National Audit Office (2001) published in 2001 found that cases can drag on for an average of five and a half years before settlement and that this delay can significantly increase the costs. The same report found that in 44% of cases the final legal bill was substantially higher than the compensation paid to patients and their families. Similarly, legal fees often account for more than one third of compensation paid to injured parties in the United States. For this reason, several states have established 'accelerated compensable events'. Payments can be made for certain classes of adverse events, mainly in obstetrics where most high-value claims are settled, without requiring that patients and their relatives prove who is to blame for the medical 'error'.

These US systems illustrate the use of 'no fault liability' as a means of reducing the costs associated with adverse healthcare events (Vincent, 2003). Both the UK and the US rely on the law of tort to resolve most healthcare claims. Tort law is based on an adversarial process in which the claimant must prove harm has been caused by a breach of care. This focus on establishing blame may prevent the exchange of information that might prevent future adverse events. Supporters of the current system argue that litigation acts as a deterrent to substandard care. In contrast, the proponents of no-fault liability argue that the claimant must only show a medical error was a causative factor in an injury. They do not need to establish who was to blame for the causative error. In this model, the burden of proof focuses on causative mechanisms rather than establishing the fault of a particular individual or team. The arguments in favor of 'no fault liability' are counter intuitive. The intention is to reduce the total liability by making it easier to establish a claim. However, the proponents of tort reform argue that lower legal and administrative costs and a lower level of payouts will offset the costs associated with a greater number of claimants.

Just as the advocates of capping point to the success of the MICRA legislation in California, the proponents of 'no fault liability' also have a number of existing successes to substantiate their arguments. For instance, Virginia and Florida have set up selective forms of 'no-fault' compensation to cover birth-related neurological injuries. New Zealand has established a more sustained system. They replaced a tort-based approach with a form of no-fault litigation following the Woodhouse Commission report in 1972. The initial scheme was criticized because it was felt to offer undue protection to negligent clinicians. The relevant legislation was then amended to increase the accountability of individual clinicians. This revised act established a model for several other countries. For example, Canada operates a 'twin track' approach. Deliberate violations and negligence are separated from the other adverse events that are considered under a 'no fault' scheme. The parallel approach satisfies the twin demands of economy and of protecting the public through a formal disciplinary process. There are other legal models. For example, French medical negligence claims against the state are handled under administrative rather than civil law and 'compensation for hospital mistakes is automatic' (Gaine, 2003).

While there is a clear dissatisfaction with the current system of tort, it is difficult to find reliable quantitative information that can inform the policy changes being considered in the UK and the USA. Davis et al (2003) report that 5.2% of admissions in New Zealand

led to a preventable in-hospital event. This rate is similar rate to that in the UK. Vincent (2003) argues that this figure also lies in the broad range established by studies in other countries including the US. He goes on to argue that there is little evidence to support the claim that 'no fault' systems will encourage the reporting of errors. He provides a useful shift in perspective when he argues that the "most important criterion for assessment of any compensation system should be its impact on injured patients and their families, not just in providing appropriate financial recompense where necessary but in ensuring that explanations, apologies, and long term support and care are regarded as the expectation rather than the exception".

## **M.2 Usability Issues and Medical Device Reporting Systems**

Tort reform has been proposed as a means of reducing the costs associated with adverse medical events. These initiatives have been justified by the observation that the value of claims has risen at a time when there is little evidence of an increasing error rate. However, other initiatives have sought to reduce liabilities by reducing the frequency of adverse healthcare events. In particular, there have been a number of initiatives to establish 'lessons learned' and incident reporting systems. These can be used to ensure that information about previous failures and near-misses can be used to inform the subsequent operation of a healthcare system. Incident reporting systems offer a number of benefits. The most obvious is that they provide a source of information about adverse events. There are further advantages if these schemes capture near miss information as well as reports of adverse occurrences. These near misses can be used to find out why accidents DON'T occur. Incident reports also provide a reminder of hazards. They provide means of monitoring potential problems as they recur during the lifetime of an application. They can be used to elicit feedback that keeps staff "in the loop". The data (and lessons) from incident reporting schemes can be shared. Incident reporting systems provide the raw data for comparisons both within and between industries. If common causes of incidents can be observed then, it is argued common solutions can be found. Incident reporting schemes are cheaper than the costs of an accident. A further argument in favour of incident reporting schemes is that organisations may be required to exploit them by regulatory agencies.

There are many different types of reporting system in healthcare. One class of applications has been developed for reporting problems with medical devices. For instance, the US Center for Devices and Radiological Health operates a range of schemes that feed into the Manufacturer and User Facility Device Experience Database (MAUDE). For example, the following report describes how the drug calculator of a medication assistant in a patient monitoring application would occasionally round up values to a second decimal place. The users complained that this could easily result in a medication error and that the manufacturer was failing to acknowledge the problem. The manufacturer initially responded that vigilant nursing staff ought to notice any potential problems when calculating the medication. The clinicians countered this by arguing that they had explicitly taught nursing staff to trust the calculation function as a means of *reducing human error*. Subsequent reports from the device manufacturer stressed that clinicians can configure the resolution of medication measurements through a unit manager menu:

THIS IS BEST METHOD FOR CLINICAL STAFF, IT PRE-CONFIGURES DRUG CALCULATIONS AND ALLOWS SETTINGS TO REFLECT HOW DRUGS ARE PREPARED BY THE PHARMACY. CUSTOMER WAS TOLD, DRUG CONCENTRATION ROUNDING TO NEAREST HUNDREDTHS, COULD BE EASILY ADDRESSED IN UNIT MANAGER SETUP, TO REFLECT HIGHER RESOLUTION. THEREBY, ADDRESSING ANY CONCERN OF A ROUNDING ISSUE. manufacturer HAS REVIEWED CUSTOMER'S CONCERN AND HAVE DETERMINED THAT "DRUG CALCULATIONS" FEATURE IS FUNCTIONING AS DESIGN. ADDITIONALLY, manufacturer HAS REVIEWED WITH CUSTOMER, THE USER'S ABILITY TO CHANGE UNITS OF MEASURE, TO ACHIEVE DESIRED RESOLUTION. THE DEVICE IS PERFORMING AS DESIGNED (MDR TEXT KEY: 1601404 )

The UK Medicines and Healthcare Products Regulatory Agency also, provides several mechanisms for reporting adverse healthcare events including the Manufacturers' On-line Reporting Environment (MORE). These applications help to implement a series of different national and international requirements. In Europe, three directives regulate the marketing and monitoring of medical devices. These are Directive 90/385/EEC-OJL189/20.7.90 on Active Implantable Medical Devices, Directive 98/79/EC-OJ331/7.12.98 on In Vitro Diagnostic Devices and Directive 93/42/EEC-OJ169/12.7.93 the Medical Devices Directive. Section 3.1 of Annex II of the Medical Devices Directive requires that manufacturers “institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them: (i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health; (ii) any technical or medical reason connected with the characteristics or performance of a device leading for the reasons referred to in subparagraph (i) to systematic recall of devices of the same type by the manufacturer”. These provisions are important not simply for the reporting of device failures; it can be argued that these reporting obligations extend beyond the reporting of functional system failures to include adverse events that stem from usability or human factors issues during the operation of the device. Each member state within the European Union enacts national legislation to ensure that they conform with the requirements in these directives. For instance, the UK regulatory framework is based around the Medical Devices Regulations 2002 (SI 2002 No 618) and Medical Devices (Amendment) Regulations 2003 (SI 2003 No 1697). The net effect of all of this is to ensure that incident reports are one of several events that will trigger regulatory intervention and inspection by the Medicines and Healthcare Products Regulatory Agency. In addition, they will intervene to inspect a sample of manufacturers who market their devices in the UK market whether or not those companies have had any adverse events.

The US Safe Medical Devices Act of 1990 (SMDA) guides the reporting of adverse events involving healthcare technology. Under the provisions of this act, end users must report device-related deaths to the FDA and the manufacturer. Serious injuries must also be reported to the manufacturer or to the FDA if they do not know how to contact the manufacturer. The FDA established a number of schemes to meet the requirements of the SMDA. These were confirmed under the Medical Devices Amendments of 1992 (Public Law 102-300; the Amendments of 1992) to section 519 of the Food, Drug, and Cosmetic Act relating to the reporting of adverse events. This established a single reporting standard for device user facilities, manufacturers, importers, and distributors. The Medical Devices Reporting Regulation implements the reporting requirements contained in the Safe Medical Devices Act of 1990 and the Medical Device Amendments of 1992. More recently, the 1998 Food and Drug Administration Modernization Act (FDAMA) reduced some of the regulatory burden on manufacturers by removing an obligation to provide annual reports on adverse events. End users could file an annual report instead of semi-annual reports to summarize adverse event reports.

The Canadian reporting system is governed by the Medical Devices Regulations. Australian practice is guided by the Therapeutic Goods Act. Japanese regulations are informed by the Ministry of Health and Welfare. The key point here is to recognize the diversity of different national reporting systems. This can create vulnerabilities if information about adverse events in one country cannot easily be used to inform practice in another. The Global Harmonization Task Force has recently been established to improve established to support communication about healthcare incidents and accidents across international boundaries. This is a voluntary group of representatives from medical device regulatory agencies and device manufacturers, distributors etc. Figure 1 presents the findings of their recent review which points to considerable differences in the perceived objectives of different reporting systems in different countries.

| <b>Region</b> | <b>Purpose of Device Reporting</b>   |
|---------------|--|
| Europe        | The purpose of the Vigilance System is to improve the protection of health and safety of patients, users and others by reducing the likelihood of the same type of adverse incident being repeated in different places at different times. This is to be achieved by the evaluation of reported incidents and, where appropriate, dissemination of information, which could be used to prevent such repetitions, or to alleviate the consequences of such incidents. The Vigilance System is intended to allow data to be correlated between Competent Authorities and manufacturers and so facilitate corrective action earlier than would be the case if data were collected and action taken on a State by State basis. |
| USA           | The purpose of the Medical Device Reporting Regulation is to ensure that manufacturers, (including those foreign), and importers promptly inform FDA of all serious injuries, deaths or malfunctions associated with marketed devices. User facilities report deaths and serious injuries. As the principal US public health agency responsible for ensuring that devices are safe and effective, FDA needs such information to evaluate the risk associated with a device in order to take whatever action is necessary to reduce or eliminate  |

|           |   |
|-----------|---|
|           | the public's exposure to this risk.   |
| Canada    | The purpose of Mandatory Problem Reporting is to reduce the likelihood of recurrence of serious adverse incidents related to medical devices by evaluation of reported incidents and, where appropriate, dissemination of information which could be used to prevent repetitions or to alleviate the consequences of such incidents.  |
| Australia | The purpose of the Incident Reporting and Investigation Scheme is to support the Post market monitoring processes under the Therapeutic Goods Act. Only a small, select group of high-risk, registered devices are evaluated by the TGA prior to being approved for sale on the market, the majority of products being listed on the Australian Register of Therapeutic Goods without evaluation. Postmarket monitoring is considered an important process to evaluate on-going quality, safety and efficacy of therapeutic devices available in the market.  |
| Japan     | The purpose is to ensure that safety and effectiveness have been carefully evaluated before approval time, and expected adverse events and contraindications must be described on the labeling. Before the approval stage, the number of patients is restricted and only narrow ranged group of patients is involved in clinical trial. After approval, the device is used for a wide range of patients, and there is the possibility of unexpected adverse events which cannot be foreseen when the device is being approved. Therefore any adverse events must be tracked to ensure safety for marketed device. |

**Figure 1:** Global Harmonization Task Force's (2002) Review of Reporting Motivations

Figure 2 extends this analysis to present the Global Harmonization Task Force's assessment of the provision that each of the regions/countries makes for the reporting of human error. As can be seen, there is again a considerable diversity. In particular, the US requirement covers a broad range of usability issues including poor labelling and instruction as well as design flaws. In contrast, European regulations are perceived not to address usability issues except where they stem from manufacturing problems or inadequate labelling. It is also important to acknowledge the wider limitations of these device related reporting systems. The focus on particular items of equipment implies that many human-related incidents will fall beyond the scope of these national and international schemes. A spate of reports, therefore, argued that these systems be extended to cover, for example, errors that stem from the interaction between different teams of specialists rather than from interaction with particular devices. For example, the 1999 US Institute of Medicine report 'To Err is Human' identified a broad range of adverse healthcare events including "transfusion errors and adverse drug events; wrong-site surgery and surgical injuries; preventable suicides; restraint-related injuries or death; hospital-acquired or other treatment-related infections; and falls, burns, pressure ulcers, and mistaken identity". Many of these preventable incidents fall outside of the scope of the existing device related reporting systems. In consequence, it was argued that a new national reporting framework should be established to ensure that as much information as possible is gathered about adverse events in healthcare. The proposal was to establish a

wide-ranging mandatory system for more serious occurrences and a voluntary scheme to elicit information about less serious incidents and near misses. This multi-tiered approach was intended to ensure that lessons were learned both from those adverse vents that did occur but also more proactively to learn from those that were narrowly avoided in the past but which might occur in the future.

| <b>Region</b> | <b>Coverage of User ‘Error’ in Device Reporting</b>   |
|---------------|---|
| Europe        | User errors are generally outside of the adverse reporting system except when; Examination of the device or labeling (inaccuracies in the instruction leaflet or instruction for use include omissions and deficiencies) indicated some factors which could lead to an incident involving death or serious deterioration in health  |
| USA           | Use error (errors induced by poor design, poor labeling, poor instruction, etc. which could lead to an incident involving death or serious injury).   |
| Canada        | Examination of the device or labeling (inaccuracies in the instruction leaflet or instruction for use include omissions and deficiencies) indicated some factors, which could lead to an incident involving death or serious deterioration in health.   |
| Australia     | User error is not specifically defined, but is taken to be: A situation where patient or operator injury, or near injury, is caused by incorrect use, i.e. not following instructions or labeling when these are assessed as adequate for a “normal” or “reasonable” user. “Off label” use when either the device is not specified for the application or specifically contraindicated within the instructions for use or labeling. |
| Japan         | Recall provisions address inadequate labeling, which could lead to an incident involving death or serious injury. There no such definite provisions in adverse incident reporting.  |

**Figure 2:** Review of User ‘Error’ in Device Reporting (GHTF, 2002)

Shortly after the Institute of Medicine Report, the UK NHS (2000) Expert group on learning from adverse events in healthcare issued a document entitled ‘Organization with a Memory’. This argued that reporting systems are “vital in providing a core of sound, representative information on which to base analysis and recommendations”. It was critical of current reporting practice in the national healthcare system and made four key recommendations. Firstly, a ‘unified’ mechanism should be developed for reporting and analysis when things go wrong. Secondly, that a more open culture should be established to ensure that errors or service failures can be reported and discussed. Thirdly, techniques should be developed for ensuring that necessary changes are put into practice. Finally, that there be a wider appreciation of the value of the system approach in preventing, analyzing and learning from errors. A number of authors have challenged the usefulness of this systems view (Johnson, 2003). For now it is sufficient to observe that these requirements not only encourage greater reporting of adverse events involving human factors issues. Requirements to improve the reporting ‘culture’ also crucially depend upon an appreciation of human factors issues in order to encourage reporting in the first place.

### **M.3 Usability Issues and Patient Safety Reporting Systems**

The publication of 'To Err is Human' and 'Organisation with a Memory' served to increase the prominence of voluntary reporting systems that were already in existence at a local or regional level in several different countries. For instance, the New York state NYPORTS programme was established in 1985. These early state-based schemes tended to focus on more severe accidents that resulted in patient injuries or on facility issues, including structural problems and fire hazards. The early systems also focused on eliciting reports from large secondary healthcare providers, such as regional hospitals and nursing homes. In Connecticut, 14,000 of the 15,000 reports received in 1996 came from these homes. The success of these local systems was very mixed (IoM, 1999). For example, the Colorado's program initially received less than eight reports per year. However, with a concerted campaign to increase awareness over the benefits of reporting this increased over a ten-year period to more than 1000 reports per annum.

There were a number of similar initiatives scattered throughout the UK. The Edinburgh incident reporting scheme was set up in an adult intensive care unit in 1989. It continues to be maintained by Dr David Wright, an anaesthetist ICU consultant (Busse and Wright, 2000). The scale of this system can be illustrated by the observation that the unit has 8 beds with roughly 3 medical staff, one consultant, and up to 8 nurses per shift on the ward. A study of the incidents reported over the first ten years of this scheme found that most fell into four task domains: relating to ventilation, vascular lines, drug administration, and a miscellaneous group. The scheme encouraged staff to describe adverse events in narrative form, as well as noting contributing factors, detection factors, grade of staff involved in the event and that of the reporting staff. A number of studies based on this scheme found that approximately one third of the reporters had been involved in the incident that was being reported. Fewer than ten per cent of the reports were made by medical as opposed to nursing staff.

One of the main problems faced by these early systems was the difficulty of exchanging and aggregating data to determine whether specific incidents formed part of a wider pattern. It was for this reason that the Australian Patient Safety Foundation's system was established in 1989. The work of Runciman and his colleagues at the APSF had a profound impact on many healthcare professionals because it helped to establish a framework for what was arguably the first national, voluntary reporting system with a specific remit to elicit information about human factors in adverse healthcare events. The Federal Agency for Health Care Research and Quality (AHRQ) and the National Patient Safety Foundation (NPSF) were established to co-ordinate similar initiatives in the United States. The National Patient Safety Agency (NPSA) fulfils this role in the United Kingdom. These organizations promote a range of initiatives that are intended to reduce 'human error' in healthcare. They are, however, arguably most closely associated with the use of voluntary incident reporting systems as a means of detecting and then addressing common features in adverse events. The NPSF Research Agenda stresses the importance of "learning about systemic vulnerabilities when incidents and accidents occur; anticipating new areas of concern as change occurs; finding deeper and more generic patterns in failures; developing, prototyping, and evaluating new approaches; and

linking the patterns in these to specific health care contexts" (NPSF, 2001). The UK NPSA is in the process of launching a National Reporting and Learning System (NRLS) across the NHS during 2004. The national system is intended to complement local reporting arrangements so that reports entered into a local proprietary system will be automatically forwarded to the NPSA for further processing. The intention is that healthcare staff will be able to submit anonymous patient safety reports. These will then be 'analyzed to identify national patterns, to identify patient safety priorities and to develop practical solutions' (NPSA, 2003).

The NPSA's National Reporting and Learning System was initially intended to help the NHS meet a series of targets. By 2005 the aim was to "reduce by 25% the number of instances of negligent harm in the field of obstetrics and gynecology which result in litigation (currently these account for over 50% of the annual NHS litigation bill); by 2005, reduce by 40% the number of serious errors in the use of prescribed drugs (currently these account for 20% of all clinical negligence litigation); by 2005, reduce to zero the number of suicides by mental health inpatients as a result of hanging from non-collapsible bed or shower curtain rails on wards (currently hanging from these structures is the commonest method of suicide on mental health inpatient wards)" (NHS, 2000).

A number of prosaic problems limit the effectiveness of incident reporting systems. For instance, there is a danger that they will act as repositories of information without inspiring direct intervention to correct particular problems. This can lead to incident starvation if potential contributors feel that their reports are being ignored. Further problems stem from the observation that reporting systems often elicit information about known issues, such as mal-administered spinal injections or communications problems between particular hospital departments. The collection of such information does little to suggest possible interventions that might be used to address these long-term and deep-seated problems. Many of the issues that jeopardize incident reporting can be directly related to human factors issues. These include the problems of underreporting. The Royal College of Anesthetist's pilot reporting system found that self-reporting retrieves only about 30% of incidents that can be detected by independent audit. Other issues relate more narrowly to the biases that can affect the analysis of incident reports once they have been achieved. Finally, the human factors of incident reporting can also complicate the monitoring that must be used to determine whether local and national systems are having any measurable impact on patient safety.

#### **M.4 Human Factors of Incident Reporting**

Previous sections have explained recent initiatives to establish incident reporting as a primary means of reducing adverse healthcare events in several different countries. They have also introduced some of the problems that must be addressed if these initiatives are to be successful. Some of these problems are largely technical, for instance automated support may be necessary to identify common patterns across the thousands of documents that can be submitted to national schemes (Johnson, 2003). However, most barriers to the successful application of incident reporting stem from human factors issues. This creates the '*recursive irony of incident reporting*' in which we must first address a series of human factors issues in order to elicit reports about the

underlying causes of, for example, human 'error' in medicine. The following pages focus in on several aspects of this problem. These include the difficulty of eliciting reports in the first place. This issue can be divided into two sub-problems, firstly how to persuade potential contributors of the benefits of their involvement and second how to ensure that they then provide all necessary information. We also briefly examine the problems of causal analysis; it can be difficult to avoid blaming individuals so that systemic failures can be examined. Equally, there are some incidents in which personal responsibility should not be ignored if external bodies are to believe in the probity of the system. A sustained discussion of this topic will be postponed until the following chapter. Finally, we consider the human factors issues that arise in the development and implementation of recommendations that are intended to ensure previous events do not recur.

#### ***M.4.1 Under-reporting***

A number of attempts have been made to estimate the scale of under-reporting in healthcare systems. For instance, Barach and Small (2000) state that the 'underreporting of adverse events is estimated to range from 50%-96% annually'. The UK Royal College of Anaesthetists concluded that only about 30% of the total number of incidents detected by independent audit will be contributed by voluntary reporting systems. These caveats also affect device related reporting systems. The US General Accounting Office conducted a study into submission frequencies two years after the requirement was introduced for manufacturers and importers to report all device-related deaths, serious injuries, and certain malfunctions to the FDA. They concluded that less than one percent of device problems occurring in hospitals were reported to the FDA. The more serious the problem, the less likely it was to be reported. A GAO follow-up study concluded that the subsequent implementation of the Medical Device Reporting (MDR) regulation, introduced in previous sections, had not corrected the problems of underreporting (FDA, 2002).

These more general assessments are based on more detailed studies. For example, Mackenzie et al (1996) compared 'deficiencies' in the management of patient airways using self-reporting and through exhaustive video analysis. The self-reporting fell into three different categories: Anesthesia Records constructed during the treatment, retrospective Anesthesia Quality Assurance reports and a post-trauma treatment questionnaire that was filled in immediately after each case. Video analysis of 48 patient 'encounters' identified 28 deficiencies in 11 cases (23%). These included the omission of necessary tasks and practices that 'lessened the margin of patient safety'. In comparison, Anesthesia Quality Assurance reports identified none of these incidents. Anesthesia Records identified two and the post-trauma treatment questionnaire suggested contributory factors and corrective measures for five deficiencies. Similarly, Jha, Kuperman, Teich, Leape, Shea, Rittenberg, Burdick, Segerand, Vander Vliet and Bates' (1998) work on adverse drug events compared the efficacy of three different detection techniques: voluntary incident reporting; the computer-based analysis of patient records and exhaustive manual comparisons of the same data. In one study, they focused on patients admitted to nine medical and surgical units in an eight-month period. Both the automated system and the chart review strategies were independent and blind. The

computer monitoring strategy identified 2,620 incidents. Only 275 were determined to be adverse drug events. The manual review found 398 adverse drug events. Voluntary reporting only detected 23.

A number of arguments can be used to explain the wide variation in under-reporting within voluntary systems. Differences stem, in part, from the obvious methodological problems that arise when assessing the total number of adverse events that might have been reported but which were not. The work of Mackenzie et al shows that the retrospective use of patient records will yield different observations of the baseline error rate than the use of more detailed contemporary video analysis. Similarly, the study by Jha et al show that further differences in the base-line rate can be obtained if manual inspections are supported by computer based search techniques within medical records. It is important not to underestimate the practical consequences of inaccuracies in these baseline rates. For instance, a number of agencies have sought to establish reporting quotas based on estimates of underlying error rates. The ability to meet this quota is then interpreted as a measure of the quality of the reporting system. This then provides an indirect measure of the safety culture in the host organisation. In 1998 there was considerable controversy when the US Health Care Financing Administration attempted to place a cap of 2% on the medication error rate in the Medicare Conditions of Participation. This implied that it was 'acceptable' if there were errors in up to 2% of medications (Shaw Phillips, 2001). The subsequent controversy also pointed to the difficulty of establishing this 2% figure as a benchmark for adverse medication events. Many different factors could introduce local variations on the underlying error rate. These include differences in the size of healthcare institutions, their funding profile and equipment provision, the nature and extent of the demands on their services, the profile and characteristics of the population they serve etc.

Having raised caveats about the difficulty of assessing baseline figures for adverse events, it is still possible to assess changes in the contribution rate over time. However, this is more complex than might at first appear. For instance, the introduction of a reporting systems can encourage a 'confessional' phase in which the rate of submissions is temporarily increased by the publicity and availability of a new scheme. It can also be difficult to interpret the cause of any longer term changes in submission rates. For instance, an increase in the number of contributions might reflect a rise in the error rate and this, in turn, can be the result of changes in the activities of the reporting organization (Johnson, 2003). Alternatively, any increase may be due to an increase in the willingness to report adverse events. This ambiguity can have unfortunate implications if risk managers are forced to explain why the reported number of adverse events appears to increase over time. Conversely, any fall in the number of submissions might either be due to specific safety improvements or to a lack of interest in the benefits of contributing to a reporting system. Several other factors can influence submission rates. Most notably, individual participation can depend upon individual confidence in the people running the system. For instance, one Scottish hospital based system received no contributions while the consultant who established the system was on sabbatical. When they returned the submissions quickly returned to their previous rate of around one hundred and twenty reports per year (Busse and Wright, 2000).

Having recognized the difficulty of accurately assessing the scale of underreporting, a number of authors have sought to identify the reasons why healthcare professionals fail to contribute to incident reporting systems. For instance, Lawton and Parker issues a series of questionnaires to 315 doctors, nurses, and midwives who volunteered to take part in the study from three English NHS trusts (Lawton and Parker, 2000). These questionnaires included nine short scenarios describing either a violation of a protocol, compliance with a protocol, or improvisation, where no protocol exists. Different versions of the questionnaire were presented to different volunteers so that each scenario was presented with a good, poor, or bad outcome for the patient. Participants were asked to indicate how likely they were to report the incident described in the scenario to a senior member of staff. The study showed that doctors were particularly reluctant to report adverse events to a superior. The participants were more likely to report incidents with an adverse outcome than those that might be described as 'near misses'. They were also more likely to report to a senior member of staff, irrespective of outcome, if the incident involved the violation of a protocol rather than incidents in which a protocol was followed or the clinicians improvised in the absence of such guidelines. The results of this study are, however, difficult to apply across many reporting systems because the questionnaires and the associated scenarios were drafted to identify the likelihood of report to a 'senior colleague' rather than through a confidential or anonymous reporting system.

Van Geest and Cummins build on this work when they assess the reasons why physicians fail to report or even detect adverse events (Van Geest and Cummins, 2003). Their work formed part of a National Patient Safety Foundation project that was established in 2001 to better understand the physicians' and nurses' experience of healthcare errors. The intention was then to identify the needs of each group in order to help them 'combat' these adverse events. The needs assessment was conducted in two phases. Firstly, the NPSF convened a series of focus groups to determine the origins of, and ways to reduce, healthcare error. These groups considered the cultural and systemic barriers to identifying, reporting, and analyzing errors in health care. The second phase of this requirement elicitation was conducted through a self-administered mail survey of physicians and nurses. The physician survey utilized a random sample of 1,084 physicians from the American Medical Association's database of all physicians practicing in the United States. The nurse survey used a sample of 1,148 nurses from the American Nursing Association.

The focus group discussions with the physicians helped to reveal a common concern over the growing complexity of many healthcare systems. This complexity increases the likelihood of adverse events because clinicians may not have a full understanding of the technology that they are expected to operate. Similarly, increasing complexity also stems from the close interaction between varied groups of co-workers. Communication and coordination issues also increase the likelihood of misunderstandings and other forms of adverse events. These problems result in 'inefficient therapeutic approaches, lack of follow-up on ordered tests, and failure to monitor medications'. The physician's focus groups went on to argue that thus complexity can prevent clinicians from identifying and,

therefore, reporting adverse healthcare events. This observation has recently been confirmed by an independent study of telemedical incidents (Johnson, 2003a). The focus groups identified further barriers to reporting that help to account for the lack of participation in some systems. In particular, the US physicians argued that the current culture of health care was one of tolerance to error. The authors of the NPSF report argued that denial and complacency were important factors; 'individual egos and marketplace pressures make it unlikely that error will be recognized, let alone addressed'. A feeling that reporting adverse events will not generate the funds or political support necessary to make sustained improvements within and between healthcare institutions compounded these underlying cultural issues. In consequence, few were prepared to act as 'whistle blowers' or to question the professional competence of their colleagues. This reluctance to participate was also explained in terms of the previous history of adverse event reporting within local institutions; including the tendency to blame individuals rather than seek more appropriate safeguards. These insights illustrate some of the ambiguities that characterize attitudes towards incident reporting. The physicians perceived that certain forms of error were tolerated whilst others would elicit a punitive response. In the questionnaire survey, 69% of respondents had identified errors in patient care. However, only 50% reported 'working with' non-punitive systems for error reporting and examination. It is unclear whether this specifically refers to the reporting of events that they had previously witnessed. 36% said they had read the Institute of Medicine reports on patient safety, referred to in previous sections. Not only did this survey reveal the barriers to reporting, it also helped to dismiss a number of other potential causes for under-reporting. The physicians stated they knew the proper channels to report safety concerns (61%). 62% said that they were actively involved with practices to identify and reduce medication error (61.4 percent).

The focus groups involving nurses identified safety more as a 'systems issue' rather than an issue that might be associated with particular individual erroneous actions. This was again explained in terms of the growing integration and complexity of many healthcare applications. It also reflected the nurses' perception that their individual work was embedded within that of their team of co-workers. However, only 49% of survey respondents agreed that safety was best addressed at the patient level. They argued that safety was better focused at the level of adverse effects on individual patients. The authors of the NPSF study argued that the nurses in the focus group felt communications failures were one of the most important barriers to the reporting of medical errors. The adverse reporting 'culture' was also identified. The nurses explained this tolerance of error in terms of a historical focus on efficiency in healthcare provision rather than on safety. Nurses also identified a 'code of silence' that permeates much of the healthcare system. They felt this to be particularly problematic for nurses who often are the first to identify the consequences of an adverse event but are not 'empowered' within the medical hierarchy. The focus groups described the sense of isolation that nurses can feel when they either commit or observe an adverse event. Both of these events can alienate them from their co-workers. More than 80% of the survey respondents stated that they had identified error in health care. 35% percent indicated that they had worked with non-punitive systems for error reporting or examination. 87% of respondent nurses indicated that they knew the proper channels to report safety concerns. 93% reported

discussing patient safety concerns with colleagues and/or supervisors. Only 30% stated that they had read one of the Institute of Medicine's reports on patient safety. 72% of nurses were actively engaged in practices to identify medication errors.

Similar evidence for the causes of under-reporting can be obtained from Cohen, Robinson and Mandrack's (2003) survey of 775 nurses across the United States. Although this study focuses on attitudes towards the reporting of medication errors, it reveals a number of more general attitudes and opinions. The survey seemed to provide a consensus in favor of the benefits of incident reporting. 58% of respondents agreed that error reporting is a valuable tool to measure a nurse's medication competency while 42% disagreed with this statement. 91% concurred that 'A good way to understand why errors occur is through a thorough analysis of information obtained from incident reports'. While only 36% agreed with the statement that 'during my nursing career, I failed to report one or more medication errors because I thought reporting an error might be personally or professionally damaging' and 64% disagreed. These positive statements in support of incident reporting cannot easily help to explain the problems of underreporting. However, greater insights are provided by the 51% of respondents who observed that incident reports of my medication errors are placed in my personnel file. Individuals may be reluctant to submit reports about their colleagues if it is felt that those reports will adversely affect the career prospects of co-workers. Further insights are provided by the results for the question 'I initiate an incident report when I catch:

- another nurse's mistake

|             |                |          |
|-------------|----------------|----------|
| Always: 37% | Sometimes: 54% | Never: 9 |
|-------------|----------------|----------|

- a pharmacist's mistake

|             |                |           |
|-------------|----------------|-----------|
| Always: 45% | Sometimes: 42% | Never: 14 |
|-------------|----------------|-----------|

- a physician's mistake.

|             |                |           |
|-------------|----------------|-----------|
| Always: 42% | Sometimes: 39% | Never: 19 |
|-------------|----------------|-----------|

As can be seen, nurses reveal a slightly greater ambivalence when reporting another nurses mistake. Cohen, Robinson and Mandrack then went on to analyse these responses in terms of their respondersnts' experience and work setting. Nurses working in a hospital were less likely to report another nurses 'error'. Those in intensive care (23%) and orthopedic settings (29%) were least likely to report another nurse's mistake compared to other hospital settings. The proportion of nurses stating that they would always report varied from 32% to 53% in these areas. Nurses working in 'home health care' were least likely to report a physician's mistake (32%). 67% of student nurses admitted being prepared to initiate a report for a nurse's mistake compared with 32% of Licenced Practical Nurses and 50% of Registered Nurses. Nurses with less than 1 year's (54%) or more than 15 years' experience (50%) are more likely to report a pharmacist's or physician's mistake than nurses with 1 to 15 years' experience. The proportion stating that they would report such incidents in this group varied from 21% to 45%. Finally, this survey also probed some of the ethical issues involved in terms of admitting adverse events to patients and their relatives. Only 18% agreed that they would always tell a

patient or their relative if they had made a mistake. 52% would sometime take this action and 31% admitted that they would never disclose these details.

These findings and those of previous projects, cited earlier in this chapter, provide insights into the problems of underreporting. They do not, however, suggest immediate solutions. This is regrettable because unless we address these human factors barriers to reporting then it is unlikely that we will obtain detailed insights into many adverse healthcare events. One approach would be to make all reporting mandatory rather than voluntary. This could be extended both to near miss and to minor mishaps as well as the more serious incidents that are covered in existing reporting requirements. For example, the Joint Commission on Accreditation of Health Care Organizations ran a voluntary scheme between 1995 and 2000. Only 798 adverse events were submitted. Two thirds of these came from self-disclosure, however, one third were notified as a result of media involvement (MDH, 2000). This level of participation can be contrasted with a mandatory system operating across New York state where 1,200 mishaps were reported by hospitals in a single year with approximately 20,000 total submissions. Mandatory systems provide the opportunity to offer a 'carrot and stick' approach; the incentive of 'no blame' reporting can be combined with legal sanctions for the failure to participate. However, this raises important ethical questions, especially for near-miss or low criticality events. It can be difficult to determine whether or not a clinician had the opportunity to observe an incident or even whether an incident was reportable in the first place. There may, therefore, be a tendency for clinicians to report almost any adverse event that could conceivably be covered by the system and hence high reporting frequencies belie the problem that these systems are 'cluttered' with relatively minor events. It is for this reason that mandatory systems tend to be used to ensure accountability but only for more serious mishaps. It can also be argued that the fixation on under-reporting misses many important issues in patient safety. Rather than focusing on the information that might not be contributed through a voluntary system, more progress could be made by addressing those concerns that are elicited from healthcare professionals. In this view, we should focus more on improving safety and less on counting mistakes.

Cohen's (2000) review of mandatory and voluntary reporting systems reiterates many of these points. He identifies the US Safe Medical Devices Act of 1990 as an example of a mandatory reporting system that has been 'unsuccessful in gaining compliance with reporting requirements for user error'. As we have seen, the intention behind this Federal bill was that healthcare facilities and manufacturers must report adverse events related to the failure or misuse of specific medical devices. However, Cohen argues that little action is taken unless the system receives reports about a large number of similar adverse events. He also argues that the State based mandatory systems are used 'almost exclusively to punish individual practitioners or healthcare organisations'. In consequence, mandatory systems often fail to provide insights into the deeper causes of adverse events, which Cohen argues are largely 'systemic' rather than 'individual'. Cohen's view is typical of that put forward by many clinicians working in the area of patient safety. It is well intentioned but often too narrowly focussed on process improvement rather than the

patient's concerns; which can also include a desire for greater transparency and equity in the handling of adverse events.

This apparent conflict has been exposed by Robinson et al's (2002) study of physician and public opinion on the quality of health care and medical 'error'. They compared the results of a mail survey of 1,000 Colorado physicians (n = 594) and 1,000 national physicians (n = 304) with a telephone survey of 500 Colorado households. The main aim was to assess their differing attitudes towards some of the main findings in the Institute of Medicine report 'To Err is Human', mentioned in previous sections. They found that 69.7% of Colorado physicians believed the reduction of medical errors should be a national priority. However, only 29.1 of physicians believed that 'quality of care was a problem' compared to 67.6% of the wider population in this sample. Similarly only 24.1% of physicians believed that a national agency is needed to address the problem of medical errors while 59.8% of the public agreed with this statement. All of the physicians believed that fear of medical malpractice was a barrier to reporting of errors and that greater legal safeguards are necessary for a mandatory reporting system to be successful. 60.1% of the physicians agreed that it is difficult to differentiate errors due to negligence from unintended errors.

In April 2000, the US National Academy for State Health Policy conducted an investigation into the State Reporting of Medical Errors and Adverse Events. They found that fifteen states (Colorado, Florida, Kansas, Massachusetts, Nebraska, New Jersey, New York, Ohio, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Washington) required the mandatory reporting of adverse events from general and acute care hospitals. The levels of participation and the scope of these schemes were very different. The types of events to be reported included: unexpected deaths, wrong site surgery, major loss of function and errors in medication. The results National Academy for State Health Policy also conducted a survey of states in February 2000 to examine the way in which various states were addressing the issue of medical error reporting. All 50 states and the District of Columbia responded to the survey. The survey found that most states, including the ten with mandatory schemes, aggregated the data to identify trends. Nine states administer sanctions and assure corrective action.. Eight states issue public reports. In another study of state-based reporting programs by the same agency several states expressed concerns that their mandatory reporting systems suffer underreporting from hospitals (Raymond and Crane, 2001). The diverse practices identified in these reports motivated a not-for-profit group, known as the US National Quality Forum, to propose a national strategy for health care quality measurement and reporting. This formed part of the pressure that led to the development of the Federal Agency for Health Care Research and Quality, mentioned in previous paragraphs.

The proponents of mandatory systems argue that some adverse events are so serious that they must be reported in order to reassure the public and ensure that appropriate action is taken. The proponents of voluntary systems, in contrast, point to the problems of under-reporting in mandatory systems and to the difficulty in 'policing' reporting requirements. They also point to the success that some voluntary systems have had in encouraging participation when healthcare professionals are offered protection against legal sanction.

For example, United States Pharmacopoeia and Institute for Safe Medication Practices have established the Medication Errors Reporting Program. This confidential, voluntary medication error-reporting scheme has received around 1000 error reports each year. Cohen (2000) has argued that the quality of reports made to this voluntary system is just as significant as the number of submissions. He also cites the example of cisplatin. After a series of accidents, the Institute for Safe Medication Practices persuaded manufacturers to include the maximum dose on phial caps and seals.

Few of the proponents on either side of this debate advocate exclusively mandatory or voluntary schemes as a solution to the problems of under-reporting. In contrast, controversy surround the extent to which healthcare professionals should have the discretion to determine what is reportable under each of the various schemes. As mentioned, the Institute of Medicine advocates a national mandatory system for more serious mishaps and a local voluntary system feeding information up through regional schemes in the case of less serious adverse events. This architecture is intended to ensure that a national voluntary system is not inundated by a mass of low risk incidents; local managers help to filter the passage of information up through state schemes to national systems whereas the more serious events merit a more immediate focus at a higher level. This mixed approach of mandatory and voluntary reporting will only successfully tackle the problems of under-reporting if the schemes are supported by legal protection for individual participants. Any breach of confidentiality in general and the (ab)use of voluntary reports in any consequent litigation would undermine confidence in the scheme. For example, the American Medical Association's (2002) recent statement to the Subcommittee on Health, Committee on Energy and Commerce in the U.S. House of Representatives on Reducing Medical Errors argued that Congress must 'pass legislation that will encourage reporting of health care errors without the fear of punishment'. The primary goal of this legislation would be to facilitate the development of a 'confidential, non-punitive, and evidence-based system' for reporting health care errors. They went on to argue that 'Congress can help create a culture of safety by allowing medical professionals to convene to discuss patient safety problems and potential solutions without having their discussions, findings, or recommendations become the basis for class action or other lawsuits'. Partly as a result of these concerns, a number of initiatives have attempted to reduce under-reporting by ensuring that voluntary incident reports are subject to the same legal protection offered by similar schemes in other domains, in particular by NASA and the FAA's Aviation Safety Reporting System (ASRS).

The ASRS operates an elaborate mechanism whereby reports are initially passed to NASA. They then screen each submission to ensure that information relating to a criminal offence is passed to the Department of Justice and the FAA. Information about accidents rather than incidents is passed to the NTSB and the FAA. All remaining reports fall within the scope of the ASRS and are, therefore, protected under the following provisions. Section 91.25 of the Federal Aviation Regulations prohibits the use of any reports submitted to NASA under the in any disciplinary action. However, appropriate action can be taken if information about an incident is derived from a source other than the ASRS submission. In addition to the provisions that protect contributors,

the action of filing a report is considered to be 'indicative of a constructive attitude'. Accordingly, the FAA will not seek to impose a civil penalty or suspend a licence if the individuals involved submit a report within ten days of the incident and the violation was inadvertent, if it did not involve a criminal offence, or accident. These exemptions apply providing that the person has not committed a violation for a 5-year period prior to the date of the incident. These guidelines within the field of aviation are worth citing because they have provided a blueprint for similar protection, which is being offered under healthcare reporting systems. For example, the Veterans Health Administration's (VA) National Center for Patient Safety has established two systems. The first is a mandatory reporting scheme for more serious adverse events. This is similar to the FAA and NTSB provision within the ASRS. The second confidential, voluntary Patient Safety Reporting System (PSRS) is closer to the ASRS itself. The PSRS was established in 1999 and allows for local initiatives both to encourage reporting and to initiate remedial actions. This scheme depends upon an interagency agreement between the VA and NASA. Modeled on the provisions for the ASRS that were cited above. Unlike the ASRS, the VA's PSRS is intended to collect information on adverse events, as well as near misses. NASA collects the reports and maintains the confidentiality of the system. Under the agreement, the VA may not review any report or data until it has been de-identified. Concern over the inadvertent disclosure of contributor information has led to the decision that their will not be held once the event has undergone an initial analysis. The contributors' identity is also protected under Privacy Act and recognized exemptions to the Freedom of Information Act. Records created for the VA as part of a medical quality assurance program, such as patient safety reports, have additional protections beyond those of other government agencies. United States Code (USC) 5705 with certain exceptions provides that records and documents created by the VA "as part of a medical quality-assurance program" are "confidential and privileged and may not be disclosed to any person or entity". One recent review of these confidentiality measures raises the caveat that 'although federal law appears to provide the VA considerable protection against the discovery and disclosure of data, these unique legal shields are not afforded to non-VA hospitals' (Raymond and Crane, 2001).

Previous paragraphs have described how a range of human factors issues, including a fear of retribution and concern over the efficacy of any contribution, help to create the problems associated with under-reporting. We have also reviewed a wide range of initiatives to address these problems including the development of mandatory and voluntary schemes as well as the provision of legal protection against disclosure in confidential systems. There are other approaches that help to address the problem of under-reporting. In particular, Sentinel schemes acknowledge that under-reporting will always be a limitation of large scale systems. In contrast, these schemes focus resources more narrowly on a small number of representative institutions or work teams. These groups are given additional training and resources to both encourage and support any reporting. Monitoring systems and exhaustive reviews of patient records may also be used to catch any incidents that are missed. The results from these investigations can then be extrapolated to provide additional insights into the potential scale of any problems at a regional or national level. The FDA were amongst the first to recognise the potential benefits of this approach (FDA, 1999). They recognised that under-reporting was often a feature of what can be described as 'passive' national monitoring systems. In contrast, a more active approach would be to take steps that continually remind staff of

the benefits from incident reporting. Unfortunately, the FDA lack the resources necessary to train every potential contributor in when and how to submit an incident report. Estimates suggest there may be 50-60,000 'end user' organisations for healthcare related devices. They, therefore, decided to conduct a trial in which a small number of organisations were provided with additional support to explicitly encourage participation in a voluntary reporting system.

Seventeen hospitals and six nursing homes were, therefore, recruited to participate in a twelve month 'DEVICENET' study. Coordinators were identified in each institution; these individuals were typically clinical risk managers. They were either offered a one-day group training in Washington DC or a slightly shorter course in their own organisations. Videos were also prepared for each of the participant institutions. These were intended for use during in-house staff orientation and in-service training sessions. The video encouraged individuals to follow their facility's internal procedures for reporting of adverse events. After viewing the video, each staff member in the participating institution was given a one-page sheet summarising the local provision. These sheets also provided information about the confidentiality safeguards offered to participants. Each report had any individual identification information removed as soon as possible after it had been received. After 30 days the Facility ID was removed so that it was no longer possible to link the report to the facility. This period enabled the study team to link the original report with any follow-up reports and provided an opportunity to discuss any questions about the report with the Study Coordinator. The Sentinel trial also enabled participants to contribute anonymous reports. At the end of the year's study, the coordinators had gathered 315 reports of which 14 were anonymous. They argued that this level of activity was 'far above' the average for reporting device related incidents. By a broad-brush extrapolation, the proponents of this approach suggested that the FDA would receive 100,000 reports per year rather than the 5,000 incidents that were actually filed during the year of the study. However, it is important to note that this study also illustrated some of the limitations of Sentinel reporting. A continuing problem for the FDA is that many nursing homes fail to contribute any reports of adverse events even though they operate many of the devices and procedures that give rise to problems in other healthcare settings. In spite of all of the additional support offered in this trial, none of the 315 reports came from any of the six participating nursing homes.

Sentinel schemes reduce the problems of under-reporting by focusing resources on a number of 'representative' institutions. A limitation with this is that Sentinel schemes may lack the resources to ensure that focused support is provided across all procedures and departments even within one of these favoured organisations. In consequence, patient safety organisations have also funded centres to focus on different aspects of patient safety. The VA has established four Centres of Inquiry with an annual budget of approximately \$500,000. For example, Gaba heads a centre looking at patient safety in the operating room and is looking at the use of patient simulators in anaesthesia (Weeks and Bagian, 2000). Other centres focus on elderly patients. These Patient Safety Centers of Inquiry act as focal points for research and development. They are not primarily intended to support incident reporting. However, it seems clear that their research activities must draw upon those adverse events that the VA and other organisations elicit

about their main interests. It is also important to recognise that current plans for regional and national reporting systems are often very general. They accept reports from a broad range of healthcare professionals. There is a risk that they will fail to elicit the support that has been obtained for more specialised systems, such as the pilot scheme promoted by the UK Royal College of Anaesthetists (1998). If this is not addressed then a number of subject-specific Sentinel systems are likely to be used by professional organisations to augment the more general national, voluntary schemes being promoted by groups such as the NPSA.

#### ***M.4.2 Elicitation and Form Design***

The previous section has focused on the human factors issues that lead to under-reporting. In contrast, the following pages look more at the problems of ensuring that adequate information is obtained once a healthcare worker has decided to submit an incident report. This is not as simple as it might seem. In particular, it may not be possible to interview staff in order to elicit additional details in anonymous schemes. In confidential systems there is also the danger that any subsequent contacts with managers may inadvertently disclose the identity of the contributor in the process of providing further information. In such circumstances, it is imperative that human factors and human computer interaction expertise be used to ensure that the design of reporting forms is tailored to support the skills and expectations of potential contributors. The difficulties associated with this task are exacerbated by requirements, such as those proposed by the US Quality Interagency Coordination Task Force's report to the President, which strongly urge the provision of facilities for members of the general public also to contribute to healthcare reporting systems (AIA, 2000). However, this document focuses on possible improvements to the usability of clinical applications and products. They argue that there "is a real need to involve clinicians and other users in the design of systems at an early stage to optimize usability... manufacturers need to ensure that usability testing occurs throughout development, especially in the pre-market design phase of medical device development". This document neglects the problems of developing usable reporting systems. This is an omission that is common amongst almost all of the other reports advocating the development of healthcare incident reporting systems. Those that do consider these issues often make passing comments to the development of web-based interfaces as a panacea for the problems of form design.

Some studies do acknowledge the importance of developing 'usable' submission systems for adverse event reports. For instance, a recent roundtable discussion on 'Design Considerations for a Patient Safety Improvement Reporting System' organized by the Kaiser Permanente Institute for Health Policy, NASA Aviation Safety Reporting System and The National Quality Forum identified the last of eleven optimal requirements '(the system) should be broadly understood and easy to use' (Kaiser Permanente, 2000). This is a laudable aim but it provides few insights into the mechanisms and techniques that might be used to satisfy such usability requirements. The UK National Patient Safety Agency has addressed these concerns through a sustained pilot study for its National Reporting and Learning System. Their aim was to gather feedback on the best ways of reporting to a national system. They evaluated the proposed NPSA standardised method for collecting information. In particular, they studied the usability of the different forms

that were 'tailored' for each healthcare sector. Part of this process involved an analysis to ensure that they were asking the right questions to ask NHS organisations and staff to 'elicit the maximum amount of meaningful national learning' (NPSA, 2003).

The design of incident reporting forms has remained a focus of debate amongst the handful of research groups that are active in this area (Johnson, 2000). Meanwhile, hundreds of local, national and international systems are using ad hoc, trial and error techniques to arrive at appropriate forms. It is important to stress that there are several different approaches to the presentation and dissemination of incident reporting forms. For example, some organisations provide printed forms that are readily at hand for the individuals that work within particular environments. This approach clearly relies upon the active monitoring of staff who must replenish the forms and who must collect completed reports. Other organisations rely on computer-based forms. These can either exist in printable formats such as Adobe's PDF, which must be printed and completed by hand, or in electronic form so that they can be completed on-line. In either case, there is an assumption that staff will have access to appropriate hardware and software resources. This is not always the case in many healthcare domains. Many of these machines may also be located in public areas where colleagues and co-workers can observe the submission of an incident report. Each of these different approaches may also be supplemented by; for instance, telephone based reporting for situations in which forms are unavailable. This plethora of submission techniques is further complicated by the observation that personnel are increasingly expected to file reports through multiple systems. For instance, local voluntary systems such as those proposed by the Institute of Medicine currently operate alongside several mandatory state based schemes at the same time as Federal agencies, including the CDRH, also operate national systems. There are also often different parallel schemes for reporting incidents that injure employees rather than patients.

Given this diversity, it can be very difficult to establish which system to file a report under. For instance, many of these schemes define the severity of an incident that should be reported to them. In many cases, however, healthcare workers may not know what the ultimate outcome of a mishap will be. For instance, medication errors often have uncertain, long-term effects. Should an individual begin by reporting to a local system and then file successive reports to regional and national systems and the results of the incident become more certain? Alternatively, some hospitals have established 'one-stop-shops' where all reports are filed via a risk manager who ensures that local information is fed into regional and national schemes depending on the nature of the incident. For instance, Spectrum Health facilities (2002) have recently introduced a wide-ranging Patient Safety Plan. Employees are required to report any 'defect, error, medical accident, near miss, good catch, significant procedural variance, other risk to safety that could result in patient injury, hazardous condition, or risk in the environment of care'. Area managers must ensure completion of each report. They must then pass on information about critical events to the Vice President, Risk and Compliance and the Vice President, System. The Chief Operating Officer, in consultation with the VP of Risk & Compliance and the VP of Quality Improvement then together determine if the event is reportable to the JCAHO and any additional regulatory bodies. Any approach

that relies on such a filtering process must ensure that personnel are confident their reports will be passed on in a timely fashion. They must also be assured of the ‘just culture’ that was mentioned in the previous section if they are to direct all reports via these gatekeepers to the reporting systems.

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| <p style="text-align: center;"><b>Critical Incident Study</b></p> <p>This is a study that looks at <b>how and why</b> people make mistakes. Information is collected from incident reporting forms (see overleaf) and will be analysed. The results of the analysis and the lessons learnt from the reported incidents will be presented to staff in due course. The reporting forms are <b>anonymous</b>, there is <b>no interest in criticism or blame</b>. We would encourage everyone working in the NICU, at whatever level of experience, to take part. Every incident reported, <b>no matter how trivial</b>, will give information about the way people work and may help to save a life.</p> <p>When you have completed the form please place it in the <b>Incident Form Box</b>.</p> <p style="text-align: center;"><b>Definition of a “Critical Incident”</b></p> <p>A critical incident is an occurrence that might have led (or did lead) – if not discovered in time - to an undesirable outcome. Certain requirements need to be fulfilled:</p> <ol style="list-style-type: none"> <li>1. It was <b>caused by an error</b> made by a member of staff, or by a failure of equipment</li> <li>2. It can be described in detail by a person who was involved in or who observed the incident</li> <li>3. It occurred while the patient was under our care</li> <li>4. It was clearly preventable</li> </ol> <p>Complications that occur despite normal management are <b>not</b> critical incidents. But if in doubt, fill in a form.</p> <p>Thank you for your interest.</p> | <p style="text-align: center;"><b>Critical Incident Reporting Form</b><br/>(See overleaf for instructions)</p> <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <p><b>The Incident</b></p> <p>Description of what happened:</p> <br/><br/> <p>What factors contributed to the incident?</p> <br/> <p>What factors minimised the incident?</p> </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <p><b>The Circumstances</b></p> <p>Date: _____ Time: _____ Place: _____</p> <p>What procedure was being carried out?</p> <br/> <p>What monitoring was being used?</p> <br/> <p>If equipment failure give details of equipment:</p> </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <p><b>Personnel</b></p> <p>Grade of relevant responsible staff: _____ Grade of staff discovering the incident: _____</p> </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <p><b>Outcome</b></p> <p>What happened to the patient?</p> </div> <div style="border: 1px solid black; padding: 5px;"> <p><b>Prevention</b></p> <p>How might such incidents be avoided in the future?</p> </div> |
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**Figure 3:** Reporting Form for a Neonatal Intensive Care Unit (Busse and Wright, 2000)

The design and layout of reporting forms remains a critical issue irrespective of whether individuals report directly to external agencies or via a local safety manager. If potential contributors cannot use the fields of these documents to accurately provide necessary information then there is little likelihood that incident reporting systems will provide an effective tool for ‘organisational learning’. Form design is, therefore, a critical area for human factors input in the development of most reporting systems. It is surprising; therefore, that many systems are implemented without even the most cursory forms of user testing (Johnson, 2003). In consequence, it can be difficult to determine whether underreporting stems from a widespread rejection of the system or from acute frustration with the electronic and paper-based forms that are intended to elicit feedback about past failures. User testing is important because a vast range of different approaches have been used to elicit information about adverse events. For example, Figure 3 illustrates a reporting form that was developed for a local system within a UK Neonatal Intensive Care Unit (Busse and Wright, 2000). There are open of ‘free-text’ fields for individuals to describe the incident that they have witnessed. Such open-ended questions are appropriate in systems where it is possible for analysts to go back and ask additional questions to clarify any information that is either missing or only partially understood.

The benefit of the approach is that it makes only minimal assumptions about the information that the contributor wishes to report. They are not forced to select particular items from a predefined list that may unduly constrain their selections. However, problems arise when analysts must translate the information provided by these 'open' forms into the format that is required by regional or national agencies. For example, the NPSA have developed the UK National Reporting and Learning System (NRLS) to 'define the questions and reply options that will be used to collect incident information. One of these questions focuses on 'What happened?'. Contributors are expected to categorize Patient Safety Incidents according to a large number of predefined choices. These include high-level categories such as incidents involving 'Access, admission, transfer, discharge (including missing patient)' or problems involving 'Clinical assessment (including diagnosis, scans, tests, assessments)'. Each of these high-level categories is further refined into more detailed choices. For instance, more detailed assessment problems 'Assessment - lack of clinical or risk assessment', 'Cross-matching error' and 'Delay / difficulty in obtaining clinical assistance'. Similarly, the high-level category of 'Patient accidents' is refined into 'Ambulance / patient in road traffic accident', 'Collision / contact with an object', 'Contact with sharps (includes needle stick)', 'Exposure to hazardous substance', 'Exposure to cold / heat (includes fire)', 'Inappropriate patient handling / positioning', 'Slips, trips, falls' or 'Other'. The need to collect national statistics helps to justify the use of such narrow categories. It is important that data about national trends can be gathered in a consistent format. However, this depends upon a team of analysts being able to examine free-text accounts and then reclassify them according to the guidelines laid down by regional or national organizations. It is not always possible to define an ideal match between the details of a particular adverse event and these different categories, particularly, if for example an incident involved a mixture of events such as a problem in patient access that led to an incorrect clinical assessment.

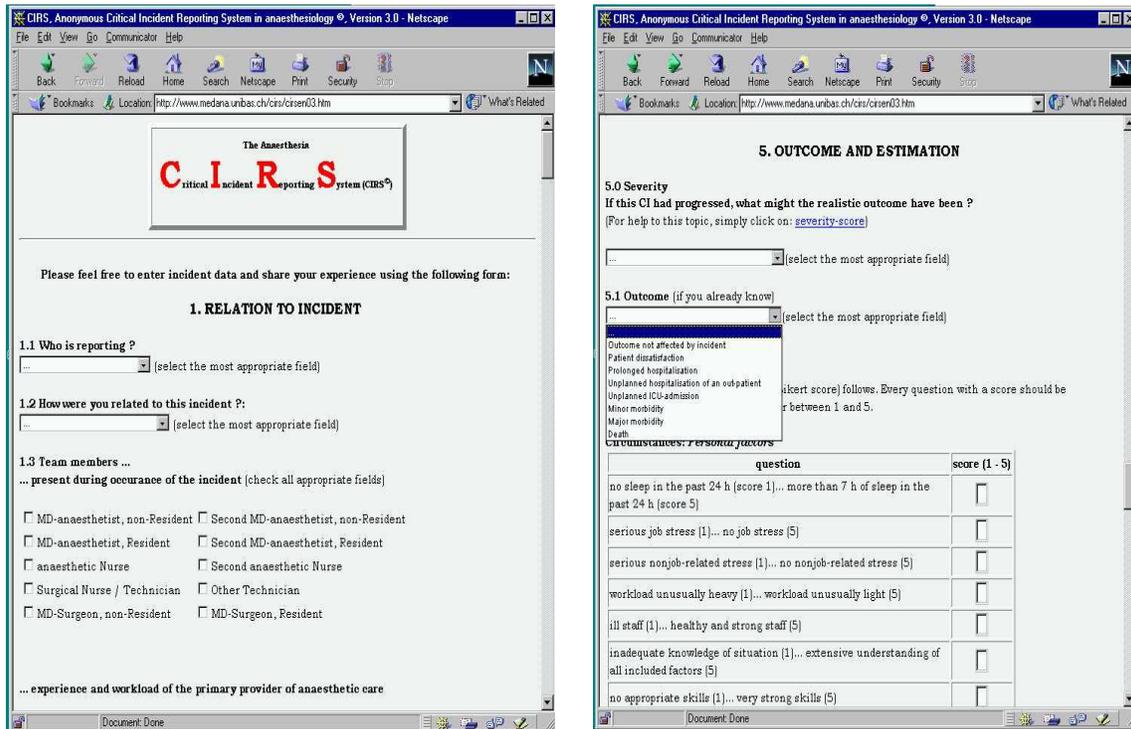
The NPSA have developed a number of alternatives to the free-text approach for incident reporting. They have collaborated with a number of software developers so that computer-based tools guide potential contributors through the classification process. Participants need never see the hundreds of individual fields in the full taxonomy. Instead, they are only shown those options that are relevant to the incident they are reporting. This relevance is partially determined by the contributor's previous responses to questions about the adverse event. In this limited sense, these computer-based tools are context sensitive. They tailor the elicitation to match the incident that is being described. A limitation, however, is that it can be difficult to ensure that any two contributors will assign the same keywords to similar incidents. This is, arguably, more likely to happen when risk managers are trained to classify the free text accounts of their co-workers (Johnson, 2003). It is difficult to ensure that every potential contributor receives a similar level of training. Similarly, problems can arise when potential participants cannot find the keywords to match the incident that they have witnessed. The NPSA taxonomy addresses this problem in a number of ways. Firstly, the detailed categories usually include the value 'other' under each of the high-level terms such as 'Patient accidents'. This broad classification can act as a catchall. There is, of course, a danger that contributors will too readily use the 'other' classification if do not understand

what is meant by the more detailed terms. Secondly, the NPSA include a question at the end of their classification, which asks contributors to state 'Please tell us how you think this form could be improved (optional)'.

Previous paragraphs have argued that incident reporting systems will be undermined if they embody an incomplete taxonomy; contributors will not be able to provide sufficient information about the incident by ticking appropriate boxes etc. This problem can be overcome by extending the taxonomy to ensure that it is broad enough to cover every likely eventuality. However, this creates further problems if users have to navigate hundreds and even thousands of complex terms. Computer-based reporting systems can help to overcome these problems by guiding the users so that the answers to previous questions can help to filter the options that they are presented with. For example, if the user indicates that they have witnessed a patient related accident then they are not usually presented with menu options or check boxes that relate to an error in diagnosis. Of course, there may be some unusual incidents that stem from precisely this combination of issues and so extensive user testing is required to ensure that users can exploit tool support without becoming so frustrated that they will abandon a submission. User testing can also help to reveal other biases. For instance, there is a tendency for users always to select items from the top of a scrolling list or menu. Few users will scroll to the bottom of long and complex widgets. This can have an unfortunate influence on the findings that may be derived from a reporting system where the position of an item on the display can determine whether or not users recognize it as an attribute of a particular incident. The NPSA has acted to address these problems by conducting a series of field studies into the application of the National Reporting and Learning System (NRLS) between January and May 2003. 39 organizations from a range of healthcare settings worked with the NPSA to test reporting methods. Most of this work focused on the completeness and consistency of the taxonomy rather than an evaluation of the computer-based systems being developed by the NPSA's commercial partners. However, it did examine whether an electronic reporting form could 'provide a standardised method for collecting information, and the best way to tailor the form to each healthcare sector' (NPSA, 2003).

The local, paper-based reporting system from an Intensive care Unit, illustrated above, forms a strong contrast with the demands for national reporting, illustrated by the NPSA's initiatives. There are, however, a number of other reporting systems that do not fit into either of these different stereotypes. For instance, Figure 4 illustrates part of the on-line system that has been developed to support incident reporting within Swiss Departments of Anaesthesia (Staender, Kaufman and Scheidegger, 1999). CIRS embodies a number of assumptions about the individuals who are likely to use the form. Perhaps the most obvious is that they must be computer literate. This is significant because CIRS exploits a diverse range of dialogue styles, or interface widgets. These include check boxes and pull-down menus as well as free-text fields. This system is different from the one proposed by the NPSA because it was established as the result of a self-help initiative from a number of motivated clinicians. It was not set-up as part of a government system, although it subsequently attracted this support. Equally, it differs from the local system because it developed beyond a single hospital and hence could not

easily be sustained using limited resources and a paper-based approach. As can be seen, CIRS also exploits a number of predetermined categories to characterise each incident. Users must select from one of sixteen different types of surgical procedure that are recognised by the system. They must also characterise human performance along a number of numeric Likert scales. These are used to assess lack of sleep, amount of work-related stress, amount of non-work related stress, effects of ill or healthy staff, adequate or inadequate knowledge of the situation, appropriate skills and appropriate experience. For example, if the individuals involved in the incident had no sleep in the last 24 hours then the score should be 1. If they had more than seven hours sleep then the score should be five. Scores between these two extremes should be allocated in proportion to the amount of sleep that had been obtained by the participants. This approach is relatively straightforward when referring to objective amounts of sleep. However, the CIRS workload scale is more difficult to interpret in the same range from 5 (unusually heavy) to 1 (unusually light). The introspective ability to independently assess such factors and provide reliable self-reports again illustrates how many incidents reporting forms reflect the designers' assumptions about the knowledge, training and expertise of the target workforce.



**Figure 4:** The CIRS Reporting System (Staender,. Kaufman and Scheidegger, 1999)

One of the most innovative features of the CIRS system is that it is possible for healthcare professionals to use the Internet as a means of reviewing information about previous incidents. The anonymous cases can be read on-line and comments can be appended to create a dialogue between individuals who either request additional (anonymous) information or who have experienced similar incidents in other organisations. For example, the following report describes a drug misadministration:

**INCIDENT DESCRIPTION:** Female patient 11 y/o was scheduled for tonsillectomy. She was NORMAL as regards the physical examination and lab values. The operation was done as usual without any abnormal events in anesthesia or the recovery. She was discharged awake from PACU to the ward. Shortly after her arrival, the ward's nurse injected her by what she was thinking that is antibiotic. But soon she discovered that this was BROFEN (Ketoprofen) suspension. The poor child developed convulsions and cyanosis at once. She was transmitted quickly again to the OT. The patient was hypotensive (70/40) tachycardic (180) O2 saturation was 75% and the end tidal CO2 was 70.

Another clinician accessing this report left the following observation and request for additional information:

*Sorry about the sad case. Side question: why was an antibiotic given and why afterwards? It seems that some accidents occur as a consequence of an action that wasn't unnecessary in the first place. For example, I once heard of an appendicectomy case that got an epidural injection where a mix-up also occurred with fatal consequences*

A key point here is that the initial report acts as a focus for further discussion about common factors in previous incidents. From a technical standpoint, this type of facility also requires that the reporting system be extended beyond the forms that elicit information about the initial adverse event to include some mechanism for further dialogue.

#### ***M.4.3 Form Content and Delivery Mechanisms***

Irrespective of whether a reporting system is intended to collect information about local incidents or national statistics about adverse events, it is important that managers consider the range of information that must be elicited in the aftermath of an accident or a near miss. This includes factual data about what precisely happened. Reporting forms can also prompt potential contributors for more analytical information about what they consider to be potential causes for an adverse event. This section reviews some of the human factors issues that must be considered during the development of reporting forms. It also considers the usability issues that affect the different delivery mechanisms, which enable potential contributors to submit information about near-misses and adverse events.

#### ***Delivery Mechanisms***

Most of the early reporting systems relied upon simple paper-based forms, similar to that illustrated in Figure 3. Increasingly, however, as the CIRS and NPSA initiatives show, more schemes are relying upon Internet technologies such as the web. This approach has numerous benefits. For example, managers do not need to continually check the supply of paper based forms nor do they have to monitor drop-boxes to check for new submissions. Electronic forms can be revised and then made accessible across many different healthcare organisations without the overheads associated with conventional distribution networks. The use of appropriate interface design techniques can support users by providing default values for common fields in electronic forms. Inferences can

be made to populate these on-line documents. For example, the date of the report can be set to the day on which the form is accessed unless the end-user decides to change it. Similarly, the organization in which an incident occurs might default to the one in which the reporting system is accessed.

A range of problems also complicates the use of computer-based reporting systems. In particular, many organizations have significant concerns about the security of on-line systems that can be vulnerable to attack from people both inside and outside the reporting organization. These considerations are particularly important given the sensitive nature of confidential and anonymous reporting. There are technical solutions for many of these issues. For instance, digital signatures can be used to authenticate the sender of particular information. Electronic watermarks can be used to ensure that reports are not overwritten or unnecessarily altered after submission. However, many of these technical solutions increase the burdens of system operators. For example, they may be excluded from the system if they do not authenticate their access through the use of an appropriate password. The importance of password protection can be illustrated by a recent mishap reported to the FDA.

SINCE THE PLACEBO TREATMENT IS STILL ACTIVE IN THIS VERSION OF SOFTWARE (REVISION 9), IT IS POSSIBLE TO UNINTENTIONALLY DELIVER A PLACEBO TREATMENT. THIS SITE WAS NOT INVOLVED IN ANY OF THE PAST CLINICAL TRIALS ... AND IT APPEARS COINCIDENTAL THAT THE reporter USED THIS PARTICULAR PASSWORD... ONE POSSIBLE SCENARIO DICUSSED WAS THE X-RAY TECH OPERATING THE UNIT DURING THIS TIME SOMEHOW MISTOOK THE DEFAULT PHYSICS PASSWORD "9999" FOR "4444", WHICH MEANS THE OPERATOR WOULD HAVE ALSO CONFUSED THE TREATMENT PASSWORD WITH THE PHYSICS PASSWORD. HOWEVER, THIS IS SPECULATION AND COULD NOT BE CONFIRMED. (MDR TEXT KEY: 1490034)

Although this incident did not involve password access to an incident reporting system, it does illustrate the generic problems that arise from security mechanisms in healthcare applications. The use of such a simple numeric password for a placebo was likely to lead to problems in the future. This is illustrated by the potential conflict with the default physics password. The physics department might, in turn, also be criticized for their choice of '9999'. This cannot easily be justified as a secure password. There are common examples of such security 'failures' across most healthcare systems (Johnson, 2003). In consequence, many potential contributors can be dissuaded from participating in a system if they believe that their identity will be compromised by unauthorized access in the future.

Further limitations also affect the use of computer-based forms to elicit incident reports. In particular, it can be difficult to ensure that all potential contributors have easy access to the necessary technical resources. There is a non-uniform distribution of staff with home-access to the Internet. Many healthcare professionals only have work-time access to shared computers in public spaces. They can easily be interrupted or observed as they fill out a confidential or anonymous reporting form on-line. It can also be possible for other users to access information that their colleagues have entered either by accessing system logs or cached information that has inadvertently been left on disk after a session has ended. Usability issues also determine whether or not potential contributors can easily use computer-based submission systems. The developers of on-line reporting

schemes often assume that end-users will have similar technical resources to themselves. For instance, many web-based forms are formatted for large, high-resolution displays. However, US statistics for 2002 indicate the 45% of web users have access to 1024x768 pixel displays, 50% use 800x600 and 2% are still using 640x480. This creates problems because the users of lower resolution equipment will have to scroll through forms in order to access all of the necessary fields. Usability studies have shown that the completion rates for on-line forms are inversely proportional to the amount of scrolling that users must engage in. For example, many potential contributors quickly become frustrated if they have to move up and down a screen to refer between linked items of information (Johnson, 2003). The problems of heterogeneous display hardware are exacerbated by software incompatibilities. For instance, cascading style sheets enable designers to ensure that all of the pages in web site possess a common look and feel. Changes can easily be propagated through different areas of the site in response to changes in the style sheets rather than forcing manual updates across dozens of pages. However, there is no guarantee that every potential contributor will have access to a machine that implements these style sheets. Early versions of Microsoft's Internet Explorer and Netscape's Communicator do not support this facility. Those that do enable the use of this implementation technique do not all render them in the same manner. From this it follows that the results of usability tests performed under particular software and hardware configurations will seldom provide a coherent view of the diverse user experience when on-line systems 'go live'. The difficulties in ensuring access to computer-based reporting forms have led many national and regional systems to operate hybrid approaches. On-line systems are provided alongside paper-based forms or telephone numbers that can be used to leave verbal accounts of adverse events on answering machines.

### ***Preamble and Definitions of an Incident***

It is important to provide users with a clear idea of when they should consider making a submission to the system. The NPSA dataset does this through the enumerations that are provided to the user. Each of the items and subsections provides some indication about the types of adverse event that fall within the scope of the system. This guidance is not available within the local system that relies more on free-text fields. In consequence, the local scheme in Figure 3 explicitly states that an incident must fulfil the following criteria: "1. It was caused by an error made by a member of staff, or by a failure of equipment. 2. A person who was involved in or who observed the incident can describe it in detail. 3. It occurred while the patient was under our care. 4 It was clearly preventable. Complications that occur despite normal management are not critical incidents. But if in doubt, fill in a form". It can be surprising that incidents, which occur in spite of normal management, do not fall within the scope of the system. This effectively prevents the system from targeting problems within the existing management system. However, such criticisms neglect the focused nature of this local system, which is specifically intended to "target the doable" rather than capture all possible incidents. CIRS exploits a wider definition of an adverse incident. "Defining critical incidents unfortunately is not straightforward. Nevertheless we want to invite you to report your critical incidents if they match with this definition: an event under anaesthetic care, which had the potential to lead to an undesirable outcome if left to progress. Please also

consider any team performance critical incidents, regardless of how minimal they seem”. This could potentially cover a vast range of adverse events. Such a definition would stretch the limited resources of many local or national systems. It also illustrates the way in which the definition of an incident both determines and is determined by the reporting system that is intended to record it. The definition must be broad enough to capture necessary information about adverse events. However, if the definition is drawn too widely then the system may be swamped by a mass of low-risk mishaps and near misses so that it can be difficult to identify critical events in time to take corrective actions.

It is important also not to forget that the definitions of what should be reported are one of many contributory factors that help to determine whether or not a healthcare professional will actually submit a report. For example, Lawton and Parker show that adverse events are more likely to be reported when staff deviate from written protocols. They argue that professionals are unwilling to challenge a fellow professional without strong grounds. They are also reluctant to report behaviour that has negative consequences for the patient when the behaviour reflects compliance with a protocol or improvisation where no protocol is in place. The key issue here is that such observations about reporting behaviour are often orthogonal to the abstract definitions of adverse events that form the basis of many reporting systems (Lawton and Parker, 2002).

### ***Identification Information***

Previous sections have described Spectrum Health’s reporting system as an example of a ‘gatekeeper architecture’. Key managers have a responsibility to determine whether reports should be handled locally or whether they should be passed to external agencies. These managers act as the ‘gatekeepers’ to various reporting systems. This approach has numerous benefits in terms of accountability. However, these schemes rely upon employees providing identification information so that risk managers can gather further data if a mishap requires subsequent investigation. These systems, therefore, provide confidentiality rather than anonymity. In contrast, neither the NPSA dataset nor the local Intensive Care system elicits any direct information about the contributor’s identity. This anonymity is intended to encourage participation. However, it clearly creates problems during any subsequent causal analysis. It can be difficult to identify the circumstances leading to an incident if analysts cannot interview the person making the report. Without a ‘gatekeeper’ approach, the developers of confidential systems have to provide considerable additional details to ensure that their system does not short-circuit or filter reports that should be submitted under mandatory or regional systems. For instance, the NPSA must distinguish their system from the Serious Untoward Incident (SUI) reporting system that informs Strategic Health Authorities and the Department of Health about incidents that require urgent attention; “They may not necessarily be patient safety incidents, and will often include identifiable information to enable action at a local level. For this reason it is not appropriate to combine the two systems”. Similarly, the NPSA are keen to point out that any incidents involving the use of a medical device will be shared with the Medicines and Healthcare products Regulatory Agency (MHRA); “because the anonymous nature of NPSA information will prevent the MHRA from investigating what happened, you should instead report these incidents directly to the MHRA” (NPSA, 2003a).

The anonymity of a reporting system can be compromised in local reporting systems. Inferences can be made about the identity of a contributor based on shift patterns, on clinical procedures and on the limited number of personnel who have the opportunity to observe an incident. Clearly there is a strong conflict between the desire to prevent future incidents by breaking anonymity to ask supplementary questions and the desire to safeguard the long-term participation of staff within the system. The move from paper-based schemes to electronic systems raises a host of complex socio-technical issues surrounding the anonymity of respondents. For instance, each client computer connecting to a website will potentially disclose location information through its Internet Protocol (IP) address. This address is not linked to a particular user but it can be used to trace a report back to a particular machine. If logs are kept about user activity then it will be possible to identify the contributor. Alternatively, many healthcare organisations routinely log users' keyboard activity hence; there may also be more direct means of identifying the person who contributes an electronic incident report. Balanced against this concern for anonymity and confidentiality, there can also be problems if groups or individuals deliberately seek to distort the findings of a system by generating spurious reports. These could, potentially, implicate third parties. The problems of malicious reporting together with the technical difficulties of providing anonymous reports, therefore, makes it likely that future electronic systems will follow the ASRS approach of confidential submissions.

### ***Time and Place Information***

There is a tension between the need to learn as much as possible about the context in which a mishap occurred and the need to preserve the confidentiality or the anonymity of the person contributing a report. A frequent criticism is that in order to protect the identity of those involved in an adverse event, reporting systems also remove information that is vital if other managers and operators are to avoid future mishaps (Johnson, 2003). As mention in the previous paragraph, this is a particular problem in local systems where it may be possible to infer who was on duty if respondents provide information about the time at which an incident occurred. However, if this data is not provided then it may not be possible to determine whether or not night staffing patterns played a role in the incident or whether an adverse event was effected by particular hand-over procedures between different teams of co-workers. Similarly, if location information is not provided then it can be difficult to determine whether ergonomic issues and the configuration of particular devices contributed to a mishap. If location information is provided, for instance within an ICU, it is then often possible to name a small number of professionals to be identified as responsible for healthcare provision within that area. The difficulties created by the omission of location information can be seen by the frequent requests for additional unit information in the dialogues that emerge after the contribution of an incident to the CIRS application.

Location information falls into several different types. Geographical information may be important in national and regional systems to detect common patterns within specified areas. These can emerge if local groups of hospitals adopt similar working practices that may contribute to adverse events. Similarly, geographical information can be important

to identify 'hot spots' that can be created by a batch of medication or other common supply problems. These details need not be explicitly requested from the individuals who contribute a report. They can often be inferred from the delivery mechanism that is used to collect the report. These inferences can be relatively straightforward, for example if reports from a particular hospital regularly arrive on a specific day of the week. They can also be based on more complex information, such as the IP address of a contributing machine. These assumptions can, however, be unfounded. For instance, problems will arise if contributors work in one location and submit a report from another. This scenario is likely to occur because many healthcare workers benefit from increasing job flexibility; especially in the delivery of specialist care across a relatively wide geographical area.

As mentioned, the location information requested from contributors can take several different forms. Not only do analysts often need to identify geographical patterns within a series of incident reports. They may also need to locate functional similarities within the different areas of a healthcare system. For instance, the NPSA's National Reporting and Learning Service dataset asks 'in which service did the patient safety incident occur'. As before, contributors must select from a number of predefined fields. The nine options range from 'acute/general hospitals' through to 'general practice' and 'learning disabilities service'. They also note that individuals may report an incident within a healthcare service that is different from the one in which they themselves work. The NPSA also ask 'in which location did an incident occur'. The FDA takes a similar approach when it offers thirty or more locations in their medical devices reporting system. This taxonomy includes '612 Mobile Health Unit' and '002 Home' as well as '830 Public Venue' and '831 Outdoors'. The diversity in the classification reflects the diverse locations in which mass market healthcare devices might fail.

In confidential systems, location information must be obtained so that analysts can contact reporters in order to follow up any necessary additional details. Even in anonymous systems it can be necessary to provide location information. For example, if a device has failed or if a problem involves a sub-contractor then it may be necessary for the reporter to provide information about the location and identity of the supplier who was involved in the adverse event. This creates considerable opportunity for error in reporting system software. Arguably the most frequent problems centre on the misspelling of names. For example, Siemens has been entered into the FDA system under Seimens and Simens. Incidents have also been recorded under SIEMENS MEDICAL, SIEMENS MEDICAL SOLUTIONS, SIEMENS MEDICAL SYSTEMS etc. Any analysis and retrieval software must cope with such alternative spellings if potentially relevant information is not to be overlooked. An alternative approach is for the system to prevent users from typing in this information. Instead, they are compelled to select a supplier identifier from an enumerated list or menu. This is liable to have several hundred items. Such widgets pose a considerable challenge for human computer interface design (Johnson, 2003). They can also introduce considerable frustration in users who must scroll through the names of dozens of medical suppliers before they reach the one that they are looking for. This frustration is likely to increase if the supplier identity information is missing from the enumerated list. However, one benefit from this

approach is that most software reporting systems can use a supplier list to automatically update address information so that users need not type in their location details. This is a significant benefit given that many end-users will not have this information to hand as they begin to file a report in the aftermath of an adverse event.

Most reporting forms also prompt contributors for the time when an incident occurred. As with location information, the elicitation of this information is not as simple as it might appear. As mentioned above, temporal information can be used with geographical data to support inferences about the identity of a potential contributor or about the work group who are implicated in a report. A number of other human factors issues also complicate the elicitation of this information. For example, CIRS prompts the reader ‘at what time of the day did the incident happen (1 - 24)?’ In contrast, the NPSA dataset asks two related questions. Firstly, contributors must determine the ‘date on which the incident occurred’ by giving the day, month and year. It is, however, possible for the date to be ‘unknown’. The second related question asks for the ‘time of the incident’. There is slightly more flexibility here than in the previous question. Respondents can supply the precise hour and minute or a time slot from 08.00-11.29, 12.00-15.59, 16.00-19.59, 20.00-23.59, 00.00-03.59, 04.00-07.59. Alternatively, as before, contributors can also state that the time was ‘unknown’. The NPSA dataset enables contributors to specify precise times and also intervals. However, there are additional complexities. For example, some incidents only emerge slowly over a prolonged period. For instance, an infusion device may administer the incorrect medication over several of these intervals. Other mishaps can take place over an even longer timescale, even extending to months and years. Similarly, the same adverse event might occur several times before it is detected or might occur at different times to several patients. It is unclear how these different circumstances might be coded within many reporting schemes. For example, contributors might be required to complete a separate form for each instance of the adverse event even though they were strongly connected by sharing the same causes and consequences for the patient. Further complexity arises because the time at which an incident occurs can be different from the time at which an adverse event is detected or reported. These additional details are often elicited so that safety managers can review the monitoring mechanisms that are intended to preserve patient safety. If an adverse event is only detected many months after it has taken place, for example if a patient returns to report the adverse consequences of a mishap, then many internal quality control and monitoring systems can be argued to have failed.

### ***Detection Factors and Key Events***

It is important to determine how adverse events are detected. Many incidents come to light through a combination of luck and vigilance. Unless analysts understand how contributors identified the mishap then it can be difficult to determine whether there have been other similar incidents. CIRS provides an itemised list of detection factors. These include direct clinical observation, laboratory values, airway pressure alarm and so on. The respondent can identify the first and second options that gave them the best indication of a potential adverse event. The local Intensive Care Unit scheme of figure 3 simply asks for the “Grade of staff discovering the incident”. Even though it explicitly

asks for factors contributing to and mitigating the incident, it does not explicitly request detection factors.

The reporting of detection factors raises a number of problems. For example, clinical training often emphasises the importance of ‘making errors visible’. Nolan (2000) identifies the "double checking," of physician medication orders (prescriptions) by the pharmacist and the checking of a nurse's dose calculations by another nurse or by a computer are examples of making errors visible. Similarly, if patients are educated about their treatment then they can also play an important role in identifying errors. However, as these checks and balances become more widely integrated into healthcare practice it is less and less likely that they will trigger incident reports. There is a paradox that the most effective detection factors are likely to be those that are mentioned least often in incident reports because they are accepted as part of the standard practice. Unfortunately, things are seldom this straightforward. For example, a recent report to the FDA described how the drug calculator of a medication assistant in a patient monitoring application would occasionally round up values to a second decimal place. The users complained that this could easily result in a medication error and that the manufacturer was failing to acknowledge the problem. The manufacturer responded that vigilant nursing staff ought to notice any potential problems when calculating the medication. The clinicians countered this by arguing that they had explicitly taught nursing staff to trust the calculation function as a means of *reducing human error* (Johnson, 2004). This illustrates the recursive nature of incident detection. Manufacturers assume that healthcare professionals will crosscheck any advice to detect potential errors. Conversely, healthcare professionals increasingly assume that automated systems will provide the correct advice that is necessary to help them detect adverse events.

Many detection factors are focussed on the proximal or immediate events that can lead to an adverse outcome. For example, a nurse observing a patient’s adverse reaction to a particular medication can trigger a report. It is rare for reports to be filed when healthcare professionals detect the latent conditions that may eventually contribute to an incident or accident. Many nurses and doctors accept a culture of coping with limited resources and high demands on their attention. Lawton and Parker (2002), therefore, argue that the UK National Health Service should take a more proactive approach to incident reporting. Individuals and teams must be sensitised so that they are more likely to detect and report the conditions that will lead to error before an error actually occurs:

“Proactive systems work in part by asking people to judge how frequently each of a number of factors such as staffing, supervision, procedures, and communication impact adversely on a specific aspect of their work. So, for example, if nurses in intensive care are experiencing problems with the design of a particular piece of equipment, this will be recorded and action taken to improve the design. This kind of proactive approach allows the identification of latent failures before they give rise to errors that compromise patient safety.”

Vincent, Taylor-Adams and Stanhope (1998) build on this analysis when they identify those latent conditions that should be monitored and detected prior to an adverse event.

Their enumeration includes items such as heavy workload; inadequate knowledge or experience; inadequate supervision; a stressful environment; rapid change within an organisation; incompatible goals (for example, conflict between finance and clinical need); inadequate systems of communication and inadequate maintenance of equipment and buildings. They observe that these latent factors will affect staff performance, can make errors more likely and will impact on patient outcomes. However, few existing reporting systems or research studies have found concrete means of encouraging respondents to detect and report these latent conditions within healthcare institutions. Part of the explanation for this may lie in the observation that many of the latent conditions for adverse events are almost characteristic of many modern healthcare organisations. These include rapid change within an organisation and conflict between clinical and financial need.

Most reporting forms prompt the contributor to explain what happened. In many systems, this field is left open so that individuals and teams can describe the critical events in their own words. Additional prompts are often used to help ensure that contributors provide sufficient detail for subsequent analysis. For instance, the local Intensive Care Unit system breaks down the 'what happened' information into a number of different categories. Respondents are first prompted to elicit information about 'The Incident'. This information is broken down into a 'Description of what happened' and 'What factors contributed to the incident?'. They are also asked for mitigation factors, however, a more detailed discussion about this part of the form is postponed to the next section of this paper. The local system also prompts for other information about what happened. A further section of questions address the 'Circumstances' of the incident. This includes temporal information, mentioned previously as well as 'What procedure was being carried out', 'What monitoring was being used?' and 'If equipment failure give details of equipment'. A final section about what happened is intended to elicit general information about the personnel involved. Respondents are asked for the 'Grade of relevant responsible staff' and the 'Grade of staff discovering the incident'. In keeping with the rest of this form, contributors can complete the form using their own terms. They are not expected to select individual items from a predetermined enumeration.

Similar to the local system, the NPSA's National Reporting and Learning System dataset also includes a section to elicit information about 'What happened'. In contrast to the previous example, this scheme exploits a mixed approach using both a predefined taxonomy and open textual responses. For instance, contributors are asked to provide information about 'What happened' by categorising the incident according to a number of choices. These range from problems involving Access, admission, transfer, discharge (including missing patient) through to problems involving treatment procedures. In addition respondents can provide a free text response to describe 'what happened' in their own words. The NPSA also ask a series of more detailed questions about the circumstances in which an incident occurred. These include the location information, described in previous sections. They also include a series of questions about the patients involved in an adverse event. This information is not explicitly prompted for by the local system and arguably reflects the greater diversity of conditions that will be covered by the national reporting system. For instance, respondents are asked whether 'Does the

patient have any of the following known / diagnosed impairments or disabilities?'. The options include Learning disability(ies); Physical disability(ies); Sensory impairment(s) or Other. Additional questions ask whether the patient was sedated at the time of the incident, whether they were being detained under the Mental Health act etc. The NPSa also elicit contributory factors. They ask respondents to tick any of the following factors that apply to an incident Communication factors (includes verbal, written and non-verbal between individuals, teams, and/or organisations); Education and training factors (e.g. availability of training); Equipment and resources factors (e.g. clear machine displays, poor working order, size, placement, ease of use); Medication factors (where one or more drugs directly contributed to the incident); Organisation and strategic factors (e.g. organisational structure, contractor / agency use, culture); Patient factors (e.g. clinical condition, social / physical / psychological factors, relationships); Task factors (includes work guidelines / procedures / policies, availability of decision making aids); Team and social factors (includes role definitions, leadership, support, and cultural factors); Work and environment factors (e.g. poor/excess administration, physical environment, work load and hours of work, time pressures); Other and Unknown. The inclusion of these contributory factors is an important strength in the NPSA's approach because it provides reporters with a means of commenting on the latent factors that may have created the preconditions for an adverse event to occur.

One of the problems with the NPSA's elaborate approach is that respondents may become disillusioned, fatigued or irritated by the large number of questions that they are being asked. One consequence is that users may spend most of their time completing the free text description and will, therefore, pay less attention to ticking the relevant boxes in other areas of a reporting form. Conversely, the tickable boxes may arguably reduce the load on the contributor who might then feel it unnecessary to provide additional details in the natural language section. It is difficult to determine which of these interpretations will prove correct as the initial implementation of this approach have been running for a relatively short period of time. However, the NPSA have addressed some of the potential problems by using software suppliers to develop context sensitive reporting systems. Users are guided to answer only those questions that relate to what happened in their particular incident. For example, if they state that the incident did not involve a medication error then they would not need to select options such as Adverse drug reaction (when used as intended), Contra-indication to the use of the medicine in relation, Mismatching between patient and medicine; Omitted medicine / ingredient, Patient allergic to treatment, Wrong / omitted / passed expiry date and so on. Similarly, the software would only present specific questions about what happened to a particular device once the user had confirmed that the incident did involve a device failure. The dynamic nature of the form content helps to filter out irrelevant questions. This avoids an important limitation of more complex paper based forms where users are often directed to skip ahead 10 or 20 questions if necessary. Users can become lost as they turn over pages and pages of irrelevant questions.. However, the use of context sensitive software can also create problems if users have to report 'hybrid' incidents that bring together complex combinations of, for example, adverse drug reactions and device failures. There is also a body of human factors research that points to the confusion that can result when systems dynamically alter the information that users are presented with

when they navigate through on-line support (Johnson, 2003). Again, further experience with applications based on the NPSA dataset will be necessary before any sustained analysis can be made of the costs and benefits of this approach within healthcare organizations.

The CIRS on-line system also adopts a mixed approach. Initially, the web-based form prompts participants to enter information about what has happened by checking boxes associated with the various team members who were involved in an adverse event. They must then enter the number of hours “on duty without sufficient rest (if known)”. This is intended to provide an insight into the workload on the provider of anaesthetic care. The subjective nature of this question makes it very difficult to interpret any results. Different individuals can have very different ideas about what represents “sufficient rest” (Johnson, 2003). This again illustrates the importance of conducting usability studies and of considering the human factors issues when constructing the questions that will be asked as part of a reporting form. Like the NPSA dataset, respondents are then asked to provide information about the patients involved. In this case, a radio button widget is used to indicate the sex of the patient. Respondents can type numeric values into an age field. Radio buttons are also used to indicate whether the patient is undergoing elective or emergency procedure and their ASA status (Class I-V). The ASA Status refers to the American Society of Anaesthesiologists Physical Status Classification where class I refers to a normal and healthy patient and class V refers to a patient who is unlikely to survive without an operation. This classification provides a crude approximation to the a priori risk involved in anaesthesia. The CIRS form assumes that each incident only affects a single patient. This common assumption is often not warranted, for example if a common ‘error’ is replicated in a number of similar procedures. The key point is that significant testing should be conducted to determine whether such assumptions can be justified within a particular domain. This testing can be performed in several different ways. For example, a sentinel scheme can be used in the manner described in previous paragraphs if representative institutions pilot the system before it is made more widely available. Similarly, potential contributors might be asked to use a prototype system to report information about an incident that they have observed in the past. They can also be given information about stereotypical mishaps and then asked to enter relevant information into the system ‘as if’ they had witnessed such an adverse event.

The CIRS system elicits further information about ‘what happened’ by asking contributors to select the ‘Overall anaesthetic technique’ during which the incident occurred. A pull-down menu offers nine broad categories of activity that range from general anaesthesia to regional anaesthesia and care of a multiple trauma patient. These constrained fields are then followed by a number of more open questions. Contributors are asked to describe the incident in their own words. They are warned to be ‘careful not to present data here, that could identify the patient, the team or the institution’. This section elicits information about the events leading to an incident. A second question asks respondents to ‘describe the management of the situation in your own words’ from the moment of occurrence on. In passing it is worth noting that CIRS warns users that ‘if you wish to print out this report, please stay in between the margins of the text field’. This stems from a problem in the formatting of the on-line form that does not have a dedicated print function. Such issues are less significant for voluntary reporting systems

where great pains are taken to preserve the anonymity of individual contributors. The need to keep a printed record of particular reports assumes a greater priority within mandatory and confidential schemes.

### ***Consequences and Mitigating Factors***

Vincent and Coulter (2002) argue that it is vital to consider the patients' perspective when assessing the consequences of an adverse healthcare event. They refer to the psychological trauma both as a result of an adverse outcome and through the way that an incident is managed. They urge that "if a medical injury occurs it is important to listen to the patient and/or the family, acknowledge the damage, give an honest and open explanation and an apology, ask about emotional trauma and anxieties about future treatment, and provide practical and financial help quickly". They also argue that patients are often best placed to report the consequences of an adverse event. Schemes similar to the Swedish system operated by KILEN, the Consumer Institute for Medicines and Health, should be established to help patients report these incidents. However, most existing reporting systems rely upon clinicians to assess the outcomes of adverse events when they submit information about an incident or near-miss.

Most schemes explicitly prompt respondents for information about the consequences of an adverse event. However, this raises a number of complex issues for healthcare systems. For example, it can often be difficult to determine whether or not a mishap had any appreciable impact upon the patient outcome. CIRS asks contributors to respond to this question. They then select an outcome from an enumeration that includes: outcome independent from the event; patient dissatisfaction, prolongation of hospitalisation; unplanned hospitalisation of an outpatient; unplanned admission to an ICU; minor morbidity; major morbidity and death. This contrasts with the local system that simply provides a free text area for the respondent to provide information about "what happened to the patient?". The NPSA is similar to CIRS, it also begins with a prompt to state whether or not any patients were actually harmed by an event. If so then additional information must be provided about the degree of harm or severity of the adverse event. The contributor must determine whether the patient suffered a low severity event that required extra observation or minor treatment; moderate or short-term harm that required further treatment; severe or long-term harm, or death. If more than one patient was affected by an adverse event then contributors should indicate the number of individuals falling into each of these different categories. Further questions probe the nature of any adverse impact on the patient. For example, contributors are asked to state whether the effect was physical, such as an allergic adverse reaction, blood loss or neurological effect. A free-text field is also provided to record additional details about the nature of psychological or social consequences.

None of these forms resolves the practical problems that arise when individuals have to determine the outcomes of an adverse event. An incident might have no immediate effect. Hence, the distinction between immediate and long-term outcomes is an important issue. Similarly, the administration of an incorrect medication may include side effects that increase the probability of adverse consequences in the future. In such circumstances, it may only be possible to consider the likelihood of an effect rather than

commit to a certain outcome. Further problems arise because the individuals who witness an incident may only be able to provide information about the consequences of that event. The lack of clinical audit and of agreed outcome measures in some areas of healthcare creates additional complexity. Finally, healthcare professionals can inadvertently compromise the confidentiality of a report by carefully monitoring the progress of particular patients involved in an incident.

Further complexity is created by the need to assess the potential consequences of near miss incidents. Few healthcare systems explicitly address this issue. However, it is a common concern in aviation and maritime systems (Johnson, 2003). Given that no adverse event has actually taken place it can be argued that the incident resulted in minor or negligible consequences. However, this may ignore the way in which chance occurrences may have intervened to prevent what otherwise might have been a very serious mishap. In consequence, many risk managers adopt the heuristic of 'worst plausible consequences' when assessing the severity of a near miss. The interpretation of 'plausible' consequences is subjective and varies from system to system. For example, some air traffic management systems will treat a report of an air proximity violation 'as if' a collision had actually occurred if the crew rather than the controllers were forced to initiate an avoiding action.

Voluntary reporting systems are often intended to elicit information about the low consequence and near miss incidents that are not covered by mandatory schemes. Van Der Schaaf (1996), therefore, argues that these reporting systems provide as much information about how to mitigate failure as they do about the causes of adverse events. The local Intensive Care Unit system, introduced in previous paragraphs simply asks what 'minimised' the incident. In contrast, the NPSA illustrate the importance of mitigation information by including a series of questions about the barriers that intervened to protect patient safety. For instance, the subsection entitled 'Impact on the Patient' includes the question 'Did any actions prevent the incident from reaching the patient? (i.e. was this a 'near miss'?)'. Contributors are then asked an optional question intended to determine the nature of any preventative actions that were taken. Other questions ask 'Did any actions minimize the impact of the incident on the patient?' and if so, respondents must describe those actions in their own words.

The CIRS system adopts a mixed approach to the elicitation of mitigating factors. Like both the local system and the national NPSA dataset, respondents are prompted to describe the management of the situation in their own words. CIRS then provides a number of explicit prompts. The on-line form asks 'What led you successfully manage the event (recoveries)?'. Respondents must select the most important factor using radio buttons that are grouped into a number of categories. Personal factors include knowledge, skill, experience, situation awareness and use of appropriate algorithms. A further category of mitigation factors focuses on team intervention described in terms of extraordinary briefings, extraordinary teambuilding, extraordinary communication within the anaesthetic team, extraordinary communication in the surgical team and extraordinary communication between the teams. The form also prompts for system factors including additional monitoring or material, replacement of monitoring or material, additional

personnel and replacement of personnel. Finally, there is an 'other' category. As before, this detailed enumeration can help to guide users who may not be used to thinking in terms of 'mitigation factors'. There is a danger that schemes which ask more open questions may fail to elicit critical information about the ways in which managerial and team factors helped to mitigate the consequences of an incident.

In some incidents, it can be relatively easy to interpret information about the mitigation of adverse events. For instance, one study identified that there were 6.5 adverse drug events for every 100 admissions in a US hospital (Bates et al 1995). Of those, it was argued that 28% could have been detected and avoided mainly by changing the systems used to order and administer drugs. Similarly, another study showed that computerized monitoring systems were significantly more likely to identify and prevent severe adverse drug events than those identified by chart review (51% vs. 42%,  $p=0.04$ ) (Jha et al 1998). However, it can be far harder to interpret incident reports where claims are made about human intervention in the mitigation of adverse events. It can be difficult to identify what precisely protected patient safety if another member of staff intervenes to prevent an adverse event. At one level, a safety manager might praise the vigilance of that individual. At another level, they might use this as an example of the success of the monitoring systems within a team of co-workers. Further investigation is required to determine whether such confidence is warranted. Individuals often identify potential incidents in ways that are not directly linked to official monitoring procedures. Conversely, well-developed routines can successfully detect potential incidents even when individuals are tired or operating under extreme workload (Johnson, 2003).

### ***Causes and Prevention***

The Veteran's Affairs National Center for Patient Safety (2004) use their vision statement to motivate the development of voluntary reporting systems. They argue that we must "take advantage of lessons present in *close calls* where things almost go awry, but no harm is done". In order to exploit these lessons we must understand "the real underlying causes (so that) we can better position ourselves to prevent future occurrences". This vision statement also goes on to suggest that people 'in the front line' are in the best position to identify the causes of problems and to propose potential solutions. Similar sentiments are expressed by the UK NPSA and by the proponents of the CIRS reporting system. Both of these schemes actively seek to elicit information from respondents about what they perceive to be the causes of an adverse event. For example, the National Learning and Reporting System dataset includes the question 'in your view, what were the underlying causes or events which, if rectified, may prevent another patient safety incident?'. This prompts the contributor to provide a free text explanation of the events leading to an adverse outcome or near miss. It also raises a host of complex human factors issues. Many issues center on the problems of counterfactual reasoning. Counterfactual arguments lie at the heart of most forms of causal analysis. We can say that some factor A caused an accident if the accident would have been avoided if A had not occurred. This is counterfactual in the aftermath of an adverse event because we know that A did happen and so also did the mishap. The NPSA question embodies this counterfactual style of reasoning about causation 'what were the underlying causes or events which, if rectified, may prevent another patient

safety incident?' The local system reporting system also asks respondents to suggest, "how might such incidents be avoided". This open question is, in part, a consequence of the definition of an incident in this scheme, which included occurrences "that might have led (if not discovered in time) or did lead, to an undesirable outcome". It also provides a further illustration of this counterfactual approach to causal information.

Byrne and Handley (1997) have conducted a number of studies into human reasoning with counterfactuals. They have shown that deductions from counterfactual conditionals differ systematically from factual conditionals. For example, the statement 'either the medication was prescribed too late or the disease was more advanced than we had thought' is a factual disjunction. Studies of causal reasoning suggest that readers will think about these possible events and decide which is the most likely. It is often assumed that at least one of them took place. The statement that 'had the medication been prescribed sooner or the disease been less advanced then the patient would have recovered' is a counterfactual disjunction. This use of the subjunctive mood not only communicates information about the possible outcome of the incident but also a presumption that neither of these events actually occurred. This theoretical work has pragmatic implications for incident investigation. If factual disjunctions are used then care must be taken to ensure that one of the disjunctions has occurred. If counter-factual disjunctions are used then readers may assume that neither disjunction has occurred. The key point here is that most reporting systems rely upon counterfactual definitions of causation. Human factors studies of counterfactual reasoning have identified systematic biases that make it critical for risk managers to carefully analyze the causal arguments that they receive in response to adverse events.

The close association between causation and counter-factual arguments can also be seen in supplementary questions posed in the NPSA dataset. For example, respondents are explicitly asked about potential means of preventing an accident; 'in your view, what were the underlying causes or events which, if rectified, may prevent another patient safety incident?' and 'please describe any actions planned or taken to date to prevent a reoccurrence'. These questions are again intended to elicit a natural language response. The relationship to counterfactual reasoning is explicit in the way that they ask responders to think what *might have* prevented the adverse event. The CIRS system adopts a similar approach. However, this reporting form provides an enumeration that is intended to guide the contributor in their analysis. This is similar to the way in which CIRS uses a list of potential causes that, arguably, can reduce some of the difficulties associated with informal forms of counterfactual arguments. CIRS asks 'What would you suggest for prevention?' and respondents must select the most important item from a varied list. There potential preventative measures include additional monitoring or material, improved monitoring or material, better maintenance of existing monitoring/equipment, improved management of drugs, improved arrangement of monitoring/equipment. The CIRS enumeration also provides items for improved training/education, better working conditions, better organization, better supervision, more personnel, better communication, more discipline with existing checklists, better quality assurance, development of algorithms/guidelines, abandonment of old routine.

Finally, there is an opportunity to include other preventative measures but this time using free-text descriptions.

The NPSA dataset also probes for information about factors that did not directly cause an adverse event but that contributed to the course of an incident or accident. Respondents are requested to indicate whether any of the following contributory factors were involved: communication factors; education and training factors; equipment and resources factors; medication factors; organization and strategic factors; patient factors; task factors; team and social factors; work and environment factors; other and unknown. It remains to be seen whether the elements of this taxonomy will have to be revised after prolonged use of the national systems. For instance, most healthcare mishaps would involve work and environmental factors. It seems likely that additional information would be required to identify specific interventions to address this broad range of contributory factors. A further question asks for any additional 'important factors'. This question can be interpreted to provide additional details about the context in which an incident occurred. By enumerating potential causes, this list may avoid some of the potential pitfalls of counterfactual reasoning, mentioned above. This list of important factors includes: failure to refer for hospital follow-up; poor transfer / transcription of information between paper and/or electronic forms; poor communication between care providers; use of abbreviation(s) of drug name / strength / dose / directions; handwritten prescription / chart difficult to read; omitted signature of healthcare practitioner; patient /carer failure to follow instructions; failure of compliance aid / monitored dosage system; failure of adequate medicines security (e.g. missing CD); substance misuse (including alcohol); medicines with similar looking or sounding names; poor labeling and packaging from a commercial manufacturer.

The CIRS reporting form mirrors this use of an enumeration rather than a counterfactual approach to causal information. Contributors must select whether the most 'important field' to identify "what led to the incident (cause)?" These fields include personal factors such as diminished attention without lack of sleep, diminished attention with lack of sleep, insufficient knowledge etc. They also include team factors such as insufficient communication or briefing. System factors include lack of personnel and unfamiliar surroundings. It is important to stress again that the answers to causal questions should be interpreted with care. Although the individuals who directly witness an incident can provide valuable information about how future adverse events might be avoided, they may also express views that are influenced by remorse, guilt or culpability. Subjective recommendations can also be biased by the individual's interpretation of the performance of their colleagues, their management or of particular technical subsystems. Even if these factors did not obscure their judgement, they may simply have been unaware of critical information about the causes of an incident. These caveats must be balanced against the strengths and weaknesses of alternative analysis techniques. As mentioned in the introduction, previous studies have relied on quantitative approaches for quality improvement using the statistical analysis of nationwide data. These epidemiologic techniques help to analyse the distribution and incidence of adverse events that occur with reasonable frequency and for which it is possible to obtain reliable statistics. However, a number of industries ranging from public transportation through to power

generation have not begun to complement epidemiological approaches with more qualitative forms of root cause analysis (Johnson, 2003). Root Cause Analysis techniques are the focus of the next chapter. For now it is sufficient to observe that they provide structured means of minimising the biases that affect 'informal' approaches such as the counterfactual arguments described in the previous paragraphs.

Root cause analysis is having an increasing impact on healthcare. For instance, the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) recently recommended the extension of these techniques into the investigation of sentinel events. Wald and Shojania (2001a) argue that root cause analysis can help to uncover "common root causes that link a disparate collection of accidents" in healthcare. They also highlight a number of methodologic limitations. They argue that the qualitative nature of many of these techniques results in "uncontrolled case studies". Such investigations can also be affected by hindsight bias; in the aftermath of an adverse event it is easy to assume that others could have prevented an incident if only they had modified their behaviour appropriately. They argue that qualitative methods, including root cause analysis techniques, should supplement more traditional quantitative methods. For example, the detailed analysis of an adverse event can be used to generate new hypotheses that might then be tested using epidemiological techniques.

#### ***M.4.4 Explanations of Feedback and Analysis***

The human factors issues involved in incident reporting do not end with the submission of a report. Potential contributors must be confident that the information that they submit will be taken seriously. This does not imply that every report must initiate change within the host organisation. It is, however, important that contributors know their reports have been successfully received and attended to. In other domains, electronic tracking systems have been introduced so that contributors can monitor who has responsibility for handling their submission from the moment that it is logged (Johnson, 2003). Such techniques have not yet been introduced within healthcare applications. In confidential systems it is more usual for contributors to receive an acknowledgement slip in return for their contribution. Such feedback is obviously difficult to provide in anonymous schemes. Most reporting forms provide participants with information about how their contributions will be processed. For example, the local system in Figure 3 includes the promise that: "Information is collected from incident reporting forms (see overleaf) and will be analysed. The results of the analysis and the lessons learnt from the reported incidents will be presented to staff in due course". This informal process is again typical of systems in which the lessons from previous incidents can be fed-back through ad hoc notices, reminders and periodic training sessions. The CIRS web-based system is slightly different. It is not intended to directly support intervention within particular working environments. Instead, the purpose is to record incidents so that anaesthetists from different healthcare organisations can share experiences and lessons learned; "Based on the experiences from the Australian-Incident-Monitoring-Study, we would like to create an international forum where we collect and distribute critical incidents that happened in daily anaesthetic practice. This program not only allows the submission of critical incidents that happened at your place but also serves as a teaching instrument:

share your experiences with us and have a look at the experiences of others by browsing through the cases. CIRS© is anonymous”.

The NPSA clearly has a far wider set of responsibilities than either CIRS or the local scheme mentioned above. A recent overview of their activities explains to potential contributors that the NPSA “will collect reports from across the country and initiate preventative measures, so that the whole country can learn from each case, and patient safety throughout the NHS will be improved every time” (NPSA, 2004b). The main mechanisms for achieving this will be by collecting and analysing information on patient safety incidents from local NHS organisations, patients and carers through the datasets mentioned in previous paragraphs. They will also use information from other reporting systems. Potential contributors are assured that their data will be used to ‘learn lessons’ and ‘ensuring that they are fed back into health care and (the ways that) treatment is organised and delivered’. Potential contributors are also assured that work will be ‘undertaken on producing solutions to prevent harm, and to specify national goals and establish mechanisms to track progress’ where any risks are identified. As can be seen, these healthcare reporting systems are rather vague on the precise mechanisms that will be used to combat any recurrence of an adverse event. This ambiguity can be explained in a number of ways. Firstly, the NPSA are in the process of establishing their reporting system. They have adopted a step-wise policy of encouraging the establishment of local schemes prior to the development of their over-arching national voluntary system. For this reason, they rely on individual healthcare organisations to develop complementary mechanism for intervening in the immediate aftermath of an adverse event. Secondly, it can be difficult to predetermine all of the techniques that might be used to address the vast range of different adverse events covered by this national system. Over time, it is hoped that details will be provided to illustrate the diversity of interventions that will be based on contributions to the reporting system. Thirdly, in the case of the local system there is little need to provide great detail about the analysis and interventions that will result from a submission because this information can be directly transmitted through staff meetings, newsletters and other information sources. The next chapter will provide details about the particular interventions recommended as a result of submissions to this local system. Finally, CIRS acts as a medium of exchange rather than an active agent of intervention. Contributors provide information to promote discussion and raise awareness. It is also assumed that they will take local measures to prevent any immediate recurrences through their local system. This illustrates the similarity between aspects of CIRS and the NPSA scheme.

As mentioned, the local scheme referred to in this paper provided feedback to staff through periodic newsletters. CIRS provides feedback in the form of an on-line dialogue or forum through which professionals can add comments to the various reports that are received. It is likely that the NPSA will also use the web as a primary means of providing feedback to potential contributors. This approach is justified by the relatively low cost of web site development. However, it relies upon a form of information ‘pull’. Healthcare professionals have to keep going back to the site to download, or pull, updated information about patient safety initiatives. In contrast, email dissemination provides a form of information ‘push’ to ensure that lessons learned are sent out to healthcare

institutions in a timely fashion. Unfortunately, this approach raises a host of additional human factors issues. For example, the increasing problem of spam mail has increased the likelihood that many individuals will overlook or automatically delete messages that have such a mass distribution. Similarly, not everyone has convenient access to email or to the web. This is less of a problem for systems that elicit information from, and provide feedback to, healthcare professionals. These groups are likely to have access provided through their workplace. However, electronic dissemination suffers from significant limitations for systems that are intended to provide the general public with reporting facilities. Both in the US and the UK, slightly over 50% of the population currently have regular Internet access either at home or at work (Johnson, 2003).

The limitations of computer-based dissemination have persuaded other healthcare reporting systems to explore a range of alternate mechanisms, including telephone and fax based applications. A pre-recorded message can be used to list all of the most recent recommendations and other documents issued by the reporting system. Callers can then dial another number to request that paper-based copies of the full version are sent to them. This is cheap and simple; the prerecorded messages can be changed frequently and at minimal cost. However, the list of bulletins can become extremely long and tedious to list to. A further problem is that specialized equipment with multiple inputs must be used if callers are not to find that the call-back lines are frequently engaged. The use of pre-recorded messages to provide an index of updates to incident reports still does not address many of the administrative and resources problems that can arise from the paper-based distribution of these documents. At some point, copies of the report have to be printed and shipped to the prospective readers. One solution to these problems is to use fax-servers. These devices automatically ensure that a document is sent to every number on a preprogrammed list. The FDA pioneered the development of a 'Facts on Demand' system. The user dials up the service and they then hear a series of instructions. If, for example, they press '2' on their keypad then they can hear more detailed instructions on how to use the system. If they press '1' then they can choose to order a document. If they dial 'INDX' or 4639 on the keypad then they can order an index of all documents on the system. The only technical requirement for the user of such a system is that they have access both to a fax machine and to a touch-tone telephone.

Most incident reporting systems continue to use paper-based dissemination techniques. This situation is gradually changing as a result of financial and administrative pressures. For example, in 1997 the decision was taken to stop printing the FDA's User Facility Reporting Bulletin: "Time, technology, and budget restrictions have come together in the Food and Drug Administration. Ten years ago, our computer capability allowed us to communicate only within FDA. Now, with advanced computer technology we can globally communicate through the Internet and through Fax machines. As you would expect, Congressional budget cuts have affected all parts of government. FDA did not escape these cuts. In the search for ways to reduce our expenses, printing and mailing costs for distribution of publications in traditional paper form have come to be viewed as an extravagant expenditure... Now, budget restrictions prevent future distribution in paper form. We regret the need to move to this new technology if it means that many of our current readers will no longer have access to the Bulletin. We would like to remind you

that you can also obtain copies through our Facts-on-Demand System or the World Wide Web” (Wollerton, 1997).

## **M.5 Conclusions**

This chapter has provided a high-level survey of the human factors issues involved in the reporting of adverse healthcare events. It began by reviewing recent initiatives from the US Institute of Medicine and a range of national patient safety agencies that have encouraged the development of voluntary and mandatory reporting schemes. Later sections went on to exemplify the problem of under-reporting. Potential contributors are often concerned that they will be blamed for any involvement in an incident or near-miss. Several schemes have arranged for limited legal protection to support participants in voluntary reporting systems. These arrangements were described and the exceptions to this protection were identified.

The middle sections of this paper introduced a range of different architectures for incident reporting. These included local systems that are designed and operated by individual healthcare professionals within single units. We also described different regional and national systems. For instance, the FDA has pioneered the use of Sentinel reporting to reduce the reporting biases that affect large-scale schemes. This approach focuses training resources and support onto a number of representative institutions so that all staff are sensitised to the importance of incident reporting and hence may be more likely to participate in the scheme. It is, typically, not possible to provide similar levels of resourcing across all of the thousands of organisations who contribute to less focussed national systems. The increasing diversity of mandatory and voluntary reporting systems has made it difficult for many staff to know which scheme they should use after a particular adverse event, particularly when they may not be certain of the ultimate impact on any patients who were involved. In consequence, an increasing number of hospitals have introduced ‘gate keeper’ systems where all reports are first submitted to a local safety manager who then assumes responsibility for passing them to the relevant schemes.

Form design and distribution have a significant impact on the human factors of reporting systems. It can be difficult for individuals to access on-line systems even once they are persuaded to share information about an adverse event. Conversely, it can be difficult to sustain the levels of funding and management interest necessary to replenish and monitor supplies of paper based forms. Usability problems can affect on-line systems if users do not have access to displays with adequate resolution to present increasingly complex forms. Similarly, it can be difficult to ensure that all potential contributors have access to the software that is required for many Internet based systems. Even if paper based forms are used, careful consideration must be given to the design of reporting systems. Even apparently simple information requirements, such as the date when an incident occurred, can lead to problems. For instance, many forms provide no means of specifying that the same adverse event recurred on several occasions. This means that several different forms may be submitted if, for instance, an incorrect medication was administered to the same patient over a course of several days. Many forms include questions about why and how the incident occurred and how it might have been avoided. The

closing sections of this chapter have examined recent human factors work that has pointed to the biases that influence causal analysis. The next chapter, therefore, introduces techniques to support the causal analysis of healthcare incidents that increasingly stem from complex combinations of system 'failure', human 'error' and managerial 'problems'.

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