Who reports: Reports are received from hospitals or health care organizations.

How they report: Any hospital or healthcare organization can voluntarily report to accrediting bodies. There is a mandatory requirement to report to the Japan Council for Quality Health Care. Information is reported electronically.

Analysis: The Agency will provide analysis of incident causation and feedback of analysis to the reporter. The data are classified and summary results are disseminated to healthcare providers and to the public.

Response, dissemination and application of results: Cases deemed particularly important are evaluated individually. Otherwise, reports are aggregated for statistical analysis (further details not available). The Japan Council for Quality Health Care produces summary reports of events and disseminates them to healthcare providers and to the public.

U.S.A. - Institute for Safe Medication Practices (ISMP)

Type of reporting system: ISMP is a national, confidential medication error reporting system. that distributes hazard alerts and other medication safety information to 600,000 providers every other week.

What is reported: ISMP is a focused reporting system for adverse drug events and hazards in medication delivery and management.

Who reports: Reports are accepted from health care professionals, organizations, or patients.

How they report: Reports from organizations or professionals can be submitted online, electronically, by telephone, mail, or fax.

Analysis: Over half of reporters are called back to elicit details about hazardous medication packaging or devices information of brand name, model number, or a photograph illustrating the problem This detailed information is extracted to enable specific, direct and immediate influence on hazard reduction. Medication information is classified according to 10 key elements. Hazard identification is done by human expertise; a group of experts observes recurrent reports, works closely together, and applies their knowledge to appreciate the urgency of a problem. Rapid turnaround permits numerous hazard alerts, so that an overall analysis for prioritization is unwarranted.

Response, dissemination and application of results: ISMP is engaged in numerous actions to support hazard reduction, such as promoting maximum dose statements on chemotherapy vial caps, elimination of pre-filled syringes for hazardous cardiac medications, identification and reduction of hazardous medical abbreviations among providers and pharmaceutical advertisements, and several other collaborations with pharmaceutical companies, device manufacturers, and the United States FDA.

Further information: www.ismp.org

U.S.A - Joint Commission on Accreditation of Healthcare Organizations (JCAHO)

Type of reporting system: The Joint Commission on Accreditation of Healthcare Organizations implemented a Sentinel Event Reporting System in 1996. The system is designed to facilitate identification and learning among healthcare organizations of sentinel events and their prevention strategies. The system is voluntary and confidential. Accreditation status is not penalized for any organization that reports an error and applies due process to its future prevention.

What is reported: Reported sentinel events include: event has resulted in an unanticipated death or major permanent loss of function, not related to the natural course of the patient's illness or underlying condition, or the event is one of the following (even if the outcome was not death or major permanent loss of function unrelated to the natural course of the patient's illness or underlying condition): suicide of any individual receiving care, treatment or services in staffed around-the-clock care setting or within 72 hours of discharge; unanticipated death of a full-term infant; abduction of any individual receiving care, treatment or services; discharge of an infant to the wrong family; rape; hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities; surgery on the wrong individual or wrong body part; unintended retention of a foreign object in an individual after surgery or other procedure.

Who reports:Reports are received from health care organizations and other sources such as media, complaints and the State Health Department.

How they report:Any accredited healthcare organization may submit reports.

Analysis: JCAHO require organizations to conduct a root cause analysis accompanied by an action plan. JCAHO also require access to review the organization's response to the sentinel event (which may or may not include actually reviewing the RCA). Guidance on conducting root cause analysis is offered by JCAHO on their website or upon request. Although reporting is voluntary, providing a root cause analysis is required.

Before the data describing the event, its root causes, and risk reduction strategies can be accepted into the database, the organization's response must meet certain defined criteria for acceptability.

Response, dissemination and application of results: Using their database and collaborating with experts, JCAHO periodically chooses a reported event type and develops a Sentinel Event Alert describing the events, causes, and strategies gathered from organizations for prevention. Publications began in 1998; to date 34 issues of Sentinel Event Alert have been published.

The individual organization's action plan is monitored by the JCAHO in a manner similar to the monitoring of corrective actions of other quality concerns. On a broader scale, hospitals' responses to the "Sentinel Event Alerts" are considered

during accreditation survey. The JCAHO have instituted National Patient Safety Goals as an influential derivative of the Sentinel Event reporting process.

Further information: www.jcaho.org

U.S.A - United States Pharmacopoeia MedMARx^{SM}

Type of reporting system: MedMARx^{SM} is a voluntary system designed to identify hazards and systems vulnerabilities, identify best practices, and gather information that will support the standard-setting activities of USP.

What is reported: Adverse drug events, near misses, and errors can all be submitted to MedMARx^{SM}.

Who reports: MedMARx^{SM} accepts reports from healthcare professionals,organizati ons, and patients. Since its introduction in 1998, over 900 healthcare facilities have contributed over 630,000 medication error reports (Personal communication with J.Silverstone National Patient Safety Foundation email listserve, editor. 4-20-2004). Currently, they receive approximately 20,000 reports each month (Personal communication with D. Cousins 5-19-2004) or about 20 per month for each of their 900 healthcare facilities.

How they report: Reports can be submitted directly through a web-based portal, submitted electronically, or by telephone, mail, and fax.

Analysis: Reports are entered into a database that can be searched and used to count, sort, and correlate events.

Response, dissemination and application of results: USP analyzes the errors in MedMARx^{SM} and provides an annual summary report. The database gathered by the USP is provided to the US Food and Drug Administration. A research partnership is underway with the Agency for Healthcare Research and Quality (AHRQ) to study the data for further improvement opportunities.

Further information: www.medmarx.com

References

1. National Patient Safety Agency *National Reporting and Learning System Dataset* (http://www.npsa.nhs.uk/dataset/dataset.asp. accessed on 9 November 2005)
2. Runciman WB. Lessons from the Australian Patient Safety Foundation: setting up a national patient safety surveillance system - is this the right model? *Quality and Safety in Health Care* 2002; 11:246-251.

6. CHARACTERISTICS OF SUCCESSFUL REPORTING SYSTEMS

Key messages

A successful reporting and learning system to enhance patient safety should have the following characteristics:

- **reporting is safe for the individuals who report;**
- **reporting leads to a constructive response;**
- **expertise and adequate financial resources are available to allow for meaningful analysis of reports;**
- **the reporting system must be capable of disseminating information on hazards and recommendations for changes.**

The ultimate measure of the success of a reporting system is whether the information it yields is used appropriately to improve patient safety. How that is done varies greatly according to the aims of its sponsor. While both learning and accountability systems seek to improve learning from mistakes, the fiduciary objectives of the latter impose an additional constraint: satisfying the public's interest in making sure that known mechanisms for injury prevention are being used (rules and safe practices) and that new hazards are promptly addressed when they are uncovered. This may require some departure from the following concepts, particularly regarding confidentiality and independence.

Successful patient safety reporting systems have the following characteristics:

- reporting must be safe for the individuals who report;
- reporting is only of value if it leads to a constructive response, and meaningful analysis;
- learning requires expertise and adequate financial resources. The agency that receives reports must be capable of disseminating information and making recommendations for changes, and informing the development of solutions.

Table One lists the characteristics that have been identified by various authors as essential to the success of any reporting systems concerned with patient safety (1-4). Many of these characteristics are derived from long experience both in health care (for example, the Institute for Safe Medication Practice) and in other industries, particularly aviation. These essential characteristics are discussed below.

Non-punitive. The most important characteristic for success of a patient safety reporting system is that it must be non-punitive. Neither reporters nor others involved in the incidents can be punished as a result of reporting. For public systems, this requirement is the most difficult to achieve, since the public often assumes an individual is to blame, and there can be strong pressure to punish the "culprit". While perhaps temporarily emotionally satisfying, this approach is doomed to fail. People will not report any errors they can hide. It is important for national systems to protect reporters from blame. The best way to do this is by keeping the reports confidential.

Confidential. The identities of the patient and reporter must never be revealed to any third party. At the institutional level, confidentiality also refers to not making public specific information that can be used in litigation. Although, historically, breach of confidentiality has not been a problem in public or private systems, concern about disclosure is a major factor inhibiting reporting for many voluntary reporting programmes (5).

Independent. The reporting system must be independent of any authority with the power to punish the reporter or organization with a stake in the outcome. Maintaining a "firewall" between the reporting agency and the disciplinary agency in a governmental system can be difficult, but it is essential if trust in reporting is to be maintained.

Expert analysis. Reports must be evaluated by experts who understand the clinical circumstances under which the incidents occur and who are trained to recognize underlying systems causes. While it seems obvious that collecting data and not analysing it is of little value, the most common failure of governmentally run reporting systems is to require reporting but not to provide the resources needed to analyse the reports. Huge numbers of reports are collected only to sit in boxes or on computers. Expertise is a major, and essential, resource requirement for any reporting system.

Credible. The combination of independence and the use of content experts for analysis is necessary if recommendations are to be accepted and acted upon.

Timely. Reports must be analysed without delay, and recommendations must be promptly disseminated to those who need to know. When serious hazards are identified, notification should take place rapidly. For example, the Institute for Safe Medication Practice issues prompt alerts through its regular publication when new hazards in drugs are discovered.

Systems-oriented. Recommendations should focus on changes in systems, processes or products, rather than being targeted at individual performance. This is a cardinal principle of safety that must be reinforced by the nature of recommendations that come from any reporting system. It is based on the concept that even an apparently egregious individual error results from systems defects, and will recur with another person at another time if those systems defects are not remedied.

Responsive. For recommendations to result in widespread systems changes, the organization receiving reports must be capable of making and disseminating effective recommendations, and target organizations must make a commitment to implement recommendations. A good example is the National Reporting and Learning System in England and Wales which allows the National Patient Safety Agency to develop new solutions that are disseminated throughout the system.

Table 1 Characteristics of Successful Reporting Systems (7)

Non-punitive	Reporters are free from fear of retaliation against themselves or punishment of others as a result of reporting.
Confidential	The identities of the patient, reporter, and institution are never revealed.
Independent	The reporting system is independent of any authority with power to punish the reporter or the organization.
Expert analysis	Reports are evaluated by experts who understand the clinical circumstances and are trained to recognize underlying systems causes.
Timely	Reports are analysed promptly and recommendations are rapidly disseminated to those who need to know, especially when serious hazards are identified.
Systems-oriented	Recommendations focus on changes in systems, processes, or products, rather than being targeted at individual performance.
Responsive	The agency that receives reports is capable of disseminating recommendations. Participating organizations commit to implementing recommendations whenever possible.

Several of these characteristics are included among the attributes that Runciman has proposed for national reporting and learning systems (6):

- an independent organization to coordinate patient safety surveillance;
- agreed frameworks for patient safety and surveillance systems;
- common, agreed standards and terminology;
- a single, clinically useful classification for things that go wrong in health care;
- a national repository for information covering all of health care from all available sources;
- mechanisms for setting priorities at local, national and international levels;
- a just system which caters for the rights of patients, society, and health-care practitioners and facilities;
- separate processes for accountability and "systems learnings";
- the right to anonymity and legal privilege for reporters;
- systems for rapid feedback and evidence of action;
- mechanisms for involving and informing all stakeholders.

References

1. Cohen M. *Discussion paper on adverse event and error reporting in healthcare*. Institute for Safe Medication Practices, 2000.
2. Cohen M. Why error reporting systems should be voluntary. *British Medical Journal*, 2000, 320:728-729.
3. Gaynes R et al. Feeding back surveillance data to prevent hospital-acquired infections. *Emerging infectious diseases*, 2001, 7:295-298.
4. Billings CE. The NASA aviation safety reporting system: lessons learned from voluntary incident reporting. 1998. *Enhancing Patient Safety and Reducing Errors in Health Care*. Annenberg Conference, Rancho Mirage, CA.
5. O'Leary D. Testimony before the House Committee on Ways and Means. *House Committee on Ways and Means*, 106th Congress, 2000.
6. Runciman WB. Lessons from the Australian Patient Safety Foundation: setting up a national patient safety surveillance system - is this the right model? *Quality and Safety in Health Care*, 2002, 11:246-251.
7. Leape, L.L. Reporting adverse event. *New England Journal of Medicine*, 2002, 347 (20): 1633-8

7. REQUIREMENTS FOR A NATIONAL ADVERSE EVENT REPORTING AND LEARNING SYSTEM

Key messages

Certain capacities are needed for all reporting systems, whether simple or complex. These are:

- **clear objectives;**
- **clarity about who should report;**
- **clarity about what gets reported;**
- **mechanisms for receiving reports and managing the data;**
- **expertise for analysis;**
- **capacity to respond to reports;**
- **a method for classifying and making sense of reported events;**
- **the capacity to disseminate findings;**
- **technical infrastructure and data security.**

Before deciding whether to establish a national adverse event reporting and learning system, states should carefully consider (i) what the objectives of the system are (ii) whether they can develop the capacity to respond to reports; and (iii) the resources that will be required. It is also important to decide the scope of what is to be reported and the data to be collected.

Appendix 2 provides a quick reference checklist of issues to consider in developing a reporting system.

Objectives

Ideally, the objectives of a reporting system emerge from the perceived needs of a patient safety programme. Reporting is a tool for obtaining safety information. A national reporting system, therefore, can usefully be regarded as a tool to advance public policy concerning patient safety. It should be an extension of a programme

of quality improvement and error prevention. To be effective, learnings from the analysis of reports must feed into a mechanism for developing and disseminating changes in policy and practice that improve safety.

If the commitment to improvement is weak, or if there is no infrastructure to carry out implementation of changes, such as an agency charged with improving safety, a reporting system will be of little value. Stating it simply, it is more important to develop a response system than a reporting system. If there is a commitment to improvement of patient safety and some infrastructure, but resources are scant, alternative methods of identifying problem areas may be preferable (See Section 4).

Capacity to respond

Certain capacities are needed for all reporting systems, whether simple or complex. These are a mechanism for receiving the reports and managing the data, some capacity to get additional information, a technical infrastructure, a method for classifying events, expertise for analysis, and the capacity to disseminate findings.

Mechanism for collecting reports and database management

The optimal process for receiving, inputting, analysing, and disseminating reports will vary according to the specific objectives and focus of an individual reporting system. For example, a structured input can help with analysis, whereas story telling captures rich detail and context. Personal contact from phone calls or reading written reports engages the receiver with each report, whereas direct electronic transmission facilitates ease of use and direct database entry. Keeping in mind the essential objectives of the reporting system and considering available types of technical support and overall resources will help developers determine which methods are most suitable.

When reports are received by mail, phone, or fax, front-line staff must have a process for the initial sorting and triage of reports. Staff may be called upon to judge whether a report can be entered directly into the database, or requires forwarding to an internal expert for further understanding.

One advantage of reports being received by individuals (as opposed to automatic data transfer) is that staff may recognize that reports of certain types of events have recurred and then query the database to confirm a trend. Reporting systems that receive reports in this fashion require resources to perform data entry and manage the integrity of the database for organizing identifying information about each report.

Capacity to investigate

Even with simple systems that focus primarily on recognizing hazards, resources should be available to support follow-up on reports, provide feedback to the reporter, and conduct at least a limited investigation when indicated. More sophisticated systems will have the capacity to find out more about the context in which the event occurred and conduct a systems analysis or other process for understanding the clinical issues and systems flaws underlying the event. This may also require further discussions with the reporter or an on-site investigation. Experts who perform this function must be sufficiently familiar both with the clinical context and with systems principles to identify potential themes and extract the essential learnings from the event.

Technical infrastructure

The technical infrastructure required to support reporting systems may be very simple or quite sophisticated. Reporting systems that use phone, mail or fax require as a minimum an efficient method for communicating with internal or external experts, tracking the database and generating reports. Web-based systems offer ease of use to reporters and also eliminate the need for staff to do data entry. The technical infrastructure to enable entered reports to be downloaded into a database is most readily achieved with standardized data fields.

Finally, all systems must provide technical support to users who may require assistance, whether with paper forms or on-line reporting functions.

Method for classifying events

There are three key factors in determining what classification system should be used:

- the purpose of the reporting system, and thus the type of information desired and how the classification scheme will facilitate the purpose for which data are being collected;
- the nature of the data available since underlying systems causes cannot be included in a classification scheme if those data are not reported;
- Resources, bearing in mind that elaborate classification systems that require substantial expertise can be expensive.

Reporting systems with predefined events may have a minimal classification scheme that sorts events into simple categories. Such a scheme yields a count and possibly trends but provides little opportunity for further analysis.

A more sophisticated classification scheme will include categories such as causal factors, severity, probability of recurrence, and type of recovery. An ideal system will also obtain, and classify, information about contributing factors (see Section 3 for a detailed discussion of classification systems).

Expert analysis

Whether analysing relatively simple reports to identify and understand new hazards, or searching for common underlying contributing factors in serious adverse events, all reporting systems need experts who understand the content and context of reported events. Experts determine whether reports are for identifying trends only, require follow-up with the reporter for further information, should trigger an on-site investigation, or herald an emerging hazard that warrants alerting the health-care organizations.

To provide meaningful recommendations, it is necessary to have experts who understand the practice concerns, clinical significance, systems issues, and potential preventive measures for the problems raised by the reports. Ultimately, it is human experts who must translate the knowledge gleaned from aggregated reports into meaningful recommendations for action to improve care.

Capacity to disseminate findings and recommendations

To fulfill their mission, reporting systems must communicate back to the community from which the reports are received. Reports, newsletters, communications, or alerts distill the meaning of aggregated reports into meaningful themes, identify proposed actions to prevent harm, inform policy-makers of issues, broadcast solutions and best practices, or alert pharmaceutical companies, device manufacturers, or health-care providers to new hazards. This requires staff to write reports and a mechanism to disseminate reports, such as large-scale mailings, press releases, newsletters, or electronic bulletins.

At a higher level, findings from the reporting system inform new safety initiatives that are generated and implemented by the appropriate authority. The National Reporting and Learning System of England and Wales, for example, feeds information and recommendations to the National Patient Safety Agency, which develops initiatives and campaigns to implement solutions.

While ultimately the effectiveness of a reporting system is measured by improvements in clinical outcomes, an intermediary measure is the number of recommendations generated from analyses of reports.

Security issues

Whereas reports within a health-care organization often have rich detail and usually contain information that makes it possible to identify the people concerned, it is important that such information is removed from external reports and de-identified to protect patients, providers and reporters. Confidentiality protection against unauthorized access must be implemented with a data security system. This may include a process for de-identifying reports upon their receipt or after a follow-up

investigation has occurred. A lock box or "firewall" may be indicated to protect against inadvertent data sharing with other parties or agencies. Data encryption methods are essential for web-based reporting systems. Data security systems also should have a mechanism for identifying breaches of security.

8. RECOMMENDATIONS TO WHO MEMBER STATES

1. Adverse event reporting and learning systems should have as their main objective the improvement of patient safety through the identification of errors and hazards which may warrant further analysis and investigation in order to identify underlying systems factors.

2. When designing adverse event reporting and learning systems, the responsible parties should clearly set out:

- the objectives of the system
- who should report
- what gets reported
- mechanisms for receiving reports and managing the data
- sources of expertise for analysis
- the response to reports
- methods for classifying and making sense of reported events
- ways to disseminate findings
- technical infrastructure and data security.

3. Health-care workers and organizations should be encouraged to report a wide range of safety information and events.

4. Health-care workers who report adverse events, near misses and other safety concerns should not be punished as a result of reporting.

5. Reporting systems should be independent of any authority with power to punish the reporter.

6. The identities of reporters should not normally be disclosed to third parties.

7. Reported events should be analysed in a timely way.

8. Reported events should be analysed by experts who understand the clinical circumstances and care processes involved and who are trained to recognize underlying systems causes.

9. The entity that receives reports should be capable of making and disseminating recommendations. Participating organizations should agree to implement recommendations wherever possible.

10. Recommendations for preventative strategies should be rapidly disseminated, especially when serious hazards are identified.

APPENDIX 1
EXCERPT FROM INSTITUTE OF MEDICINE REPORT TO ERR IS HUMAN

Why Do Errors Happen?

The common initial reaction when an error occurs is to find and blame someone. However, even apparently single events or errors are due most often to the convergence of multiple contributing factors. Blaming an individual does not change these factors and the same error is likely to recur. Preventing errors and improving safety for patients require a systems approach in order to modify the conditions that contribute to errors. People working in health care are among the most educated and dedicated workforce in any industry. The problem is not bad people; the problem is that the system needs to be made safer.

This chapter covers two key areas. First, definitions of several key terms are offered. This is important because there is no agreed-upon terminology for talking about this issue.[1] Second, the emphasis in this chapter (and in this report generally) is about how to make systems safer; its primary focus is not on "getting rid of bad apples," or individuals with patterns of poor per-formance. The underlying assumption is that lasting and broad-based safety improvements in an industry can be brought about through a systems approach.

Finally, it should be noted that although the examples may draw more from inpatient or institutional settings, errors occur in all settings. The concepts presented in this chapter are just as applicable to ambulatory care, home care, community pharmacies, or any other setting in which health care is delivered.

This chapter uses a case study to illustrate a series of definitions and concepts in patient safety. After presentation of the case study, the chapter will define what comprises a system, how accidents occur, how human error contributes to accidents and how these elements fit into a broader concept of safety. The case study

will be referenced to illustrate several of the concepts. The next section will examine whether certain types of systems are more prone to accidents than others. Finally, after a short discussion of the study of human factors, the chapter summarizes what health care can learn from other industries about safety.

WHY DO ACCIDENTS HAPPEN?

Major accidents, such as Three Mile Island or the Challenger accident, grab people's attention and make the front page of newspapers. Because they usually affect only one individual at a time, accidents in health care delivery are less visible and dramatic than those in other industries. Except for celebrated cases, such as Betsy Lehman (the Boston Globe reporter who died from an overdose during chemotherapy) or Willie King (who had the wrong leg amputated),[2] they are rarely noticed. However, accidents are a form of information about a system.[3] They represent places in which the system failed and the breakdown resulted in harm.

The ideas in this section rely heavily upon the work of Charles Perrow and James Reason, among others. Charles Perrow's analysis of the accidentat Three Mile Island identified how systems can cause or prevent accidents.[4] James Reason extended the thinking by analyzing multiple accidents to examine the role of systems and the human contribution to accidents.[5] *"A system is a set of interdependent elements interacting to achieve a common aim. The elements may be both human and non-human (equipment, technologies, etc.)."*

Systems can be very large and far-reaching, or they can be more localized. In health care, a system can be an integrated delivery system, a centrally owned multihospital system, or a virtual system comprised of many different partners over a wide geographic area. However, an operating room or an obstetrical unit is also a type of system. Furthermore, any element in a system probably belongs to multiple systems. For example, one operating

An Illustrative Case in Patient Safety

Infusion devices are mechanical devices that administer intravenous solutions containing drugs to patients. A patient was undergoing a cardiac procedure. This patient had a tendency toward being hypertensive and this was known to the staff.

As part of the routine set-up for surgery, a nurse assembled three different infusion devices. The nurse was a new member of the team in the operating room; she had just started working at the hospital a few weeks before. The other members of the team had been working together for at least six months. The nurse was being very careful when setting up the devices because one of them was a slightly different model than she had used before.

Each infusion device administered a different medication that would be used during surgery. For each medication, the infusion device had to be programmed according to how much medication would flow into the patient (calculated as "cc's/hour"). The medications had different concentrations and each required calculation of the correct dose for that specific patient. The correct cc's/hour were programmed into the infusion devices.

The anesthesiologist, who monitors and uses the infusion devices during surgery, usually arrived for surgery while the nurse was completing her set-up of the infusion devices and was able to check them over. This particular morning, the anesthesiologist was running behind from a previous surgery. When he arrived in the operating room, the rest of the team was ready to start. The anesthesiologist quickly glanced at the set-up and accepted the report as given to him by the nurse.

One of the infusion devices was started at the beginning of surgery. About halfway through the surgery, the patient's blood pressure began to rise. The anesthesiologist

room is part of a surgical department, which is part of a hospital, which is part of a larger health care delivery system. The variable size, scope, and membership of systems make them difficult to analyze and understand.

In the case study, one of the systems used during surgery is the automated, medication adminstration system, which includes the equipment, the people, their interactions with each other and with the equipment, the procedures in place, and the physical design of the surgical suite in which the equipment and people function.

When large systems fail, it is due to multiple faults that occur together in an unanticipated interaction,[6] creating a chain of events in which the faults grow and evolve.[7] Their accumulation results in an accident. "An accident is an event that involves damage to a defined system that disrupts the ongoing or future output of that system." [8]

The *Challenger* failed because of a combination of brittle O-ring seals, unexpected cold weather, reliance on the seals in the design of the boosters, and change in the roles of the contractor and NASA. Individually, no one factor caused the event, but when they came together, disaster struck. Perrow uses a DEPOSE (Design, Equipment Procedures, Operators, Supplies and materials, and Environment) framework to identify the potential sources of failures. In evaluating the environment, some researchers explicitly include organizational design and characteristics.[9]

tried to counteract this by starting one of the other infusion devices that had been set up earlier. He checked the drip chamber in the intravenous (IV) tubing and did not see any drips. He checked the IV tubing and found a closed clamp, which he opened. At this point, the second device signaled an occlusion, or blockage, in the tubing by sounding an alarm and flashing an error message. The anesthesiologist found a closed clamp in this tubing as well, opened it, pressed the re-start button and the device resumed pumping without further difficulty. He returned to the first device that he had started and found that there had been a free flow of fluid and medication to the patient, resulting in an overdose. The team responded appropriately and the patient recovered without further incident.

The case was reviewed two weeks later at the hospital's "morbidity and mortality" committee meeting, where the hospital staff reviews cases that encountered a problem to identify what happened and how to avoid a recurrence.

The IV tubing had been removed from the device and discarded. The bioengineering service had checked the pump and found it to be functioning accurately. It was not possible to determine whether the tubing had been inserted incorrectly into the device, whether the infusion rate had been set incorrectly or changed while the device was in use, or whether the device had malfunctioned unexpectedly. The anesthesiologist was convinced that the tubing had been inserted incorrectly, so that when the clamp was open the fluid was able to flow freely rather than being controlled by the infusion device. The nurse felt the anesthesiologist had failed to check the infusion system adequately before turning on the devices. Neither knew whether it was possible for an infusion device to have a safety mechansim built into it that would prevent free flows from happening.

In the case study, the accident was a breakdown in the delivery of IV medicationsduring surgery.

The complex coincidences that cause systems to fail could rarely have been foreseen by the people involved. As a result, they are reviewed only in hindsight; however, knowing the outcome of an event influences how we assess past events.[10] Hindsight bias means that things that were not seen or understood at the time of the accident seem obvious in retrospect. Hindsight bias also misleads a reviewer into simplifying the causes of an accident,

highlighting a single element as the cause and overlooking multiple contributing factors. Given that the information about an accident is spread over many participants, none of whom may have complete information,[11] hindsight bias makes it easy to arrive at a simple solution or to blame an individual, but difficult to determine what really went wrong.

Although many features of systems and accidents in other industries are also found in health care, there are important differences. In most other industries, when an accident occurs the worker and the company are directly affected. There is a saying that the pilot is always the first at the scene of an airline accident. In health care, the damage happens to a third party; the patient is harmed; the health professional or the organization, only rarely. Furthermore, harm occurs to only one patient at a time; not whole groups of patients, making the accident less visible.*

In any industry, one of the greatest contributors to accidents is human error. Perrow has estimated that, on average, 60–80 percent of accidents involve human error. There is reason to believe that this is equally true in health. An analysis of anesthesia found that human error was involved in 82 percent of preventable incidents; the remainder involved mainly equipment failure.[12] Even when equipment failure occurs, it can be exacerbated by human error.[13] However, saying that an accident is due to human error is not the same as assigning blame. Humans commit errors for a variety of expected and unexpected reasons, which are discussed in more detail in the next two sections.

Understanding Errors

The work of Reason provides a good understanding of errors. He defines an error as the failure of a planned sequence of mental or physical activities to achieve its intended outcome when these failures cannot be attributed to chance.[14] It is important to note the inclusion of "intention." According to Reason, error is not meaningful without the consideration of intention. That is, it has no meaning when applied to unintentional behaviors because errors depend on two kinds of failure, either actions do not go as intended or the intended action is not the correct one. In the first case, the desired outcome may or may not be achieved; in the second case, the desired outcome cannot be achieved.

Reason differentiates between slips or lapses and mistakes. A slip or lapse occurs when the action conducted is not what was intended. It is an error of execution. The difference between a slip and a lapse is that a slip is observable and a lapse is not.

---

* *Public health has made an effort to eliminate the term, "accident," replacing it with unintentional injuries, consistent with the nomenclature of the International Classification of Diseases. However, this report is not focused specifically on injury since an accident may or may not result in injury. See Institute of Medicine, Reducing the Burden of Injury, eds. Richard J. Bonnie, Carolyn Fulco and Catharyn Liverman. Washington, D.C., National Academy Press, 1999).*

For example, turning the wrong knob on a piece of equipment would be a slip; not being able to recall something from memory is a lapse.

In a mistake, the action proceeds as planned but fails to achieve its intended outcome because the planned action was wrong. The situation might have been assessed incorrectly, and/or there could have been a lack of knowl- edge of the situation. In a mistake, the original intention is inadequate; a failure of planning is involved.

In medicine, slips, lapses, and mistakes are all serious and can potentially harm patients. For example, in medicine, a slip might be involved if the physician chooses an appropriate medication, writes 10 mg when the intention was to write 1 mg. The original intention is correct (the correct medication was chosen given the patient's condition), but the action did not proceed as planned. On the other hand, a mistake in medicine might involve selecting the wrong drug because the diagnosis is wrong. In this case, the situation was misassessed and the action planned is wrong. If the terms "slip" and "mistake" are used, it is important not to equate slip with "minor." Patients can die from slips as well as mistakes. For this report, *error is defined as the failure of a planned action to be completed as intended (e.g., error of execution) or the use of a wrong plan to achieve an aim (e.g., error of planning)*. From the patient's perspective, not only should a medical intervention proceed properly and safely, it should be the correct intervention for the particular condition. This report addresses primarily the first concern, errors of execution, since they have their own epidemiology, causes, and remedies that are different from errors in planning. Subsequent reports from the Quality of Health Care in America project will consider the full range of quality-related issues, sometimes classified as overuse, underuse and misuse.[15]

Latent and Active Errors

In considering how humans contribute to error, it is important to distinguish between active and latent errors.[16] *Active errors occur at the level of the frontline operator, and their effects are felt almost immediately. This is sometimes called the sharp end.*[17] *Latent errors tend to be removed from the direct control of the operator and include things such as poor design, incorrect installation, faulty maintenance, bad management decisions, and poorly structured organizations*. These are called the blunt end. The active error is that the pilot crashed the plane. The latent error is that a previously undiscovered design malfunction caused the plane to roll unexpectedly in a way the pilot could not control and the plane crashed

In the case study, the active error was the free flow of the medication from the infusion device.