Latent errors pose the greatest threat to safety in a complex system because they are often unrecognized and have the capacity to result in multiple types of active errors. Analysis of the Challenger accident traced contributing events back nine years. In the Three Mile Island accident, latent errors were traced back two years.[18] Latent errors can be difficult for the people working in the system to notice since the errors may be hidden in the design of routine processes in computer programs or in the structure or management of the organization. People also become accustomed to design defects and learn to work around them, so they are often not recognized.

In her book about the *Challenger* explosion, Vaughan describes the "normalization of deviance" in which small changes in behavior became the norm and expanded the boundaries so that additional deviations became acceptable.[19] When deviant events become acceptable, the potential for errors is created because signals are overlooked or misinterpreted and accumulate without being noticed.

Current responses to errors tend to focus on the active errors by punishing individuals (e.g., firing or suing them), retraining or other responses aimed at preventing recurrence of the active error. Although a punitive response may be appropriate in some cases (e.g., deliberate malfeasance), it is not an effective way to prevent recurrence. Because large system failures represent latent failures coming together in unexpected ways, they appear to be unique in retrospect. Since the same mix of factors is unlikely to occur again, efforts to prevent specific active errors are not likely to make the system any safer.[20]

In our case study, a number of latent failures were present:

• Multiple infusion devices were used in parallel during this cardiac surgery. Three devices were set up, each requiring many steps. each step in the assembly presents a possibility for failure that could disrupt the entire system.

• Each of the three different medications had to be programmed into the infusion device with the correct dose for that patient.

• Possible scheduling problems in the operating suites may have contributed to the anesthesiologist having insufficient time to check the devices before surgery.

• A new nurse on the team may have interrupted the "normal" flow between the team members, especially communication between the anesthesiologist and the nurse setting up the devices. There was no standardized list of checks between the nurse and anesthesiologist before starting the procedure.

• Training of new team members may be insufficient since the nurse found herself assembling a device that was a slightly different model. As a new employee, she may have been hesitant to ask for help or may not have known who to ask.

Focusing on active errors lets the latent failures remain in the system, and their accumulation actually makes the system more prone to future failure. [21] Discovering and fixing latent failures, and decreasing their duration, are likely to have a greater

effect on building safer systems than efforts to minimize active errors at the point at which they occur.

> *In the case study, a typical response would have been to retrain the nurse on how to assemble the equipment properly. However, this would have had no effect on weaknesses in equipment design, team management and communications, scheduling problems, or orienting new staff. Thus, free flow errors would likely recur.*

Understanding Safety

Most of this chapter thus far has drawn on Perrow's normal accident theory, which believes that accident are inevitable in certain systems. Al- though they may be rare, accidents are "normal" in complex, high technology industries. In contrast to studying the causes of accident and errors, other researchers have focused on the characteristics that make certain industries, such as military aircraft carriers or chemical processing, highly reliable.[22] High reliability theory believes that accidents can be prevented through good organizational design and management.[23] Characteristics of highly reliable industries include an organizational commitment to safety, high levels of redundancy in personnel and safety measures, and a strong organizational culture for continuous learning and willingness to change.[24] Correct performance and error can be viewed as "two sides of the same coin."[25] Although accidents may occur, systems can be designed to be safer so that accidents are very rare.

The National Patient Safety Foundation has defined patient safety as the avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the processes of health care.[26] Safety does not reside in a person, device or department, but emerges from the interactions of components of a system. Others have specifically examined pharmaceutical safety and defined it to include maximizing therapeutic benefit, reducing risk, and eliminating harm.[27] That is, benefit relates to risk. Other experts have also defined safety as a relative concept. Brewer and Colditz suggest that the acceptability of an adverse event depends on the seriousness of the underlying illness and the availability of alternative treatments.[28] The committee's focus, however, was not on the patient's response to a treatment, but rather on the ability of a system to deliver care safely. From this perspective, the committee believes that there is a level of safety that can and should be ensured. Safety is relative only in that it continues to evolve over time and, when risks do become known, they become part of the safety requirements.

Safety is more than just the absence of errors. Safety has multiple dimensions, including the following:
- an outlook that recognizes that health care is complex and risky and that solutions are found in the broader systems context;

- a set of processes that identify, evaluate, and minimize hazards and are continuously improving, and

- an outcome that is manifested by fewer medical errors and minimized risk or hazard.[29]

For this report, safety is defined as freedom from accidental injury. This simple definition recognizes that from the patient's perspective, the primary safety goal is to prevent accidental injuries. If an environment is safe, the risk of accidents is lower. Making environments safer means looking at processes of care to reduce defects in the process or departures from the way things should have been done. Ensuring patient safety, therefore, involves the establishment of operational systems and processes that increase the reliability of patient care.

ARE SOME TYPES OF SYSTEMS MORE PRONE TO ACCIDENTS?

Accidents are more likely to happen in certain types of systems. When they do occur, they represent failures in the way systems are designed. The primary objective of systems design ought to be to make it difficult for accidents and errors to occur and to minimize damage if they do occur.[30]

Perrow characterizes systems according to two important dimensions: complexity and tight or loose coupling.[31] Systems that are more complex and tightly coupled are more prone to accidents and have to be made more reliable.[32] In Reason's words, complex and tightly coupled systems can "spring nasty surprises."[33]

In complex systems, one component of the system can interact with multiple other components, sometimes in unexpected or invisible ways. Although all systems have many parts that interact, the problem arises when one part serves multiple functions because if this part fails, all of the dependent functions fail as well. Complex systems are characterized by specialization and interdependency. Complex systems also tend to have multiple feedback loops, and to receive information indirectly, and because of specialization, there is little chance of substituting or reassigning personnel or other resources.

In contrast to complex systems, linear systems contain interactions that are expected in the usual and familiar production sequence. One component of the system interacts with the component immediately preceding it in the production process and the component following it. Linear systems tend to have segregated subsystems, few feedback loops, and easy substitutions (less specialization).

An example of complexity is the concern with year 2000 (Y2K) computer problems. A failure in one part of the system can unexpectedly interrupt other parts, and all of the interrelated processes that can be affected are not yet visible. Complexity is also the reason that changes in long-standing production processes must be made cautiously.[34] When tasks are distributed across a team, for example, many interac-

tions that are critical to the process may not be noticed until they are changed or removed.

Coupling is a mechanical term meaning that there is no slack or buffer between two items. Large systems that are tightly coupled have more timedependent processes and sequences that are more fixed (e.g., y depends on x having been done). There is often only one way to reach a goal. Compared to tightly coupled systems, loosely coupled systems can tolerate processing delays, can reorder the sequence of production, and can employ alternative methods or resources.

All systems have linear interactions; however, some systems additionally experience greater complexity. Complex interactions contribute to accidents because they can confuse operators. Tight coupling contributes to accidents because things unravel too quickly and prevent errors from being intercepted or prevent speedy recovery from an event.[35] Because of complexity and coupling, small failures can grow into large accidents.

> *In the case study, the medication adminstration system was both complex and tightly coupled. The complexity arises from three devices functioning simultaneously, in close proximity, and two having problems at the same time. The tight coupling arises from the steps involved in making the system work properly, from the steps required to assemble three devices, to the calculation of correct medication dosage levels, to the operation of multiple devices during surgery, to the responses when alarms start going off.*

Although there are not firm assignments, Perrow considered nuclear power plants, nuclear weapons handling, and aircraft to be complex, tightly coupled systems.[36] Multiple processes are happening simultaneously, and failure in one area can interrupt another. Dams and rail transportation are considered tightly coupled because the steps in production are closely linked, but linear because there are few unexpected interactions. Universities are considered complex, but loosely coupled, since the impact of a decision in one area can likely be limited to that area.

Perrow did not classify health care as a system, but others have suggested that health care is complex and tightly coupled.[37] The activities in the typical emergency room, surgical suite, or intensive care unit exemplify complex and tightly coupled systems. Therefore, the delivery of health care services may be classified as an industry prone to accidents.[38]

Complex, tightly coupled systems have to be made more reliable.[39] One of the advantages of having systems is that it is possible to build in more defenses against failure. Systems that are more complex, tightly coupled, and are more prone to accidents can reduce the likelihood of accidents by simplifying and standardizing processes, building in redundancy, developing backup systems, and so forth.

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Another aspect of making systems more reliable has to do with organizational design and team performance. Since these are part of activities within organizations, they are discussed in Chapter 8.

Conditions That Create Errors

Factors can intervene between the design of a system and the production process that creates conditions in which errors are more likely to happen. James Reason refers to these factors as psychological precursors or preconditions.[40] Although good managerial decisions are required for safe and efficient production, they are not sufficient. There is also a need to have the right equipment, well-maintained and reliable; a skilled and knowledgeable workforce; reasonable work schedules, well-designed jobs; clear guidance on desired and undesired performance, et cetera. Factors such as these are the precursors or preconditions for safe production processes.

Any given precondition can contribute to a large number of unsafe acts. For example, training deficiencies can show up as high workload, undue time pressure, inappropriate perception of hazards, or motivational difficulties.[41] Preconditions are latent failures embedded in the system. Designing safe systems means taking into account people's psychological limits and either seeking ways to eliminate the preconditions or intervening to minimize their consequences. Job design, equipment selection and use, operational procedures, work schedules, and so forth, are all factors in the production process that can be designed for safety.

One specific type of precondition that receives a lot of attention is technology. The occurrence of human error creates the perception that humans are unreliable and inefficient. One response to this has been to find the unreliable person who committed the error and focus on preventing him or her from doing it again. Another response has been to increase the use of technology to automate processes so as to remove opportunities for humans to make errors. The growth of technology over the past several decades has contributed to system complexity so this particular issue is highlighted here.

Technology changes the tasks that people do by shifting the workload and eliminating human decision making.[42] Where a worker previously may have overseen an entire production process, he or she may intervene now only in the last few steps if the previous steps are automated. For example, flying an aircraft has become more automated, which has helped reduce workload during nonpeak periods. During peak times, such as take-off and landing, there may be more processes to monitor and information to interpret.

Furthermore, the operator must still do things that cannot be automated. This usually involves having to monitor automated systems for rare, abnormal events[43] because machines cannot deal with infrequent events in a constantly changing environment.[44] Fortunately, automated systems rarely fail. Unfortunately, this means that

operators do not practice basic skills, so workers lose skills in exactly the activities they need in order to take over when something goes wrong.

Automation makes systems more "opaque" to people who manage, maintain, and operate them.[45] Processes that are automated are less visible because machines intervene between the person and the task. For example, automation means that people have less hands-on contact with processes and are elevated to more supervisory and planning tasks. Direct information is filtered through a machine (e.g., a computer), and operators run the risk of having too much information to interpret or of not getting the right information.

> *In the case study, the infusion device administered the medication and the professional monitored the process, intervening when problems arose. The medication administration process was "opaque" in that the device provided no feedback to the user when the medication flowed freely and minimal feedback when the medication flow was blocked.*

One of the advantages of technology is that it can enhance human performance to the extent that the human plus technology is more powerful than either is alone.[46] Good machines can question the actions of operators, offer advice, and examine a range of alternative possibilities that humans cannot possibly remember. In medicine, automated order entry systems or decision support systems have this aim. However, technology can also create new demands on operators. For example, a new piece of equipment may provide more precise measurements, but also demand better precision from the operator for the equipment to work properly.[47] Devices that have not been standardized, or that work and look differently, increase the likelihood of operator errors. Equipment may not be designed using human factors principles to account for the human–machine interface.[48]

> *In the case study, safer systems could have been designed by taking into consideration characteristics of how people use machines and interact with each other in teams. For example:*
> *• Redesign the devices to default to a safe mode*
> *• Reduce the difficulties of using multiple devices simultaneously*
> *• Minimize the variety of equipment models purchased*
> *• Implement clear procedures for checking equipment, supplies, etc., prior to beginning surgery*
> *• Orient and train new staff with the team(s) with which they will work*
> *• Provide a supportive environment for identifying and communicating about errors for organizational learning and change to prevent errors.*

Technology also has to be recognized as a "member" of the work team. When technology shifts workloads, it also shifts the interactions between team members.

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Where processes may have been monitored by several people, technology can permit the task to be accomplished by fewer people. This affects the distributed nature of the job in which tasks are shared among several people and may influence the ability to discover and recover from errors.[49]

In this context, technology does not involve just computers and information technology. It includes "techniques, drugs, equipment and procedures used by health care professionals in delivering medical care to individuals and the systems within which such care is delivered."[50] Additionally, the use of the term technology is not restricted to the technology employed by health care professionals. It can also include people at home of differentages, visual abilities, languages, and so forth, who must use different kinds of medical equipment and devices. As more care shifts to ambulatory and home settings, the use of medical technology by non-health professionals can be expected to take on increasing importance.

RESEARCH ON HUMAN FACTORS

Research in the area of human factors is just beginning to be applied to health care. It borrows from the disciplines of industrial engineering and psychology. *Human factors is defined as the study of the interrelationships between humans, the tools they use, and the environment in which they live and work.*[51]

In the context of this report, a human factors approach is used to under- stand where and why systems or processes break down. This approach examines the process of error, looking at the causes, circumstances, conditions, associated procedures and devices and other factors connected with the event. Studying human performance can result in the creation of safer systems and the reduction of conditions that lead to errors. However, not all errors are related to human factors. Although equipment and materials should take into account the design of the way people use them, human factors may not resolve instances of equipment breakdown or material failure.

Much of the work in human factors is on improving the human–system interface by designing better systems and processes.[52] This might include, for example, simplifying and standardizing procedures, building in redundancy to provide backup and opportunities for recovery, improving communications and coordination within teams, or redesigning equipment to improve the human–machine interface.

Two approaches have typically been used in human factors analysis. The first is critical incident analysis. Critical incident analysis examines a significant or pivotal occurrence to understand where the system broke down, why the incident occurred, and the circumstances surrounding the incident.[53] Analyzing critical incidents, whether or not the event actually leads to a bad outcome, provides an

understanding of the conditions that produced an actual error or the risk of error and contributing factors.

> *In the case study, researchers with expertise in human factors could have helped the team investigate the problem. They could examine how the device performed under different circumstances (e.g., what the alarms and displays did when the medication flow changed), varying the setup and operation of the infusion device to observe how it performed under normal and abnormal conditions. They could observe how the staff used the particular infusion device during surgery and how they interacted with the use of multiple infusion devices.*

A critical incident analysis in anesthesia found that human error was involved in 82 percent of preventable incidents. The study identified the most frequent categories of error and the riskiest steps in the process of administering anesthesia. Recommended corrective actions included such things as labeling and packaging strategies to highlight differences among anesthesiologists in the way they prepared their workspace, training issues for residents, work–rest cycles, how relief and replacement processes could be improved, and equipment improvements (e.g., standardizing equipment in terms of the shape of knobs and the direction in which they turn).

Another analytic approach is referred to as "naturalistic decision making."[54] This approach examines the way people make decisions in their natural work settings. It considers all of the factors that are typically controlled for in a laboratory-type evaluation, such as time pressure, noise and other distractions, insufficient information, and competing goals. In this method, the researcher goes out with workers in various fields, such as firefighters or nurses, observes them in practice, and then walks them through to reconstruct various incidents. The analysis uncovers the factors weighed and the processes used in making decisions when faced with ambiguous information under time pressure.

In terms of applying human factors research, David Woods of Ohio State University describes a process of reporting, investigation, innovation, and dissemination (David Woods, personal communication, December 17, 1998). Reporting or other means of identifying errors tells people where errors are occurring and where improvements can be made. The investigation stage uses human factors and other analyses to determine the contributing factors and circumstances that created the conditions in which errors could occur. The design of safer systems provides opportunities for innovation and working with early adopters to test out new approaches. Finally, dissemination of innovation throughout the industry shifts the baseline for performance. The experience of the early adopters redefines what is possible and provides models for implementation. Aviation has long analyzed the role of human factors in performance. The Ames Research Center (part of the National Aeronautics and Space Administration) has examined areas related to information technology, automation,

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and the use of simulators for training in basic and crisis skills, for example. Other recent projects include detecting and correcting errors in flight; interruptions, distractions and lapses of attention in the cockpit; and designing information displays to assist pilots in maintaining awareness of their situation during flight.[55]

SUMMARY

The following key points can be summarized from this chapter.

1. Some systems are more prone to accidents than others because of the way the components are tied together. Health care services is a complex and technological industry prone to accidents.

2. Much can be done to make systems more reliable and safe. When large systems fail, it is due to multiple faults that occur together.

3. One of the greatest contributors to accidents in any industry including health care, is human error. However, saying that an accident is due to human error is not the same as assigning blame because most human errors are induced by system failures. Humans commit errors for a variety of known and complicated reasons.

4. Latent errors or system failures pose the greatest threat to safety in a complex system because they lead to operator errors. They are failures built into the system and present long before the active error. Latent errors are difficult for the people working in the system to see since they may be hidden in computers or layers of management and people become accustomed to working around the problem.

5. Current responses to errors tend to focus on the active errors. Although this may sometimes be appropriate, in many cases it is not an effective way to make systems safer. If latent failures remain unaddressed, their accumulation actually makes the system more prone to future failure. Discovering and fixing latent failures and decreasing their duration are likely to have a greater effect on building safer systems than efforts to minimize active errors at the point at which they occur.

6. The application of human factors in other industries has successfully reduced errors. Health care has to look at medical error not as a special case of medicine, but as a special case of error, and to apply the theory and approaches already used in other fields to reduce errors and improve reliability.[56]

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APPENDIX 2
CHECKLIST FOR DEVELOPING
A REPORTING SYSTEM

1. Clarify objectives

- Learning
- Accountability
- Both

2. What types of learning are the priorities?

- Alerts regarding significant new hazards
- Lessons learned by hospitals
- Analysis of trends
- Analysis of systems failures
- Recommendations for best practices

3. Voluntary or mandatory?

- Voluntary
- Mandatory

4. Confidential or public disclosure?

- Confidential
- Public disclosure of individual reports
- Public disclosure of analysis or trends

5. What is the process for the reporting system?

- What is reported?
- Who can report?
- How does one report?

6. Is confidential information held secure?

- Patient confidentiality
- Reporter confidentiality
- Organization confidentiality

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7. What is the data infrastructure?

- Human receiver recognizing hazard reports
- Simple spreadsheet
- Relational database

8. What is the approach to classification?

- By event type
- By risk
- By causation

9. What is the approach to analysis?

- Hazard identification
- Summaries and descriptions
- Trend and cluster analysis
- Correlations
- Risk analysis
- Causal analysis
- Systems analysis

10. How will responses be generated and disseminated?

- Acknowledgement to reporter
- Alerts generated to organizations
- Trends, themes, or best practices in periodic newsletters

11. Are there sufficient resources?

- Mechanism for collecting reports
- Database management
- Capacity to investigate
- Technical infrastructure
- Method for classifying events
- Expert analysis
- Capacity to disseminate findings and recommendations

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