Section V Safety

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A medical device is just one component of a minisystem that delivers a clinical benefit to the patient. As device-related minisystems increase in number, the hazards associated with their use become more varied, and the clinical environment, more complex. Devices can become nonfunctional because of electromagnetic interference (EMI), or they can become fire-ignition sources for patients who are undergoing treatment in oxygen-enriched environments. Such medical device-related events require a clinical engineering investigation of the event and recommendations to prevent similar, future events. Because corrective recommendations frequently involve hospital professional staff and processes, they must be integrated into the total hospital safety program. The authors of the chapters in this section on safety address many of these issues and make recommendations for assuring a safe clinical environment.

Methodologies for making the clinical environment safer are described in the first four chapters. Patail (Patient Safety and the Clinical Engineer) gives the perspective of an experienced clinical engineer working within the National Center for Patient Safety (NCPS), showing that the clinical engineer is ideally suited a leadership role in promoting patient safety. Such systematic techniques as root cause analysis and failure mode and effects analysis, and tools such as process-flow diagrams, hazard-scoring matrices, and decision trees have enabled the NCPS to make measurable positive strides in a short time. Epstein and Harding (Risk Management), with their extensive experience in advising health care organizations on risk-management issues, present a comprehensive overview of this subject and present guidelines for adoption of effective techniques and programs. Vegoda and Abramson (Patient Safety Best Practices Model) bring their formidable expertise in information technology (IT) to bear on the patient safety issue as they outline a model system for patient safety best practices. Baretich (Hospital Safety Programs) provides an expanded view of hospital safety going beyond safety as applied only to medical devices. He describes the safety structure and requirements of a complete hospital safety program as required by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). The program encompasses the safety of staff, patients, and visitors from the various hazards in a health care environment. He emphasizes that, in order to be most effective, the safety-related aspects of clinical engineering practice must be integrated into this hospital-wide safety program.

Shepherd (Systems Approach to Medical Device Safety) identifies the five fundamental components of a medical device-related minisystem, a system that delivers at least one clinical benefit. In addition, he discusses the way these components can fail in such a manner as to prevent the clinical benefit from being delivered and may result, instead, in an injury or death. By means of this generic model, one can understand ways in which a patient might experience a particular hazard as well, and one can employ methodology to trace the fundamental causes of an injury back to the latent causes that were present in the minisystem. As the number and complexity of medical devices have increased, so have reports of interactions between various minisystems. Miodownik (Interactions between Medical Devices) explores some of the interactions among device-related minisystems when they are connected and operating simultaneously on or around a patient. Through case studies, he shows that the patient-selection criteria might not always identify those within a population who might be harmed by a diagnostic or therapeutic intervention. Device–device and device–patient interactions might directly result in an injury or a malperforming minisystem. His engineering analysis gives warning that clinical engineers must remain vigilant in order to detect unexpected minisystems interactions.

Cheng (Single-Use Injection Devices) details the safety aspects of needles and syringes, with an emphasis on their use and safety in developing countries. Recognizing that reuse of single-use injection devices is a leading cause of infection, Cheng recommends alternatives to this practice, such as auto-disable syringes, safety boxes, and the disposal of used sharps. He applies life cycle management concepts to injection devices to ensure safety in health-program planning and delivery.

Tan and Hinberg (Electromagnetic Interference with Medical Devices) provide a review of international EMI standards and an overview of EMI issues, including the effects of wireless telecommunication, wireless LAN, metal detectors, and article-surveillance equipment on medical devices is also included. Their chapter, developed from both the regulatory and the practical viewpoint, includes suggestions on managing the risks of EMI. Health care facilities are experiencing an increasingly hostile EMI environment. To ensure that a clinical environment is safe from EMI-provoked disturbances, clinical engineers must proactively manage the environment through detection, correction, and prevention of EMI. Paperman, David, and Hibbetts (Electromagnetic Interference in the Hospital) describe components of such a management program and present case studies from their own experiences to illustrate its value.

The role of the clinical engineer as medical device-safety officer or as independent forensic engineer requires specific skills in accident investigations. Dyro (Accident Investigation) provides a comprehensive overview of device-related accident investigations and describes the knowledge, skills, and investigative techniques that are necessary for a competent investigator. He emphasizes that the intended result of any investigation is to identify the latent (root) causes of an event and the minisystem modifications that are necessary to prevent similar events in the future. Accident investigators estimate that as many as 70% of all device-related, adverse events have some contribution from the human operator, often from the limitations of human abilities but frequently from inadequate human-factors-design considerations of the device manufacturer. Dyro discusses the fundamentals of human error and human factors design and their contributions to accidents. Clinical engineers, who should direct accident and incident investigations, must become familiar with the fundamentals of human error and human factors designs as they affect minisystem processes.

Finally, Ridgway (Electrical Safety in Perspective) describes the history of "microshock," a device-related hazard that appears to have been more imagined than real but nevertheless resulted in many unnecessary and expensive corrective actions in hospitals. In the early 1960s, small electrical currents that caused microshock were alleged to have killed thousands of hospital patients annually. Over the following twenty years, the concern for microshock emerged through both misinformation and a lack of information. Ridgway's insightful retrospective on microshock and the ensuing preoccupation with electrical safety describes the effort and resources that were expended and largely wasted in addressing this relatively minor hazard.

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Patient Safety and the Clinical Engineer

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The clinical engineer (CE) is ideally suited for a leadership role in promoting patient safety. The safety of patients has gained widespread attention with reports of unusually high incidents of errors occurring in the administration of therapeutic and diagnostic interventions. Some of the reasons for the apparent compromising of patient safety explored in this chapter include financial constraints, fear of legal liability, and reluctance to admit to commission of errors. The Veterans Administration National Center for Patient Safety is in the vanguard of the patient safety movement as it attempts to change the culture of blame in its system of hospitals to the culture of patient safety. With proven systematic techniques such as the root-cause analysis and failure mode and effects analysis and the expertise of the CE, the NCPS has made measurable positive strides in a short time. Some of the tools, such as process-flow diagrams, hazard scoring matrices, and decision trees, used by the Center are described in this chapter.

The Clinical Engineer: Well-Suited for Patient Safety

The concept of patient safety is not new to CEs. In the past three decades since one of the first in-house clinical engineering departments was conceived and developed, safety has been the mission of such a department. A mission statement of a typical clinical engineering department is: "To assure a cost-effective, safe, quality environment for patients, employees, volunteers, visitors, and medical staff of the hospital, relative to patient care, diagnostic, therapeutic, and life-support medical devices, instruments, and systems." The American College of Clinical Engineering (ACCE) defines a *clinical engineer* as: "a professional who supports and advances patient care by applying engineering and managerial skills to heath care technology." One of the missions of ACCE is "to promote safe and effective application of science and technology in patient care."

Clinical engineers are uniquely positioned to address patient safety issues for the following reasons:

By Law

The minute one claims to be an engineer, one is bound by fiduciary responsibility for the safety of the public. Webster's Dictionary defines *fiduciary* as "a person who stands in a special relation of trust, confidence, or responsibility in his/her obligation for public safety."

By Education

In any bona fide engineering school, core courses such as statics, dynamics, thermodynamics, mechanics of materials, physics and mathematics (calculus) prepare one to better understand the cause and effect relations of most problems and incidents. Engineers are known for their problem solving abilities. Most CEs hold undergraduate degrees in the calculus-based engineering discipline such as electrical engineering, mechanical engineering, or computer engineering, and a graduate degree in biomedical/clinical engineering. Some also hold a doctoral degrees. In addition, many CEs are certified as certified clinical engineers (CCE).

By Experience

Over the past 30 years, CEs have participated in prospective approaches to ensure patient safety vis-à-vis technology assessment (T/A) projects. They have developed and published consensus standards (as members of AAMI) for almost all critical medical devices and systems, and many are now ANSI standards. Some CEs work as company consultants or collaborate with companies to conduct alpha or beta site testing of medical devices. Some spend enough on devices from one manufacturer to cultivate the influence to provide feedback and/or participate in the design of fault-tolerant medical devices and systems.

These activities are possible only if the CEs are also involved in retrospective assessments to ensure patient safety vis-à-vis incident investigations and since 1991 because of the Safe Medical Devices Act of 1990, CEs have been reporting all medical device vulnerabilities to the manufacturer and/or a central database (FDA MAUDE). The knowledge gained from reading investigations of incidents that occurred elsewhere allows CEs to plug back into the prospective risk-assessment process.

By Reputation

In addition to being credentialed with degrees and certification, CEs are well respected by their peers, appreciated by their co-workers, and trusted by their employers and customers. They usually have excellent track records in participating, educating, and consulting activities to improve patient safety. A high percentage of CEs participate in professional activities.

By Position in the Institution

Staff vs. Line?

Most staff positions protect the institution from exposure/liability; CEs work closely with the Legal Affairs department and lawyers' fiduciary responsibility is to protect their client the institution, which is sometimes in conflict with a CE's fiduciary responsibility to protect the public. Therein lies the problem. Solutions to this problem are presented later in this chapter.

On the other hand, aline position, or in some cases called operations, is responsible to produce the actual product (crank out the widgets). Someone in this position is expected to produce tangible, cost-saving, production support for the caring of the patients. Clinical engineering departments in most hospitals are relegated to repairing medical devices (mostly electronic devices). Therein lies another problem.

Leadership

Most reputable CEs also hold leadership positions in their hospitals. A CD is usually a department head, chairperson of a committee or committees, process owner, educator, or consultant.

Despite the unique position the CE might hold in a hospital or a heath care organization to ensure safety, it has been estimated that close to 98,000 deaths occur annually in U.S. hospitals due to medical errors (Kohn et al., 2000). One is compelled to ask:

- What happened?
- Why did it happen?
- What are the root causes?
- What can we do to prevent it from happening again?

Factors Contributing to Medical Errors

There are many dynamics that played a part to reach to this point, and several are listed here.

Heath Care Reimbursement

What Happened?

The changing landscape of heath care reimbursement process in the U.S. played an important role in reaching the current state of affairs. Over three decades reimbursement went from a cost, plus a certain margin contractual fee-for-service arrangement, to a Diagnostic Related Groups (DRGs) capitated payment system, to HMOs and PPOs. The whole issue of treating heath care as a business is the culture change that had devastating long-term impacts on patient safety. Strictly bottom-line orientation is the modus operandi of most hospital administrators (MBAs). Some nonprofit heath care facilities are spinning off profit making arms and the COO of one of these service companies, LLC, told me "Patient safety initiatives are diametrically opposed to the objectives of this company." Quality of care and safety of patients took the back seat. The theme of hospitals these days is to do more with less. Is this the best way management can save money?

Why Did it Happen?

Many hospitals are struggling to stay afloat. When one is fighting to survive, one forgets the real mission of the hospital. Core values take the back seat and/or are missing.

What Are the Root Causes?

Our business schools must stop teaching MBA students the notion that "all is fair in love, war, and business." Business leaders and CEOs must understand that they have an obligation to the community that provides them with the infrastructure, services, and other resources to conduct their businesses.

A CE, who is usually the department head, is bogged down with the daily tasks of managing the department, working with budgets, operations reports, meetings, and employees' needs and demands. He or she does not have the time and resources to attend to the RCAs and technology/systems-related prospective and retrospective assessments. Therefore, in order to survive, many CEs manage to carve out their scope of responsibility to only repairable medical devices (mostly electronic devices) because the technicians in the department came from an electronics technician educational program or the ranks of electronic technicians.

What Can One Do About It?

Identify a need to reevaluate the core curriculum of MBAs. Teach them that the community provides a certain infrastructure, services, and other resources to allow them to conduct business in the community, and they have certain obligations to the community and the patients they serve. Core curricula of BMETs and CEs need to be reevaluated also. Teach and share with them the different kinds of failures/incidents/injuries that can occur in hospitals. Include not only the repairable medical devices arena, but also problems with the application of these devices, processes that have failed with nonrepairable devices, and the systems failures that have occurred so far. Teach them how to conduct root cause analysis and some of the successful forcing functions and other robust, fault-tolerant solutions that have been implemented to solve these problems. If the expectation is to have these people get involved in improving patient safety, consider some of the unsolved problems and how to conduct HFMEA™ to look at solutions and use new technologies and new processes to solve these problems. The CE's job functions must meet the mission statement of his or her department.

Administrators Need to See Tangible Results

What Happened?

Myopic: Most administrators see tangible results of their investment in a few full time equivalents (FTEs) to repair medical devices as opposed to contracting out with the manufacturer for a maintenance program to save money. Did the administrators lose sight of the real mission of hospitals? CFOs literally control the direction of the business enterprise. The business people have done an excellent job to change the culture of the hospitals to think in terms of budgets and bottom lines. We are in the business culture. Although we are in the patient care business, patients are not number one–*business* is number one. However, the quality and safety people have not yet done an adequate job. If all the constituents in the hospital are properly represented, and their voices are heard equally, then there should not be a skewing of emphasis toward business.

Why Did it Happen?

Businesses complain about the spiraling cost of heath care. The automotive industry estimated that heath care cost accounts for $300 of each car's cost. So what? The American public demands the latest and best technology for its care. It is more glorious to have an MRI than an X-ray.

The ratio of Biomedical Equipment Technicians (BMETs) to CEs is 100 to 1. If you mention Biomed to a heath care worker, the first thing that pops into his or her head is the repairman. Why? Because they see and meet the BMETs more often than they see and meet the CEs. Since the CE department is relegated to repairs, the CEs are also looked upon as repairmen.

Litigious Society

What happened?

Medical malpractice suits are on the rise. The U.S. public, in general, has become enamored with lawsuits and expects to become rich from the inconveniences and/or injuries sustained as a result of medical care. They perceive the physician, the hospital, and the medical device manufacturers as people with deep pockets and unlimited funds to pay for damages. The cover story in the June 9, 2003, issue of *Time* delineated how the soaring cost of malpractice insurance is driving some physicians out of certain regions, out of certain high-risk specialties, or out of medicine completely. And so the pattern continues.

Why did it happen?

Personal injury lawyers may be encouraged by the recent malpractice award of $140 million in New York, chronicled in an article in *The New York Times* titled "New York Hospitals Fearing Malpractice Crisis" by Richard Perez-Pena.

What happened?

CONFIDENTIAL: CEs are not privy to all the patient safety incidents in a facility. Everything is confidential. The pattern repeats itself. In order to avoid litigations, physicians, nurses, health care workers ,and hospitals treat all medical adverse events as confidential and do not discuss them with the front-line care providers. Many facilities take meticulous steps to avoid discovery of such events.

Why Did It Happen?

A punitive environment is a factor as well. Many surveys have shown that a high percentage of heath care workers chose to work in heath care to make a difference in curing the sick, healing the injured, and saving lives. They are dedicated, compassionate, intelligent, and motivated individuals. However, when a mistake is made and/or a patient is injured, the first question that most bosses ask is "Who did it?" Disciplinary action is often the first recourse. Mistakes or are not tolerated. Root causes are not identified, and eliminating an individual from a position seems to be the norm to solve problems.

What Are the Root Causes?

- Pharmacies conduct their own investigations on their own employees.
- Labs conduct their own investigations on their own employees.
- Radiology labs investigate their own employees.
- Operating rooms investigate their own employees.
- Nurses investigate their own employees.
- Cardiologists investigate their own employees.

What Can One Do About It?

Create a non-punitive environment, form multidisciplinary teams, invite subject-matter experts and process owners to the table, and discuss all patient safety issues. Make the discussion a learning experience, with the focus on preventing adverse events in your facility.

Solutions

Creating a Culture of Safety

Only by viewing the health care continuum as a system can truly meaningful improvements be made. A systems approach that emphasizes prevention, not punishment, can create patient safety success stories. Other high-risk businesses such as airlines and nuclear power plants have used this approach to accomplish safety goals. To make the prevention effort effective, we use methods of gathering and analyzing data from the field that allow the formation of the most accurate picture possible. People on the front line are usually in the best position to identify issues and solutions, so both root cause analysis teams and heath care failure modes and effects analysis teams formulate solutions, test, and implement strategies, and measure outcomes in order to improve patient safety. Findings from the teams are shared with other facilities in the system. This is really at the core of what we mean "by building a culture of safety." It is portrayed as the engine that propels the system toward the goal of maximum safety. This kind of cultural change does not happen overnight. It can only happen as a result of effort on everyone's part to take a different approach to the way we look at things. We must constantly ask whether we can do things in a better, more efficient, and safer manner. We must never let "good enough" be good enough. We must be relentless in our pursuit of finding ways to improve our safety systems. We do not believe that people come to work to do a bad job or to make an error, but given the right set of circumstances any of us can make a mistake. We must force ourselves to look past the easy answer–that it was someone's fault – to answer the tougher question of why the error occurred. There is seldom a single reason. Through understanding the real underlying causes of errors, we can better position ourselves to prevent future occurrences. Although the saying goes, "Experience is the best teacher," it is one of the most expensive teachers as well. One of the best ways to reduce the expense is to take advantage of lessons present in close calls, where things almost go awry, but no harm is done. Establishing a culture of safety where people are able to report both adverse events and close calls without fear of punishment is the key to creating patient safety.

Challenges

Historically, accident prevention has not been a primary focus of medicine. Hospital systems were not engineered to be prevent or absorb errors; they changed reactively without being proactive. The hospital system had misguided reliance on faultless performance by heath care professionals. Medical culture rewards perfection and punishes errors in a complex system not engineered for risk.

Unrealistic expectations discourage openness and honesty, and preclude learning from close calls. Mistakes may be made by capable, conscientious, and compassionate individuals trying to do the right things.

Tradition and values are also important; they were important to me. (that is the way I used to do it ... now you can do the same)

Human performance is fallible.

Create a Culture of Safety the VA Way

The following is a list of the steps that the Veterans Administration took to create a culture of safety:

- Assured a nonpunitive environment, except for intentional unsafe acts.
- Received a public commitment from heath care leadership tied to the performance appraisal process of every health care facility director.

- Dedicated resources: 200 Patient Safety Managers (PSMs) and 22 Network Patient Safety Officers (NPSOs)
- Established Special Patient Safety Centers of Inquiry (SPSCIs)
- Provided Incentives for the VHA workforce to promote safety
- Directed safety efforts
- Created the National Center for Patient Safety
- Trained 1000 patient safety managers, patient safety officers, and others from 163 VA facilities and several private sector health care facilities over 3 years at a 3-day course on Patient Safety 101 and about 200 safety professionals at a 3-day course on Patient Safety 202.
- Developed and published the *VA Patient Safety Handbook*
- Created the Patient Safety Website at www.patientsafety.gov
- Developed tools such as RCA Software (SPOT) and the RCA database, HFMEA,™ and distributed them to every hospital CEO in the United States through the American Hospital Association
- Developed and distributed of cognitive aids
- Disseminated patient safety alerts and advisories
- Participated as consultants in the procurement and standardization of medical devices, products, and services
- Established a patient safety work group in the information systems (Office of Information) support team.

Since taking these actions, close-call reports in the VA have gone up by 900%, an indication that the blameless reporting system is working well.

Vehicles to Change the Culture

Root Cause Analysis (RCA)

Root cause analysis RCA is a process or technique used to identify the most fundamental reason or contributing causal factor as to why a problem occurred. It is a retrospective assessment, focused on finding vulnerabilities in the system and developing countermeasures. The process of RCA addresses four basic questions. 1. What happened? 2. Why did it happen? 3. What are the contributing causal factors? 4. What can we do to prevent it from happening again? The emphasis must be on developing effective countermeasures. The RCA team must be interdisciplinary in nature, involving experts from the front line who are closest to the safety process and who have the best ideas to solve the problem. RCA is a process that continually digs deeper by asking, "Why, why, why?" at each level of an event. It is a process that identifies changes that need to be made to systems, is as impartial as possible, and moves beyond blame. The RCA process must consider human factors and other factors, related processes, and systems, and analyze the underlying cause-and-effect relationships. Relevant literature must be reviewed during the process and internal consistency must be achieved. The RCA must identify risks and their potential contributions to safety errors, and must determine potential improvements in processes or systems. To be credible, an RCA must include the participation and support of the leadership of the organization and those most closely involved in the safety process and systems. Figure 55-1 is a flow diagram of an RCA team process.

The following are five rules of causation adapted for patient safety from a publication by David Marx on the NCPS website, www.patientsafety.gov:

Rule 1–Causal statements must clearly show the cause and effect relationship.

This is simplest of the rules. When describing why an event occurred, show the link between the root cause and the bad outcome, and each link should be clear to the RCA team and others. Focus on showing the link from the root cause to the undesirable patient outcome under investigation. Even a statement such as "resident was fatigued" is deficient without adescription of how and why this led to a close call or mistake. The bottom line is that the reader needs to understand the logic in linking the cause to the effect.

Rule 2–Negative adjectives such as poorly or inadequate are not used in causal statements.

As humans, we try to make each job we have as easy as possible; unfortunately, this human tendency works its way into the heath care documentation process. We may shorten our findings by saying, "Maintenance manual was poorly written" when we really have a much more detailed explanation in mind. To force clear cause and effect descriptions and avoid inflammatory statements, do not use negative descriptors that are merely placeholders for more accurate, clear descriptions. Even words such as "carelessness" and "complacency" are bad choices, because they are broad, negative, judgments that do little to describe the actual conditions or behaviors that led to the mishap.

Rule 3–Each human error must have a preceding cause.

Most of our mishaps involve at least one human error. Unfortunately, the discovery that a human erred does little to aid the prevention process. Investigate to determine WHY the human error occurred. It can be a system-induced error, such as a step not included in the medical procedure or an at-risk behavior, such as doing task by memory, instead of with a checklist. For every human error in your causal chain, there must be a corresponding cause. The cause of the error, not the error itself, leads to productive prevention strategies.

Rule 4–Each procedural deviation must have a preceding cause.

Procedural violations are like errors, in that they are not directly manageable. Instead, we can manage the cause of the procedural violation. If a clinician is violating a procedure because it is a local norm, address the incentives that created the norm. If a technician is missing steps in a procedure because he is not aware of the formal checklist, improve education.

Rule 5–Failure to act is only causal when there was a preexisting duty to act.

We can all find scenarios in which our investigated mishap would not have occurred – but this is not the purpose of causal investigation. Instead, we need to find out why this mishap occurred in our system as it is designed. A doctor's failure to prescribe a medication can only be causal if he is required to prescribe the medication initially. The duty to perform may arise from standards and guidelines for practice or from other duties involving patient care.

Health Care Failure Mode and Effect Analysis (HFMEA)™

To optimally meet the needs of a prospective risk assessment of heath care processes, the National Center for Patient Safety (NCPS), with assistance from Tenet Health Systems of Dallas, Texas, developed a hybrid method, the Healthcare Failure Mode and Effects Analysis (HFMEA)™, that combines concepts of FMEA from industry with the Hazard Analysis and Critical Control Point (HACCP) from food safety, as well as tools and concepts that are integral to the VA's RCA process (Stalhandske et al., 2000).

The HFMEA™ is a systematic approach to identify and prevent problems with products and processes before they occur. It is a prospective assessment that identifies and improves steps in a process, reasonably ensuring a safe and clinically-desirable outcome. HFMEA(streamlines the hazard analysis steps found in the traditional FMEA process by combining the detectability and criticality steps of the traditional FMEA into an algorithm presented as a decision tree. It also replaces calculation of the risk priority number (RPN) with a hazard score that is read directly from a Hazard Matrix Table developed by NCPS specifically for this purpose.

Prologue

During a midnight shift on an intensive care unit, a patient with an infectious disease was monitored by a physiological monitor while on a ventilator in an isolation room with an anteroom. While the patient was asleep, the assigned caregiver decided to help transfer her other patient, who was recovering well, back to a regular floor. While the caregiver was out of the isolation room, the first patient managed to extubate himself. No one heard the ventilator alarm or the physiological monitor alarm. When the caregiver came back to the room she immediately called a code and then attempted to resuscitate the patient, but the patient could not be revived.

What is the relevance of this story to proactive risk assessment and HFMEA™? A team examining this high-risk situation might have identified a number of vulnerabilities that could have been mitigated without the harm and tragedy that occurred. The following example depicts how this outcome may have been avoided by using the HFMEA™ proactive risk-assessment model.

Basics of HFMEA™

HFMEA™ is a five-step process that uses a multidisciplinary team to proactively evaluate a health care process. The team uses process-flow diagramming, a Hazard Scoring Matrix™ (Table 55-1), accompanying Severity Rating System (Table 55-2) and Probability Rating System (Table 55-3), and the HFMEA™ Decision Tree (Figure 55-2) to identify and assess potential vulnerabilities. The HFMEA™ Worksheet is used to record the team's assessment, proposed actions, and outcome measures. HFMEA™ includes testing to ensure that the system functions effectively and new vulnerabilities have not been introduced elsewhere in the system.

STEP 1 DEFINE the HFMEA™ TOPIC

- Define the topic of the HFMEA along with a clear definition of the process to be studied. Think about narrowing the scope so that the review is manageable and the actions operationally sound (see Figure 55-4).

STEP 2 ASSEMBLE the TEAM

- The team should be multidisciplinary including subject matter expert(s) and an advisor (see Figure 55-4).

STEP 3 GRAPHICALLY DESCRIBE the PROCESS

- Develop and verify the flow diagram (this is a process vs. chronological diagram).
- Consecutively number each process step identified in the process flow diagram (see Figure 55-5).
- If the process is complex, identify the area of the process to focus on (i.e., take manageable bites).
- Identify all subprocesses under each block of this flow diagram. Letter these subprocesses consecutively under each block (i.e., Under block 1 as A, B, ..., D, under block 2 as A, B, ... E) (see Figure 55-5).
- Create a flow diagram composed of the subprocesses (see Figure 55-6).
- Transfer these to the HFMEA™ Worksheet, Line 1 (see Figure 55-7).

A Helpful Hint: It is important that all process and subprocess steps be identified before proceeding.

STEP 4 CONDUCT a HAZARD ANALYSIS

- List all possible/potential failure modes under the subprocesses identified in Step 3. Transfer the failure modes to the HFMEA™ Worksheet. (Hint: Failure modes include anything that could go wrong that would prevent the subprocess step from being carried out; they describe what could go wrong. For example: If logging onto a laptop computer is the process step, two possible failure modes are (1) not being able to log in and (2) delayed login. Use various methods including the NCPS triage/triggering questions, literature reviews, and brainstorming to identify potential failure modes.)

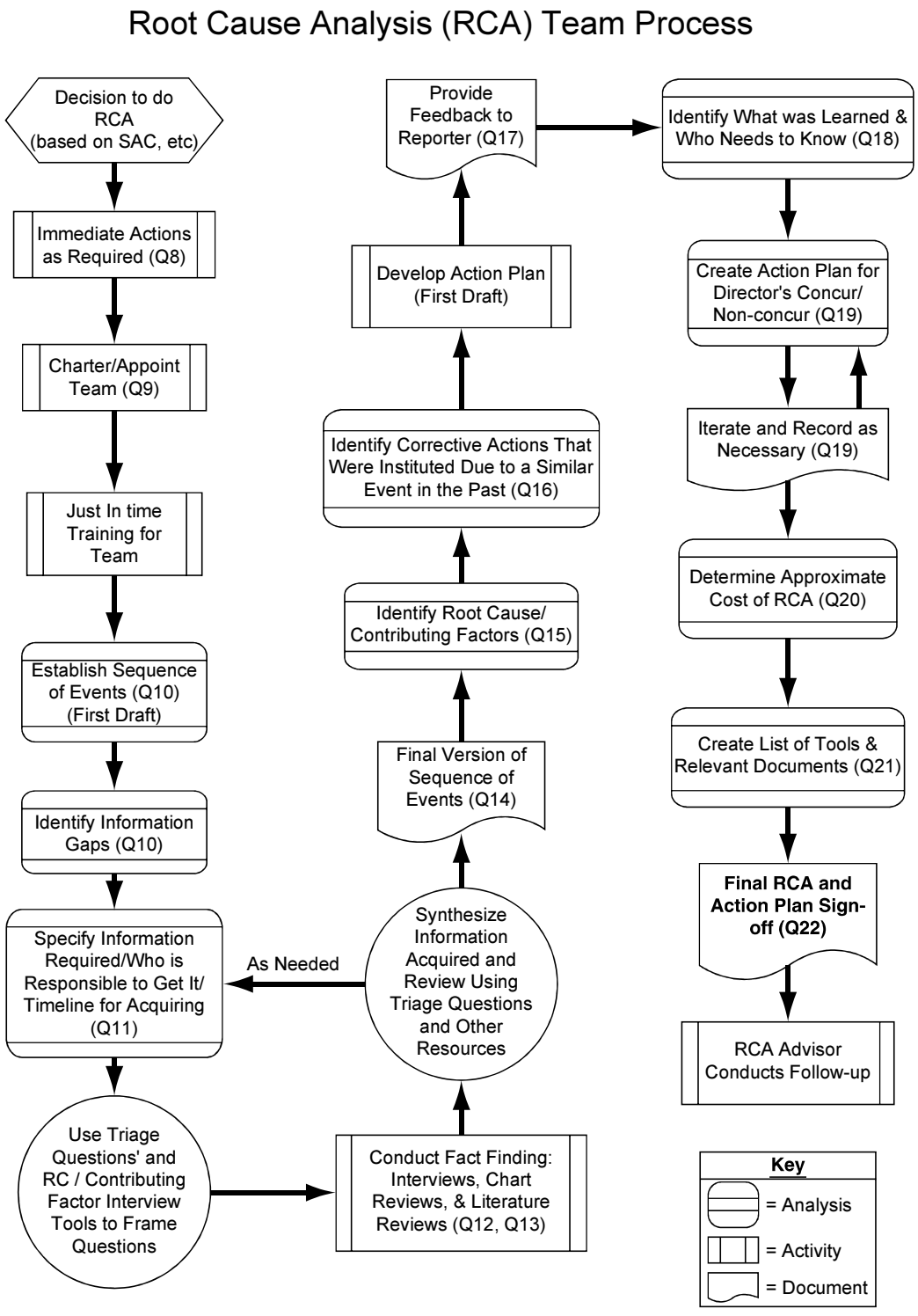

Figure 55-1 RCA team process.

- Determine the severity (Table 55-2) and probability (Table 55-3) of the potential failure mode and look up the hazard score on the Hazard Score Matrix™ (Table 55-1). Go to the HFMEA™ Decision tree (Figure 55-2). Use the decision tree to determine whether the failure mode warrants further action. Record the action to "proceed" or to "stop" on the HFMEA™ Worksheet (Figure 55-3).
- List all of the failure-mode causes for each failure mode where the decision is to "Proceed" and record them on the HFMEA™ Worksheet, Line 3. *(Hint: Remember that failure-mode causes are the reasons why something could go wrong. Each failure mode may have multiple failure-mode causes. For example, possible failure-mode causes for not being able to log in and delayed login with a computer would include the computer not being available, no power, and no log-in ID for the operator.)*

STEP 5 ACTIONS and OUTCOME MEASURES

- Identify a Description of Action for each failure mode that will be eliminated or controlled.
- *(Hint: Place the control measure in the process at earliest feasible point. Multiple control measures can be placed in the process to control a single hazard. A control measure can be used more than once in the process. Solicit input from the process owners if they are not represented on the team. Try to simulate any recommended process change to test them before facility-wide implementation.)*
- Identify outcome measures that will be used to analyze, and test the redesigned process.

Table 55-1 Hazard scoring matrix

Probability	*Severity of effect*			
	Catastrophic	*Major*	*Moderate*	*Minor*
Frequent	16	12	8	4
Occasional	12	9	6	3
Uncommon	8	6	4	2
Remote	4	3	2	1

To use this matrix: (1) Determine the severity and probability of the hazard based on the definitions included with this matrix. (NOTE: These definitions are the same as those used in the RCA safety assessment code.) (2) Look up the hazard score on the matrix.

- Identify a single, responsible individual by title to complete the recommended action.
- Indicate whether top management has concurred with the recommended action.
- Test to ensure that the system functions effectively and that new vulnerabilities have not been introduced elsewhere in the system.

How to Develop Reasonable and Concrete Failure Modes

There are several techniques besides brainstorming that should be used to develop reasonable and concrete failure modes once process diagrams are complete and the focus areas are chosen. Reviewing databases, such as the United States Food and Drug Administration (FDA) Manufacturer and User Device Experience (MAUDE), could provide malfunctions and user-interface design issues such as inadvertent shutdown of external pacemaker machines. Usability tests that are done by the HFMEA™ team or found in a literature search can be useful (Welch, 1998). Usability testing is a human-factors-engineering technique that can be done on devices, work areas, or larger processes (Gosbee et al., 2001).

Another technique is patient safety rounds. For example, upon sitting down with ICU nurses and residents, the CE may find that the nurses are worried about missing alarms several times a week because of distractions or noise levels and that they have nearly missed important alarms because of distraction or noise level. Another approach is to use the findings from routine safety-assessment tool "audits." For example, the CE may find that many of the hospital's compressed air wall outlets have green Christmas tree light adaptors attached; the VA's approach to this issue has been to send out an alert that all facilities should switch to a clear adaptor. This thereby avoids the potentially hazard and vulnerability caused by matching the wrong color adaptor and thereby providing the wrong color cue.

In a complex and difficult HFMEA,™ video documentation can be done on high-hazard areas. The video analysis provides data on close calls or adverse events, and is one of the most concrete development tools to list failure modes. For example, the University of Maryland has used this for research into safety issues during respiratory arrest resuscitation (Xiao and Moss, 2001).

Those that have FMEA experience and skills may find themselves in demand to respond to the new JCAHO standards and need for proactive risk assessment within heath care.

JCAHO Standards

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) drives much of the activity within heath care through its standards that must be met to gain accreditation. While voluntary, almost all hospitals choose to apply for JCAHO accreditation. The new LD 5.2 JCAHO patient safety standard reads as follows: "Leaders ensure that an ongoing, proactive program for identifying risks to patient safety and reducing medical/health care errors is defined and implemented." The intent section clarifies that annually at least one high-risk process be examined. For this process it is required to identify failure modes, and for each failure mode identify the possible effects. For the most critical effects, conduct analysis of the systems issues that allow this to occur, and mitigate the serious issues.

Table 55-3 Probability rating

Frequent–Likely to occur immediately or within a short period (could happen several times in one year)
Occasional–Probably will occur (could happen several times in 1 to 2 years)
Uncommon–Possible to occur (could happen sometime in 2 to 5 years)
Remote–Unlikely to occur (could happen sometime in 5 to 30 years)

Procurement Using Proactive Risk Assessment Model

CEs are called upon to fix, repair, maintain, and update equipment throughout the hospital and clinic environment. Skills gained in engineering schools and practical knowledge developed through work experience are applied in these traditional activities. However, CEs can broaden their impact by influencing procurement activities, thereby increasing the visibility of the CE department, improving the safety of the procurements, and improving the bottom line.

Engineers are taught to think in terms of systematic, logical, objective-based, well-supported conclusions. Consider researching the ways procurement decisions are reached and selling the capital acquisition committee on the added benefit of applying CE skills to the procurement process.

- Provide a proactive approach to procurement; think about what might go wrong with the different models under consideration and provide a modified failure mode effect analysis to compare different models
- Encourage end-user input into the procurement decision process
- Include consideration of past experience (good or bad) with the particular manufacturer
- Use existing data from databases of fellow CEs, ECRI, and MAUDE to support the safest purchase
- Develop explicit criteria to enhance an objective evaluation of the equipment

The CE department will be involved downstream in maintaining and fixing equipment brought into the facility. Why not become involved initially to make the most prudent purchase considering full life cycle costs, safety, and usability in your decision process?

Definitions

Effective Control Measure: A barrier that eliminates or substantially reduces the likelihood of a hazardous event occurring.

Health Care Failure Mode and Effect Analysis (HFMEA™): (1) A prospective assessment that identifies and improves steps in a process, thereby reasonably ensuring a safe and clinically desirable outcome; (2) a systematic approach to identify and prevent product and process problems before they occur.

Hazard Analysis: The process of collecting and evaluating information on hazards associated with the selected process. The purpose of the hazard analysis is to develop a list of hazards that are of such significance that they are reasonably likely to cause injury or illness if not effectively controlled.

Failure Mode: Different ways that a process or subprocess can fail to provide the anticipated result.

Probability: See the Probability Rating System (Table 55-3).

Severity: See the Severity Rating System (Table 55-2).

Table 55-2 Severity rating

Catastrophic event (Traditional FMEA rating of 10-Failure could cause death or injury)	*Major event (Traditional FMEA rating of 7-Failure causes a high degree of customer dissatisfaction.)*
Patient outcome: Death or major permanent loss of function (sensory, motor, physiologic, or intellectual), suicide, rape, hemolytic transfusion reaction, surgery/procedure on the wrong patient or wrong body part, infant abduction, or infant discharge to the wrong family	**Patient outcome:** Permanent lessening of bodily functioning (sensory, motor, physiologic, or intellectual), disfigurement, surgical intervention required, increased length of stay for 3 or more patients, increased level of care for 3 or more patients
Visitor outcome: Death; or hospitalization of 3 or more.	**Visitor outcome:** Hospitalization of 1 or 2 visitors
Staff outcome:* A death or hospitalization of 3 or more staff	**Staff outcome:** Hospitalization of 1 or 2 staff or 3 or more staff experiencing lost time or restricted duty injuries or illnesses
Equipment or facility: **Damage equal to or more than $250,000	**Equipment or facility:** **Damage equal to or more than $100,000
Fire: Any fire that grows larger than an incipient	**Fire:** Not applicable – See Moderate and Catastrophic
Moderate event (Traditional FMEA rating of "4" – Failure can be overcome with modifications to the process or product, but there is minor performance loss.)	*Minor event (Traditional FMEA rating of "1" – Failure would not be noticeable to the customer and would not affect delivery of the service or product.)*
Patient outcome: Increased length of stay or increased level of care for 1 or 2 patients	**Patient outcome:** No injury, nor increased length of stay nor increased level of care
Visitor outcome: Evaluation and treatment for 1 or 2 visitors (less than hospitalization)	**Visitor outcome:** Evaluated and no treatment required or refused treatment
Staff outcome: Medical expenses, lost time or restricted duty injuries or illness for 1 or 2 staff	**Staff outcome:** First aid treatment only with no lost time, nor restricted duty injuries nor illnesses
Equipment or facility: **Damage of more than $10,000 but less than $100,000	**Equipment or facility:** **Damage of less than $10,000 or loss of any utility? without adverse patient outcome (e.g. power, natural gas, electricity, water, communications, transport, heat/air conditioning)
Fire: Incipient stage‡ or smaller	**Fire:** Not applicable – See Moderate and Catastrophic

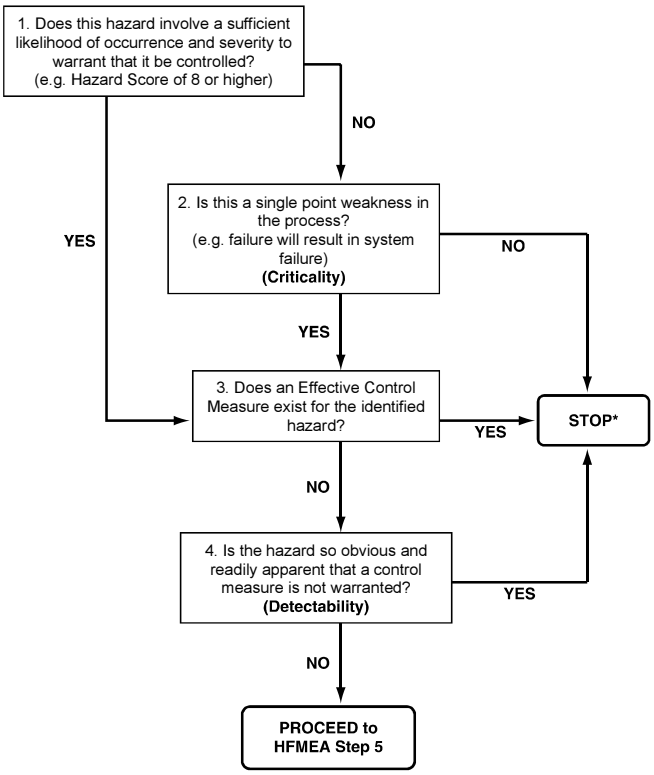

Figure 55-2 HFMEA™ Decision Tree.

HFMEA™ Step 4 Hazard Analysis										HFMEA™ Step 5 - Identify Actions and Outcomes				
Failure Mode: First Evaluate failure mode before determining potential causes	Potential Causes		Scoring			Decision Tree Analysis				Action Type (Control, Accept, Eliminate)	Actions or Rationale for Stopping	Outcome Measure	Person Responsible	Management Concurrence
			Severity	Probability	Haz Score	Single Point Weakness?	Existing Control Measure?	Detectability	Proceed?					
	→													

Figure 55-3 HFMEA™ Worksheet.

Step 1. Select the process you want to examine. Define the scope (Be specific and include a clear definition of the process or product to be studied).

This HFMEA ™is focused on _____

Step 2. Assemble the Team
HFMEA™ Number _____
Date Started _____ Date Completed _____
Team Members 1. _____ 4. _____
2. _____ 5. _____
3. _____ 6. _____
Team Leader _____
Are all affected areas represented? YES NO
Are different levels and types of knowledge represented on the team? YES NO
Who will take minutes and maintain records? _____

Figure 55-4 HFMEA™ Process Steps 1 and 2.

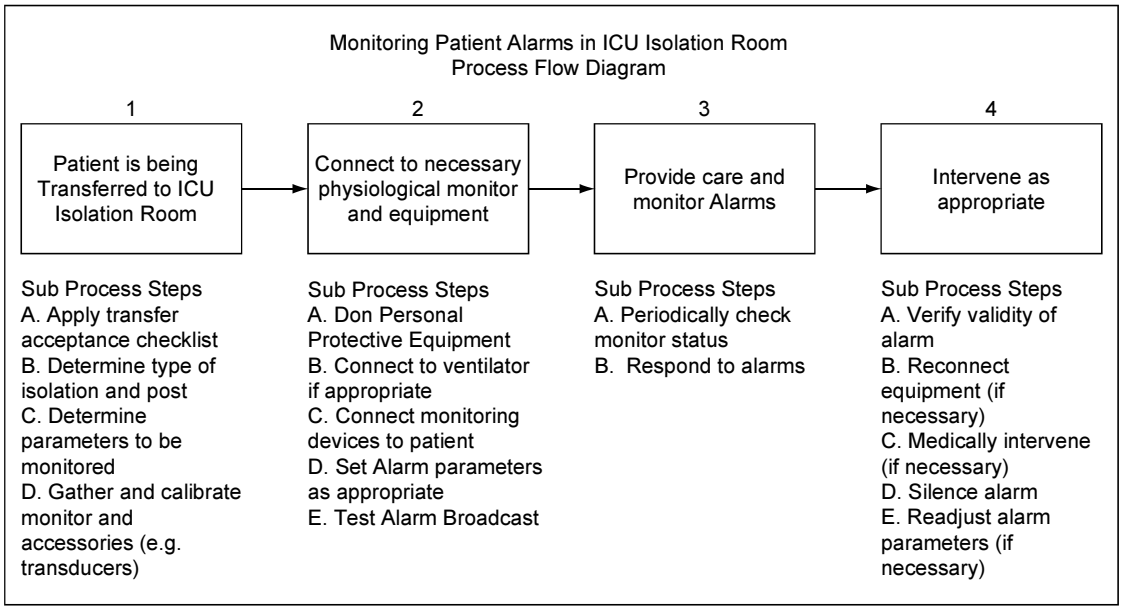

Figure 55-5 Monitoring patient alarms in ICU isolation room: Process flow diagram.

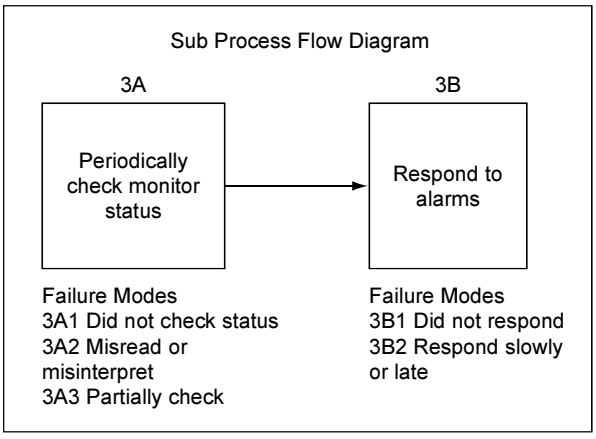

Figure 55-6 Sub Process flow diagram.

Solutions

Staff vs. Line? Be neither. If one is serious about patient safety and is truly passionate about it, the ideal chain of command is an autonomous arm reporting directly to the board. The National Center for Patient Safety serves as a good model. The IOM report also recommends forming a National Center for private-sector hospitals using NCPS as a model. This will overcome two problems, delineated earlier in the document.

Conclusion

CEs are uniquely positioned to address patient safety issues. They have the proper education, the proper mindset, and solid experience, entrusted by the public and trusted by their peers. They are performing prospective and retrospective risk assessment on certain groups of medical devices. They need to expand their horizons and get involved with the multidisciplinary teams to conduct these risk assessment in all heath care technologies and processes. Close to 90% of the hospitals in the United States are looking at the Practitioner Order Entry Systems (POE) and the Bar Code Medication Administration Systems (BCMA) to mitigate well-documented Adverse Drug Events (ADEs). These are truly complex, high-cost technologies with complicated process issues to which CEs should apply their expertise. CEs must play the role of Stewarts to

HFMEA™ Step 4 Hazard Analysis											HFMEA™ Step 5 - Identify Actions and Outcomes			
Failure Mode: First Evaluate failure mode before determining potential causes	Potential Causes		Scoring			Decision Tree Analysis				Action Type (Control, Accept, Eliminate)	Actions or Rationale for Stopping	Outcome Measure	Person Responsible	Management Concurrence
			Severity	Probability	Haz Score	Single Point Weakness?	Existing Control Measure?	Detectability	Proceed?					
Don't respond to alarm	→		Catastrophic	Frequent	16	→	N	N	Y					
	3B1a	Ignored alarm (desensitized)	Catastrophic	Frequent	16	→	N	N	Y	C	Reduce unwanted alarms by: changing alarm parameter to fit patient physiological condition and replace electrodes with better quality that do not become detached.	Unwanted alarms on floor are reduced by 75% within 30 days of implementation.	Nurse Manager	Yes
	3B1b	Didn't hear; caregiver left immediate area	Catastrophic	Occasional	12	→	N	N	Y	C	Alarms will be broadcast to Central Station with retransmission to pagers provided to care staff.	Alarms will be broadcast to the central station within 4 months; complete by mm/dd/yyyy	Biomedical Engineer	Yes
	3B1c	Didn't hear; alarm volume too low	Catastrophic	Occasional	12	→	N	N	Y	C	Set alarm volume on isolation room equipment such that the lowest volume threshold that can be adjusted by staff is always audible outside the room.	Immediate: within 2 working days; complete by mm/dd/yyyy	Biomedical Engineer	Yes
	3B1d	Didn't hear alarm; remote locatin (doors closed to isolation room)	Catastrophic	Frequent	16	→	N	N	Y	C	See 3B1b	See 3B1b		
	3B1e	Caregiver busy; alarm does not broadcast to backup	Catastrophic	Occasional	12	→	N	N	Y	C	Enable equipment feature that will alarm in adjacent room(s) to notify caregiver or partner(s).	Immediate: within 2 working days; complete by mm/dd/yyyy	Biomedical Engineer	Yes

Figure 55-7 HFMEA™ sub process step: 3B1—Respond to alarms.

change the culture of safety in health care facilities. Make patient safety everybody's business and create that "engine that continues to propel the system toward the goal of maximum safety."

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