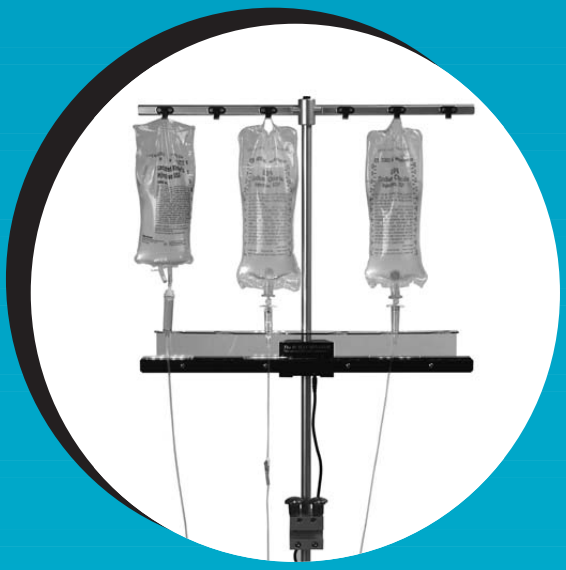

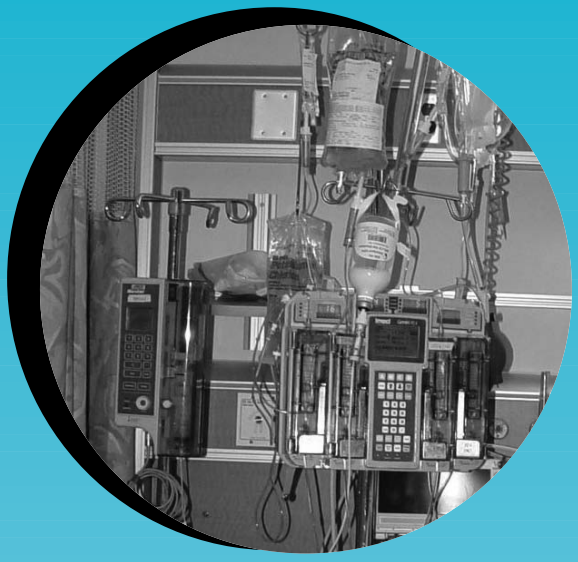

Mistake-Proofing the Design of Health Care Processes

DEPARTMENT OF HEALTH & HUMAN SERVICES • USA

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PATIENT SAFETY

Mistake-Proofing the Design of Health Care Processes

Prepared for:

Agency for Healthcare Research and Quality
U.S. Department of Health and Human Services
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Preface

It has been more than 7 years since the Institute of Medicine (IOM) released its landmark report, To Err Is Human: Building a Safer Health System, which galvanized attention on the serious and pervasive problem of errors in health care. Research into the causes of medical errors and ways to prevent them increased dramatically in the ensuing years after publication of the IOM report in 1999. We certainly have made great progress, but we still have much more to do to improve patient safety at all levels of our health care system.

The Agency for Healthcare Research and Quality (AHRQ) has been involved in research on patient safety and medical errors for many years. This publication is the latest in a long line of AHRQ-sponsored resources devoted to patient safety. It sheds light on a little-known but very promising approach to preventing medical errors and reducing the adverse outcomes that result from them.

Mistake-Proofing the Design of Health Care Processes was compiled for AHRQ by John Grout, Ph.D., of Berry College in Rome, GA. Dr. Grout has been working for many years to disseminate information about the use of mistake-proofing devices in health care. This volume represents a compendium of information and ideas to broaden our understanding of mistake-proofing and its emerging role in health care and patient safety.

Our hope is that the information and resources presented in this publication will lead to more and better error-prevention efforts in our Nation's hospitals, medical offices and clinics, laboratories, and residential care settings. Mistake-proofing has great potential as a quality improvement tool. It has been successfully applied over many years in industry, and many mistake-proofing devices are already being used to improve health care here in the United States and in other countries. We have only scratched the surface, however; as many other devices and applications are still in the pipeline or have yet to be discovered and disseminated.

We thank Dr. Grout for his hard work in putting together this excellent resource and for his dedication to improving the safety of health care in America. We welcome your feedback on this publication. Comments and questions may be sent in writing to AHRQ, Office of Communications and Knowledge Transfer, 540 Gaither Road, Rockville, MD 20850.

Carolyn M. Clancy, M.D.
Director
Agency for Healthcare Research and Quality

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I thank Hal Kaplan, M.D., of Columbia University Medical Center, and Jim Battles, Ph.D., of AHRQ's Center for Quality Improvement and Patient Safety, for their support, expert advice, and encouragement during the development of this text. Sonny Rigas and Brad Roberts, who were MBA students at Berry College while this document was in development, researched and contributed many examples of mistake-proofing devices, as did many other individuals and organizations. Special thanks go to Douglas M. Stewart, who wrote the first draft of the lost skills section in Chapter 4, and to those contributors who participated in the Patient Safety Improvement Corps and the participants in workshops sponsored by Health Insights, Inc., the National Patient Safety Agency in the United Kingdom, the Georgia Hospital Association, and hospitals in the State of Georgia. Thanks also to Steve Newlon, Becky Smith, Deborah Branton, Mike Silver, and Lynda Eden, as well as the many individuals and organizations who gave permission for their photographs to appear in this book.

I want to recognize the significant contributions of AHRQ staff from the Office of Communications and Knowledge Transfer, Division of Print and Electronic Publishing. They include Randie Siegel, Barry Nix, and Mary Grady, who provided editorial support; Frances Eisel, graphic designer for the project; and David Lewin, Eve Shaprio, and Salina Prasad who also provided support for this endeavor.

Lastly, I thank my family for their unfailing patience and support throughout this project.

John Grout

About Dr. Grout

John Grout, Ph.D., is the David C. Garrett, Jr., Associate Professor of Business Administration in the Campbell School of Business, Berry College, Rome, GA, where he joined the faculty in 1997. Dr. Grout has also taught at Pennsylvania State University and Southern Methodist University in Dallas, TX. Dr. Grout earned his doctorate from Pennsylvania State University and a bachelor's degree from Brigham Young University. He has researched mistake-proofing extensively for the past 12 years. To learn more about Dr. Grout and his extensive body of knowledge about mistake-proofing, visit his Web site at www.mistakeproofing.com.

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Chapter 1. What Is Mistake-Proofing?

Introduction

The process of turning on a burner on a stove is a simple one. It is an everyday task that most people have performed hundreds of times. Have you ever turned on the wrong burner? Have you ever gone from one room to another in your house only to forget why you went there in the first place? Have you ever put something in the refrigerator that belonged in the cupboard?

Patients should experience health care processes that are more reliable than manufacturing processes. Regrettably, that is not yet the case.[1]

These are common errors. Their consequences are usually not very serious. Once you have made these errors, what can you do to ensure that they never happen again? Are willpower and determination enough to avoid them? If one believes that "to err is human," then the answer to these questions is, "No." People who make these errors are not unmotivated or negligent. More importantly, they cannot eliminate the errors simply by telling themselves to do better and deciding not to commit them. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO)[2] adds that "it assumes that no matter how knowledgeable or careful people are, errors will occur in some situations and may even be likely to occur."

If executed correctly, many of the tasks that medical professionals perform as part of their jobs offer the potential to heal. The same tasks performed incorrectly, however, can also contribute to harming patients.

Clinicians need to become comfortable performing a wide variety of tasks, some of which are not very different from those performed in everyday life. If the infusion pump does not behave the way a nurse intended it to because the wrong control was adjusted, is the cause of the error really much different from turning on the wrong burner on the stove? The main difference between health care errors and errors in everyday life is that errors that occur in a health care setting can result in serious harm or death.

Whether outcomes are insignificant or life threatening, one question remains to be asked: "What can be done to reduce or eliminate errors and their negative consequences?" Part of the answer, mistake-proofing, is the focus of this book. No single tool can solve every problem; often, the answer will lie in the discovery, implementation, and execution of several tools. Croteau and Schyve[3] state that "techniques for designing safe processes are known, waiting only to be adapted to health care." Mistake-proofing is one of these techniques; it is a crucial addition to the tools employed to improve patient safety.

Mistake-Proofing Defined

Mistake-proofing is the use of process or design features to prevent errors or the negative impact of errors. Mistake-proofing is also known as poka-yoke (pronounced poka-yokay), Japanese slang for "avoiding inadvertent errors." Shigeo Shingo[4] formalized mistake-proofing as part of his contribution to the production system for Toyota automobiles. There are substantial differences between automotive manufacturing and health care operations, yet at least a few health care organizations are beginning to incorporate aspects of the Toyota production system into their efforts to reduce medical errors.[5,6,7,8]

Shingo,[4] Hinckley,[9] and other authors of books on manufacturing[11] include many examples of mistake-proofing that can be adapted to health care settings, some of which are included in this book. The examples are intended to serve as as a catalog of solutions that can be directly implemented to reduce the number of errors and as a catalyst for creating new ways to think about mitigating human error. The approaches taken in the examples can be modified to fit specific situations.

Everyday Examples

The 3.5-inch diskette is an example of mistake-proofing. The diskette can only be inserted if it is oriented correctly. It cannot be inserted sideways because it is not square; the sides are too long to fit. It cannot be inserted backwards or

Figure 1.1. A 3.5-inch diskette with chamfered corner.

inverted. The drive is designed to stop the diskette unless the right front corner is chamfered (angled) (Figure 1.1). When the disk is inserted correctly, the mistake-proofing device is not noticeable. When it is inserted incorrectly, however, the device completely stops the process. The only cost is that of initial design implementation. No user training is required. The members of the design team that created the disk drive believed that getting the orientation right was important enough to design a process that allowed users only one way to use the device. Their decision also indicates a preference for using design as an error-prevention strategy instead of alternatives such as training, instructions, or warning labels.

Mistake-proofing has even been applied to yo-yos. Most yo-yo tricks require that the yo-yo spin freely or "sleep" at the end of its string. The common (and dreaded) human error that occurs while one is doing tricks with a yo-yo is that of failing to snap the yo-yo up while it still has enough spin to make it back up to the top. The yo-yo shown in Figure 1.2 has been equipped with a clutch that reduces the level of expertise and attention to detail needed to execute tricks. On either side of the axle is a jaw that is held in position by a post on one end and a spring

Figure 1.2. A yo-yo clutch.

in the middle. On the far end of the jaw is a round weight. As the yo-yo spins, the centrifugal force of the weights pushes out against the springs, allowing the jaw to disengage from the axle, and causing the yo-yo to "sleep." When the rate of spin slows, the jaws come back into contact with the axle, and the yo-yo automatically stops sleeping. The spring and the weight in the jaws are engineered to provide just enough spin to propel the yo-yo back up to the user's hand.

Tons of paper are stored in file cabinets. If more than one file drawer is opened at a time, the center of gravity might move forward enough to cause the file cabinet to fall on the user. Modern file cabinets are designed to avoid this type of injury (Figure 1.3). Opening one drawer locks the rest. The design facilitates (perhaps even forces) correct behavior and only allows for proper use.

If engineers found it worthwhile to reduce human error in performing yo-yo tricks, wouldn't it be worthwhile to focus similar attention on the more consequential errors of health care?

History of Mistake-Proofing

Although it was formalized by Japanese manufacturers in the 1960s (and published in English in the 1980s), mistake-proofing did not start in Japan and its utility was not limited to factories. Inventors, designers, and problem solvers led by common sense implemented mistake-

Figure 1.3. Donald Norman calls this type of mistake-proofing a "forcing function."

proofing devices long before the 1960s. The question of which mistake-proofing device appeared first remains unanswered. However, an example of mistake-proofing from 1853 disproves that mistake-proofing first appeared in the 1960s.

The device was the Otis elevator brake. At the Crystal Palace Exposition of 1853 in New York, Elisha Otis rode an elevator above the crowd and had an assistant cut the cable. The elevator brake stopped the elevator and Otis from falling (Figure 1.4). Examples from everyday life such as this one and others demonstrate that the usefulness of mistake-proofing is not limited to manufacturers.[12]

Disk drive, yo-yo, and file cabinet designers were able to design processes that reduced or eliminated certain errors. Medical organizations should incorporate these safety considerations in their processes more often.

A Review of Human Error

A brief review of the concepts and language of human error will be useful. Human error has been studied extensively by cognitive psychologists. Their findings provide concepts and language that are vital to this discussion.

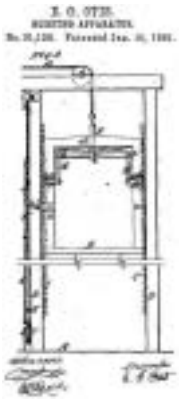


Figure 1.4. Illustration of an elevator brake. Note: Elisha Otis made elevators safe by installing an elevator brake. Otis and his invention are widely credited with making skyscrapers feasible. Photo: © 2003 James E. White, Taletyano Press. Used with permission.

Errors of Intent vs. Errors in Execution

The process humans use to take action has been described in several ways. One description divides the process into two distinct steps: 1) determining the intent of the action, and 2) executing the action based on that intention. Failure in either step can cause an error. Norman[13] divided errors into two categories, mistakes and slips. Mistakes are errors resulting from deliberations that lead to the wrong intention. Slips occur when the intent is correct, but the execution of the action does not occur as intended.

Generally, mistake-proofing requires that the correct intention be known well before the action actually occurs. Otherwise, process design features that prevent errors in the action could not be put in place. This means that Shingo's[4] concept of mistake-proofing is more effective on slips than on mistakes. Norman's definition[14] of the term mistake is more precise and narrower than the common usage of the word.[a]

[a]Andrew P. Dillon translated Shingo's book. His selection of the term "mistake" might have been different had he read Norman.[13] Perhaps it would now be referred to as "slip-proofing." However, since the term mistake-proofing is common, no attempt is made to alter that terminology here.

Rasmussen[14] and Reason[15] divide errors into three types, based on how the brain controls actions. They identify skill-based, rule-based, and knowledge-based actions. Their theory is that the brain minimizes effort by switching among different levels of control, depending on the situation.

Common activities in routine situations are handled using skill-based actions, which operate with little conscious intervention. These are actions that are done on "auto-pilot." Skill-based actions allow you to focus on the creativity of cooking rather than the mechanics of how to turn on the stove. Errors that occur at the skill-based level are comparable to Norman's concept of slips.

Rule-based actions utilize stored rules about how to respond to situations that have been previously encountered. When a pot boils over, the response does not require protracted deliberations to determine what to do. You remove the pot from the heat and lower the temperature setting before returning the pot to the burner.

When novel situations arise, conscious problem solving and deliberation are required. The result is knowledge-based actions. Knowledge-based actions are those actions that use the process of logical deduction to determine what to do on the basis of theoretical knowledge. Every skill- and rule-based action was a knowledge-based action at one time. Suppose you turn a burner on high but it does not heat up. That is unusual. You immediately start to troubleshoot by checking rule-based contingencies. When these efforts fail, you engage in knowledge-based problem solving and contingency planning. Substantial cognitive effort is involved.

Knowledge in the Head vs. knowledge in the World

Norman[13] introduces two additional concepts that will be employed throughout this book. He divides knowledge into two categories:

1. Knowledge in the head is information contained in human memory (Figure 1.5).
2. Knowledge in the world is information provided as part of the environment in which a task is performed (Figure 1.6).

Historically, medicine has focused on improving knowledge in the head. A comprehensive and elaborate mental model of physiology is an example of knowledge in the head. A significant infrastructure has been developed to support this dependence on memory, including lengthy standard operating procedures that indicate how tasks are to be performed. These procedures are not intended to be consulted during the actual performance of the task, but rather to be committed to memory for later recall. Retaining large volumes of instructions in memory so that they are ready for use requires significant ongoing training efforts. When adverse events occur in health care, organizational responses also tend to involve attempts to change what is in the memory of the health care worker. These include retraining the worker who errs, certifying (i.e., testing) workers regularly, attempting to enhance and manage worker attentiveness, and altering standard

Figure 1.5. Work instructions: intended to put knowledge in the head.

Figure 1.6. Work instructions: designed to put knowledge in the world.

operating procedures. The passage of time will erase any gains made once the efforts to change memory are discontinued.

The traditional approach … was to stress the responsibility of the individual … the way to eliminate adverse events is to get individual clinicians to perfect their practices.[16]

Putting "knowledge in the world" is an attractive alternative to trying to force more knowledge into the head. Knowledge can be put in the world by providing cues about what to do. This is accomplished by embedding the details of correct actions into the physical attributes of the process. In health care, for example, mental energies that were used to generate precise action and monitor compliance with procedures stored in memory are now freed to focus on those critical, non-routine deliberations required for the best possible patient care.

How do you recognize knowledge in the world when you see it? Here is a crude rule of thumb: if you can't take a picture of it in use, it probably is not knowledge in the world. Mistake-proofing involves changing the physical attributes of a process, and mistake-proofing devices can usually be photographed. Mistake-proofing is one way of putting knowledge in the world.

The rule is crude because there are gray areas, such as work instructions. If the instructions are visible and comprehensible at the point in the process where they are used, then they would probably be classified as knowledge in the world. Otherwise, work instructions are a means of creating knowledge in the head.

Mistake-Proofing Approaches

There is no comprehensive typology of mistake-proofing. The approaches to error reduction are diverse and evolving. More innovative approaches will evolve, and more categories will follow as more organizations and individuals think carefully about mistake-proofing their processes. Tsuda[17] lists four approaches to mistake-proofing:

1. Mistake prevention in the work environment.
2. Mistake detection (Shingo's informative inspection).
3. Mistake prevention (Shingo's source inspection).
4. Preventing the influence of mistakes.

Each of these four approaches is discussed in more detail below. Additional information about the basics of mistake-proofing and other typologies is available.[4,9,10,16,18]

Tsuda's approaches are similar to those recommended by the Department of Health and the Design Council[19] in England:

- Prevent user error from occurring.
- Alert users to possible dangers.
- Reduce the effect of user errors.

Mistake Prevention in the Work Environment

This approach involves reducing complexity, ambiguity, vagueness, and uncertainty in the workplace. An example from Tsuda[17] is having only one set of instructions visible in a notebook rather than having two sets appear on facing pages. When only one set of instructions is provided, workers are unable to accidentally read inappropriate or incorrect instructions from the facing page.

In another example, similar items with right-hand and left-hand orientations can sometimes lead to wrong-side errors. If the design can be altered and made symmetrical, no wrong-side errors can occur; whether the part is mounted on the left or right side, it is always correct. The orientation of the part becomes inconsequential. Likewise, any simplification of the process that leads to the

elimination of process steps ensures that none of the errors associated with that step can ever occur again.

Norman[13] suggests several process design principles that make errors less likely. He recommends avoiding wide and deep task structures. The term "wide structures" means that there are lots of alternatives for a given choice, while "deep structures" means that the process requires a long series of choices. Humans can perform either moderately broad or moderately deep task structures relatively well. Humans have more difficulty if tasks are both moderately broad and moderately deep, meaning there are lots of alternatives for each choice, and many choices to be made. Task structures that are very broad or very deep can also cause difficulties. More of Norman's recommendations are summarized in Table 1.1.

Another method of mistake prevention in the work environment is the implementation of "visual systems,"[19] also known as 5Ss (Figure 1.7). The term comes from Japanese manufacturing, in which the 5Ss are Seiri (organization), Seiton (orderliness), Seisou (cleanliness), Seiketsu (standardization), and Shitsuke (discipline).

Visual systems involve sharing information in the work environment visually. Individuals in the work environment should be able to "know by looking."[20] A visual workplace is "a work environment that is self-ordering, self-regulating, and self-improving—where what is supposed to happen does happen, on time, every time, day or night—because of visual devices."[21]

Seiri (organization) focuses on removing unneeded items from the workplace. Items that are actually used all the time are sorted from those that are superfluous. Unneeded items are tagged and removed to a holding area to await alternate allocation or disposal.

Table 1.1. Summary of Norman's[13] strategies for putting knowledge in the world

Natural Mappings	Design one-to-one physical correspondence (See figure1.8) between the arrangement of controls and the objects being controlled.
Affordances	Provide guidance about the operation of an object by providing features that allow or afford certain actions.
Visibility	Make observation of the relevant parts of the system possible.
Feedback	Give each action an immediate and obvious effect.
Constraints	Provide design features that either compel or exclude certain actions. Constraints may be physical, semantic, cultural, or logical in nature.

Figure 1.7. Visual systems also known as the 5Ss in Japanese manufacturing.

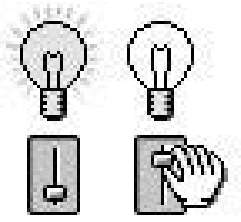


Figure 1.8. No natural mapping here. The right switch turns on the light at left. Illustration Courtesy of BadDesigns.com. Used with permission.

Seiton (orderliness) involves arranging needed items so that they are easy to find, use, and put away. Often, the focus of these efforts is to minimize motion.

Seisou (cleanliness) involves making sure that the workplace is clean and stays clean on a daily basis. Galsworth[20] emphatically states, "It's not about being clean." Rather, it is about creating an environment that can effectively contain and communicate information. This step reduces the visual "noise" that would impede communication.

Seiketsu (standardization) focuses on maintaining and institutionalizing organization, orderliness, and cleanliness. It includes preventive steps that reduce the effort required to maintain the improvements already made.

Shitsuke (discipline) involves avoiding a return to the comfortable behavior of the past. It focuses on aligning the culture and habits of the organization with its new approach to organizing work.

Figure 1.9 shows a series of before and after photos of 5S implementations at a large urban hospital. The photos illustrate how dramatic changes in the environment can encourage the addition of more knowledge in the world.

Note that there are fringe benefits to the 5Ss (in addition to patient safety): Sometimes the unneeded items found while implementing 5S are still valuable. Cleaning two rooms as shown in Figure 1.9 yielded the following:

- $1,600 in hoses (four hoses @ $400 each)
- $1,000 OSI cart
- $ 500 case cart table
- $1,000 in numerous rigid containers

- $4,100 Total

The reduction in clutter also reduced the time spent moving and searching for items by an estimated 156 person hours per year.

Mistake Detection

Mistake detection identifies process errors found by inspecting the process after actions have been taken. Often, immediate notification that a mistake has occurred is sufficient to allow remedial actions to be taken in order to avoid harm. Shingo called this type of inspection informative inspection.[5] The outcome or effect of the problem is inspected after an incorrect action or an omission has occurred. Informative inspection can also be used to reduce the occurrence of incorrect actions. This can be accomplished by using data acquired from the inspection to control the process and inform mistake prevention efforts. Another informative inspection technique is Statistical Process Control (SPC). SPC is a set of methods that uses statistical tools to detect if the observed process is being adequately controlled.

SPC is used widely in industry to create and maintain the consistency of variables that characterize a process.

Shingo[5] identifies two other informative inspection techniques: successive checks and self-checks. Successive checks consist of inspections of previous steps as part of the process. Self-checks employ mistake-proofing devices to allow workers to assess the quality of their own work. Self-checks and successive checks differ only in who performs the inspection. Self-checks are preferred to successive checks because feedback is more rapid.

Setting functions

Whether mistake prevention or mistake detection is selected as the driving mechanism in a specific application, a setting function must be selected. A setting function is the mechanism for determining that an error is about to occur (prevention) or has occurred (detection). It differentiates between safe, accurate conditions and unsafe, inaccurate ones. The more precise the differentiation, the more effective the mistake-proofing can be. Chase and Stewart[19] identify four setting functions that are described in Table 1.2.

Before

After

Figure 1.9. Examples of 5S implementation. Is the before or the after environment capable of communicating more information?

Table 1.2. Setting functions

Setting Function	Description
Physical (Shingo's contact)	Checks to ensure the physical attributes of the product or process are correct and error-free.
Sequencing (Shingo's motion step)	Checks the precedence relationship of the process to ensure that steps are conducted in the correct order.
Grouping or counting (Shingo's fixed value methods)	Facilitates checking that matched sets of resources are available when needed or that the correct number of repetitions has occurred.
Information enhancement	Determines and ensures that information required in the process is available at the correct time and place and that it stands out against a noisy background.

Control functions. Once the setting function determines that an error has occurred or is going to occur, a control function (or regulatory function) must be utilized to indicate to the user that something has gone awry. Table 1.3 describes four categories of control functions for detecting and preventing mistakes.[22] Table 1.4 shows medical examples for each cell described in Table 1.3.

Not all mistake-proofing is equally useful. Usually, mistake prevention is preferred to mistake detection. Similarly, forced control, shutdown, warning, and sensory alert are preferred, in that order. The preferred devices tend to be those that are the strongest and require the least attention and the least discretionary behavior by users.

Mistake Prevention

Mistake prevention identifies process errors found by inspecting the process before taking actions that would result in harm. The word "inspection" as it is used here is broadly defined. The inspection could be accomplished by physical or electronic means without human involvement. The 3.5-inch disk drive is an example of a simple inspection technique that does not involve a person making a significant judgment about the process. Rather, the person executes a process and the process performs an inspection by design and prevents an error from being made. Shingo[5] called this type of inspection "source inspection." The source or cause of the problem is inspected before the effect—an incorrect action or an omission—can actually occur. Donald Norman's concept of forcing functions[13] is also included in mistake prevention. He calls them forcing functions because they are designed to force, or ensure, that correct actions occur.

Preventing the Influence of Mistakes

Preventing the influence of mistakes means designing processes so that the impact of errors is reduced or eliminated. This can be accomplished by facilitating correction or by decoupling processes.

Table 1.3. Control (or regulatory) functions		
Regulator function	Mistake prevention	Mistake detection
Forced control	Physical shape and size of object or electronic controls detect mistakes that are being made and stop them from resulting in incorrect actions or omissions.	Physical shape and size of object or electronic controls detect incorrect actions or omissions before they can cause harm.
Shut down	The process is stopped before mistakes can result in incorrect actions or omissions.	The process is stopped immediately after an incorrect action or omission is detected.
Warning	A visual or audible warning signal is given that a mistake or omission is about to occur. Although the error is signaled, the process is allowed to continue.	A visual or audible warning signal is given that a mistaken action or omission has just occurred.
Sensory alert	A sensory cue signals that a mistake is about to be acted upon or an omission made. The cue may be audible, visible, or tactile. Taste and smell have not proved to be as useful. Sensory alerts signal mistakes but allow the process to continue.	A sensory cue signals that a mistake has just been acted upon or an omission has just occurred (Figure 1.10).

Facilitating correction. This could include finding easy and immediate ways of allowing workers to reverse the errors they commit. While doing things right the first time is still the goal, effortless error corrections can often be nearly as good as not committing errors at all. This can be accomplished through planned responses to error or the immediate reworking of processes. Typewriters have joined mimeograph machines and buggy whips as obsolete technology because typing errors are so much more easily corrected on a computer. Errors that once required retyping an entire page can now be corrected with two keystrokes. Software that offers "undo" and "redo" capabilities also facilitates the correction of errors (Figure 1.11). Informal polls suggest that people use these features extensively. Some users even become upset when they cannot "undo" more than a few of their previous operations. Also, computers now auto-correct errors like "thsi" one.

Figure 1.10. Smell as a sensory alert has been used in natural gas delivery. An additive, mercaptan, is used to create an unpleasant smell, so that gas leaks can be detected. [23,24]

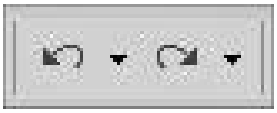
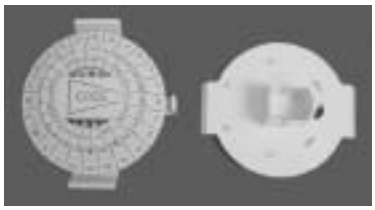


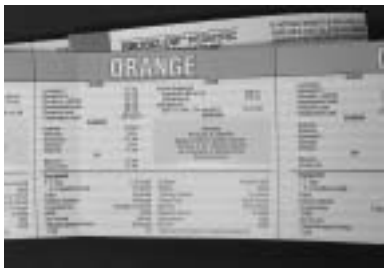
Figure 1.11. "Undo and Redo" allow users to prevent the influence of mistakes.

Table 1.4. Medical examples of control functions

Effect	Prevent error	Detect error
Forced control	Pre-mix scald anti-scald valve	Infant abduction sensor locks the exit in case of an abduction
	 For a detailed description, see Chapter 5, example 5.2.	 For a detailed description, see Chapter 8, example 8.1.
Shut down	Medical gas connectors with indexing pins  For a detailed description, see Chapter 5, example 5.4.	Bloodloc™  For a detailed description, see Chapter 7, example 7.8.

(continued)

Table 1.4. Medical examples of control functions (continued)

Effect	Prevent error	Detect error
Warning	Computerized physician order entry  For a detailed description, see Chapter 8, example 8.9.	Esophageal intubation detector  For a detailed description, see Chapter 5, example 5.6.
Sensory alert	Broselow® Tape   For a detailed description, see Chapter 7, example 7.1.	Sign your site  For a detailed description, see Chapter 7, example 7.11.

These features significantly increase the effectiveness of users. They did not come into being accidentally but are the result of intentional, purposeful design efforts based on an understanding of the errors that users are likely to make.

Automotive safety has been enhanced by preventing the influence of mistakes. Air bags do not stop accidents. Rather, they are designed to minimize injuries experienced in an accident. Antilock brakes also prevent the influence of mistakes by turning a common driving error into the correct action. Prior to the invention of antilock brakes, drivers were instructed not to follow their instincts and slam on the brakes in emergencies. To do so would increase the stopping distance and cause accidents due to driver error. Pumping the brakes was the recommended procedure. With anti-lock brakes, drivers who follow their instincts and slam on the brakes are following the recommended emergency braking procedure. What once was an error has become the correct action.

"Decoupling" means separating an error-prone activity from the point at which the error becomes irreversible. Software developers try to help users avoid deleting files they may want later by decoupling. Pressing the delete button on an unwanted e-mail or computer file does not actually delete it. The software merely moves it to another folder named "deleted items," "trash can," or "recycling bin." If you have ever retrieved an item that was previously "deleted," you are the beneficiary of decoupling. Regrettably, this type of protection is not yet available when saving work. The files can be overwritten, and the only warning may be a dialogue box asking, "Are you sure?"

Sometimes the separation of the error from the outcome need not be large. Stewart and Grout[25] suggest a decoupling feature for telephoning across time zones.

> The first outward manifestation of forgetting or miscalculating the time difference is the bleary eyed voice of a former friend at 4:00 a.m. local time instead of the expected cheery voice at a local time of 10:00 a.m. One way to decouple the chain would be to provide an electronic voice that tells the caller the current time in the location being called. This allows the caller to hang up the phone prior to being connected and thus avoid the mistake.

Customer and provider mistake-proofing. Chase and Stewart[26] point out that in service operations, as opposed to manufacturing, mistake-proofing is needed for both the person providing the service and the person receiving the service. They assert that "one-third of customer complaints relate to problems caused by the customers themselves." In health care, this means that mistake-proofing that helps the health care professional perform tasks correctly is not

Figure 1.12. Problem (Left): Where is the chart in the photo?
Solution (Right): hang the chart on a door knob where other items are less likely to be placed over it, and where the number of possible locations to search for it is dramatically reduced.

enough. Chase and Stewart[26] divide the mistake-proofing of both providers' efforts and customers' actions into three categories each. As shown in Table 1.5, the categories for providers are task, treatment, and tangibles; the categories for customers are preparation, encounter, and resolution.

Preparation for mistake-proofing. Patients should know the location of their charts so home health workers can consult the charts to ensure the care they are planning to provide is correct and appropriate. The patient error lies in not keeping the chart accessible. It takes only a few moments for the chart to be covered with clutter (Figure 1.12).

The "solution" presented in Figure 1.12 is not "strong mistake-proofing." A patient would not be prohibited from moving the chart to a good hiding place. However, in actual practice the solution improves safety and productivity. (For a detailed description, see Chapter 7, example 7.2).

Attributes of Mistake-Proofing

Several attributes of mistake-proofing are presented below. Although this book extols its benefits, mistake-proofing can encompass liabilities as well as benefits. It is equally important to know what mistake-proofing cannot do and which liabilities need to be addressed, as it is to know what mistake-proofing can do to reduce errors.

Mistake-Proofing is Inexpensive

The cost of mistake-proofing devices is often the fixed cost of the initial installation plus minor ongoing calibration and maintenance costs. Shingo's book contains 112 examples.[4] He provides the cost (in 1986 U.S. dollars) of each example. Their distribution is shown in Table 1.6. The median cost of a device is approximately $100. Ninety percent of the devices cost $1,000 or less. Others[26,27] implementing mistake-proofing report similar outcomes. A device's incurred cost per use can be zero, as it is with the 3.5-inch diskette drive. The cost per use can also be negative in cases in which the device actually enables the process to proceed more rapidly than before.

Table 1.5. Areas of focus for service provider and customer mistake-proofing

Service Providers	
Task	Doing work incorrectly, not requested, wrong order, too slowly.
Treatment	Lack of courteous, professional behavior.
Tangible	Errors in physical elements of service.
Customers	
Preparation	Failure to bring necessary materials, understand role, or engage correct service.
Encounter	Inattention, misunderstanding, or memory lapses.
Resolution	Failure to signal service failure, provide feedback, or learn what to expect.

Table 1.6. Implentation cost for Shingo's mistake-proofing examples[4]

Cost (1986 U.S. Dollars)	Probability	Cumulaltive Probability
Cost ≤$25	25.5%	25.5%
$25 < Cost ≤$100	29.1%	54.6%
$100 < Cost ≤$250	23.6%	78.2%
$250 < Cost ≤$1,000	13.6%	91.8%
Cost > $1,000	8.2%	100.0%

The costs of implementing mistake-proofing in health care may be greater than the associated costs in manufacturing. More caution will be required to assess all possible risks of implementation. In some cases, clinical trials will be needed to ensure the efficacy of the device. In others, regulatory approval will be needed. All these steps will add to the cost.

At this writing, many health care providers are implementing bar coding, computerized physician order entry (CPOE), and robotic pharmacies (Figure 1.13). These are technologically sophisticated examples of mistake-proofing, which are effective responses to human error but are very complex and expensive to implement. They are not typical of the majority of mistake-proofing approaches, which are based on simplicity and ingenuity.

Bar coding and CPOE are technologically sophisticated examples of mistake-proofing.

In manufacturing, where data are available, mistake-proofing has been shown to be very effective. There are many management tools and techniques available to manufacturers. However, many manufacturers are unaware of mistake-proofing.

The TRW Company reduced its defect rate from 288 parts per million (ppm) defective to 2 parts per million.[29]

Figure 1.13. The inventory picking arm of a robotic pharmacy.

Federal Mogul had 99.6 percent fewer customer defects than its nearest competitor and a 60 percent productivity increase by systematically thinking about the details of their operation and implementing mistake-proofing.[30] DE-STA-CO manufacturing reduced omitted parts from 800 omitted ppm to 10; in all modes, they reduced omitted parts from 40,000 ppm to 200 ppm and, once again, productivity increased as a result.[31] These are very good results for manufacturing. They would be phenomenal results in health care. Patients should be the recipients of processes that are more reliable than those in manufacturing. Regrettably, this is not yet the case.[1]

Mistake-Proofing Can Result in Substantial Returns on Investment

Even in manufacturing industries, however, there is a low level of awareness of mistake-proofing as a concept. In an article published in 1997, Bhote[32] stated that 10 to 1, 100 to 1, and even 1,000 to 1 returns are possible, but he also stated that awareness of mistake-proofing was as low as 10 percent and that implementation was "dismal" at 1 percent or less.

Exceedingly high rates of return may seem impossible to realize, yet Whited[33] cites numerous examples. The Dana Corporation reported employing one device that eliminated a mode of defect that cost $.5 million dollars a year. The device, which was conceived, designed, and fabricated by a production worker in his garage at home, cost $6.00. That is an 83,333 to 1 rate of return for the first year. The savings occur each year that the process and the device remain in place.

A worker at Johnson & Johnson's Ortho-Clinical Diagnostics Division found a way to use "Post-It® Notes" to reduce defects and save time that was valued at $75,000 per year. If the "Post-It® Notes" cost $100 per year, then the return on investment would be 750 to 1. These are examples of savings for a single device.

Lucent Technologies' Power System Division implemented 3,300 devices over 3 years. Each of these devices contributed a net savings of approximately $2,545 to their

company's bottom line The median cost of each device was approximately $100. The economics in medicine are likely to be at least as compelling. A substantial amount of mistake-proofing can be done for the cost of settling a few malpractice suits out of court.

Mistake-proofing Is Not a Stand-Alone Technique

It will not obviate the need for other responses to error. Chapter 2 includes a discussion of how mistake-proofing relates to other common patient safety initiatives.

Mistake-Proofing Is Not Rocket Science

It is detail-oriented and requires cleverness and careful thought, but once implementation has been completed, hindsight bias will render the solution obvious. Chapter 3 presents tools and techniques that help to create mistake-proofing devices and analyze their impact on the process.

Mistake-Proofing Is Not a Panacea

It cannot eliminate all errors and failures from a process. Perrow[34] points out that no scheme can succeed in preventing every event in complex, tightly-linked systems. He argues that multiple failures in complex, tightly-linked systems will lead to unexpected and often incomprehensible events. Observers of these events might comment in hindsight, "Who would have ever thought that those failures could combine to lead to this?" Perrow's findings apply to mistake-proofing as they do to any other technique. Mistake-proofing will not work to block events that cannot be anticipated. Usually, a good understanding of the cause-and-effect relationship is required in order to design effective mistake-proofing devices. Therefore, the unanticipated events that arise from complex, tightly-linked systems cannot be mitigated using mistake-proofing.

Although health care is a complex, tightly-linked system, many potential adverse events can be anticipated. In fact, some of the more common errors occur in hospitals daily or hourly. When a patient is misidentified, a specimen is mislabeled, or a wrong-site operation occurs, people familiar with patient safety will not say, "Wow. Who would ever have believed that could happen?" It is in this domain of anticipated events that mistake-proofing is beneficial.

Mistake-Proofing Is Not New

It has been practiced throughout history and is based on simplicity and ingenuity. Mistake-proofing solutions are often viewed post hoc as "common sense." Senders and Senders[35] provide an example of mistake-proofing, the dispensing of medications in the mid-1800s (Figure 1.14). Bottles of poison are variously identified by their rectangular shape, blue-colored glass, or the addition of small spikes to make an impression on inattentive pharmacists. Most organizations will find that examples of mistake-proofing already exist in their processes. The implementation of mistake-proofing, then, is not entirely new but represents a refocusing of attention on certain design issues in the process.

Figure 1.14. "Dangerous" medication bottle from mid-1800s.

Creating Simplicity Is Not Simple

In hindsight, mistake-proofing devices seem simple and obvious. A good device will lead you to wonder why no one thought of it before. However, creating simple, effective, mistake-proofing devices is a very challenging task. Significant effort should be devoted to the design process. Organizations should seek out and find multiple approaches to the problem before proceeding with the implementation of a solution.

This book is intended to help organizations design mistake-proofing devices. Its goal is to provide a process and a vocabulary for thinking about patient safety and error reduction. It is hoped that this book will also help reduce the amount of creativity needed to devise novel approaches to eliminating problems and reducing risk. Each organization's mistake-proofing needs may be different, depending on the differences in their processes. Consequently, some mistake-proofing solutions will require new, custom-made devices designed specifically for a given application. Other devices could be off-the-shelf solutions. Even off-the-shelf devices will need careful analysis—an analysis that will require substantial process understanding–in the light of the often subtly idiosyncratic nature of their own processes.

Chapter 2 reviews current patient safety tools and proposes a flowchart view of how existing tools inform the process of mistake-proofing device design or selection. Existing tools provide the foundation of process understanding that enable us to make sense of events and errors, which is vital to effective mistake-proofing. Mistake-proofing cannot be effective without a sound understanding of what happens in the process and why. Chapter 3 proposes a new use for an existing tool and combines it with other tools to facilitate mistake-proofing efforts. Chapter 4 is devoted to discussing important design issues, caveats, and limitations of mistake-proofing. Chapters 5, 6, 7, and 8 provide examples of mistake-proofing in health care. Chapter 9 describes a path forward and suggests resources to help make mistake-proofing successful.

Implementing Mistake-Proofing in Health Care

Implementing mistake-proofing in medical environments will probably be more challenging and difficult than implementing the same techniques in manufacturing. An unranked list of opportunities and difficulties is provided in Table 1.7. The difficulties are not provided as excuses or reasons why mistake-proofing should not be implemented but rather as guides to what can be expected as implementation progresses. The impact of these concerns can be mitigated by early acknowledgment of their effects on the process.

Legal Liability and Discoverability

Telling quality improvement stories requires great care. Claiming great improvements could implicitly reveal previous shortcomings. In claiming the “after,” one must own up to the “before.” This is not a significant concern in manufacturing applications because the problems are rarely safety related. Disgruntled customers simply get their money back or receive a replacement product. Remedies for poor quality in medicine are not as easily attained.

Mistake-proofing devices are physical evidence that actions have been taken to ensure patient safety. Although this book contains only examples of good practices, many of its contributors prefer to remain anonymous. Risk managers and medical system lawyers differ widely in their levels of concern about disclosing mistake-proofing devices. For this book, the range of concerns included individuals who were proud of their efforts and willing to receive all credit due them to those who required significant assurances of anonymity.

Table 1.7. Comparison of medical mistake-proofing applications with those in other industries		
1.	Legal liability and discoverability (need for anonymity?).	Difficulty
2.	Lack of shared examples.	Difficulty
3.	Careful assessment of down-side risk.	Difficulty
4.	Culture of depending on individuals, not on systems.	Difficulty
5.	Processes that depend on individuals, not on systems: lack of consistent process.	Difficulty
6.	Resource shortages.	Difficulty
7.	Medical applications that focus more on information counter-measures.	Difficulty
8.	Low barriers to diffusion.	Opportunity
9.	Substantial buying power.	Opportunity

Concerns with the litigious environment surrounding health care will remain an impediment to mistake-proofing implementation for some time to come. In addition to existing channels like the Agency for Healthcare Research and Quality's (AHRQ) Web M&M (Morbidity and Mortality) and the National Patient Safety Foundation's (NPSF) listserv, more options for "safe" (perhaps anonymous) dialogue and information sharing should be sought.

Lack of Shared Examples

Manufacturing benefits from a set of four resources[4,9,10,11] with 702 published examples. These examples provide a large set of existing solutions and approaches to problems; solutions that can stimulate thinking about additional approaches. Until now, there was no comparable set of examples of mistake-proofing in medicine. This book provides a starting place for sharing medical examples. It is not comprehensive. There are many more examples to collect for this ongoing effort.

Add to the body of knowledge in medical mistake-proofing: Submit any examples that you know of that do not appear in this book. Submissions can be made (anonymously, if desired) at www.mistakeproofing.com/medical.

Careful Assessment of Down-Side Risk

In manufacturing, one can afford to be more cavalier in trying new things. In fact, Hirano[36] proposes the following heuristic: if a device is found to have greater than a 50 percent chance of success for mistake-proofing, then it should be tried immediately. The parts can be discarded if the experiment does not work. In health care, this approach is often unacceptable, given the requirement of a careful assessment of the patient safety risk of each new mistake-proofing device. Where there is risk of patient harm, careful analysis and clinical trials may be needed. However, experimenting with a device theoretically[b] will

[b]Practically, experimenting with a device could reduce patient safety if users depend on the device instead of exercising normal levels of care and attentiveness. See the discussion of Risk Homeostasis in Chapter 4 for more information.

not make the patient "worse off" in cases in which current controls depend entirely on human attentiveness for their accuracy. If the mistake-proofing device is also a medical device, it must adhere to the same rigorous regulatory approval process required for any other device.

A Culture of Depending on People, Not on Systems

The traditional approach within medicine has been to stress the responsibility of the individual and to encourage the belief that the way to eliminate adverse events is to get individual clinicians to perfect their practices. This simplistic approach not only fails to address the important and complex system factors that contribute to the occurrence of adverse events but also perpetuates a myth of infallibility that is a disservice to clinicians and their patients.[37]

The reasons are found in the culture of medical practice… Physicians are socialized in medical school and residency to strive for error-free practice… Physicians are expected to function without error, an expectation that physicians translate into the need to be infallible.[38]

The medical culture makes implementing mistake-proofing more difficult because health care professionals are accustomed to looking for solutions involving "knowledge in the head." Getting them to consider "knowledge in the world" can be very challenging. Some aspects of the implementation may challenge long-held assumptions, beliefs, and values associated with behavior and accountability.

Barry, Murcko, and Brubaker[39] discuss this issue regarding medical software interfaces.

> The complex displays allow the specialists to apply their mastery and preserve the special knowledge they have acquired. The experts do not see a need for any help, and they do not want any help. In fields other than health care, giving experts help, even if they do not want it, is found to reduce error rates.
>
> Perhaps this is the case in the health care field, too: even though experts do not want help, maybe they could use a little anyway, for the good of the cause. Computer displays should make doing the right thing easier than doing the wrong thing… They should make it obvious, immediately, when the wrong thing has been done… All these ideas are not only common sense, they are poka-yoke.

Processes that Depend on People, Not on Systems

In medicine, the dependence on the individual is cultural, and it is exhibited in processes managed within that culture. As a result, medical processes are often customized by each practitioner of the art. Noted doctors and patient safety advocates have questioned whether there are processes in medicine at all. The lack of consistent processes will make implementation of mistake-proofing more difficult in medicine than in manufacturing. Inconsistent processes are more difficult to mistake-proof because there are fewer predictable elements that can be used to check the process.

Resource Shortages

Ideally, changes will liberate additional resources, but adequate resources are required to make those changes possible. Adequate resources and staffing levels enable process improvement. A shortage of nurses, other staff, or resources will generally make mistake-proofing more difficult. See the section of Chapter 4, titled, "Spending Too Much or Not Enough" for additional information about the ironic situations that can prevent organizations from allocating resources to process improvement efforts.

More Focus on Information Enhancement Devices

Mistake-proofing in manufacturing has primarily focused on physical, sequencing, and grouping and counting mistake-proofing devices. More information-enhancement

devices should be anticipated as mistake-proofing is more widely implemented in service industries. Health care services involve numerous "matching" tasks. These are tasks in which specific medications, medical devices, processes, and procedures are matched to specific, individual patients during specific time intervals. These tasks require the availability of substantial amounts of usable, accurate information. Mistake-proofing devices for information enhancement are needed in these circumstances. Increasing the proportion of theses devices will be challenging. There is a need for the invention and documentation of newer and better examples of these mistake-proofing devices.

Low Barriers to Diffusion

Health care enjoys an advantage over manufacturing. Because much of health care competition is geographically based, new devices can be shared with less impact on competitive advantage than there would be in the manufacturing sector. Consequently, mistake-proofing devices that would be cloaked in secrecy to foster a competitive advantage in manufacturing are more likely to be shared in the health care environment.

Substantial Buying Power

Vendors have already begun to use patient safety improvements as a marketing tool. Hospital systems and large payers possess the buying power to specify safer designs and to seek out vendors willing to provide them. Health care providers should employ a practice that Leenders and Blenkhorn[40] called "reverse-marketing." Their concept is to reverse the roles of supplier and buyer so that buyers are marketing ideas to their suppliers. Traditionally, the supplier tries to persuade the buyer to buy, but in reverse marketing the buyer tries to persuade the supplier to supply. That is, the buyer exerts influence on suppliers to encourage them to produce what the buyer wants. Leenders and Blenkhorn[38] argue that purchasing managers are mistaken in their impression that they have most of the power in the transaction because they make the final purchasing decision. The authors make a convincing case that suppliers, by having control over which product configurations are offered, have much more power to shape transactions, and that purchasers should attempt to take some of that power back by trying to influence what is offered. The British National Health Service is making an effort to shape the product offerings that affect them by seeking improved labeling of medications using this type of proactive approach (see Chapter 8, example 8.29). Larger medical systems, for-profit hospital chains, government-run hospital systems, and payer groups could be very persuasive in convincing suppliers to change the designs of equipment, devices, and supplies.

Conclusion

Mistake-proofing involves designing changes into the physical aspects of the design of processes. Design changes can prevent mistakes by simplifying or clarifying the work environment, making mistakes less likely. Mistakes can also be prevented by inspecting the source or cause of errors so that the effect cannot occur. When this is not possible, mistakes should be detected rapidly, prior to causing harm, or while remediation is still relatively easy. If the mistake itself cannot be prevented or effectively detected, then preventing the influence of mistakes (the harm) may be warranted. These mistake-proofing techniques should be applied to actions taken by patients and their loved ones as well as to the actions of health care professionals.

Changing the design of health care processes and creating mistake-proofing devices is not a simple task. Careful deliberation and analysis will be required. In some ways, implementing mistake-proofing will be more difficult in health care environments than in other industries. There are, however, efforts to lay the foundation for successful implementation already underway. Chapter 2 describes these efforts.

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Chapter 2. Relationships to Existing Patient Safety Efforts and Tools

Introduction

After the publication of the Institute of Medicine (IOM) report, *To Err is Human*,[1] patient safety deficits moved to the forefront of public attention. The goal of the report was a challenging one: to reduce medical errors by half in 5 years. Those 5 years have passed, and substantial effort has been invested in reducing errors in health care. This chapter focuses on how many of these efforts relate to mistake-proofing and how new tools can contribute to improved patient safety.

Mistake-proofing has been used effectively in other industries and has been adopted in medicine as an artifact of common sense applied to processes. More can be done. In many cases, mistake-proofing will fit into a variety of existing efforts to improve patient safety. In other cases, it provides an effective alternative direction to seek improvement in the face of ineffective actions.

Relationships to Existing Patient Safety Efforts

The relationship of mistake-proofing to current patient safety efforts is shown in Table 2.1. Many of the efforts to improve patient safety are important enablers of mistake-proofing. They create a foundation for, or aid in, mistake-proofing implementation. Others are areas of opportunity in which existing patient safety efforts create resources for identifying likely mistake-proofing projects. Some efforts address the same problems as mistake-proofing. While these techniques are listed as competing there is no requirement for mutual exclusivity. Multiple approaches are not only possible, they are recommended. In cases in which some competing approaches are onerous or ineffective, mistake-proofing can reduce the scope and burden of these efforts so that they may be used only where they are needed most. Table 2.1 includes some overlapping concepts; both "creating a just culture" and "enhancing attentiveness," for example, can be seen as subsets of safety culture. Each of the relationships in Table 2.1 is also discussed in the next several pages.

Mistake-proofing has been used effectively in other industries and has been adopted in medicine as an artifact of common sense as applied to processes.

Safety Culture

Safety culture is a set of attitudes, values, perceptions, norms, and behaviors that tend to reduce the likelihood of unsafe acts, and which encourage thorough disclosure of, and learning from, adverse events.[3] Safety culture also includes norms of high reliability organizations, as described by Weick and Sutcliffe:[4]

1. Preoccupation with failure.
2. Reluctance to simplify interpretations.
3. Sensitivity to operations.
4. Commitment to resilience.
5. Deference to expertise.

Just Culture[a]

Just culture refers to a working environment that is conducive to "blame-free" reporting but also one in which accountability is not lost.[5] Blame-free reporting ensures that those who make mistakes are encouraged to reveal them without fear of retribution or punishment. A policy of not blaming individuals is very important to enable and facilitate event reporting which in turn, enables mistake-proofing. The concern with completely blame-free reporting is that egregious acts, in which punishment would be appropriate, would go unpunished. Just culture divides behavior into three types: normal, risk-taking, and reckless. Of these, only reckless behavior is punished.

[a]For more information on Just Culture, see *Patient Safety and the just culture: A primer for health care executives* by David Marx, JD (2001), on the Web at www.mers-tm.net/support/Marx_Primer.pdf.

Table 2.1. How mistake-proofing fits into common patient safety improvement efforts

Direction	Relationship	Comment
Safety culture	Enabler	Efforts to shape the norms and values of an organization to focus on creating safety-conscious behaviors and to commit significant organizational resources to achieve patient and worker safety.
Just culture	Enabler	A subset of safety culture. Provides an open environment—one in which errors are viewed as opportunities to learn rather than events to be punished—which encourages increased event reporting.
Event reporting	Enabler	Disclosing adverse events and errors that need remedial action to prevent them in the future.
Root cause analysis	Enabler	Identifies causes "that we can act upon such that it meets our goals and objectives and is within our control."[2] Mistake-proofing cannot be done without a clear knowledge of the cause and effect relationships in the process.
Corrective action systems	Area of opportunity	Policies and procedures that ensure causes of events are properly resolved and remedial actions are taken.
Specific foci	Areas of opportunity	Those efforts in which the special focus is on particular outcomes or events, including falls, nosocomial infections, medication errors, and wrong-site surgery.
Simulation	Area of opportunity and venue for validation	Builds correct, conditioned responses; provides a laboratory for identifying and validating the effectiveness of mistake-proofing projects.
Technology	Subset	Includes bar coding, computerized physician order entry (CPOE), and robotic pharmacies; expensive, complex, more technologically sophisticated version of mistake-proofing.

Table 2.1. How mistake-proofing fits into common patient safety improvement efforts (continued)

Direction	Relation	Comment
Facility design	Complementary or a subset	Using building layout and design to put knowledge in the world is effective but difficult with large, long-lived existing infrastructure.
Revise standard operating procedures (SOPs)	Competing or complementary	Choosing to lengthen SOPs or increase their complexity is an easy but often ineffective alternative to mistake-proofing. Simplifying processes and providing clever work aids can complement or border on being mistake-proofing.
Attention management	Competing (partially)	Mistake-proofing can reduce the need for some aspects of attentiveness; it frees staff members to attend to more important issues that are more difficult to mistake-proof.
Crew resource management (CRM)	Complementary	Some mistake-proofing devices reduce the need to attend to process details. This reduced cognitive load can free resources and facilitate effective participation in decisionmaking typical in CRM.
Failure modes and effects analysis (FMEA) or failure modes, effects, and criticality analysis (FMECA)	Area of opportunity design tool	FMEA and FMECA identify and prioritize improvement efforts. Effective FMEA requires actions that lead to redundancy or mistake-proofing.
Fault trees/probabilistic risk assessment	Area of opportunity design tool	Identify all known causes of an event and the probabilities of their occurrence. This is vital information in creating informed design decisions about mistake-proofing devices. A non-traditional application of this tool is presented in Chapter 3.

Event Reporting

Event reporting refers to actions undertaken to obtain information about medical events and near-misses. The reporting reveals the type and severity of events and the frequency with which they occur. Event reports provide insight into the relative priority of events and errors, thereby enabling the mistake-proofing of processes. Consequently, events are prioritized and acted upon more quickly according to the seriousness of their consequences.

Root Cause Analysis

Root cause analysis (RCA) is a set of methodologies for determining at least one cause of an event that can be controlled or altered so that the event will not recur in the same situation. These methodologies reveal the cause-and-effect relationships that exist in a system. RCA is an important enabler of mistake-proofing, since mistake-proofing cannot be accomplished without a clear knowledge of the cause-and-effect relationships in the process. Care should be taken when RCA is used to formulate corrective actions, since it may only consider one instance or circumstance of failure. Other circumstances could also have led to the failure. Other failure analysis tools, such as fault tree analysis, consider all known causes and not just a single instance. Anticipatory failure determination[6] (AFD™) facilitates inventing new circumstances that would lead to failure given existing resources.

Corrective Action Systems

Corrective action systems are formal systems of policies and procedures to ensure that adverse events are analyzed and that preventive measures are implemented to prevent their recurrence. Normally, the occurrence of an event triggers a requirement to respond with counter-measures within a certain period of time. Mistake-proofing is an effective form of counter-measure. It is often inexpensive and can be implemented rapidly.

It is also important to look at all possible outcomes and counter-measures, not just those observed. Sometimes, mistake-proofing by taking corrective action is only part of the solution. For example, removing metal butter knives from the dinner trays of those flying in first class effectively eliminates knives from aircraft, but does not remove any of the other resources available for fashioning weapons out of materials available on commercial airplanes.[7] This is mistake-proofing but not a fully effective counter-measure.

Corrective action systems can also serve as a resource to identify likely mistake-proofing projects. Extensive discussion and consultation in a variety of industries, including health care, reveal that corrective actions are often variations on the following themes: 1) an admonition to workers to "be more careful" or "pay attention," 2) a refresher course to "retrain" experienced workers, or 3) a change in the instructions, standard operating procedures, or other documentation. All of these are essentially attempts to change "knowledge in the head."[8]

Mistake-proofing is an effective form of counter-measure. It is often inexpensive and can be implemented rapidly.

Chappell[9] states that "You're not going to become world class through just training, you have to improve the system so that the easy way to do a job is also the safe, right way. The potential for human error can be dramatically reduced."

Mistake-proofing is an attempt to do what Norman[8] recommends, put "knowledge in the world." Consequently, corrective actions that involve changing "knowledge in the head" can also be seen as opportunities to implement mistake-proofing devices. These devices address the cause of the event by putting "knowledge in the world."

Not all corrective actions deserve the same amount of attention. Therefore, not all corrective actions should be allotted the same amount of time in which to formulate a response. Determining which corrective actions should be allowed more time is difficult because events occur sequentially, one at a time. Responding to outcomes that are not serious, common, or difficult to detect should not consume too much time. For events that are serious, common, or difficult to detect, additional time should be spent in a careful analysis of critical corrective actions.

Specific Foci

Substantial efforts to improve patient safety have been focused on specific events such as falls, medication errors, use of anesthesia, transfusions, and communication. These specific foci provide areas of opportunity for the implementation of mistake-proofing.

Simulation

There have been many discussions in health care circles concerning the application of methods developed in the aviation industry to improve patient safety. In aviation, simulation is used to train pilots and flight crews. Logically enough, simulators have also begun to be employed in medicine. In addition to training, simulation can provide insights into likely errors and serve as a catalyst for the exploration of the psychological or causal mechanisms of errors. After likely errors are identified and understood, simulators can provide a venue for the experimentation and validation of new mistake-proofing devices.

Technology

Technological solutions to patient safety problems have generated substantial interest. Bar coding and computerized physician order entry (CPOE) systems, in particular, are being widely implemented. Both of these technologies are, in fact, forms of mistake-proofing, despite their tendency to be more expensive and complex than the mistake-proofing characterized in Table 1.6.

Facility Design

The study of facility design complements mistake-proofing and sometimes is mistake-proofing (Figure 2.1). Adjacency, proper handrails and affordances, standardization, and the use of Failure Modes and Effects Analysis (FMEA) as a precursor are similar to mistake-proofing. Ensuring non-compatible connectors and pin-indexed medical gases is mistake-proofing.

Figure 2.1. Floor plan of a hospital room designed with patient safety in mind.
Source: Joint Commission Resources *"Enhancing the traditional hospital design process: a focus on patient safety."* Joint Commission Journal on Quality and Safety. 2004;30(3):115-24. Reprinted with permission.

Revising Standard Operating Procedures

When adverse events occur, it is not uncommon for standard operating procedures (SOPs) to be revised in an effort to change the instructions that employees refer to when providing care. This approach can either improve or impair patient safety, depending on the nature of the change and the length of the SOP. If SOPs become simpler and help reduce the cognitive load on workers, it is a very positive step. If the corrective responses to adverse events are to lengthen the SOPs with additional process steps, then efforts to improve patient safety may actually result in an increase in the number of errors. Evidence from the nuclear industry suggests that changing SOPs improves human performance up to a point but then becomes counterproductive. Chiu and Frick[10] studied the human error rate at the San Onofre Nuclear Power Generation Facility since it began operation. They found that after a certain point, increasing procedure length or adding procedures resulted in an increase in the number of errors instead of reducing them as intended. Their findings are shown in Figure 2.2. Their facility is operating on the right side of the minimum, in the region labeled B. Consequently, they state that they "view with a jaundiced eye an incident investigation that calls only for more rules (i.e., procedure changes or additions), and we seek to simplify procedures and eliminate rules whenever

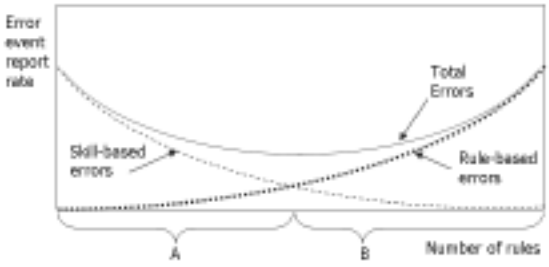


Figure 2.2. Increasing the number of rules can lead to increased error rates. Adapted from Chiu, Frick.[10]

possible." While there is no comparable study in health care, prudence suggests that increases in the complexity of standard operating procedures should be considered carefully to ensure that the benefits of the additional instructions exceed the problems generated by the added complexity. Simplifying processes and providing clever work aids complement mistake-proofing and in some cases may be mistake-proofing. When organizations eliminate process steps, they also eliminate the errors that could have resulted from those steps.

Attention Management

Substantial resources are invested in ensuring that workers, generally, and medical personnel, particularly, are alert and attentive as they perform their work. Attention management programs range from motivational posters in the halls and "time-outs" for safety, to team-building "huddles" (Figure 2.3). Eye-scanning technology determines if workers have had enough sleep during their off hours to be effective during working hours.[11] When work becomes routine and is accomplished on "autopilot" (skill-based[12]), mistake-proofing can often reduce the amount of attentiveness required to accurately execute detailed procedures. The employee performing these procedures is then free to focus on higher level thinking. Mistake-proofing will not eliminate the need for attentiveness, but it does allow attentiveness to be used more effectively to complete tasks that require deliberate thought.

Crew Resource Management

Crew resource management (CRM) is a method of training team members to "consistently use sound judgment, make quality decisions, and access all required resources, under stressful conditions in a time-constrained environment."[13] It grew out of aviation disasters where each member of the crew was problem-solving, and no one was actually flying the plane. This outcome has been common enough that it has its own acronym: CFIT – Controlled Flight Into Terrain.

Mistake-proofing often takes the form of reducing ambiguity in the work environment, making critical information stand out against a noisy background, reducing the need for attention to detail, and reducing cognitive content (see details on cognitive content in Chapter 4). Each of these benefits complements CRM and frees the crew's cognitive resources to attend to more pressing matters.

FMEA or FMECA?

FMEA and FMECA are "virtually the same,"[14] except for a few subtleties that have been more or less lost in practice (hereafter simply referred to as FMEA). These two related tools enable teams to analyze all of the ways a particular component or process can fail, predict what the consequences of that failure would be, and prioritize remedial change actions.

Figure 2.3. "Huddle for Excellence" location marked on pavement near a jet way at Atlanta's Hartsfield Jackson International Airport.

FMEA and FMECA are form- or worksheet-based approaches. Since forms are easily manipulated to meet users' needs, rarely are two forms exactly the same.[15,16,17,18] Regardless of which version of FMEA is selected, certain aspect of the analysis will be included. The FMEA process is begun by creating a graphical description of the sequence of tasks being analyzed, referred to as a process map. Several books are devoted exclusively to process mapping.[19,20,21,22,23] The team lists all the failures that could occur at each task on the FMEA form. The scope of this step must be managed carefully to keep it from becoming tremendously onerous. Often, only a small subset of tasks is considered at one time. After failures have been identified, the potential effects of each failure are specified, and the severity of each is assessed. Potential causes are identified. The team then assesses the likelihood of each occurrence and the probability of detecting the cause before harm is done. The severity, the likelihood of occurrence, and the detectability of each cause are combined into a priority ranking. A common method is to rank severity (sev), likelihood of occurrence (occ), and detectability (det) on a 10-point scale and then multiply them together. The product is often called the risk priority number (RPN). An example of these RPN calculations is shown in Figure 2.4. With FMECA, the risk priority number of each cause is summed to create a mode criticality number. Failure causes (or failure modes for FMECA) are then prioritized, and preventive actions are taken. In Figure 2.4, the cause "strip of labels with multiple patient names mixed" is the highest priority cause. "Order entry error" is the lowest priority. Little indication of what actions should be taken is provided by authors writing about FMEA. However, the logic of FMEA implies that the RPN after the prevention effort should be less severe, less likely to occur, or more easily detected. A detailed discussion is included in Chapter 3.

In an FMEA analysis, rank severity, likelihood, and detectability on a 10-point scale and multiply them to determine the risk priority number (RPN).

Fault Trees

FMEA is a bottom-up approach in the sense that it starts at the component or task level to identify failures in the system. Fault trees are a top-down approach. A fault tree starts with an event and determines all the component (or task) failures that could contribute to that event.

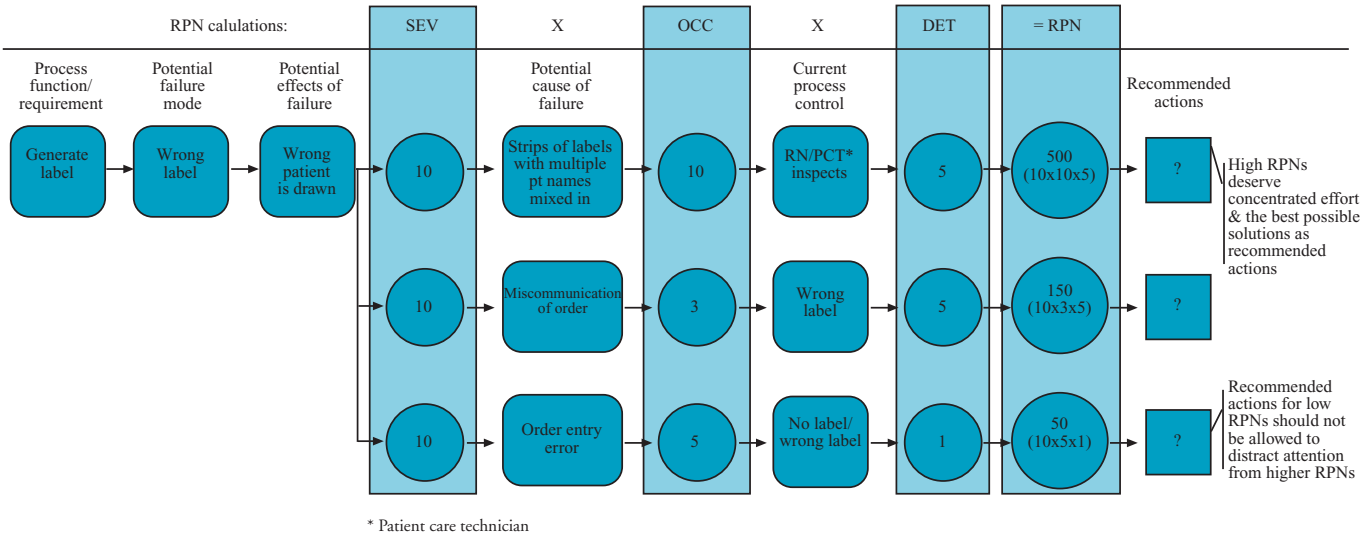


Figure 2.4. RPN calculations.

A fault tree is a graphical representation of the relationships that directly cause or contribute to an event or failure. Figure 2.5 shows a generic fault tree. The top of the tree indicates the failure mode, the "top event." At the bottom of the tree are causes, or "basic failures." These causes can be combined as individual, independent causes using an "OR" symbol. They can be combined using an "AND" symbol if causes must co-exist for the event to occur. The tree can have as many levels as needed to describe all the known causes of the event.

These failures can be analyzed to determine sets of basic failures that can cause the top event to occur, cut sets. A minimal cut set is the smallest combination of basic failures that produces the top event. A minimal cut set leads to the top event if, and only if, all events in the set occur. This concept will be employed in Chapter 3 to assess the performance of mistake-proofing device designs. These minimal cut sets are shown with dashed lines in Figure 2.5.

Fault trees also allow one to assess the probability that the top event will occur by first estimating the probability that each basic failure will occur. In Figure 2.5, the probabilities of the basic failures are combined to calculate the probability of the top event. The probability of basic failures 1 and 2 occurring within a fixed period of time is 20 percent each. The probability of basic failure 3 occurring within that same period is only 4 percent. However, since both basic failures 1 and 2 must occur before the top event results, the joint probability is also 4 percent. Basic failure 3 is far less likely to occur than either basic failure 1 or 2. However, since it can cause the top event by itself, the top event is equally likely to be caused by minimal cut set 1 or 2.

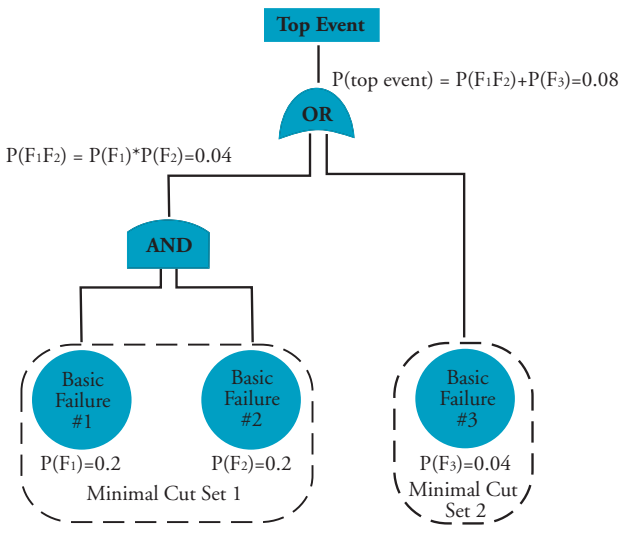


Figure 2.5. A fault tree example. P= probability, F= basic failure.

Two changes can be made to the tree to reduce the probability of the top event: 1) reduce the probability of basic failures, 2) increase redundancy in the system. That is, design the system so that more basic failures are required before a top event occurs. If one nurse makes an error and another nurse double checks it, then two basic failures must occur. One is not enough to cause the top event.

FMEA and fault trees are useful in understanding the range of possible failures and their causes.

The ability to express the interrelationship among contributory causes of events using AND and OR symbols provides a more precise description than is usually found in the "potential cause" column of an FMEA. Potential causes of an FMEA are usually described using only the conjunction OR. It is the fault tree's ability to link causes with AND, in particular, that makes it more effective in describing causes. Gano[2] suggests that events usually occur due to a combination of actions and conditions; therefore, fault trees may prove very worthwhile. FMEA and fault trees are not mutually exclusive. A fault tree can provide significant insights into truly understanding potential failure causes in FMEA.

Knowing What Errors Occur, and Why, Is Not Enough

FMEA and fault trees are useful in understanding the range of possible failures and their causes. The other tools—safety culture, just culture, event reporting, and root cause analysis—lead to a situation in which the information needed to conduct these analyses is available. These tools, on their own, may be enough to facilitate the design changes needed to reduce medical errors. Only fault tree analysis, however, comes with explicit prescriptions about what actions to take to improve the system. These prescriptions, which will be discussed further in Chapter 3, are: increase component reliability or increase redundancy. Fault trees are also less widely known or used than other existing tools. FMEA is far more widely used, in part because it is a popular method of meeting JCAHO's requirement to perform proactive risk assessment.

FMEA calls for action. Most versions of FMEA do not provide explicit prescriptive information about what action to take. Only JCAHO explicitly prescribes redesigning the process. With the exception of the less-utilized fault tree analysis, the tools used in patient safety improvement efforts are currently focused on determining what events and errors occur and what causes them. They are silent about how to fix the problem or prevent the cause of failure from recurring. Even JCAHO,[24] which explicitly identifies redesign as the preferred approach for increasing patient safety, provides little direction about how to accomplish it. JCAHO provides three questions that must be answered at the "redesign the process" step:

1. How can we change the process to prevent this failure mode from occurring?
2. What design/redesign strategies and tools should we use? How do we evaluate their likely success?
3. Who should be involved in the design/redesign process?

These are the crucial questions and, like Fermat's Last Theorem,[b] are left as an exercise for the reader.

A recurring theme in quality improvement literature is that we are good at identifying problems but not so good at devising methods to solve them. Numerous tools are available to define, measure, and analyze quality problems and control processes. Six-sigma is a popular quality improvement framework. It has an improvement cycle that involves five problem-solving steps: define, measure, analyze, improve, and control. The tools available to actually conceive of what the improvement should be are limited. In a 191-page quality management quick reference guide,[25] only 12 pages were devoted to tools for actually improving the process (Figure 2.6). Worse, those pages are devoted to managing the process of implementing the improvement, not how to determine what the improvement should be.

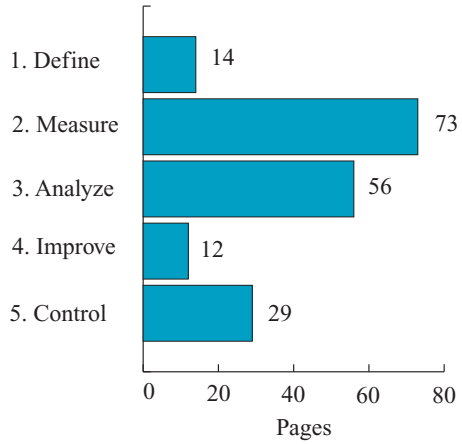


Figure 2.6. Six-sigma process improvement step—distribution of coverage length in pages.

[b]Pierre de Fermat (1601-1665) was a French lawyer and number theorist known for his last theorem, which was discussed for hundreds of years until it was solved in 1995 by mathematician Andrew John Wiles (1953-). Wiles had been working on solving the theorem since 1963. The Last Theorem states that $x^n + y^n = z^n$ has no non-zero integer solutions for x, y, and z when $n > 2$.

See http://www. groups.css.st-and.ac.uk/~history/HistTopics/Fermat's_Last_theorem.html.

Determining what the improvement should be is an inventive problem that will require some creativity. Tools to facilitate the inventive solution to determining how to design devices that will mistake-proof the process are introduced in the next section and presented in detail in Chapter 3.

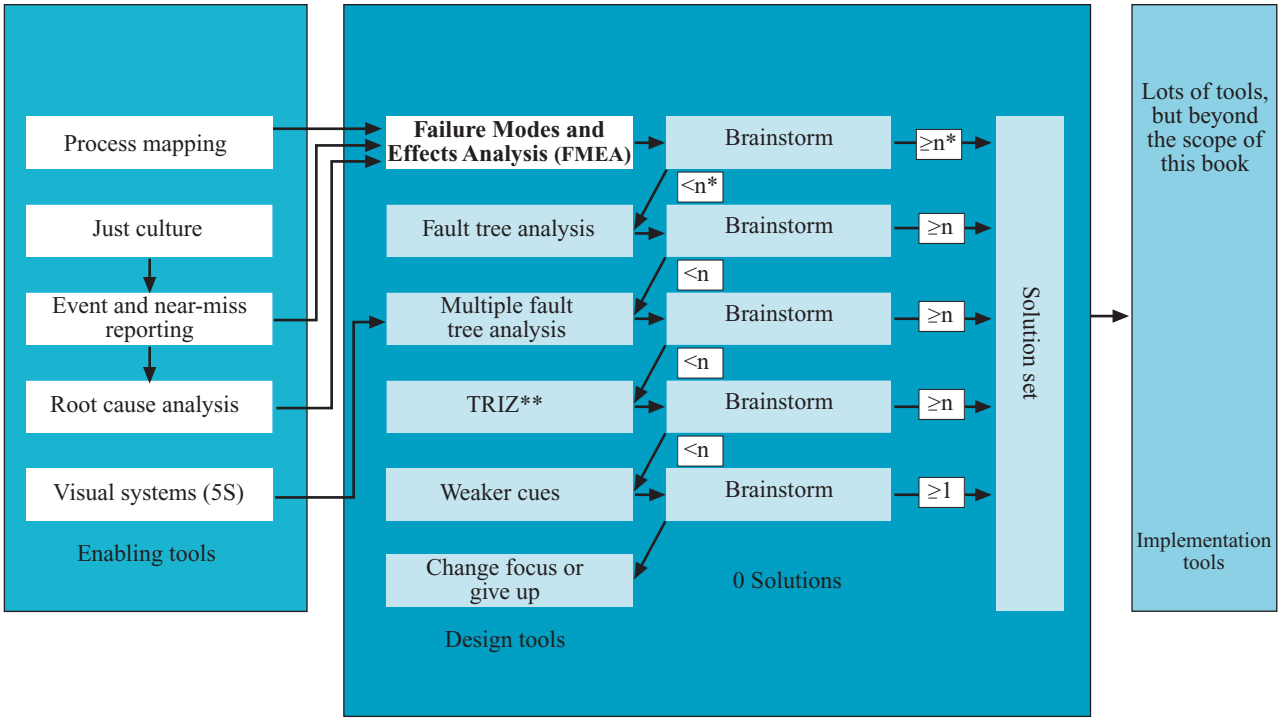
Using the Tools Together

Figure 2.7 shows a flowchart of how patient safety tools can be used together with other management tools to reduce human error and create mistake-proofing devices.

Enabling Tools

The box to the left in Figure 2.7 contains enabling tools that provide a foundation for designing effective mistake-proofing devices. The design tools in the center box require detailed information about the process and a thorough understanding of cause-and-effect relationships as inputs to be analyzed. The enabling tools provide these inputs.

Process mapping defines the current process. A process is "a collection of interrelated work tasks, initiated in response to an event, achieving a specific result for the customer and other stakeholders of the process."[16] Thinking of health care as a process and then mapping that process is a critical step in improving the process.



* The variable n equals the number of solutions you would like to generate before selecting the best one.
** TRIZ is the acronym for the "Theory of Inventive Problem Solving" translated from Russian.

Figure 2.7. Flowchart of mistake-proofing tools.

Process mapping is also an early step in performing FMEA. "Graphically describing the process" is Step 3 in healthcare failure modes and effects analysis (HFMEA)™.[12] Flow charting, one style of process mapping, is utilized in Steps 1 and 2 in JCAHO's recommended FMECA process.[16] A detailed understanding of the process also provides insights into where specific errors might be detected and how likely that detection is to occur.

Having a just culture that is fair and open will foster event and near-miss reporting. Reporting provides insights into what events occur, how often they occur, and the outcome's level of seriousness when they occur. Information about the frequency and severity of adverse events facilitates the prioritization of process improvement efforts. Knowing a failure occurred should trigger an event investigation and subsequent root cause analysis.

Root cause analysis determines what cause-and-effect relationships lead to events in the process. There is an implicit expectation that the cause-and-effect relationships of a process are understood in FMEA. The potential causes of an event must be listed for each failure mode. Fault tree analysis also assumes an understanding of cause and effect. Fault trees go beyond FMEA by stating the relationships among multiple causes that would lead to the event taking place.

Visual systems create an environment where mistake-proofing can be used more effectively (See Chapter 1). Visual cues indicating what action to take are more obvious when distractions are removed, and standardization provides points of reference to enable employees to detect and prevent errors.

Design Tools

The central box in Figure 2.7 contains tools that facilitate the design of mistake-proofing devices. The tools are listed and employed in a sequential manner. FMEA is first. No additional design tools are needed if, after conducting an FMEA and brainstorming for possible solutions, an adequate number of possible solutions is generated. The next step is to select and implement the best solution available.

There is no reason to think that the first solution arrived at will be the best overall solution. Teams should determine the optimal number of solutions to be developed before deciding on the best one, shown as "n" in Figure 2.7. Pella Window™ engineers[26] reported that they develop and test seven solutions before making a decision. One step in their decisionmaking process is to fabricate cardboard and scrap-wood prototypes of equipment that can be tested and compared by workers and engineers.

A similar approach was used by St. Joseph's Hospital in West Bend, WI. The team focused on creating a patient safety-centered design for their new building.[27] To facilitate the design process, they tore out two rooms of the existing hospital and mocked up one new room so that staff members could walk through it, visualize working in it, and identify improvements. The St. Joseph's room is shown in Figures 2.8, 2.9, and 2.10. Figure 2.10 shows a page of comments taped to the wall. This page is concerned only with the bathroom light fixture. Staff members filled several sheets as they explored the mock-up room.

St. Joseph's Hospital relied heavily on FMEA. The mock-up room helped them to identify failure modes and think through creative new solutions. The new facility opened in August 2005.[27]

Teams can employ a similar approach on a smaller scale for most mistake-proofing device implementation. As mentioned in Chapter 1, Hirano[28] suggests that if a device has a greater than 50-percent chance of success, teams should stop analyzing the situation and immediately attempt a mock-up of the solution. Some refer to this approach as "trystorming." Trystorming extends brainstorming by quickly creating mock-ups that can be rapidly and thoroughly evaluated. Given many mistake-proofing devices' low implementation cost and simplicity, it is logical to fabricate an early mock-up before continuing with analysis.

A fault tree is used to model the situation further in cases where FMEA does not yield a sufficient number of potential solutions. Fault trees add information that may not appear in FMEA. The use of AND and OR nodes, the

Figure 2.8. Extra wide door and nursing alcove.

Figure 2.9. Headwall mock-up with restroom door in background.

Figure 2.10. St. Joseph's Hospital mock-up comment form.

concept of minimal cut sets, and the use of probabilistic information in fault tree analysis enable a more accurate assessment of the impact of potential mistake-proofing devices. More brainstorming is called for after the completion of the fault tree analysis. Teams should proceed to selection and implementation only after generating a sufficient number of solutions.

If, after employing FMEA and fault tree analysis, teams still do not generate enough potential solutions, the next logical step is to employ multiple fault trees, a technique discussed in detail in Chapter 3. Multiple fault tree analysis aids in converting the problem from one of how to stop failures from happening into one of how to make failures happen. The question here is, "Which failure would be more benign, and how can we generate that failure?" Fault trees that were initially used to analyze undesirable failures are used here to explore resources and generate benign failures.

If the number of design changes resulting in benign failures is still not sufficient, the next step is to employ creativity, invention facilitation techniques, or software. A variety of techniques, methodologies, and software could be used here. One promising approach, *TRIZ*, has its genesis in the work of Genrich Altschuller.[29,30,31] He created an inventive algorithm called the "Theory of Inventive Problem Solving." Its Russian acronym is TRIZ. The TRIZ algorithm is designed for groups to find new ideas on how to approach a problem; to formulate the specific problem in general terms, then identify past approaches—which originate in a Russian patent database—that have been successful. TRIZ is complex and requires extensive reading and/or training. Learning is made somewhat easier by the TRIZ software, which assists in the learning process.

If teams still need more potential solutions, they might consider designing a process that embeds cues about how to do the work correctly.[c] Norman's concepts from Table 1.1—natural mappings, affordances, visibility, feedback, and constraints—are used here.

It would be unrealistic to assume that all problems lend themselves to a solution. If every attempt fails, teams may have to give up, at least in the short run. Before giving up, though, teams should consider a change in focus; explore sub-systems or super-system changes that might provide an alternative problem that is more easily solved. Can the process step be moved to a more advantageous area or combined with another step? What would need to change in order for this task to be entirely unneeded and eliminated?

Selecting a solution

Let us assume that a team is not forced to give up, and that the process described above yielded a cornucopia of possible solution approaches. There are now many directions in which to embark in the search for improvement, especially when employing TRIZ software. The team is now confronted with a delightful dilemma: how to determine which solutions are the most promising. Godfrey et al.,[32] provide an answer, the solution priority number (SPN). The SPN concept is very similar to FMEA's risk priority number (RPN). The SPN is the product of a solution's effectiveness, cost, and ease of implementation, as shown in Table 2.2. The best solutions will have high SPN scores: 12, 18, and 27 are the highest possible scores. (Because SPN is the product of integer scores, no intermediate scores, such as 13, 19, or 26, are possible). These high-scoring solutions will be very effective, cost very little, and be exceptionally easy to implement.

A high SPN (Table 2.3) is an indication that a solution is promising. It does not obviate the need for careful consideration of device design issues. Human factors like process usability and time constraints placed on workers still must be considered. Devices must not negatively affect the usability of a process or slow the process noticeably, particularly when resources such as nurse staffing levels are constrained. Staff will find ways to accomplish their responsibilities, even if it means disabling devices (see Chapter 4)

Conclusion

Mistake-proofing does not obviate the need for many of the tools currently in use in patient safety environments; it uses the insights these tools generate to aid in the design of safer systems and processes.

Regrettably, even with these tools at teams' disposal, determining what design change to make is not as well-defined as Figure 2.7 would suggest. Creativity, at its core, is not a linear process. The tools contribute to our ability to make sense of a situation, determine what needs to be done, and decide how to do it. The actual solutions could yet require a leap of creativity, a flash of inspiration. The intent of Figure 2.7 and the tools it contains is to reduce the size of the leap.

[c] Embedded cues about how to use the process should be placed throughout facilities, regardless of which mistake-proofing efforts are undertaken. Mutual exclusivity of tools or approaches is not warranted or advisable. Cues are often less effective in stopping errors. They can still be quite effective, however, in avoiding them.

Table 2.2. Solution priority number calculations	
Variable	
Solution priority number (SPN)	SPN= Effectiveness x cost x implementation.
Effectiveness	Very effective solution (3) The probability of occurrence can be eliminated or reduced dramatically, or a control measure capable of detecting the error can be installed.
	Effective solutions (2) The probability of occurrence can be reduced. Despite the reduction there is still significant risk of hazard. Measures capable of detecting the error are not in place.
	Ineffective solutions (1) The probability of occurrence cannot be reduced, and measures capable of detecting the error are not in place.
Cost	Low cost (3) can be paid for out of daily operating budget.
	Moderate cost (2) needs to be paid for out of unit-level budget.
	High cost (1) requires payment from hospital-level budget.
Implementation	Easy (3) requires no training.
	Moderate (2) requires a training course, and some resistance is expected.
	Difficult (1) implementation means that a culture change is needed, and strong resistance is expected.
Note: Godfrey, et al[32] described their scales for effectiveness, cost, and implementation more precisely than that presented here by tightly linking it to hazard scores in the Department of Veterans Affairs HFMEA.	

Table 2.3. Possible SPN scores and combinations

Possible SPN scores	Number of combinations resulting in that score
1	1
2	3
3	3
4	3
6	6
8	1
9	3
12	3
18	3
27	1

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Chapter 3. How To Mistake-Proof the Design

The Design Change Imperative

Donald Berwick of the Institute for Healthcare Improvement (IHI) argues that improving patient safety requires changes in the design of health care systems:

> …We are human and humans err. Despite outrage, despite grief, despite experience, despite our best efforts, despite our deepest wishes, we are born fallible and will remain so. Being careful helps, but it brings us nowhere near perfection…The remedy is in changing systems of work. The remedy is in design. The goal should be extreme safety. I believe we should be as safe in our hospitals as we are in our homes. But we cannot reach that goal through exhortation, censure, outrage, and shame. We can reach it only by commitment to change, so that normal, human errors can be made irrelevant to outcome, continually found, and skillfully mitigated.[1]

Berwick is not the only proponent of employing design as the chief approach to improving patient safety. The British Department of Health and The Design Council issued a joint report in the early stages of their patient safety program, calling for "A system-wide design-led approach to tackling patient safety in the National Health Service."[2,a]

FMEA Implicitly Requires Changes in Design

In Chapter 2, we reviewed the basic steps involved in performing failure modes and effects analysis (FMEA). With the exception of JCAHO,[3] the various versions of FMEA do not explicitly state that design changes are required. JCAHO's FMEA Step 6 is "redesign the process." In versions of FMEA that do not explicitly require them, design changes generally, and mistake-proofing particularly, are implicit requirements of FMEA.

Figure 3.1 illustrates the FMEA form used by the auto industry.[4] Failure modes and effects are prioritized according to three 1- to 10-point scales: severity, likelihood, and detectibility (a term used in the automotive version of FMEA that serves the purpose of "ensuring that the hazard is obvious"). The results are multiplied to create an overall assessment called the Risk Priority Number, or RPN. In Figure 3.1, two columns are labeled RPN. The first is an initial priority. The second is a recalculation after taking action. The idea is that any worthwhile action should improve the second RPN.

In the health care version of FMEA (HFMEA™), proposed by the Department of Veterans Affairs (VA) National Center for Patient Safety,[5] the assessments of severity, likelihood, and detectibility are accomplished by employing a decision flowchart instead of merely rating them on a 1- to 10-point scale.

The decision flowchart is shown in Figure 3.2.

The flowchart determines if action is required (proceed) or if existing systems are adequate and action is not required

Figure 3.1. Automotive industry failure modes and effects analysis form.

[a] The British Department of Health and The Design Council's book *Designing for Patient Safety* is available at http://www.designcouncil.org.uk/resources/assets/assets/pdf/Publications/Design for Patient Safety.pdf

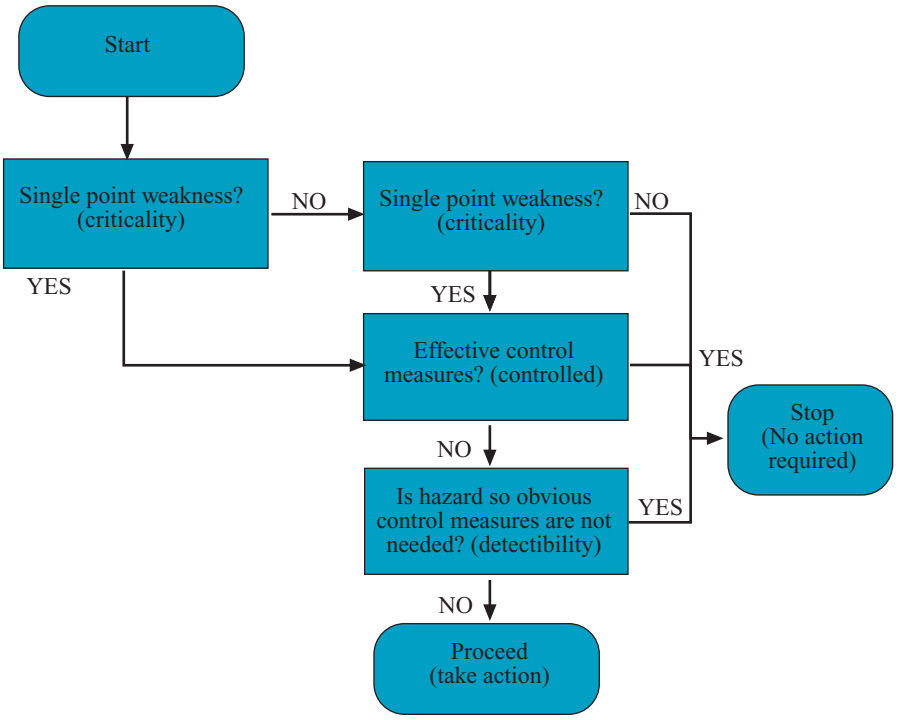


Figure 3.2. Healthcare failure modes and effects analysis decision flowchart.

(stop). HFMEA™ does not explicitly state the followup step that is explicit in the automotive version of FMEA. After the recommended actions have been taken, the improvements should eliminate the need for action the next time that an HFMEA™ analysis is revisited. Otherwise, further action is called for. The decision after taking action should be "stop (no action required)."

This implies that the actions must accomplish at least one of the following three objectives in order to be considered effective and to avoid the implied iterations of the FMEA process:

1. Remove a single-point weakness.
2. Create one or more effective control measures.
3. Make the hazard so obvious that control measures are not needed.

Removing Single-Point Weaknesses

The term single-point weakness refers to the creation of redundancies in the system. Fault trees explicitly recommend redundancy as an approach to improving system reliability. Redundancy is created by increasing the number of systems or individuals involved in the process. There are many examples from everyday life of how processes can be made more understandable. One example is shown in Figure 3.3. Having more back-up systems or more checks (double, triple, or more) increases the probability that the process will proceed correctly. Too often in health care, this redundancy is created when a second trained health care professional double-checks the first to ensure that the process has been performed correctly. However, at the time of this writing, many health care organizations are experiencing a nursing shortage; utilizing several nurses to repeat a

Figure 3.3. Processes that are simple can be made more easily understood. This aid appears on the streets in London.

task for the sake of redundancy is an approach that is too costly, if not impossible, to implement.

An alternative that would not require more staff would be to involve patients themselves, where possible, or a concerned family member or friend. In order for this alternative to work, medical processes must be rendered transparent to untrained individuals; errors must be made obvious. Creating transparency in health care's jargon-rich, complex processes can be very challenging. Implementing visual systems (5Ss, see Chapter 1, Figure 1.7) and providing the clear process cues suggested by Norman[6] could increase transparency significantly. Another option would be to employ mistake-proofing devices or design features in the error-detection process.

Effective control measures

In their article explaining HFMEA™, DeRosier, et al,[5] cite the pin indexing system in medical gases as an example of an effective control measure. They state:

> If your hospital does not use universal adaptors (for regulators), and all the connectors in the building have the correct pin index, the pin indexing would be an effective control measure; it would prevent the incorrect gas from being connected to the regulator.

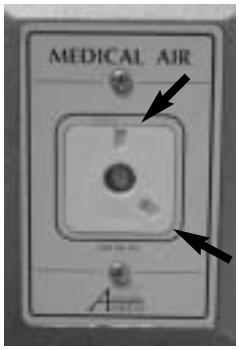


Figure 3.4. A typical pin-indexed medical air outlet. The pins on the regulator fit into the holes at 12 and 5 o'clock. Each gas regulator has a 12 o'clock pin and one other pin.

An example of pin-indexing is shown in Figure 3.4. The implication is that an effective control measure stops the process when an error occurs. This is mistake-proofing. Effective control measures are design changes that prevent or stop processes from continuing when an error has occurred by introducing a process failure (see Figure 3.5).

Figure 3.5. "Won't Connect? Don't Connect!" Here is where a "safety culture" is needed for mistake-proofing. If users do not understand that the process is communicating important information to them, they may try to override the protections provided by the process. www.fda.gov/cder/dmpq/medgas_mixup/default.htm.

Make Hazards Obvious

If hazards are made obvious, HFMEA™ does not require further action. Color-coding is a common approach to making mistakes more obvious. The face of the gauge in Figure 3.6A uses color changes to indicate the range of correct settings.

Other everyday examples of making aspects of a system more obvious are shown in Figure 3.6B-D. Figure 3.7A provides an example of a design to make errors more obvious and Figure 3.7B a secondary safeguard—the warning label.

Design changes are required actions in response to FMEA. The answer to the question of what the design changes should look like is an odd one. To create patient safety through mistake-proofing, the thing to design into processes is failure. The design changes should be carefully designed process failures.

Experts Agree on Designing Failures

Findings from engineering, cognitive psychology, quality management, and medicine all agree that to avoid human error or its impact, it is necessary to create a process that ensures failure.

Henry Petroski,[7] a noted engineering author, states:

> We rely on failure of all kinds being designed into many of the products we use every day, and we have come to depend upon things failing at the right time to protect our health and safety... Failure is a relative concept, and we encounter it daily in more frequent and broad ranging ways than is generally realized. And that is a good thing, for certain types of desirable failures, those designed to happen, are ones that engineers want to succeed at effecting. We often thus encourage one mode of failure to obviate a less desirable mode.

This approach is supported by recommendations from psychology as well. Norman[6] recommends the installation of "forcing functions." Forcing functions create "situations in which the actions are constrained so that failure at one stage prevents the next step from happening." Forcing functions are attractive because they rely "upon properties of the physical world for their operation; no special training is necessary."[6]

From a quality management perspective, Shigeo Shingo recommends that "when abnormalities occur, shut down the machines or lock clamps to halt operations, thereby preventing the occurrence of serial defects." Source inspections "are based on the idea of discovering errors in conditions that give rise to defects and performing feedback and action at the error stage so as to keep those errors from turning into defects."[8]

This approach is not unheard of in medicine. Croteau and Schyve[9] discuss this approach:

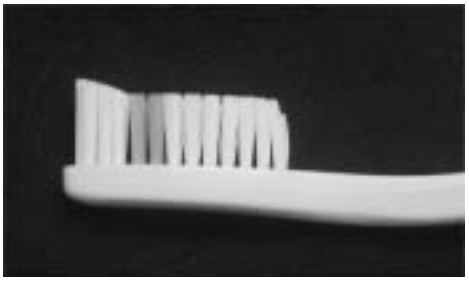
> A process that is designed to detect failure and to interrupt the process flow is preferable to a process that continues on in spite of the failure…We should favor a process that can, by design, respond automatically to a failure by reverting to a predetermined (usually safe) default mode.

Petroski[7], Norman[6], Shingo[8], and Croteau and Schyve[9] each approach the problem from a different perspective and discipline, yet their prescriptions are identical. To reduce human error, make design changes that prevent or stop processes from continuing when an error has occurred. When a process stops, it is a process failure. Under other circumstances, having the process stop would be undesirable. However, a process stoppage can be a far more benign failure than allowing a medical error to progress. Stopping the process will not always be the appropriate action. Some errors can be more benign, and stopping the process may not be necessary.

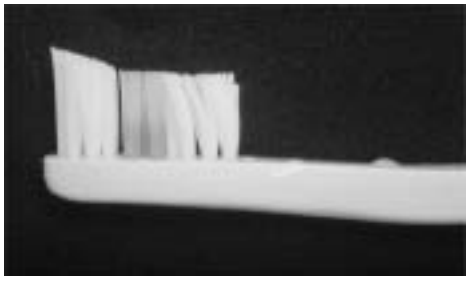
The term "benign" is used here in a relative sense to mean favorable or propitious.[10] It is possible that what is perceived to be a benign failure in some circumstances might actually be perceived to be very undesirable in others. An example will illustrate this point.

A. Gauge

B. Color coding



C. Toothbrushes. New



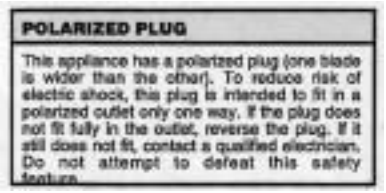
Replace

D. Buckles, Incorrect

Correct

Figure 3.6. Examples of making errors more obvious. 3.6A. Clear markings on the gauge make mistakes more obvious. 3.6B - D. Color coding (in this illustration, shading) indicates when the door lock is open, when the toothbrush should be replaced, and when the safety harness is buckled correctly.

A. Polarized plug



B. Polarized plug warning label

Figure 3.7.A - B. Polarized plugs fit into polarized outlets only one way.

In the decade prior to the U.S. Civil War (1853), Elisha Otis demonstrated his safety elevator at the New York World's Fair.[11] The novel feature of the safety elevator was the Otis Elevator Brake (see Chapter 1, Figure 1.4). This device would prevent the elevator from falling when the cable broke. What was the failure? The brake was designed to get the elevator stuck, usually between floors. Being stuck in an elevator between floors is a very undesirable failure. However, when compared with falling to one's death at the bottom of an elevator shaft, the option of being stuck between floors becomes a much more palatable alternative.

Multiple Fault Trees

Multiple fault trees can be seen in the flowchart of mistake-proofing tools (Chapter 2, Figure 2.7). Multiple fault trees are used to help design benign failures. The traditional use of fault trees is to carefully define the current situation, determine causes of undesirable failure, and identify the resources required to generate that undesirable failure. The new, second use of multiple fault trees is to determine ways to cause or create benign failures and use them as preventive measures. The use of multiple fault trees provides insights into the causes of desired failures and identifies the "resources" required to generate them. The design of the process must be changed so that the failure associated with the undesirable event causes the more benign event (desired failure) to occur instead. The objective is to move failures from the harmful event fault tree to the benign failure fault tree.

Figures 3.8 and 3.9 show both fault trees before and after the failures are moved.

In the "before" picture (Figure 3.8), the harmful event has three minimal cut sets. The first set, containing failures 1 and 2 in a redundant system (AND), has an overall probability of 0.01. The other two sets, containing single failures 3 and 4, respectively (OR), have no redundancy and have a probability of occurrence of 0.05 each. Suppose that Cause 4 is selected as the first target for improvement. Assume that a benign failure that would adequately safeguard patient safety, because it would prevent the harmful event from occurring, has been identified. The fault tree for the benign failure is shown in its initial state on the right side of Figure 3.8. The fault tree shows substantial redundancy. Three failures must occur simultaneously in order for a failure to occur, a situation that has a 0.001 chance of happening.

Figure 3.9 shows the fault trees after the mistake-proofing has been accomplished. Cause 4 now appears in the fault tree of the benign failure. The probability of the harmful event occurring has been reduced by approximately 45 percent. However, as the diagram shows, more can be done. Mistake-proofing Cause 3 by moving it to another fault tree should also be considered. If it can be moved successfully, the probability of the harmful event would be reduced to 0.01. Perhaps 0.01 is still unacceptably high. It is, however, a substantial improvement. To further reduce the probability of the harmful event would require that either Cause 1 or Cause 2 be moved to a more benign fault tree.

The fault trees in Figures 3.8 and 3.9 illustrate the logic of the changes sought through mistake-proofing. See Chapter 4 for a more technically precise version of these fault trees

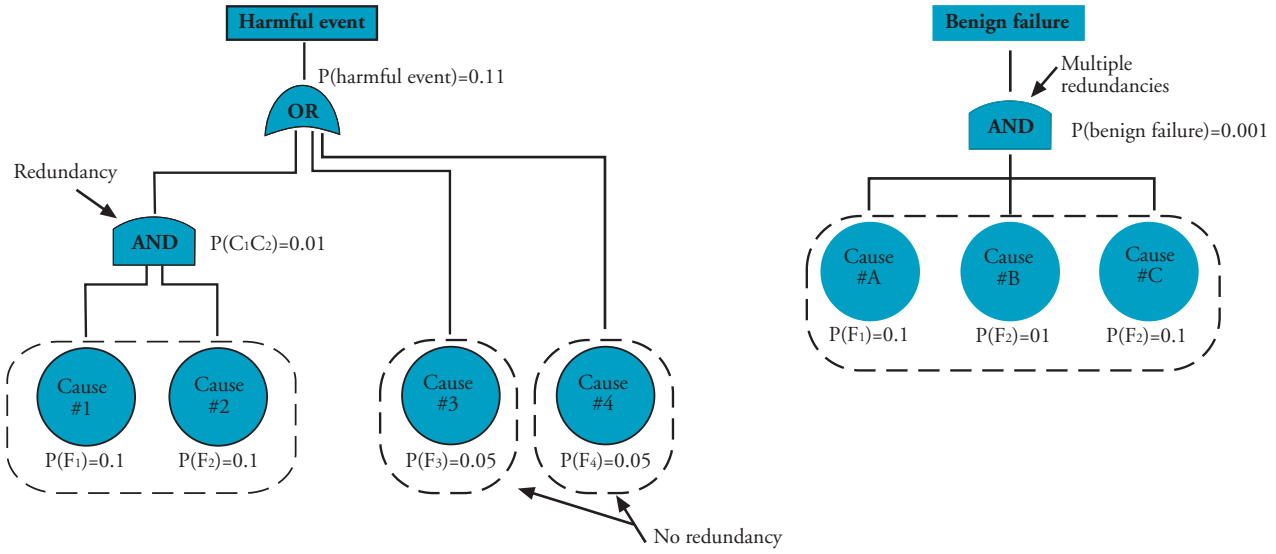


Figure 3.8. Fault trees before Cause 4 is moved.

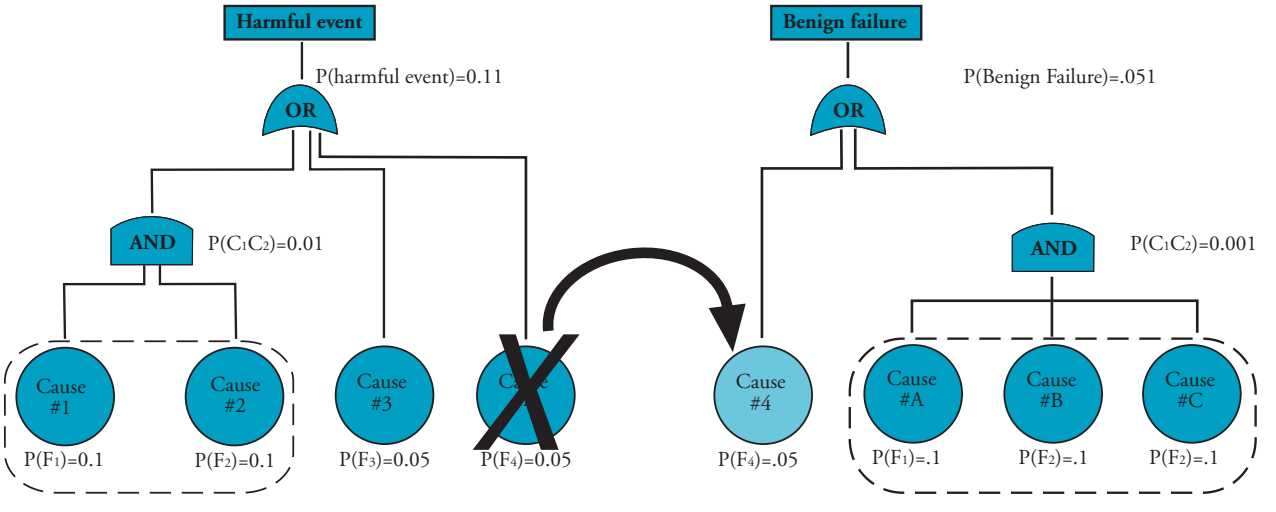


Figure 3.9. Fault trees after Cause 4 is moved.

that model mistake-proofing devices but which may be less than perfectly reliable.

Fault trees enable process designers to anticipate how the process will behave after mistake-proofing has been implemented. After mistake-proofing, the benign failure is far more likely to occur than before. When the benign failure occurs, the staff member using the process must troubleshoot it to determine the reason for the failure. The benign failure in Figure 3.9 is nearly ideal for use with one of the causes. If the benign failure shown occurs, the most likely cause is Cause 4. That cause can be confirmed quickly, and the process can be reset and restarted as needed.

It is important to ensure that a single benign event does not become the failure mode for too many mistake-proofing devices. For example, Causes 1 through 4 should not all be moved to the same benign failure. When multiple causes can stop the process in the same way, the process can become difficult to troubleshoot. The result is that team members may become uncertain about how to re-start the process after a failure.

Effective mistake-proofing should involve a diverse set of fault trees that result in a variety of benign failures.

While designing a mistake-proofed cooktop (Figure 3.10), the designer could consider that the presence of a cooking pan could be detected by the mass or the weight of the pan. The burner could be deactivated if there is no pan sitting on it. Additonal features could include a small light near each burner to indicate that the burner is on, and arranging the burner control knobs to correspond to the physical arrangement of the burners. This is a natural mapping.

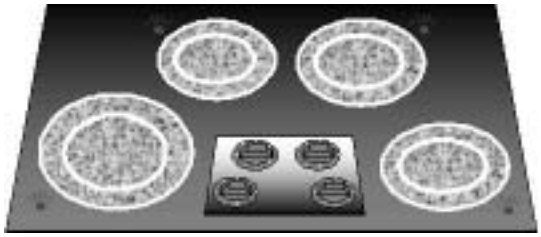


Figure 3.10. Natural mapping.

Although fault trees are central to this discussion, other failure analysis tools can be employed and will yield similar insights (relatively detailed FMEA,[4,5] anticipatory failure determination,[12] current reality trees,[13] and causal trees,[14] for example).

Fault trees have two advantages:

1. The application of the method to a situation is straightforward.
2. The failure is displayed simply and in substantial detail.

In addition to understanding fault trees, team members need information, resources, and creativity:

1. Team members must be privy to all information normally generated by the enabling tools.
2. Team members must have access to detailed knowledge of the medical processes involved.

Only then will the team be able to link the causes of undesirable failures to the outcomes of benign failures in ways that:

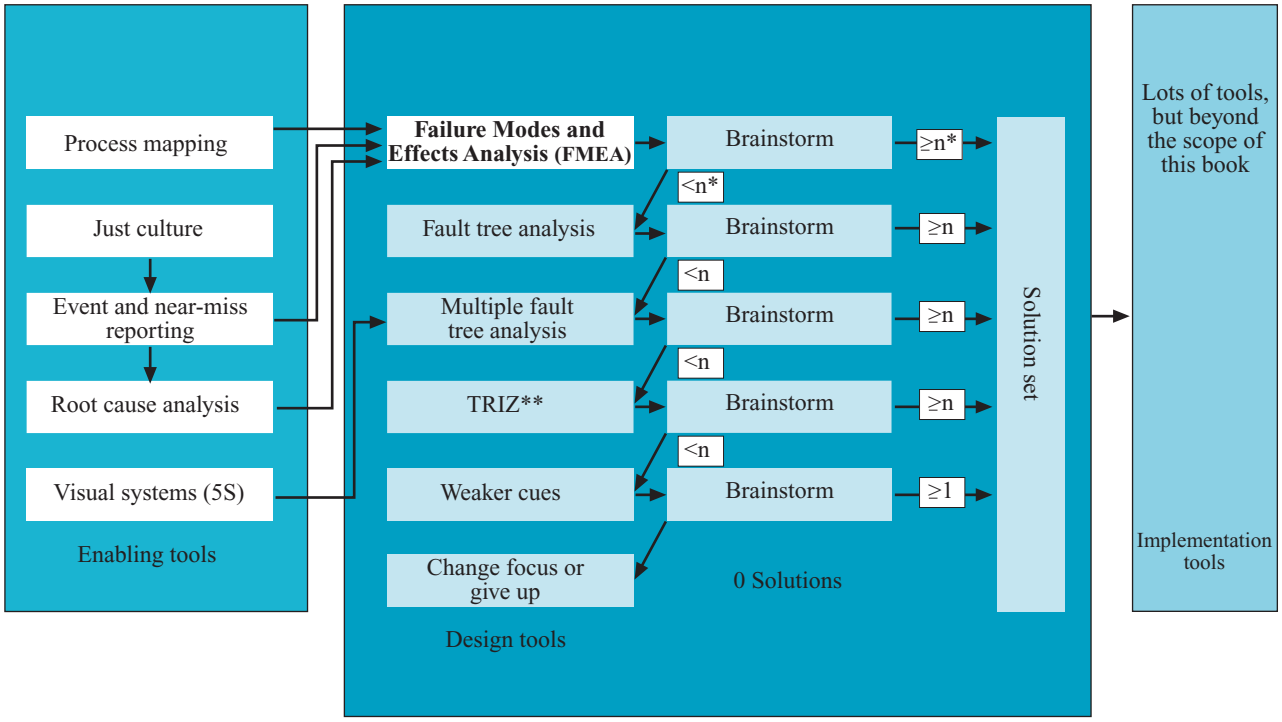
1. Are inexpensive.
2. Have minimal impact on the existing process.

Designing Mistake-Proofing Devices that Cause Benign Failures

There are eight primary steps involved in designing mistake-proofing devices.

Step 1. Select an undesirable failure mode for further analysis. In order to make an informed decision about which failure mode to analyze, the RPN or the criticality number of the failure mode must have been determined in the course of performing FMEA or FMECA.

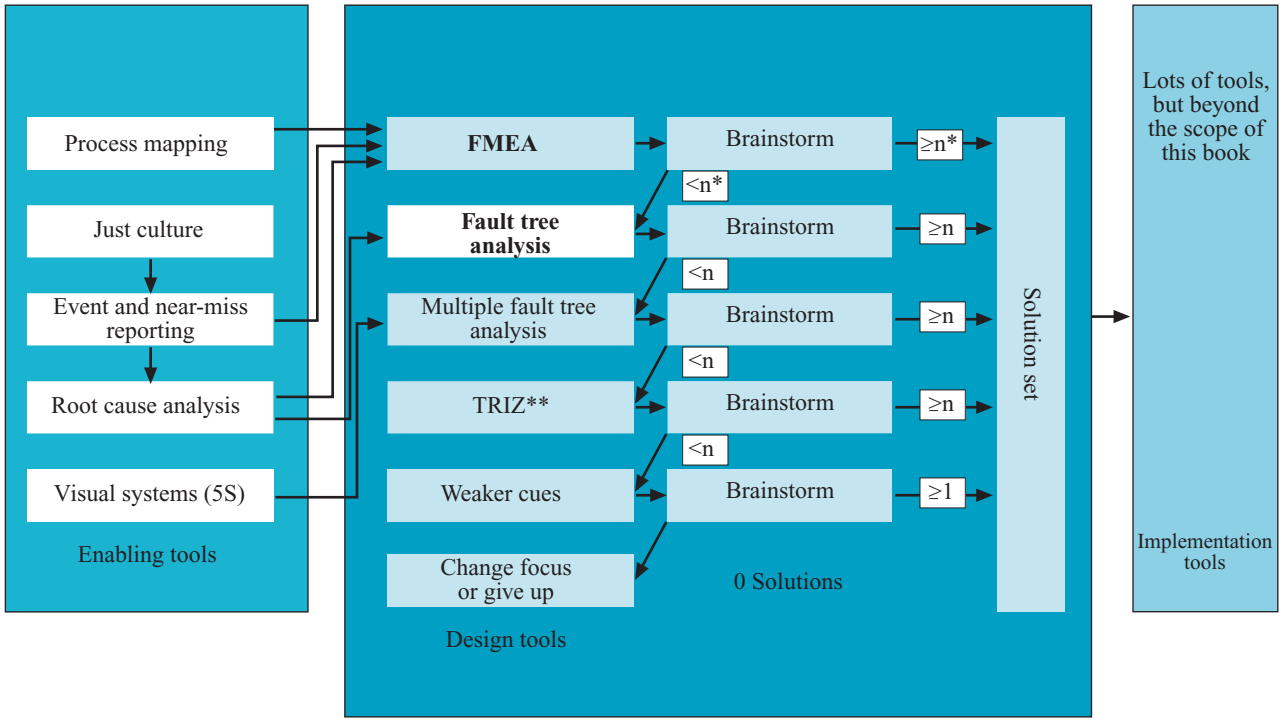
Step 2. Review FMEA findings and brainstorm solutions (Figure 3.11). Most existing mistake-proofing has been done without the aid of a formal process. This is also where designers should search for existing solutions in medicine or elsewhere. The examples in Chapter 6 include comparisons of solutions from medical, industrial, and everyday life. Many exploit the same ideas (see Chapter 6, examples 6.7 and 6.13). Common sense, creativity, and adapting existing examples are often enough to solve the problem. If not, continue to Step 3.



* The variable n equals the number of solutions you would like to generate before selecting the best one.
** TRIZ is the acronym for the "Theory of Inventive Problem Solving" translated from Russian.

Figure 3.11. Review FMEA findings and brainstorm solutions.

Step 3. Create a detailed fault tree of the undesirable failure mode (Figure 3.12). This step involves the traditional use of fault tree analysis. Detailed knowledge regarding the process and its cause-and-effect relationships discovered during root cause analysis and FMEA provide a thorough understanding of how and why the failure mode occurs. The result of this step is a list and contents of minimal cut sets. Since severity and detectibility of the failure mode could be the same for all of the minimal cut sets, the probability of occurrence will most likely be the deciding factor in a determination of which causes to focus on initially.

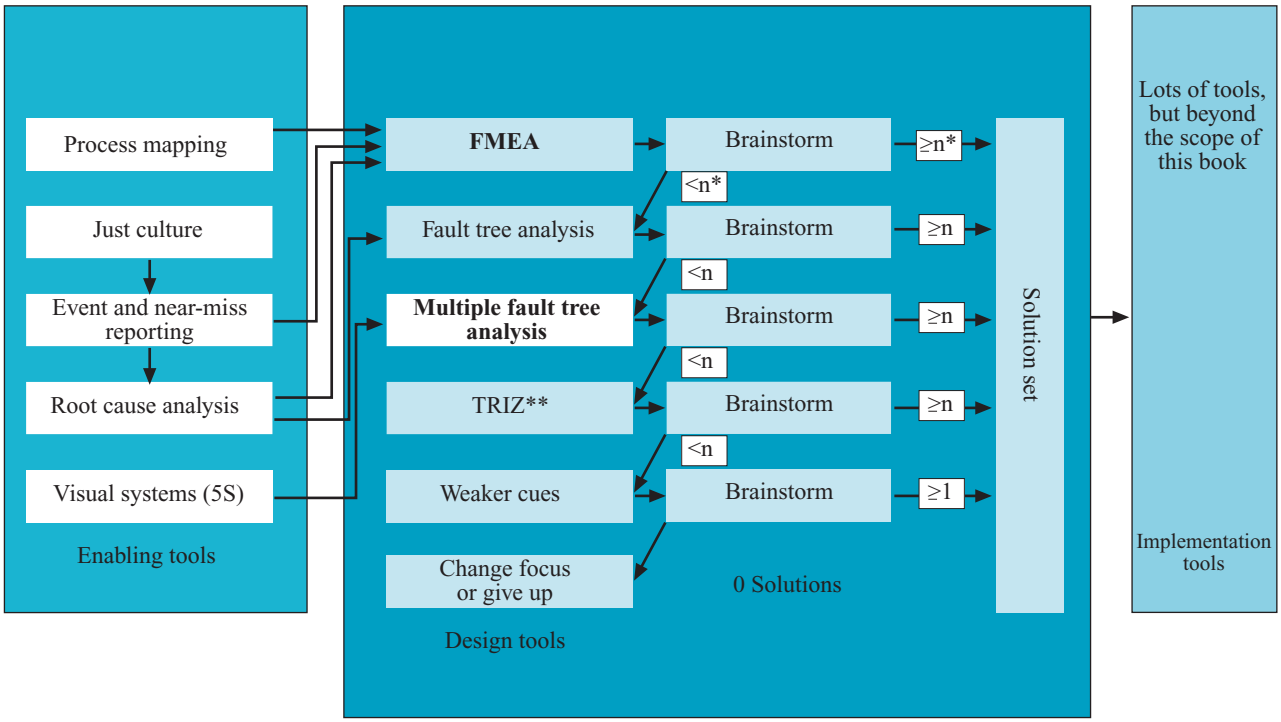


* The variable n equals the number of solutions you would like to generate before selecting the best one.
** TRIZ is the acronym for the "Theory of Inventive Problem Solving" translated from Russian.

Figure 3.12. Create a detailed fault tree of the undesirable failure mode.

Step 4. Select a benign failure mode(s) that would be preferred to the undesirable failure. The tools that precede multiple fault trees in Figure 2.7 once again provide information about other failure modes and their severity. Ideally, the benign failure alone should be sufficient to stop the process; the failure, which would normally lead to the undesirable event, causes the benign failure instead.

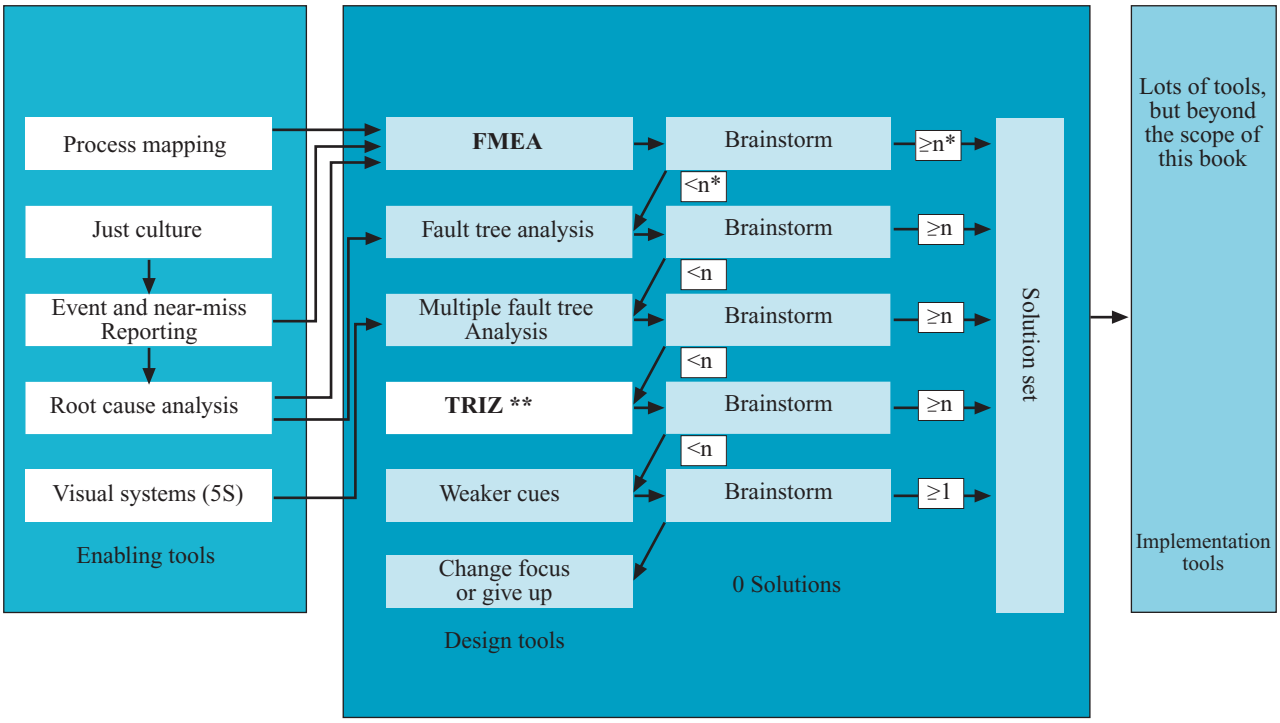
Step 5. Using a detailed fault tree, identify "resources" available to create the benign failure (Figure 3.13). These resources, basic events at the bottom of the benign fault tree, can be employed deliberately to cause the benign failure to occur.



* The variable n equals the number of solutions you would like to generate before selecting the best one.
** TRIZ is the acronym for the "Theory of Inventive Problem Solving" translated from Russian.

Figure 3.13. Identifying resources available to create the benign failure.

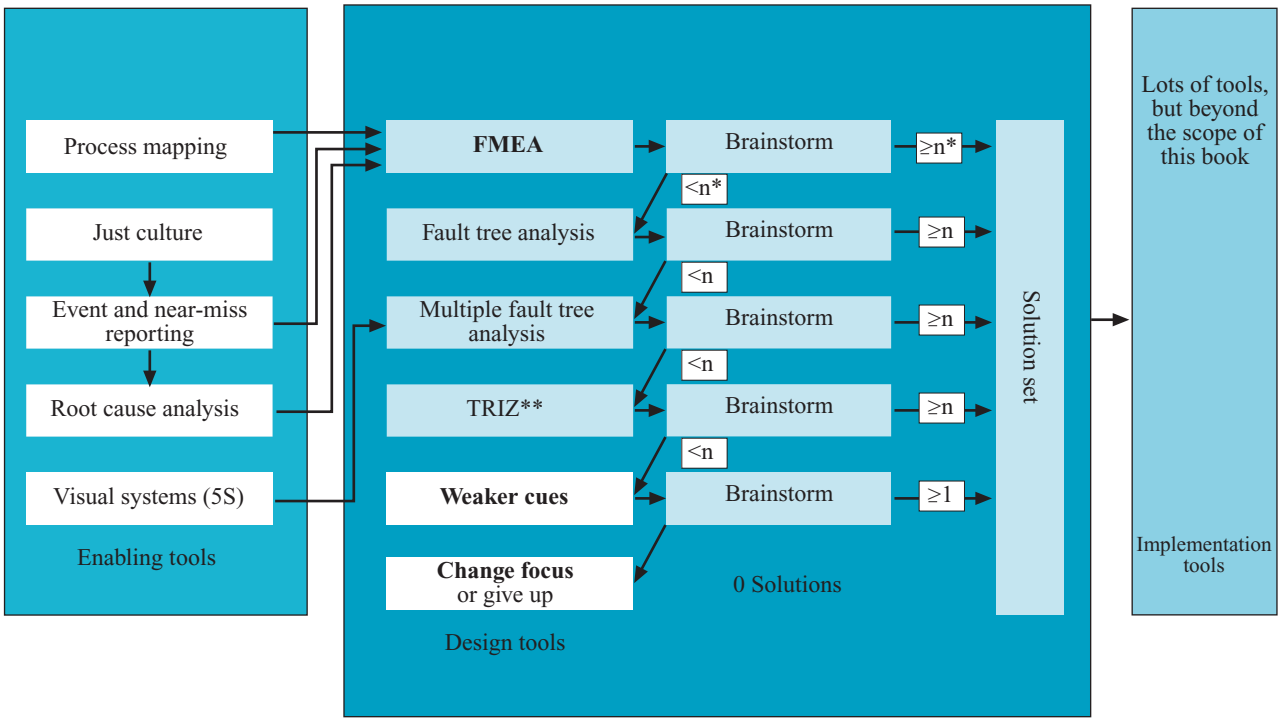
Step 6. Generate alternative mistake-proofing device designs that will create the benign failure (Figure 3.14). This step requires individual creativity and problem-solving skills. Creativity is not always valued by organizations and may be scarce. If necessary, employ creativity training, methodologies, and facilitation tools like TRIZ (described in Chapter 2) if brainstorming alone does not result in solutions.



* The variable n equals the number of solutions you would like to generate before selecting the best one.
** TRIZ is the acronym for the "Theory of Inventive Problem Solving" translated from Russian.

Figure 3.14. Generate alternative mistake-proofing device designs that will create the benign failure.

Step 7. Consider alternative approaches to designed failures (Figure 3.14). Some processes have very few resources. If creativity tools do not provide adequate options for causing benign process failures, consider using cues to increase the likelihood of correct process execution. Changing focus is another option to consider when benign failures are not available.



* The variable n equals the number of solutions you would like to generate before selecting the best one.
** TRIZ is the acronym for the "Theory of Inventive Problem Solving" translated from Russian.

Figure 3.15. Consider using weaker cues or change focus when other tools do not lead to solutions.

If you cannot solve the problem, change it into one that is solvable. Changing focus means, essentially, exploring the changes to the larger system or smaller subsystem that change the nature of the problem so that it is more easily solved. For example, change to a computerized physician order entry (CPOE) system instead of trying to mistake-proof handwritten prescriptions. There are very few resources available to stop the processes associated with handwritten paper documents. Software, on the other hand, can thoroughly check inputs and easily stop the process.

Often, responses to events appropriately include multiple actions, thereby creating their own redundancy.

Of course, there are no guarantees that a failure mode will be solved. If little or no progress is made after completing Steps 1 through 7, it may be prudent to just give up. Some inventions needed to solve patient safety concerns are not, at present, technically or financially feasible. Although it may be necessary to give up, the worst-case scenario is the continuation of the current process with no change at all.

Step 8. Implement a solution. A full discussion of solution implementation is beyond the scope of this book. A rigorous look at implementation issues is available in the change management literature. Some basic tasks usually required as part of the implementation are listed below:

- Select a design from among the solution alternatives:
  - Forecast or model the device's effectiveness.
  - Estimate implementation costs.
  - Assess the training needs and possible cultural resistance.
  - Calculate the solution priority number (SPN) as described in Chapter 2.
  - Assess any negative impact on the process.
  - Explore and identify secondary problems (side effects or new concerns raised by the device).
  - Assess device reliability.
- Create and test the prototype design:
  - Find sources who can fabricate, assemble, and install custom devices, or find manufacturers willing to make design changes (more in Chapter 9).
  - Resolve technical issues of implementation.
  - Undertake clinical trials (because of the stakes involved, medical implementations will need to be much more deliberate than those in other industries).
- Trial implementation:
  - Resolve non-technical and organizational issues of implementation.
  - Draft a maintenance plan.
  - Draft process documentation.
- Broad implementation leads to:
  - Consensus building.
  - Organizational change.

The eight steps to creating mistake-proofing devices can be initiated by a root cause analysis or FMEA team, an organization executive, a quality manager, or a risk manager. An interdisciplinary team of 6 to 10 individuals should execute the process steps. An existing FMEA or root cause analysis team is ideal because its members would already be familiar with the failure mode. Help and support from others with creative, inventive, or technical abilities may be required during the later stages of the process. A mistake-proofing device is designed using the eight steps just discussed in the application example that follows.

An Application Example

Step 1. Determine the undesirable failure mode. For this example, consider the undesirable event of a patient injured by a fall during a transfer to or from a standard (non-powered) wheelchair. Berg, Hines, and Allen.[15] report that 37.9 percent of wheelchair users fell at least once in the past 12 months. Of those who fell, 46.7 percent were injured as a result of their fall. Tideiksaar,[16] Calder and Kirby,[17] and Ummat and Kirby,[18] confirm that transfers to and from wheelchairs are common causes of injuries.

Step 2. FMEA is well-known in health care, and detailed instruction on its implementation is available.[19] It may be that a well-done FMEA would be enough to generate ideas for how to change the process design so that falls are prevented during transfers to or from wheelchairs. In order to demonstrate subsequent steps, though, assume that FMEA and brainstorming did not generate an adequate number of possible solutions, so the process continues to Step 3.

Step 3. This step calls for the creation of a detailed fault tree used to understand and make sense of how failures occur. In this case, the information from the literature on wheelchair injuries (cited in Step 1) and information from previously created FMEAs would inform the creation of the fault tree. The fault tree in Figure 3.16 shows the undesirable event—patient falls during transfer to or from a standard wheelchair. Each level of the tree provides additional detail into why the event occurred. The fault trees in this example have purposely been kept small and simplified. They are intended only to illustrate how using fault trees can assist in making sense of the causes of undesirable failures and how more benign failures can be designed into the process instead.

Given the fault tree for the undesirable event in Figure 3.16, there are several possible alternative approaches to preventing the failure. One or more of the causes (often called basic failures) shown in the bold-lined boxes in Figure 3.16 need to be addressed. To avoid "hand brake not engaged," for example, it is necessary to find ways to ensure that the patient does not forget (Box A) and to provide training (Box B). To avoid "footplate present when it should not be," requires actions to prevent patients from failing to move the footplate and to prevent the footplate from moving back into position for use (caused by Boxes 2 and 3). To prevent "Patient falls during transfer…" (the top event), preventive actions must be taken on both the left and right branches of the fault tree, "failure to land on seat…" and "trip on footplate," respectively. The next several paragraphs show how benign failures might be used to think through design changes that will prevent either branch from resulting in patient falls.

Step 4. Selecting a benign failure mode in Step 4 requires asking, "What failure would be preferable to having a patient fall"? Separating this question into sections, we arrive at:

1. What failure would be more benign than failing to land on the wheelchair's seat?
2. What failure would be more benign than tripping on the footplate?

The answer to the first of these questions might be to prevent the wheelchair from rolling (Figure 3.17). Although assuring that the wheelchair does not roll is a failure that completely defeats the purpose of having a wheelchair, this outcome could be better than that of wheelchair users injuring themselves, especially if the failure is temporary. The white box in Figure 3.17 shows one of the causes of the wheelchair rolling away, "armrest used for support, seat vacant," being moved into the fault tree for "wheelchair will not roll." This move generates creative or inventive questions. Can a mechanism be invented in which the brake is always engaged when the seat is vacant? Alternatively, is it possible to develop a brake that is activated when most of a patient's weight is on the armrests instead of on the seat? These creative or inventive questions are the starting places for changing the design of the process. It might be necessary to explore several, perhaps many, possible solutions to find the best one.

Proposing a benign failure converts a problem into a question of creativity: Can we invent a mechanism so that the brake is always engaged when the seat is vacant?

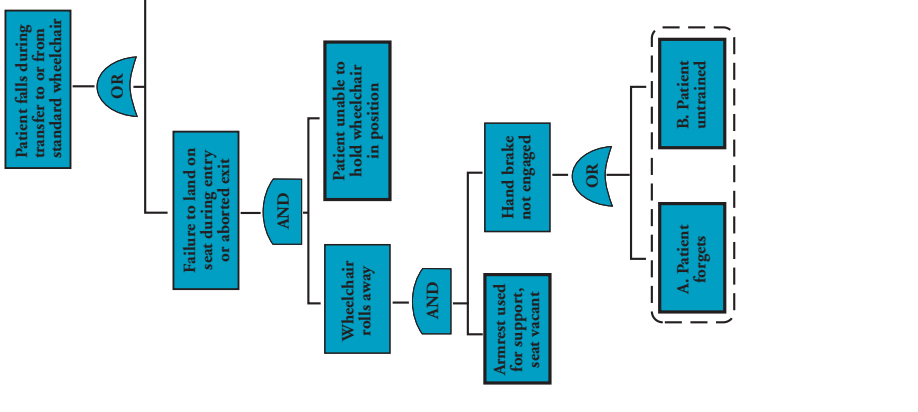


Figure 3.16. Fault tree of an undesirable event: "Patient falls during transfer."

Figure 3.17 also provides the information required by Step 5. This tree identifies the resources necessary for creating the benign failure. In many cases, the basic failure (cause) of the undesirable fault tree can be moved directly onto an existing branch of the benign fault tree, thereby employing an already-existing basic failure as a starting point for creating the benign failure. In this case, the existing basic failure "hand brake engaged" is suggestive of a device that solves the problem: an automatically engaged brake.

It turns out that Steps 6 and 7 are unneeded since an automatic locking device that creates the benign failure suggested in Figure 3.17 is already commercially available. It is a braking system that uses a spring to engage the brake whenever the wheelchair is vacant (Figure 3.18). The brake is disengaged by the weight of the wheelchair occupant, which depresses a lever beneath the seat. The device moves the basic failure, "armrest used for support, seat vacant," from the undesirable fault tree to the benign fault tree. Now, the brakes are automatically engaged when the armrest is used for support (Figure 3.19).

This device comes with a significant secondary problem: it is much more difficult to move empty wheelchairs around because their brakes are always engaged. However, this problem is not difficult to resolve. A hand-activated brake release enables attendants to override the automatic brake system.

Is this a "good" solution (part of Step 8)? The locking device is a very effective solution. The probability of falls is reduced dramatically. The device provides a control measure capable of preventing the error of not engaging the hand brake. The cost of the product is moderate. While not affordable out of daily operating funds, funds allocated from a unit-level budget would probably be adequate. The implementation would most likely be considered easy, depending on the culture of the

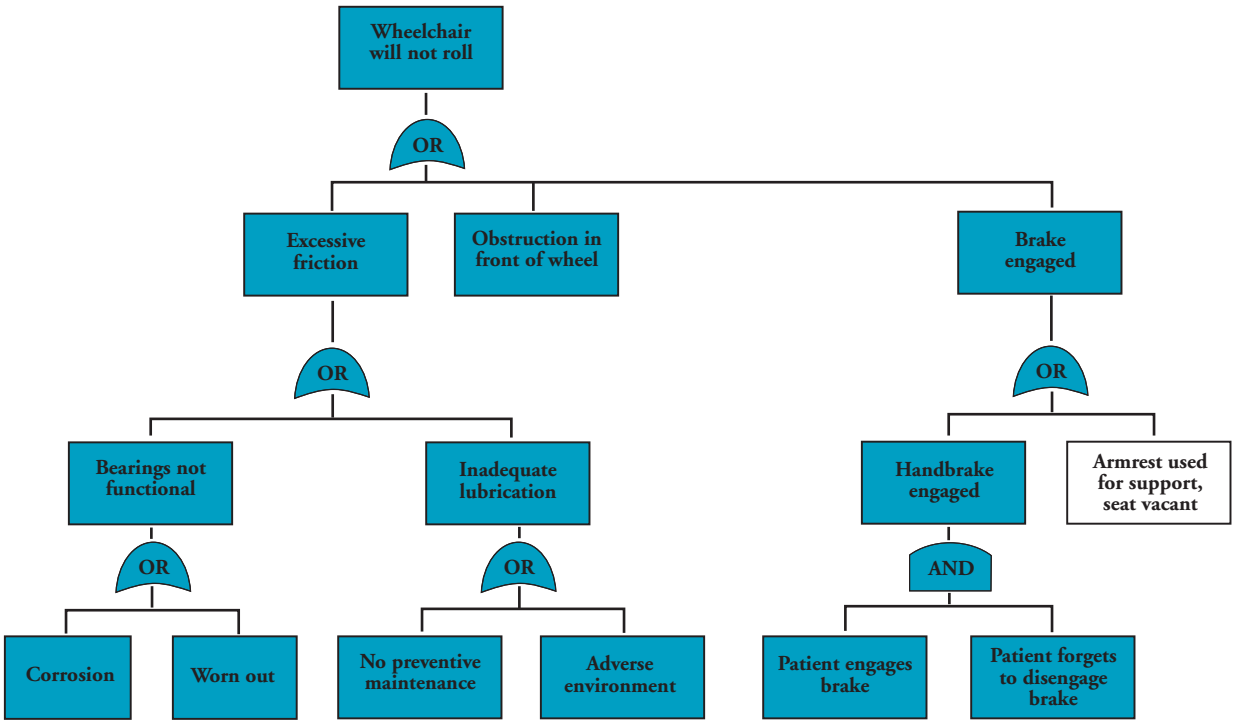


Figure 3.17. Benign failure: Wheelchair will not roll.

Figure 3.18. A commercially available, automatic wheelchair locking device.

Figure 3.19. Wheelchair does not move, locking device engaged.

organization. The only training required would be to point out the brake release to the staff. If more than minimal resistance is expected, the organization's problems go well beyond those that mistake-proofing is likely to help. Consequently, the SPN equals 18, the second highest possible score.

Calculating the SPN indicates that this device is a promising direction for improvement. It does not provide a definitive answer to the question of whether this device should or should not be implemented. The remaining tasks in Step 8 must be performed, including an assessment of device reliability, device trials, maintenance planning, drafting process documentation, etc.

Will the automatic brake eliminate the possibility of the top event, "patient falls during transfers?" No. The other branch of the tree, "trip on footplate," must also be addressed. Returning to Step 4, the second question is: What failure would be preferable to having a patient trip on a footplate? One possible response would be the failure of having the footplate absent or completely unavailable.

Step 5. What would cause the footplate of a wheelchair (Figure 3.20) to be absent or unavailable? Figure 3.21 indicates a few possibilities. It could have broken off due to an impact or other excessive force. This failure suggests solutions involving parts that break away, like the attachment of ski bindings to a boot. Under the correct amount and direction of forces, the ski breaks away from the boot and prevents injuries to the skier's legs. Perhaps the footplate should be designed so that it snaps off when the patient's entire weight is put on it; or, if the footplate is bumped from the rear, it could easily detach from the chair frame. The footplate might also be absent or unavailable because it has been disassembled and removed intentionally.

This failure suggests that the footplate should be present to hold the patient's feet while the chair is in use, but the footplate would, ideally, be absent at the time of entry or exit from the wheelchair. A situation in which the footplate is ideally both present and absent is an example of what TRIZ users call "an inherent contradiction," or a "physical contradiction."

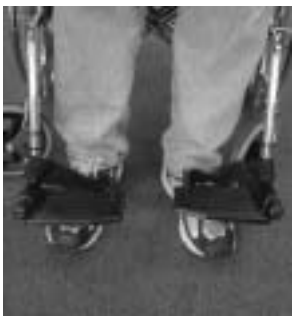


Figure 3.20. A wheelchair with footplates.

Step 6. Step 6 recommends using creative or inventive tools to find directions for further exploration. TRIZ offers ready approaches for resolving contradictions.

A contradiction is defined as:

Opposition between things or properties of things. There are two kinds of contradictions:

1. Tradeoffs—a situation in which if something good happens, something bad also happens; or, if something good gets better, something undesirable gets worse.
2. Inherent contradictions—a situation in which one thing has two opposite properties.[20]

Once a contradiction is identified in the language of TRIZ, approaches used by other inventors to solve that contradiction can be looked up on a large matrix.

TRIZ approaches for resolving the contradiction of incompatible requirements at different times include the following eight approaches. The number following each approach is the TRIZ "principle number." These numbers are consistent throughout the TRIZ literature, although their descriptive label will vary among authors (as shown in parentheses below). A brief description of each follows. More detailed information is available from other sources.[21]

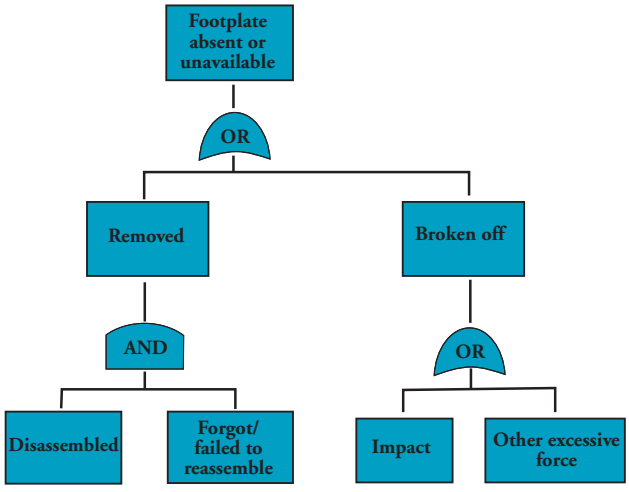


Figure 3.21. Benign failure: footplate is absent or unavailable.

1. Segmentation (fragmentation) (1): "Divide an object into independent parts."[21] "Make an object easy to disassemble."[20] Example: flexible poles of dome-shaped tents can be folded compactly when not in use (see Figure 3.22).

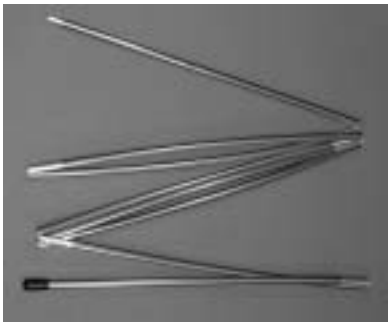


Figure 3.22. Tent poles fold compactly.

2. Preliminary counteraction (9): "Preload counter-tension to an object to compensate excessive and undesirable stress."[21]

3. Preliminary action (10): "Perform required changes to an object completely or partially in advance."[21] For example (Figure 3.23): Glue a strong cord inside a shipping box and connect a "pull here" tab before use to make it easier to open the box later.

Figure 3.23. Connecting the pull tab before use makes the box easier to open later.

4. Beforehand compensation (cushion in advance) (11): "Compensate for relatively low reliability of an object with emergency measures prepared in advance." For example: Automotive airbags or guard rails, especially the ends that are designed to attenuate impact (Figure 3.24).

Figure 3.24. Cushion in advance.

5. Dynamic parts (dynamicity) (15): Allow (or design) the characteristics of an object …to change to be optimal…"[20] "Divide an object into elements capable of changing their position relative to each other."[21] For example: Flaps on airplane wings (Figure 3.25).

Figure 3.25. On these airplane wings, each element is capable of changing its position relative to the other element.

6. Periodic action (19): "Instead of continuous actions, use periodic or pulsating actions."[20] For example: Sprinkler does not damage soil by applying water in droplets instead of a steady stream (Figure 3.26).

Figure 3.26. Pulsating action prevents damage to the soil.

7. Hurrying (rushing through) (21): "Perform harmful and hazardous operations at very high speed" (Figure 3.27). For example: For a given surgical procedure, the more rapidly it can be done, the better.[21]

Figure 3.27. Rushing through. Photo courtesy of Kelly Moore Connors and www.travelblog.org. Used with permission.

8. Discarding and recovery (Rejecting and regenerating parts) (34): "Make portions of an object that have fulfilled their functions go away (discard by dissolving, evaporating, etc.), or modify them directly during the operation. Conversely, restore consumable parts of an object directly in operation."[20] For example (Figure 3.28): Dissolvable polylactides screws and pins are used in surgery to mend broken bones, which makes the second operation for their removal unnecessary.[20]

Figure 3.28. Rocket parts are discarded when they are no longer useful.

Clearly, not all of these approaches seem promising for the solution to this particular problem of having the footplate present some of the time but not at others. However, preliminary counteraction, preliminary action, and the related approaches of segmentation, dynamic parts, and discarding and recovery seem promising.

The eight approaches suggested using multiple fault trees fit nicely into these TRIZ recommendations. Having breakaway parts is an example of discarding and recovery. Approaches suggested by the TRIZ principle of "preliminary counteraction" involve putting a barrier in place that will keep the foot from getting behind the footplate, and creating a spring-loaded footplate assembly that is raised whenever the foot is not resting on it. The barrier could take the form of a heel strap or leg strap (Figures 3.29 and 3.30). Another approach that TRIZ suggests is dynamic parts. Figure 3.31 shows that the use of dynamic parts is already available. Some wheelchairs have footplates that can be released and swung to the side. What this solution lacks is a system for causing it to happen automatically, a simple means of detecting whether the footplates should swing out of the way. Because patients could conceivably reposition themselves by putting most of their weight on the armrests, footplates, and chair back, having a seat lever mechanism similar to the previous example could be problematic. Perhaps in this case the setting function (or detection system) would need to test for total weight exerted on the wheels instead of on the seat itself. What should the final solution be? That remains an open question; but the engineering task does not appear so daunting that it would be difficult to develop if someone were so inclined.

Conclusion

Changing the design of processes is a critical task in reducing the human errors that plague health care. Of course, the term design can mean different things in different contexts. In the contexts of mistake-proofing and FMEA, it means physical changes in the design of processes. Only these design changes are adequate to escape the repetitive revisiting, followup, and preventive actions that FMEA otherwise requires.

The goal is to rapidly find inexpensive, effective solutions that are easy to implement. The process is only an aid in accomplishing this objective.

Adequate design changes will remove a single point of weakness, create one or more effective control measures, or make the hazard so obvious that control measures are not needed. All of these required actions suggest forms of mistake-proofing. Moreover, experts from the disciplines of engineering, cognitive psychology, quality management, and medicine all agree that these process design changes should not bring processes to a stop. They should introduce benign failures into a process.

A series of tools and some novel applications of those tools were presented in an eight-step process designed to generate and evaluate several potential solutions. An application example was presented. While it was presented

Figure 3.29. Wheelchair with heel strap.

Figure 3.30. Wheelchair with leg strap.

in a relatively linear step-by-step fashion, real life circumstances will occasionally prove to be less linear. While all the steps need to be considered eventually, the designer of mistake-proofing devices can opportunistically skip a step.

At other times, the designer may repeatedly return to some steps on an iterative basis. The goal is not to complete the eight steps. The goal is to rapidly find inexpensive, effective solutions that are easy to implement. The process is only an aid in accomplishing this objective.

Figure 3.31. The footplate can be released and moved to the side.

The approach presented here represents an incremental step in thinking about mistake-proofing medical processes. Future research and experience will provide additional tools, techniques, and enhanced approaches for designing effective medical processes that will have the ability to prevent specific, undesirable failure modes. Some of the limitations, drawbacks, and design issues of mistake-proofing are presented in the next chapter.

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Chapter 4. Design Issues, Caveats, and Limitations

Introduction

Mistake-proofing is not without its pitfalls. In the 15th century, knights and men-at-arms wore heavy armor to protect themselves from their enemies' weaponry. In the context of mistake-proofing, this can be thought of as a strategy to reduce the influence of the "mistake" of being injured by enemy weapons. The French's heavy armor worked against them, however, when they fought the British in the Battle of Agincourt on October 25, 1415. Instead of saving lives, it contributed to their defeat. Heavy rains on the recently-plowed battlefield created deep mud. Soldiers wearing heavy armor were unable to maneuver in the mud when they became even slightly injured or were pushed to the ground. Some even drowned in it. Lightly-armored or unarmored English archers, on the other hand, were able to move more nimbly and inflict severe damage on the French.

One lesson to be learned from the Battle of Agincourt is that it is important to take design issues into account as part of an effective implementation. Otherwise, mistake-proofing efforts intended to reduce errors or their impact could cause significant problems themselves. Implementation problems can be avoided by managing design issues and, at the same time, recognizing the limitations or liabilities of mistake-proofing. In the TRIZ methodology,[1] problems associated with a solution are referred to as secondary problems. It is no surprise that most mistake-proofing devices contain secondary problems. Almost every solution does. There are several recurring mistake-proofing design issues that must be taken into consideration. These include the need to:

- Mistake proof the mistake-proofing.
- Move errors to another location.
- Prevent devices from becoming too cumbersome.
- Commit the appropriate resources.
- Avoid Type I error problems.
- Avoid unintended utilization of benefits.
- Prevent worker detachment from the process.
- Prevent workers from losing skills.

Each of these issues is discussed in this chapter.

Mistake Proof the Mistake-Proofing

Mistake-proofing devices should be mistake-proofed themselves. They should be designed with the same rigor as the processes the devices protect. The reliability of mistake-proofing devices should be analyzed, and if possible, the device should be designed to fail in benign ways.

Reliability of Devices

Reason[2] warns that systems with extensive automatic error detection and correction mechanisms are more prone to a devious form of failure called a latent error.[3] Latent errors remain hidden until events reveal them and are very hard to predict, prevent, or correct. They often "hide" inside automatic error detection and correction devices. An error that compromises an inactive detection and recovery system is generally not noticed, but when the system is activated to prevent an error, it is unable to respond, leaving a hole in the system's security. This is an important design issue, although it is quite likely that the errors prevented by the automatic error detection and correction systems would have caused more damage than the latent errors induced by the systems.

Devices Sometime Fail

The following scenario, in which a mistake-proofing device failed, is a tragic example of the type of latent error Reason identified. In Chapter 3, devices were modeled as if they were perfectly reliable. Devices are not perfectly reliable. The analysis below suggests how device reliability can be modeled to assess the benefits and risks presented by the latent error.

In January 2002, two women died during the same routine heart procedure in the same room.[4] They were both mistakenly given nitrous oxide instead of oxygen because a device that regulates oxygen flow was plugged

Figure 4.1. Receptacles dispense oxygen and nitrous oxide.

into a receptacle that dispenses nitrous oxide (Figure 4.1). The flow regulator was missing one of the index pins designed to prevent such mix-ups. The mistake-proofing depended on pins connecting the oxygen regulator at 12 and 6 o'clock and the nitrous oxide regulator at 12 and 7 o'clock. The missing pin broke off. A mistake-proofing device failed.

The fact that devices fail, while sometimes tragic, does not mean that mistake-proofing is an unsound prevention strategy. Consider the fault trees in Figures 4.2 and 4.3. They correspond to the harmful event and benign failure

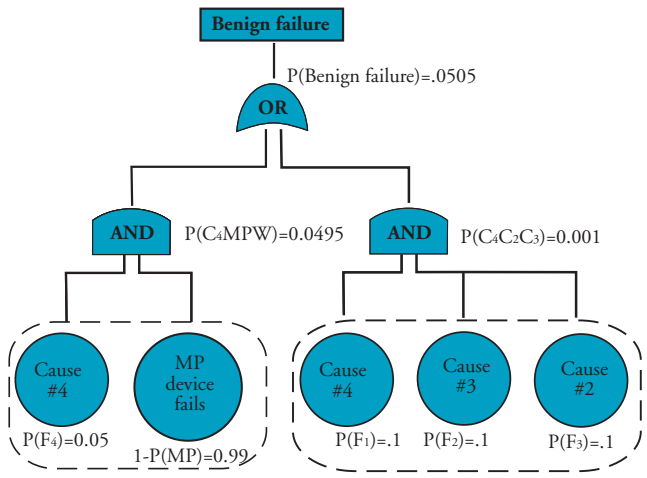

Figure 4.2. Fault tree showing the effect of less reliable mistake-proofing device.

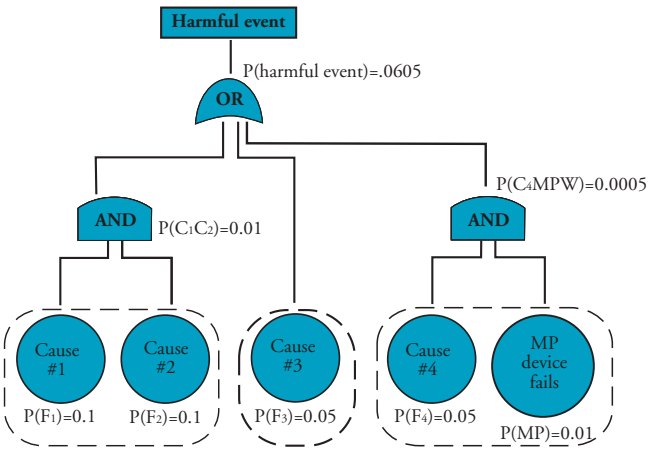

Figure 4.3. Fault tree showing reliability of a mistake-proofing device.

shown in Chapter 3, Figure 3.9, except that the mistake-proofing device is not perfectly reliable. In Chapter 3, Cause 4 was completely removed from the harmful event fault tree. Here, the mistake-proofing device is not very reliable, failing 1 percent of the time. Cause 4 remains in the tree because it can cause the harmful event any time it occurs and the mistake-proofing device also fails. The probability that both of these events will occur is 0.0005, two orders of magnitude smaller than without the device. Device failures should be a catalyst for further exploration of improvements that could be incorporated into the device's design to improve reliability.

Devices should fail benignly, too. An approach to improving the reliability of devices is to design them so that they fail in benign ways. The air brakes on tractor-trailer trucks engage if air pressure is lost. When scuba regulators fail, they are designed to deliver a constant flow of air instead of no flow at all. A different design for the pin indexing system that failed would be one that uses pressure on the index pins to open the flow of gases. If a pin is broken off, the gas would not flow. If devices cannot be designed to fail benignly, improve the reliability of the device by creating more system redundancy. Alternately, a system of careful maintenance, calibration, and inspection should be put in place.

Avoid Moving Errors to Another Location

When designing mistake-proofing devices, it is important to avoid the common problem of moving errors instead of eliminating or reducing them. For example, in jet engine maintenance, placing the fan blades in the correct position is very important. The hub where the blade is mounted has a set screw that is slightly different in size for each blade so that only the correct blade will fit. This solves numerous problems in assembly and maintenance throughout the life of the engine. It also produces real problems for the machine shop that produces the hubs; it must ensure that each set screw hole is machined properly.

Moving the error to another location can provide a benefit in the following circumstances:

1. If the error is moved to a location in the process where interruptions are more controllable or less likely.
2. If the means of detection are better.
3. If the consequences are less severe or reversible.

Prevent Devices from Becoming Too Cumbersome

How mistake-proofing devices affect processes is another design issue that must be considered. The device could be cumbersome because it slows down a process while in use or because the process, once stopped, is difficult to restart.

Slow Down the Process

If a mistake-proofing device slows down the process, workers will find coping strategies (also known as "work-arounds") to enable them to get their work done. Consider the table saw. It is a common woodworking power tool. Each saw is equipped with a blade guard in the factory (Figure 4.4A and 4.4B). The guard covers the spinning blade as the wood is passed through the saw. In an unscientific survey of manufacturing workers who own table saws at home, the majority report removing the guard from their table saws. When asked why they removed the guard, most responded that it "got in the way" or "did not operate smoothly." The lesson is that workers will circumvent cumbersome devices that make work more difficult.

Ideally, mistake-proofing should be designed so that the device is transparent to the process, like the orientation check of the 3.5-inch diskette drive. It does not slow down the process until an error occurs.

In some cases, mistake-proofing devices can actually make the correct execution of the process easier and faster. The pick-to-light bin system (Figure 4.5) is one such device. Workers select items from the bin to fill customer's orders. Each order is different. The bin system is linked to a computer that downloads each customer's order. Each bin

Figure 4.4A. A table saw without SawStop.

Figure 4.4B. Close up photo of a blade guard. SawStop is an intriguing, alternative safety device for table saws that is very effective. Workers may not even know about it until it saves their fingers. (Video of SawStop's function can be seen at www.mistakeproofing.com.)

has a light above it, and an infrared beam detects the insertion of the worker's hand. Workers fill the order by picking an item from each lighted bin. The light goes off automatically as the item is picked. An alarm sounds if workers insert a hand into the wrong bin. The subsequent operation, order packaging, will not operate until all the lights on the bin system are off. The pick-to-light system improved worker productivity dramatically compared with paper orders. Omitted parts defects were reduced from 400 per million to 2 per mllion.[5]

Difficulty Trouble-Shooting

If too many mistake-proofing devices stop the process in the same way, it can become difficult to determine which error is responsible and how to resume normal process operation.

During the Christmas season of 1997, Toymax sold a very popular toy called "Metal Molder" (Figure 4.6). This toy enabled children to mold molten metal into small charms and trinkets. The toy was thoroughly mistake-proofed to keep children's fingers separate from the molten metal. Various locking mechanisms prevented the process from proceeding until all the required conditions had been met, and all the previous steps had been completed. There were so many reasons that the process could be stopped that the children for whom it was intended (8-year-olds and older) were mystified about how to get it to work. Something was obviously wrong; they just could not figure out what it was.

Figure 4.5. A pick-to-light bin system.

Similar outcomes occurred with early computer software, when the descriptor "user-friendly" differentiated new versions from older ones. Some of these programs checked user inputs so carefully that it became difficult to know what was wrong or how to fix it.

Effective implementations of mistake-proofing must have enough different manifestations of process stoppages to make troubleshooting the error obvious and rapid.

Commit the Appropriate Resources

Because many mistake-proofing devices are simple and inexpensive, they pay for themselves very rapidly. In safety-critical industries where error costs are high, they could pay for themselves the first time an error is detected.

Under other circumstances, ensuring that a device is cost-justified requires careful cost-benefit analysis. Multi-million dollar investments in high-technology solutions like computerized physician order entry, widespread bar-coding, and robotic pharmacies certainly require careful financial deliberations. Consumable devices that have small per unit costs but are used in large quantities per error detected (i.e., errors are relatively rare) may also require careful cost justification (see the Bloodloc™ in Chapter 7, Example 7.8). In addition to the traditional cost-benefit analysis, models based on the economic design of statistical process control charts are available.[6]

Figure 4.6. This toy enabled children to mold molten metal into small charms and bracelets.

An unwillingness to invest enough in error reduction projects is common. Repenning and Sternman[7] wrote an article with a particularly salient title: "No One Ever Gets Credit For Fixing Problems That Never Happened." It seems to be easier for managers to pay for a lawsuit after the incident than it is to justify investing in prevention before the fact. Repenning and Sternman[7] describe how difficult situations that managers confront contribute to this bias against investing in prevention. They assume that productive capabilities deteriorate over time and that ongoing investments in capabilities are needed to ward off entropy. These capabilities lead to actual performance, which is assessed against the desired performance. Managers typically feel pressure to resolve performance gaps between actual and desired performance.

Applied behavior analysis suggests that people respond best to outcomes and rewards that are "soon," "certain," and "positive." As a result, managers are biased. They would rather not reallocate worker time to "improvement work" but instead concentrate on doing the core production work of the firm. Managers are biased toward production work because its impact is immediate (soon), it is completely within their control (certain), and it will likely reduce the performance gap in the short term (positive). Improvement work tends not to offer the same rewards. Outcomes, though promising (positive), will be delayed as teams organize, define, measure, improve, and control (not soon), and if the performance problem is not solved, the effort will have been in vain (not certain).

It seems to be easier for managers to justify paying for the lawsuit after an incident than it is to justify investing in prevention before the fact.

Faced with these alternatives, managers decide to concentrate on core production work that improves performance in the short term, but that allows capabilities to deteriorate in the long term. These deteriorating capabilities give rise to performance gaps that generate more pressure on managers to focus on production work instead of improvement work, and a vicious downward spiral of capabilities ensues. Consequently, improvements, including the implementation of mistake-proofing, will require managers to subordinate short-term pressures to the long-term goals of the organization. The performance gap will need to widen initially if it is to narrow in the long term (Figure 4.7).

Avoid Type I Error Problems

If mistake-proofing is used for a mistake detection application and replaces an inspection or audit process in which sampling was used, changing to the 100 percent inspection provided by a mistake-proofing device may have unintended consequences. Specifically, there will be significantly more information collected about the process than there would be when only sampling is used.

Suppose the error of inferring that something about the process is not correct when, in fact, the process is normal (Type I error) occurs only a small percentage of the time. The number of opportunities for a Type I error increases dramatically. The relative frequency of Type I errors is unchanged. The frequency of Type I errors per hour or day increases. It is possible that too many instances requiring investigation and corrective action will occur. Properly investigating and responding to each may not be feasible. Papadakis[8] discusses this problem and a possible remedy.

Avoid Unintended Utilization of Benefits

The benefits of mistake-proofing can include lower cognitive workload, reduced chances of error, and faster and more easily learned processes. Whether these benefits are used to generate patient safety or some other benefit is an important and open question. The strength of the organization's safety culture will dictate the answer.

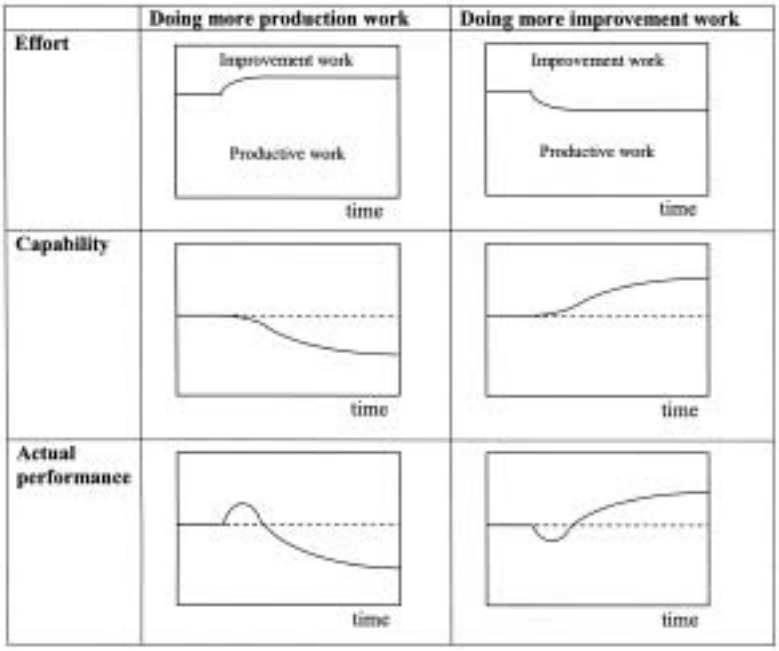

Figure 4.7. Doing more productive work at the expense of improvement work is beneficial in the short term but detrimental in the long term Copyright 2001, by The Regents of the University of California. Reprinted from the California Management Review, Vol. 43, No. 4. Used with permission.

Risk Homeostasis

Risk homeostasis, as presented by Wilde,[9] maintains that:

> In any activity, people accept a certain level of subjectively estimated risk to their health, safety, and other things they value in exchange for the benefits they hope to receive from that activity… people continuously check the amount of risk they feel they are exposed to. They compare this with the amount of risk they are willing to accept, and try to reduce any difference between the two to zero.[9]

In the context of mistake-proofing, risk homeostasis means that design changes intended to improve patient safety might actually result in changes of behavior that provide other benefits instead. Wilde[9] points out that anti-lock brakes do not result in fewer or less severe accidents. Drivers choose to go faster in inclement weather because they know they have anti-lock brakes. They use the brakes to facilitate risky behavior while maintaining a constant overall risk level. All other things being equal, drivers essentially trade safety enhancements for additional speed.

Consider the case of the oxygen flow meter with a missing index pin.[4] The flow meter was inserted in a nitrous oxide outlet where the view of the outlet was obstructed. The worker had a legitimate expectation that the flow meter could not be inserted into an incorrect outlet. One might speculate that the obstructed view was tolerated and the labeling, color-coding, and other cues about what to do were not used because of a reliance on the pin-indexing system. If the worker knew that the pin-indexing system was not in place, he might have looked at the outlets more carefully. Here, convenience and speed could have been obtained by a behavioral change facilitated by a mistake-proofing device.

Such behavioral changes should be an anticipated secondary problem during the mistake-proofing device design process. Use of FMEA, fault trees, and other analyses throughout the design process can help identify

and resolve these changes. It also highlights how critical safety culture is in monitoring and managing the risk level tolerated by individuals in the organization.

Reduced Cognitive Content

Mistake-proofing can reduce the amount of cognitive content in work tasks. However, the benefits that accrue to organizations from this reduction can be perceived very differently according to the organization's intent, culture, and stategy.

Erlandson, Noblett, and Phelps[10] studied the performance of students with cognitive impairments at Northwest Wayne Skill Center (NWWSC). These students/workers ranged in age from 15 to 22 years. Their IQ scores ranged from 45 to 86. Their job was to assemble fuel filter clamps for the automotive industry (Figures 4.8A and 4.8B). This task was initially very difficult for the students and led to low morale among those assigned to the task. Quality levels were between 35 percent and 70 percent acceptable production. The rate of production was approximately 62.5 assemblies/student-hour. Mistake-proofing was employed to create a work fixture that made it difficult to make mistakes. The mistake-proofed fixtures allowed for the use of "a much larger worker pool, reflecting a broader range of cognitive disabilities. The students were able to produce approximately 167 completed, acceptable assemblies/student-hour with accuracy rates approaching 100 percent."[10] NWWSC found that worker morale improved. Workers reported to work early and, at the end of the day, congratulated each other for their significantly increased productivity. The purchasing company was also enthusiastic about the "quality and quantity" of production. NWWSC reported a zero return rate after producing 100,000 clamps following the intoduction of mistake-proofing.

As was the case at NWWSC, when designing and implementing mistake-proofing devices, it is important to ensure that there exists a culture in which patient safety will be enhanced. This culture should use the benefits of mistake-proofing to free health care professionals from attending to the minute details of a process so that they can attend to more important aspects of patient care.

The methods employed at the NWWSC seem to be much more ominous when employed by organizations that are less interested in promoting the well-being of workers. Social critics have found fault with the dehumanization of work since the dawn of the industrial revolution. Mistake-proofing has been used to exploit workers. Unfortunately, lowering the skill level or cognitive content of work tasks encourages some companies to reduce training costs and exhibit little concern for treating employees well enough to retain them over the long term. When processes are mistake-proofed, workers become interchangeable and can be treated as a disposable commodity.

Figure 4.8A. An empty work fixture.

Figure 4.8B. A fuel filter clamp loaded in a work fixture. Photos from Erlandson et al.[10] © 1998 IEEE. Used with permission.

Pursuing such a strategy to simplify the work also enables employers to employ individuals with fewer economic options. It could be argued that the human resources policies of these companies reveal that their intent is not the same as that of the Northwest Wayne Skill Center. NWWSC employs the disabled in a meaningful way, providing them with more options and upholding their dignity in a culture that encourages respect for workers.

Prevent Worker Detachment from the Process

Bose,[11] a self-proclaimed proponent of mistake-proofing (poka-yoke), discusses concerns that the use of mistake-proofing devices may estrange workers. Over zealous mistake-proofing "generates its own cultural attributes, its own work ethic. It sows the seeds of operator detachment from the product..." Bose points out that North American industries have been trying to involve workers in process management for the past decade. Bose differentiates between the useful simplification of the process, including the elimination of the possibility to create defects, and the detrimental elimination of required skills. Mistake-proofing should "enable the operator to easily oversee the process."[11]

Prevent Workers from Losing Skills

Bainbridge[12] and Parasuraman et al[13] assert that reducing workers' tasks to monitoring and intervention functions makes their tasks more difficult. Bainbridge asserts that workers whose primary tasks involve monitoring will see their skills degrade from lack of practice, so they will be less effective when intervention is called for. Workers will tend not to notice when usually stable process variables change and an intervention is necessary. Automatic features, like mistake-proofing devices, will isolate the workers from the system, concealing knowledge about its workings, which are necessary during an intervention. And, finally, automatic systems will usually make decisions at a faster rate than they can be checked by the monitoring personnel. Parasuraman, Molloy, and Singh[13] looked specifically at the ability of the operator to detect failures in automated systems. They found that the detection rate improved when the reliability of the system varied over time, but only when the operator was responsible for monitoring multiple tasks.

Know the Third Boundry

Rasmussen[14] and Rasmussen, Pejterson, and Goodstein.[15] warn that errors play an important role in learning to become more efficient. Extensive use of automatic error detection and correction mechanisms, such as mistake-proofing devices, could have a negative effect on this learning. Rasmussen and his co-authors argue that the workers are being constrained by three boundaries:

1. The boundary of unacceptable workload, which workers will desire to move as far away from as possible.
2. The boundary of financial breakdown, from which management will drive the workers away.
3. The boundary of functionally acceptable behavior, beyond which system failures occur.

Efficiency is gained by learning the exact location of the third boundary, so that processes can take place as far from the other two boundaries as possible without crossing the third. The location of this boundary is discovered through trial and error testing. Automatic error detection and correction mechanisms, by concealing the boundary of control, can prevent learning and skill development that might otherwise promote efficiency.

Conclusion

This chapter suggests that, concerning mistake-proofing in health care, lessons can be learned from several diverse disciplines. Mistake-proofing is not a panacea, and it is not without its limitations and liabilities. Inattention to these limitations and liabilities in the design and implementation of mistake-proofing devices can lead to problems. Designing and implementing devices effectively requires careful thought. The design issues identified in this chapter should not be a deterrent to implementing mistake-proofing. Rather, they should serve as a basis for thorough and thoughtful consideration of mistake-proofing designs.

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Chapter 5. Examples of Alternative Approaches to Mistake-Proofing

Introduction

As discussed in Chapter 1, mistake-proofing can use a variety of setting functions, control functions, or categories. This chapter provides 67 examples of mistake-proofing organized into 21 sets. Each set highlights alternative approaches to similar problems. Since each organization's processes are subtly but distinctly unique, different organizations can use a variety of related approaches to address specific situations.

The inclusion of the examples in this chapter follows the pattern of books on mistake-proofing in manufacturing.[1,2,3,4] Some of these examples will be directly applicable to errors that confront organizations. Others might suggest how to approach a novel problem that is a source of concern. The following are issues for consideration as the mistake-proofing examples in this chapter are discussed:

1. Consider the most appropriate circumstances for each mistake-proofing example.
2. Consider whether processes have adequately addressed issues raised by the examples.

Pella Window engineers develop and test seven solutions before identifying and implementing the best one.

Example Set 5.1—One Exposure Only, Please

Unintentionally exposing x-ray film to light destroys images that are vital to proper patient care. These images can usually be recreated, but they cost time and money.

The entrance to the hospital darkroom door (Figure 5.1) has only one opening in a revolving drum. Passing through the vestibule ensures that the contents of the darkroom are not unintentionally exposed. The door creates a failure in that you cannot enter the darkroom under incorrect conditions.

Figure 5.1. A hospital darkroom door.

Figure 5.2 shows a film bin equipped with a special locking mechanism. The mechanism includes a light sensor that will not allow the bin to be opened when light is present in the darkroom.

Figure 5.2. A film bin with a locking mechanism.

Example Set 5.2—Variations in Scald Prevention

Data from the National Safe Kids Campaign indicate that 4,000-5,000 children are scalded each year, receiving third-degree burns that cover at least 12 percent of the body.[5] Most of these events do not take place in medical facilities, although fatalities have occurred in medical facilities. Listed below is a variety of devices designed to reduce the chance of scalding.

Figure 5.3 illustrates a device that uses color-changing plastics to warn when water reaches dangerous temperatures, and scalds can occur.

The color of the circular ring changes from purple (left) to pink (right) when water exceeds 40 °C, 104 °F. A triangular ring (not shown) changes at 37 °C.

The anti-scald plug shown in Figure 5.4 works the same way as the circular ring, but with one crucial difference: the anti-scald plug, by requiring the user to place the device in order to fill the tub, enforces its own use. In other words, the user must use the device to fill the tub, and using the device prevents scalding.

Figure 5.3. These plastic rings change color at 40 °C.

Figure 5.4. An anti-scald plug.
Courtesy of the VA National Center for Patient Safety. Used with permission.

The anti-scald valve in Figure 5.5 is attached to the end of a faucet. It contains a valve that closes when water reaches 117 °F. This device is easy to install. It is simply threaded on to the end of the faucet, replacing the standard filter or aerator. It creates a "shutdown" that prevents the possibility of scalding. This device lacks an override valve that is available on some models. A valve would allow hotter water to be obtained, if necessary, without disassembling part of the faucet.

Figure 5.5. Anti-scald valve.

The device in Figure 5.6 is inserted into the end of the shower pipe and works much like the previous device. It also contains a valve that closes when water becomes too hot. This device installs in a few minutes using an Allen wrench and is completely hidden once installed.

Figure 5.6. Valve closes when water becomes too hot.

The device in Figure 5.7 is a thermostatic mixing valve. It provides "forced control" by automatically mixing cold water with hot water to reduce the water temperature. The maximum water temperature can be set and adjusted. Installation of this type of valve is more troublesome than the other devices mentioned here. In some cases, the mixing valve is located behind the wall of the shower, and installation or adjustment requires carpentry and plumbing.

Figure 5.7. Thermostatic mixing valve.

The devices in Figures 5.5, 5.6, and 5.7 require regular maintenance for reliability and calibration.

Example Set 5.3—Medical Gas Connections

Figure 5.8 illustrates the extensive mistake-proofing that medical gas tanks undergo. Here, the fittings that connect medical gases from the tanks in the back room to the tubes leading to the patient have undergone extensive mistake-proofing.

Tanks display the color-coding scheme. The color coding serves as a "sensory alert" to ensure that the correct connections are made between the tanks and the valves in the patients' rooms. The tanks are also fitted with pin-indexed connectors to prevent incorrect connections.

The generic regulator in Figure 5.9 has a dial that indicates how many liters of oxygen are delivered. The dial clicks as each liter of oxygen is delivered. Hinckley[2] points out that converting adjustments to settings is a very powerful type of mistake-proofing because it requires far less attention to detail and can accelerate the process dramatically.

Figure 5.8. Color-coding and pin-indexed connectors for medical gas tanks.

Figure 5.9. Regulator dial indicates the amount of oxygen delivered in liters.

In this case, however, the design has a drawback which is indicated in a warning box in the instructions: "There is NO FLOW between settings. To obtain the desired oxygen flow, the indicating pointer must point to a specific number on the dial."[6] Eliminating the possibility of one mistake can create an opportunity for another.

> …a physician treating a patient with oxygen set the control knob to between one and two liters per minute, not aware that the numbers represented a discrete rather than a continuous setting. No oxygen was flowing through, yet the knob rotated smoothly, giving the suggestion that the intermediate setting of the machine was possible. The patient became hypoxic before the error was discovered. A design solution would have been a rotary control that snaps into a discrete setting along with some indication of flow.[7]

If the probability of the second mistake is lower than the probability of the first, on average, patients will benefit. Designing the device so that flow continues at the rate of the last setting, regardless of whether or not the indicator sits between settings, might be safer.

Example Set 5.4—More Connections

Often, connections are pin-indexed and color-coded. In Figure 5.10, the holes for the pins for medical air are located at 12 o'clock and 5 o'clock. Using this system, all of the gases have a pin at 12 o'clock. The other pin is different for each gas.

In their new facility in West Bend, WI, St. Joseph's Hospital has gone further by standardizing the location of each gas outlet on the head wall. Each gas outlet is located in the same place on each head wall in the hospital.

How much color-coding is too much? In this case (Figure 5.11), the clear nozzle may be the most mistake-proof choice.

It is not possible to mount the nozzle on the wrong regulator because it is universal, not color-coded. If you have to stock yellow, green, and every other colored nozzle in each location where they may be used, you not only incur additional inventory costs, you may actually cause reportable violations of operating policies or procedures that would be impossible if only clear nozzles were stocked.

Figure 5.10. The holes for the pins are located at 12 o'clock and 5 o'clock. Also, the oxygen outlet is green, and the medical air outlet is yellow.

Figure 5.11. Yellow, clear, and green nozzles.

Errors occur where things are almost the same but are subtly different. What can be made identical should be. What cannot be made identical should be made obviously, even obtrusively, different (Figure 5.11).

The regulator in Figure 5.12 is attached to the wall with a vinyl-covered steel cable in order to avoid converting the regulator into a projectile that flies across the room when it is disconnected under pressure. This is an example of what Tsuda[8] refers to as "preventing the influence of mistakes."

Figure 5.12. A regulator attached to the wall with steel cable.

The tubing can attach to a regulator with (Figure 5.13A) or without (Figure 5.13B) the nozzle attached. If either option is acceptable, this design is mistake-proof. If one option is preferred, the design should be avoided.

The tubing can attach to a regulator with or without a nozzle attached.

Figure 5.13A. Tubing attached to a regulator with a nozzle.

Figure 5.13B. Tubing attached to a regulator without a nozzle.

Example Set 5.5—Variations in Tube Identification

Ensuring that labels on samples and test tubes are correct is a very important aspect of reducing medical errors. Often, printed labels with complete information are not available at the bedside and must be retrieved from the nurses' station. This delay can contribute to the introduction of errors into the system. The following three examples represent approaches to accurately identify tubes and samples.

When multiple tubes are drawn at the same time, writing a label for each can be time-consuming. The Bloodrac™ is produced by the makers of the Bloodloc™ (see Chapter 7, example 7.8). It enables several tubes to be stored together with one handwritten label. The identification is

usually the patient's name and the Bloodloc™ code on the patient's wristband.

Another approach to reducing the effort required to accurately label multiple tubes is the use of a wristband with pre-printed, peel-off, self-adhesive labels (Figure 5.15). All the labels have the same unique identification number. As they are removed, the same number appears underneath each label.

These labels temporarily label the tubes until permanent labels containing complete information can be printed and affixed. Error rates are reduced because the preliminary labels are only available at the patient's bedside.

Although the tube in Figure 5.16 receives the temporary label with little chance of error, the possibility of errors occurring when matching permanent labels with temporary ones would also need to be addressed in the process.

Figure 5.14. One hand-written label identifies several tubes of samples.

Figure 5.15. A wristband with multiple, peel-off, adhesive labels.

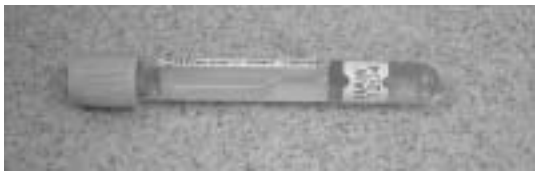

Figure 5.16. Errors can occur when matching temporary labels with permanent ones.

Example Set 5.6—Variations in Esophageal Intubation Detection

Esophageal intubation is a common error that occurs when the intubation tube is inserted in the patient's esophagus instead of in the trachea. There are several approaches to detecting this error in hospital settings. Figures 5.17-5.21 illustrate a variety of low-tech approaches that could be employed where power requirements or space prohibit more sophisticated approaches.

After the patient is intubated, a staff member squeezes the bulb (Figure 5.17) and places it over the end of the tube. If the bulb fails to re-inflate to its original shape, the tube is in the esophagus. If it re-inflates fully, the tube is placed correctly.

Figure 5.17. When inflated fully, this bulb indicates that the intubation tube has been successfully inserted into the trachea.

The bag in Figure 5.18 has a detector that changes color in the presence of carbon dioxide. If the detector fails to change color, then the tube is in the esophagus. If it changes color, the tube is in the trachea. If the mistake-proofing device fails, the device will indicate a situation requiring corrective action.

Figure 5.18. The CO_2 detector in this bag does not change colors when the tube is incorrectly inserted into the esophagus.

The round cylinder at the end of the tube in Figure 5.19 is a whistle. As the patient breathes in and out the whistle makes an audible, wheezing sound. The staff can hear the patient's breath.

Figure 5.19. The whistle at the end of the tube enables staff members to hear the patient's breath.

The device in Figure 5.20 is essentially a large caliber syringe, but instead of pushing fluids out, it pulls in anything available. If the plunger cannot be pulled out easily, or if stomach contents come out, the tube is in the esophagus. If the plunger pulls out easily and completely, the tube is in the trachea as it should be.

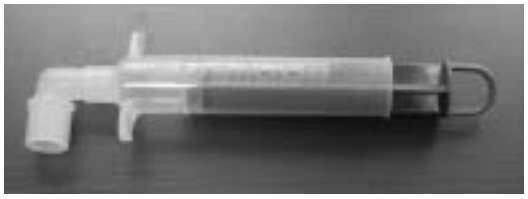

Figure 5.20. If the plunger in this syringe pulls out easily, the tube has been properly inserted.

Example Set 5.7—Variations in "Take Your Medicine," Part I

The following examples illustrate a common problem in prescribed medications. The instructions from the bottle shown in Figure 5.21 are:

Take 5 tabs once daily x 3 days,
then 4 tabs once daily x 3 days,
then 3 tabs once daily x 3 days,
then 2 tabs daily x 3 days,
then 1 tab daily x 3 days.

Complying with these instructions requires the patient to pay careful attention to detail and have a good memory or to use some additional mechanism for tracking necessary changes in dosages.

A typical prescription bottle may not adequately convey detailed instructions. One approach to managing dosage changes is to print the dosage for each day on a calendar. This approach is cumbersome and increases the probability of making an error in following the prescribed instructions.

Figure 5.21. A typical prescription bottle.

The packaging, however, puts lots of knowledge in the world (Figure 5.22) because the rows are labeled by day, and the instructions for each day are printed on the line below each row of pills. The act of taking a pill creates a record of where the patient is in the sequence. No calendar or other aid is needed.

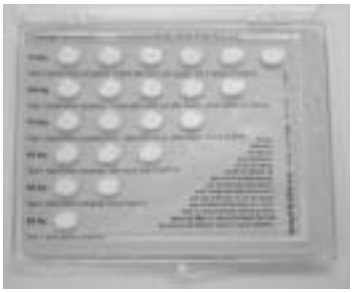

Figure 5.22. Package, conveys detailed dosing instructions.

Example Set 5.8—Variations in "Take Your Medicine," Part II

For some, taking medications four times daily is not a problem. For others, determining if they have taken their medications is more problematic. Several approaches have been created to help ensure that medications are taken as prescribed. Clearly, some devices require less attentiveness, and some approaches are more cost-effective than others. The effectiveness of each approach depends on the individual involved.

Figure 5.23 shows a daily pillbox. It is simple, straightforward, and easy to use. This mistake-proofing device is not particularly mysterious or clever. Yet, it is common enough that it must work for someone. A weakness of this device is that it provides only a visual cue to take medications. It provides no mechanism to know which pills to take at a particular time of day.

Figure 5.23. Pillbox provides only visual cues.

Birth control pills are sold packaged for use as a 1-month supply. The packaging indicates whether or not patient has been taking their medication consistently and are current, assuming they know what day it is.

Figure 5.24. Birth control pills are packaged for use as a 1-month supply.

If clever packaging is not enough, the wristwatch in Figure 5.25 can remind the user to take medications up to six times a day. Instead of an audible alarm, the watch vibrates discreetly.

Figure 5.25. This watch vibrates to remind users to take medication.
Courtesy e-pill® Medication Reminders. www.epill.com. Used with permission.

The logical extension of the simple pillbox is shown in Figure 5.26. This system has seven boxes. Each box contains four compartments and a timer to remind the patient to take the medicine in the next compartment.

Figure 5.26. This system represents the logical extension of the traditional pillbox.
Courtesy e-pill® Medication Reminders. www.epill.com. Used with permission.

If a timer is not enough, the medication dispenser in Figure 5.27 dispenses the medications and detects when they are removed. If the pills are not removed on a timely basis, the dispenser places a phone call to a family member or caregiver who can follow up with the appropriate party.

Figure 5.27. The medication dispenser dispenses medications and detects when they are removed.
Courtesy e-pill® Medication Reminders. www.epill.com. Used with permission.

Example Set 5.9—Variations in "Take Your Medicine," Part III

The next step in this progression towards more strict control of medication dosing would be a device to ensure that medications are actually administered. Even the most sophisticated dispenser ensures only that the medication is removed from the dispenser. The mistake-proofing devices that follow take a different approach. Instead of controlling the traditional process, new processes are developed. The time-release capsule (Figure 5.28) accomplishes the same goal as prescribing multiple doses of a medicine but in a more mistake-proof way. The patients need only to take a single pill.

The need to remember to take even a single pill has been further reduced. Patches are used to administer medications over much longer periods of time (Figure 5.29). The design of the medication delivery method reduces the need to remember to take medications.

Figure 5.28. The time-release capsule represented one instance of the development of a new process instead of attempting to control the traditional process of reminding patients to take their medication.

Figure 5.29. Patches administer medications over a longer period of time.

Going one step further, the Norplant® system is embedded in a woman's body for 5 years. This contraceptive is a set of six small capsules that are placed under the skin of the upper arm (Figure 5.30). They eliminate the need to remember to take medication. One drawback is that the implants must be removed after 5 years.

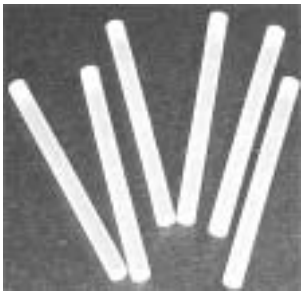

Figure 5.30. Norplant® contraceptive capsules are effective for 5 years.

Example Set 5.10—Examples from the Built Environment, Part I

New York Presbyterian Hospital covers a city block with interconnected buildings featuring addition after addition (Figure 5.31). The interconnections inside these buildings can cause navigational problems. Those familiar with the layout of the hospital know that Building A connects to Building B on the first and third floors, but not on the second, or they may know that floor 15 of Pavilion X connects to floor 16 of Y Building via the skybridge. Patients who are newcomers to these buildings find it difficult to navigate the hospital.

Figure 5.31. New York Presbyterian Hospital.

One way to improve a patient's ability to find their way around is to mark well-traveled paths throughout the facility. Paths could be marked using solid tape or painted lines (Figure 5.32) or, like Hansel and Gretel's bread crumbs, they could be marked with strategically placed icons that lead to the desired destination. The colored shoes (Figure 5.33) are from New York Presbyterian Hospital.

Figure 5.32. Solid lines show the way.

Figure 5.33. The colored shoes mark the path.

Magnetic fire doors (Figure 5.34) are widely used in many types of commercial buildings. They are linked to fire detection systems so that the doors are released, then close when the fire detection system is activated. Closing the door does not prevent fires. It temporarily prevents the influence of mistakes, the fire, from spreading further.

Figure 5.34. Magnetic fire doors.

Figure 5.35. The gate discourages further descent.

During a fire or other emergency, many factors make it easy for those descending to descend too far down the stairwell and miss the street-level exit. The gate in Figure 5.35 provides a very strong cue that descending past that point is discouraged. This gate, like the door in Figure 5.34, closes automatically when the fire alarm is tripped.

Example Set 5.11—Examples From the Built Environment, Part II

St. Joseph's Hospital has designed every patient room so that the sink is clearly visible (Figure 5.36). Patients are encouraged to watch and ensure that staff members wash their hands before interacting with them. In most rooms, the doors open toward the sink (Figure 5.37), further encouraging handwashing.

Figure 5.36. Clearly visible sinks encourage handwashing.

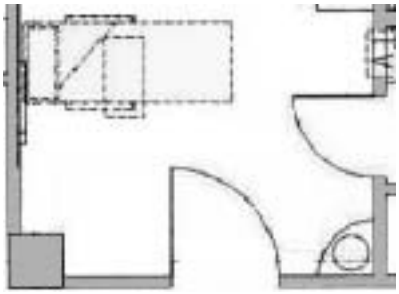

Figure 5.37. Floorplan of a room in St. Joseph's Hospital, in West Bend, WI.

Each patient room is also provided with a nurse's alcove that has all of the necessary supplies (see Chapter 7, example 7.27) and a computer for electronic documentation of care accomplished before he or she moves on to another patient. The door to the alcove has a window so that the nurse can see the patient while completing the chart (Figures 5.38 and 5.39).

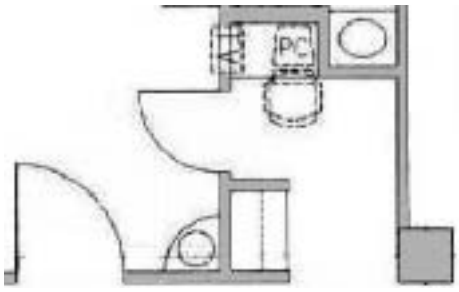

Figure 5.38. Floorplan of a patient room with nurse's alcove in St. Joseph's Hospital.

Figure 5.39. Each patient room has a nurse's alcove.

The concept of being able to see the patient is taken to the extreme in St. Joseph's intensive care unit (ICU). The ICU is located along the curved back of the building. It is engineered so that each patient's face can be seen from the work area. Being able to see patients is considered so important that the only exception to room standardization in the entire hospital occurs here. The last two rooms (most distant in Figure 5.40) had to be rotated 180 degrees so that the patients could be seen.

Figure 5.40. The St. Joseph's Hospital ICU.

Example Set 5.12—Examples from the Built Environment, Part III

At St. Joseph's Hospital, the bathroom is placed near the head of the bed for fall prevention (Figure 5.41). In many hospitals, however, the room plans for every other room are rotated 180 degrees so that two rooms share a common plumbing wall. Often, this requires the patient to cross the middle of the room where no handrails are available to support the patient and prevent falls. At St. Joseph's hospital, the patient is provided with handrails from the bedside to every part of the bathroom (Figures 5.42-5.45).

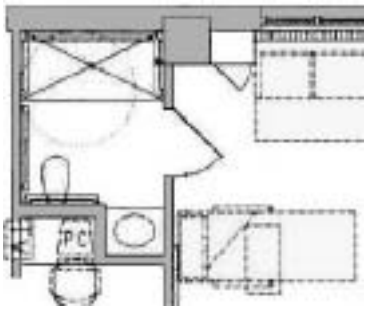

Figure 5.41. Floorplan of a patient room with bathroom.
***Floorplan images© Joint Commission Resources.**
Enhancing the traditional hospital design process: a focus on patient safety. Jt Comm J Qual Safety 2004;30(3):115-124. Reprinted with permission.

If human beings are prone to perform automatically, as if on auto-pilot, perhaps making environments where that auto-pilot will be correct is worthwhile. That is the strategy for headwalls. Every room in the hospital has a standardized arrangement; the Emergency Room (ER), ICU, and medical/surgical rooms are all identical.

Subsequently, ER activities can spill over into adjacent rooms in ICU during extremely busy times (Figures 5.46A and 5.46B).

Figure 5.42. Patient bathrooms are near bed. Note the hand rail.

Figure 5.43. Handrails are present from the bedside to the bathroom.

Figure 5.44. Another view of a patient bathroom.

Figure 5.45. A shower with handrails.

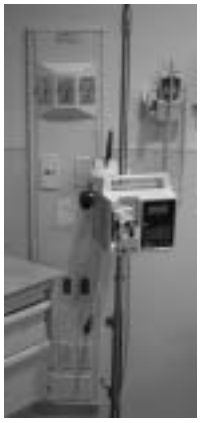

Figure 5.46A

Figure 5.46B

Figure 5.46A. Standardized headwalls allow staff members to work on 'auto-pilot'.

Figure 5.46B. Another view of a standardized headwall.

Example Set 5.13—Getting X-Rays Right

The flasher plate (Figure 5.47) is a small window on the x-ray film cassette that prevents film from becoming exposed during the flashing of the patient's name onto the film. The cassette is inserted into the name flasher, then the flasher plate is automatically pulled back to expose the film to a small light that exposes the patient's name on the film (Figure 5.48). The flasher plate will only move when it is inserted into the name-flashing device.

Figure 5.47. The flasher plate ensures that only the patient's name is exposed on film.

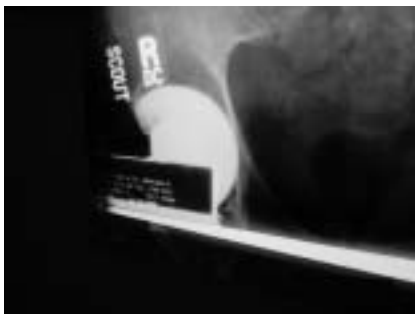

Figure 5.48. The patient's name is exposed on film.

The film is marked as 'left' or 'right' for reference to prevent the radiologist from misinterpreting the results when reading the film (Figure 5.49).

Figure 5.49. Beekley R-ID-SPOT® and Beekley L-ID-SPOT®. Photo courtesy of Beekley Corporation, Bristol, CT. Used with permision.

In addition to marking the left and right sides, a technologist's initials, film series, and other information can be recorded with a blunt writing instrument.

Figure 5.50 shows a dental x-ray film holder that is inserted in a patient's mouth. The hoop provides a target for positioning the x-ray machine so that the dental technician aligns it correctly each time.

Figure 5.50. The hoop in this dental x-ray film holder provides a target for the technician.

Example Set 5.14—Exposure Control

Figure 5.51 illustrates two mistake-proofing techniques to prevent radiation exposure. The lighted sign over the x-ray room door alerts personnel that an exposure is in progress. When the x-ray machine is emitting x-rays, the exposure light alerts personnel that they should not enter the room. The door interlock prevents exposure if the x-ray room door is left open. A small switch in the door frame will not allow an exposure to occur if the door is left open.

Figure 5.51. The door interlock prevents unwanted exposures; the lighted sign provides additional mistake-proofing.

In Figure 5.52, the mistake-proofing takes the form of personal protective equipment. The apron protects the technician from overexposure to radiation.

Figure 5.52. Mistake-proofing via personal protective equipment.
Photo courtesy of Marcy F. Grant. Used with permission.

On older x-ray units that have a cord attached to the exposure button, the relatively short cord length does not allow the technologist to make an exposure while outside the protection of the control booth.

Figure 5.53. The short cord prevents an exposure outside of the control booth.

Example Set 5.15—Bed Alarms and Fall Reduction

A number of mistake-proofing devices have been developed to protect patients at risk for falls when getting out of bed. Bed alarms (Figures 5.54 and 5.55) are designed to notify caregivers when a patient gets out of bed, come in a variety of sizes and shapes, and perform a variety of functions.

Figure 5.54. A bed monitor with sensor built into the bed.

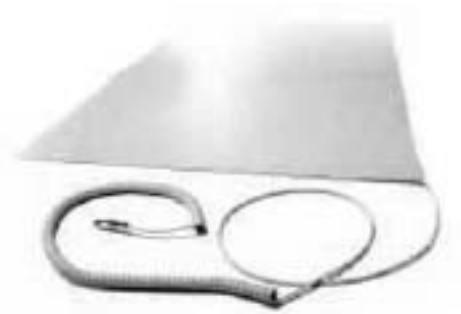

Figure 5.55. Sophisticated sensors trigger alarms when patients attempt to get up from their beds.

In some cases, the alarm is built into the bed. In other cases, it is added-on as needed. In one model, a pad is placed under the bottom sheet and detects the patient's body weight. See http://www.abledata.com/abledata.cfm?pageid=113583&top=0&productid=84241&trail=0).

Some sensors can be placed under the mattress. The alarms come with many different sound alert options, including voice warnings that can be recorded by a loved one. One version will monitor how long a patient has been out of bed and telephone a caregiver if the bed remains unoccupied for too long. See http://www.bedmonitors.com/bedmonitors_how_works.htm.

The alarm in Figure 5.56 tethers the patient to the bed. The device is strapped to the patient. The cord is attached to the bed. The alarm will sound if the patient moves in a way that pulls the cord, detaching the tether from the device.

Figure 5.56. A bed alarm with tether.

The bed alarm in Figure 5.55 is placed on the floor beside the bed so that an alarm sounds when a patient's feet touch the floor. Other approaches considered by manufacturers include the use of lasers and other sophisticated sensors to detect when a patient tries to get up. See http://www.norto.com.au/Norto-Emfit-Safebed.htm.

Example Set 5.16—Sharps

Protecting staff, patients, and visitors from the biohazard of "sharps" (exposed needles) takes many forms. The syringe in Figure 5.57 is equipped with a cover for the needle. The cover is inserted into the square base so that it stands vertically. The needle can be inserted into the cover using one hand. The other hand can be kept safely out of the way. When the cover is used as intended, a misjudgment in the insertion process will not result in a needle stick.

Figure 5.57. Syringe with a cover and a square base.

The syringe in Figure 5.58 has a hinged cover so that it can be easily closed with one hand and with a motion that provides minimal opportunity for a needle stick. The cover clicks into place and cannot be removed.

Figure 5.58. This syringe can be closed with one hand.

The needle in Figure 5.59 is nearly self-blunting. It is inserted normally, but when the needle is withdrawn, a sleeve containing a steel tip cover is held against the patient's skin. The tip of the needle catches the cover, pulling it from the sleeve. Devices that require less effort and involve a more natural motion will usually be more effective.

Figure 5.59. When this needle is withdrawn, a sleeve is held against the patient's skin.

The scalpel in Figure 5.60 has a spring-loaded, retractable blade. Push a button near the back of the handle and the blade retracts.

Figure 5.60. Push a button on this scalpel to retract the blade.

A workbook on sharps safety by the Centers for Disease Control and Prevention (CDC)[9] states: "A passive safety feature is one that requires no action by the user."

> …Few devices with passive safety features are currently available. Many devices currently marketed as self-blunting, self-resheathing, or self-retracting imply that the safety feature is passive. However, devices that use these strategies generally require that the user engage the safety feature… Although devices with passive safety features are intuitively more desirable, this does not mean that a safety feature that requires activation is poorly designed or not desirable.[9]

Example Set 5.17—Controlling the Controls

The IV pump in Figure 5.61 features a small button on the back of the machine that can be used to lock the controls so that others who are unfamiliar with the equipment cannot tamper with the settings on the control panel on the front of the machine.

Figure 5.61. This IV pump's controls can be locked by pushing a button.

The switch on this IV pump has a clear plastic cover that prevents inadvertent bumping of the switch. Donald Norman[10] recommends making it harder to do what cannot be reversed. The cover makes the equipment in Figure 5.62 more difficult to use, but apparently, the errors prevented more than compensate for the inconvenience.

Figure 5.62. The switch on the back of this machine prevents inadvertent bumping.

Example Set 5.18—Software

Although most mistake-proofing devices can be photographed, software applications cannot. A number of logical checks can be performed, however, after information has been entered into an application via computer. The examples in this set show how software interfaces can be used to mistake-proof some aspects of medical processes.

The keypad on the radiology equipment in Figure 5.63 requires patient information to be entered prior to any exam.

Figure 5.63. Patient information first, exam second.

Programmed protocols are pre-programmed instructions to the machine that control how the exam will be set up (Figure 5.64). This enables the operator to select the exam and be confident that all the correct settings are in place. It also ensures that exams are performed in a consistent manner, regardless of who is operating the machine.

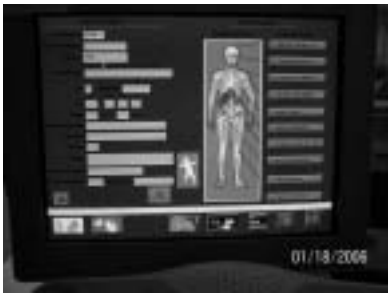

Figure 5.64. Programmed protocols ensure that all exams are performed in a consistent manner.

The system shown in Figure 5.65 reviews patient histories and gives an alert if the blood type differs from the type previously entered or if the patient's blood contained an antibody. The system will also give a warning if a blood type different from the patient's is cross-matched for transfusion. An alert is given if the patient needs special blood products.

Figure 5.65. This system alerts for conflicting information about a patient's blood and the need for special blood products.

For stereotactic breast biopsies, this unit (Figure 5.66) contains protective software that, by calculating the needle's position, prevents the improper insertion of a biopsy needle that could result in patient injury.

Figure 5.66. Software prevents improper insertion of a biopsy needle.

Example Set 5.19—Refrigeration Feedback

Blood bank refrigerators are equipped with temperature monitors that sound an alarm if and when the temperature is out of the safety range (Figure 5.67). The alarms also produce continuous chart recordings (Figure 5.68) and visual digital readings (Figure 5.69).

Figure 5.67. An alarm sounds if the refrigerator temperature becomes too warm or too cold.

Figure 5.68. Blood bank refrigerators monitor temperature and produce chart recordings and digital visual readings.

The read-out "Status OK" indicates that the refrigerators in this blood bank are operating properly. When the temperature or other operating parameters are not correct, a message scrolls across the display, indicating which refrigerator is out of specifications and which specification is violated.

Figure 5.69. The display indicates an OK status and, when necessary, provides other indications of refrigerator problems.

The alarm system in Figure 5.70 is functional but not as sophisticated as the other examples in this set. It features an audible alarm and lights to indicate which zone is down. This system benefits tremendously from the posted instructions, a simple job aid that puts knowledge in the world. It will be very useful when the alarm goes off. The instructions indicate which refrigerator corresponds to each zone and provides information about how to silence the alarm and troubleshoot the problem. Troubleshooting begins with ensuring that the door is sealed.

Figure 5.70. This system uses an audible alarm; posted instructions aid in troubleshooting.

Example Set 5.20—Mistake-Proofing Patient Interactions

As Chase and Stewart[11] indicated almost 15 years ago, the actions of the "customer" need to be mistake-proofed. These two examples show how software can reduce variation in processes for which patients' cooperation and precise responses are critical to successful outcomes. Both examples show that mistake-proofing the actions of health care staff can only partially lead to truly mistake-proofing processes. The actions and behaviors of patients, family, and loved ones must also be mistake-proofed.

It is very important that patients lie as motionless as possible during a CT exam. Breathing instructions are pre-recorded and embedded in multimedia software. When the operator begins the exam, the correct breathing instructions are automatically played to the patient at the correct time without further operator intervention, helping ensure patient cooperation and optimal results (Figure 5.71).

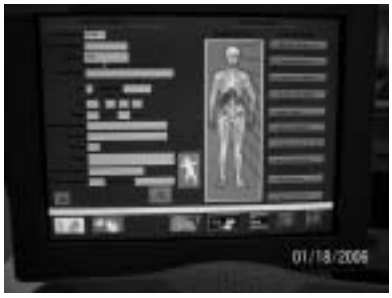

Figure 5.71. Pre-recorded patient instructions help ensure cooperation and optimal results from CT scans.

The blood donation software application in Figure 5.72 is optimized by eliciting donor information through a Web-based survey. The system provides on-screen text with added privacy via earphone audio and other options, color pictures to emphasize important aspects of questions, and touch screens to eliminate "keyboard phobia" and mouse aversions. The system contains donor self-interview and staff-review modules. It prevents the production of a donor record until the survey has been completed and a staff member has judged the information to be acceptable.

Figure 5.72. Blood donation software elicits donor information via a Web-based survey. © Talisman Limited. Used with permission.

Example Set 5.21 – Wristbands

Figure 5.73. Wristbands can contain color photos, symbols, and other patient information Copyright © 2005 Endor ID. Used with permission.

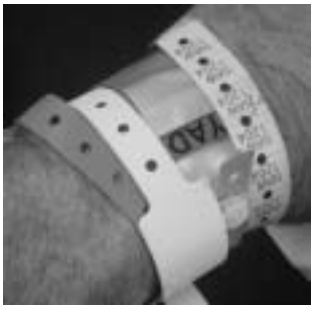

Figure 5.74. A patient wearing multiple hospital wristbands.

Figure 5.75. A patient's medical records can be stored in this wristband.

Wristbands (Figures 5.73-5.75) have been used extensively in medicine to provide sensory alerts for many different patient conditions. Wristbands provide a physical space for patient information to reside; efforts are underway to put as much information onto a wristband as possible. Color coding is widely employed to indicate allergies, fall risks, do not resuscitate (DNR) orders, etc. Improved printer functionality enables the placement of multiple symbols and photos on the wristband, along with a patient's name and date of birth. The wristband is also the locus for more sophisticated patient identification technologies such as bar coding. There is a magnetic data storage device (capable of storing medical records) mounted on the wristband in Figure 5.75.

Some hospitals place yellow wristbands on DNR patients. There is some concern that yellow LIVESTRONG™ bracelets that help support the Lance Armstrong

Foundation's efforts to fund cancer research may be mistaken for a DNR wristband. While no one has ever died because of confusion between the two, some hospitals are reportedly taping over LIVESTRONG™ bracelets with white adhesive tape to be safe.[12]

This chapter discussed related sets of mistake-proofing devices. Chapter 6 is concerned with medical and non-medical applications of mistake-proofing.

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Chapter 6. Medical and Non-Medical Examples: Differences and Similarities

Introduction

Despite the different domains in which mistake-proofing is employed, actual devices often are not very different. This chapter provides 19 pairs of examples. Each medical example is paired with an example from industry or everyday life. The examples also suggest that many solutions for medical mistake-proofing have already been implemented in other industries and only need to be adapted, or directly imported, for use in medical environments.

Maurer, et al.[1] pose the question "Are industry-based safety initiatives relevant to medicine?" Their article argues for an affirmative response:

> The fundamental concepts of these quality programs, [e.g., Six Sigma], although initially designed to improve manufacturing quality and efficiency, can be effectively applied to service-based activities such as medical care. In one case, implementing an industry-based quality program in the medical department of a large manufacturing concern initiated improvements and changes to the medical care process.

Example Pair 6.1—Color Coded Wires

Medical Application

In Figure 6.1, each monitor lead is color-coded so that it can be correctly placed on the patient and hooked to the same color-coded outlet on the machine.

Figure 6.1. Color-coded wiring.

Comparable Non-Medical Application

Color-coding is a weak but widely used mistake-proofing method shown in Figure 6.2 on the back of a computer. Depending on the application, color-coding can be very effective, despite its inability to stop the process.

Figure 6.2. Color coding on the back of a computer.

Example Pair 6.2—Automatic Wheelchair Brakes

Medical Application

Xiang, Chany, and Smith[2] reported that in 2003, more than 100,000 wheelchair-related injuries were seen and treated in US emergency rooms—twice the number reported in 1991. The authors also reported that in all age groups of wheelchair users, tipping over and falling accounted for 65 percent to 80 percent of injuries. Brechtelsbauer and Louie[3] reported on a study of incidents involving wheelchair use in long-term care and found that most injuries were a result of attempts by residents to self-transfer into or out of the wheelchair.

The wheelchair in Figure 6.3 is equipped with a device that automatically locks the wheelchair when no one is sitting in it. When empty, it can only be moved when the unlocking lever on the handle is used.

Figure 6.3. Exiting a wheelchair with automatic brakes. Photo courtesy of Safer Automatic Wheelchair Wheel Lock, Inc. Used with permission.

Comparable Non-Medical Application

Some applications of medical mistake-proofing do not differ from non-medical applications. Many riding mowers have a "dead-man's switch" on the seat. When the rider gets out of the seat for any reason, the engine turns off. The mower is equipped with an electronic sensor on the bottom of the seat (Figure 6.4). Of course, employing electronics would be an added system for non-electric wheelchairs. The purely mechanical approach could be preferred because of its simplicity.

Figure 6.4. A riding mower with an electronic sensor and "dead-man's switch."

Example Pair 6.3—Picking Up the Right Product, Part I

Medical Application

The Pyxis system controls access to medications. The drawers are locked and inaccessible unless the proper verification process is completed. The user enters patient and order information via the keyboard or the barcode reader. The information is processed, and only the correct drawer opens to allow access to the prescribed drug. The supply cabinet in Figure 6.5 features a pick-to-light system. Green lights indicate the shelf on which the selected item resides.

Figure 6.5. A pick-to-light auxiliary cabinet linked to the Pyxis system.

Comparable Non-Medical Application

Comparable systems exist in industry. The bins in Figure 6.6 are equipped with pick-to-light systems. These systems have a computer-controlled system of lights that indicate from which bin items are to be removed. Some are equipped with an infrared sensor that sounds a buzzer if an item is selected from the wrong bin.

Figure 6.6. The computer-controlled light system lets users know from which bin to remove items.
Photo of Smart Frame™ courtesy of Speastech, Inc. Used with permission.

Example Pair 6.4—Picking Up the Right Product, Part II

Medical Application

Figure 6.7 shows the interior of a robotic pharmacy. The inventory-picking robot increases the accuracy of picking and the speed/efficiency of the operation. Comparable systems, called Automated Storage and Retrieval Systems (ASRS), are used extensively in industrial settings.

Figure 6.7. The inventory-picking robot increases accuracy.
Photo courtesy of Redmond Regional Medical Center. Used with permission.

Comparable Non-Medical Application

The Oviatt Library at California State University at Northridge features an ASRS in its East Wing (Figure 6.8). The ASRS employs 13,260 steel bins that measure 2 feet by 4 feet. Infrequently used books and older periodicals are stored in the 8,000 sq. ft wing, which has a ceiling height of 40 feet. Bar codes attached to books and periodicals are mapped to their bin locations in the ASRS system. Materials are retrieved using a computerized lift that is guided by rails at the top and bottom.

Figure 6.8. This ASRS system uses a computerized lift to retrieve books and periodicals.
Used with the permission of the Oviatt Library, California State University, Northridge.

Example Pair 6.5—Close the Door to Start

Medical Application

The automatic tissue processor in Figure 6.9 is equipped with an alarm to verify that the door of the processor has been properly closed before processing begins. Processing will be halted if the door is opened for any reason.

Figure 6.9. This tissue processor stops if the door is opened.

Comparable Non-Medical Application

At times, mistake-proofing for a medical environment is not very different from existing mistake-proofing applications in everyday life. For decades, clothes dryers have been designed to stop operating when the door is opened (Figure 6.10).

Figure 6.10. The clothes dryer stops operating when the door is opened.

Example Pair 6.6—Push to Go

Medical Application

The portable x-ray machine in Figure 6.11 is equipped with a brake that disengages when a user pushes down on the handle. The mechanism prevents the x-ray machine from moving unless it is being pushed.

Successful mistake-proofing requires attention to many details

Figure 6.11. The brake disengages when a user pushes down on the handle.

Comparable Non-Medical Application

The portable x-ray machine in Figure 6.11 and the luggage cart in Figure 6.12 employ the same approach to eliminate errors. The luggage cart requires the user to depress the bar in order to disengage the cart's brake.

The shaved ice machine in Figure 6.13 requires the lid to the shaving chamber to be closed and depressed in order for the machine to operate.

Figure 6.12. Depress the bar to disengage the brake of this luggage cart.

Figure 6.13. This shaved ice machine will not operate with the lid open.

Example Pair 6.7—Collision Prevention

Medical Application

The bumper switch stops a portable x-ray machine if the front bumper comes into contact with an object (Figure 6.14). The bumper is easily pushed in so that the slightest contact causes the portable unit to stop immediately.

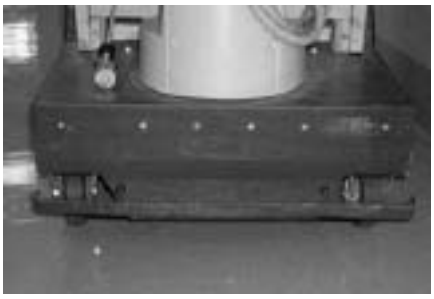

Figure 6.14. A front bumper switch stops the machine upon contact.

Comparable Non-Medical Application

In robotic manufacturing systems, material is moved using automated guided vehicle systems (Figure 6.14). The automated guided vehicles are equipped with bumpers that stop the vehicle if they contact anything in their path. It is the bumpers, not neural networks, that enable these special purpose robots to adhere to the first law of robotics: "A robot may not injure a human being, or, through inaction, allow a human being to come to harm."[4]

Similar approaches are used on jetways at major airports. Bumpers stop the jetway if it comes into contact with anything near the wheels.

Figure 6.15. A guided vehicle system stops this robot when contact is made.
Image from Frog Navigation Systems. www.frog.nl. Used with permission.

Example Pair 6.8—What Goes In Must Not Come Out

Medical Application

The sharps container in Figure 6.16 ensures that used sharps (needles) cannot be reached and removed after they are deposited. The used sharp is placed on the back part of the lid, which is then lifted to dump the sharp into the container. The lid's design makes it impossible to access the used sharps. This example is similar to the darkroom door example (Chapter 5, Figure 5.1).

Figure 6.16. This sharps container prevents injuries.

Comparable Non-Medical Application

The same techniques for preventing individuals from gaining access to deposited items are used in library book returns (Figure 6.17) and bank night depositories (Figure 6.18).

Figure 6.17. Books and other materials can be deposited, but access is controlled.

Figure 6.18. Only bank employees can access deposits made after operating hours.

Example Pair 6.9—Two Hands Required

Medical Application

As a safety mechanism, all defibrillators require the activation of two separate buttons, held by one operator, to trigger discharge of an electrical current across the thorax of patients in ventricular fibrillation (Figure 6.19). The two button feature reduces the risk of accidental discharge or misplaced electrical shock.

Figure 6.19. This defibrillator requires two-handed operation.

Comparable Non-Medical Application

The punch press in Figure 6.20 was made in the United States and exported to a factory in Asia. The American manufacturer assumed that one person would operate the machine. It has two switches, one for each of the worker's hands. Multiple switches are very common on manufacturing machinery. They provide the same safeguard as the buttons on the defibrillator in Figure 6.19.

Figure 6.20. Punch press made for two-handed operation, but in some locales six-handed operation will be seen as more efficient.

In countries with low wages and lax occupational safety laws, getting the most out of this machine means using six hands instead of two.

One bad judgment or lapse of attention can result in the maiming of a worker and the end of a productive working life. Medicine is not very different. One bad judgment or lapse of attention can maim a patient or end the career of a doctor or nurse. Neither result is acceptable.

Example Pair 6.10—How Information Is Presented Matters

Medical Application

How information is displayed makes all the difference in its utility. Clipboards filled with papers (Figure 6.21) are much more effective at providing an audit trail than they are at communicating the status of the patient or how the process should proceed.

Figure 6.21. Clipboards provide an effective audit trail, but do not indicate how to proceed.

The use of electronic medical records enables information to be reformatted in ways that are more readily understandable. Powsner and Tufte[5] propose medical charting software that renders years of data more easily understandable (Figure 6.22).

See Chapter 7, Example 7.18, for a larger image of the graphic medical chart.

Comparable Non-Medical Application

The formatting of information also matters outside of medicine. Figures 6.23 and 6.24 document the performance of a complex machine being tested before it is shipped to a customer. The company found that most of the critical information on which decisions were based could be contained on one summary page (Figure 6.24). Reportedly, the result was that decisions were made more quickly, and use of the information increased. Managers also found that the trends on the one-page graph (Figure 6.25) were easier to spot than when presented on a graph that was "three cubicles long" and folded every 11 inches (Figure 6.26).

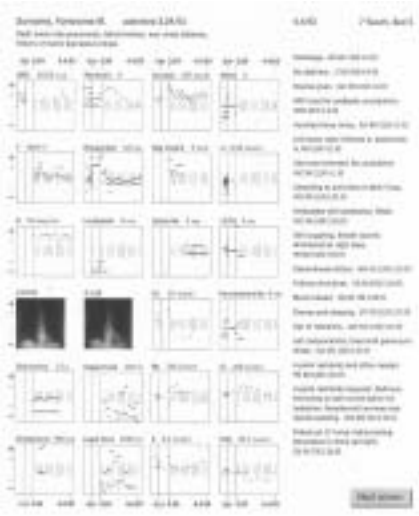

Figure 6.22. Medical charting software enables the display of years of patient data.
© 1994, Seth Powsner and Graphics Press. Used with permission.

Figure 6.23. Before; one way to document a machine's performance.

Figure 6.24. After; most of the critical information was captured in one page.

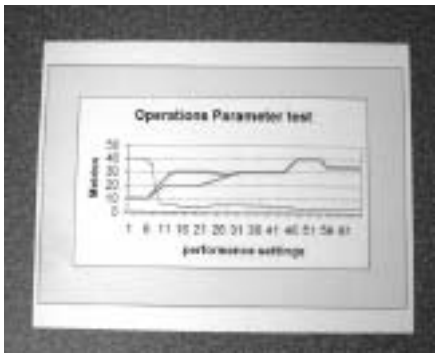

Figure 6.25. A one-page graph accurately depicted trends.

Figure 6.26. Information was hard to find in a graph that was three cubicles long.

Example Pair 6.11—Tooling: Jigs and Fixtures

While the idea of using jigs and fixtures in health care may seem distasteful, there are numerous examples of devices that allow the body to be positioned in ways that facilitate good care. In many cases, these devices are used solely to increase a patient's comfort.

Medical Application

The CT scan head holder in Figure 6.27 keeps the patient's head in the correct position during a CT scan, which is critical to an accurate reading.

Figure 6.27. A CT scan head holder.

The immobilizer (Figure 6.28) has been in use for 40 years. Designed by a technician who had many problems with positioning infants and children, it securely restrains infants during imaging.

Figure 6.28. The Pigg-O-Stat Infant Immobilizer and Positioner.
Modern Way Immobilizers, Inc. Used with permission.

Beds used in maternity wards are equipped with stirrups (Figure 6.29) to allow expectant mothers to be positioned correctly and as comfortably as possible under the circumstances.

Figure 6.29. A maternity bed with stirrups for positioning and support.

Comparable Non-Medical Application

Figures 6.30 and 6.31 depict a fixture for holding parts in the correct orientation during fabrication.

Figure 6.30. A fixture for holding parts during fabrication.
Photo by Jon Timlin. Used with permission.

Figure 6.31. Closeup of the fixture in Figure 6.30.
Photo by Jon Timlin. Used with permission.

Example Pair 6.12—Lock-Outs

Medical Application

An electromechanical door lock system on the lab centrifuge in Figure 6.32, together with a manual lock, prevents run initiation unless the door is closed and latched. When a run is in progress, the door locks automatically and can be opened only when the power is on, the rotor is virtually stopped (spinning less than 40 rpm), and the lock is in the unlocked position. An LED (light emitting diode) on the "open door" key lights up when the door can be opened.

Figure 6.32. The door on the centrifuge contains an electromechanical lock and a manual lock.

Comparable Non-Medical Application

The centrifuge in Figure 6.33 is used to stress test ceramic semiconductor packages to ensure the integrity of the hermetic seal. Heavy steel wheels full of parts are loaded into the machine. The lid is closed and locked before starting. After the machine has started to spin, the cover is locked and cannot be opened until the speed of rotation approaches zero.

Figure 6.33. The cover on this centrifuge cannot be opened until rotation approaches zero.
Copyright © 2006 Tandex Test Labs, Inc. Used with permission.

Example Pair 6.13—Visual Indication of Settings

Medical Application

Michael Westley, medical director of critical care and respiratory therapy at Virginia Mason Hospital in Seattle, Washington, reported that:

> The hospital was able to reduce cases of ventilator-associated pneumonia (VAP) from 30 in 2002 to 5 in 2004. Costs associated with each case of VAP ranged from $5,000 to $40,000. Doctors and nurses reduced the number of cases by "reliably doing boring things." The 'boring things' included frequent hand washing by doctors and nurses and keeping patients' heads elevated.[6]

Figure 6.34. In addition to the gauge on the railing, the label is mounted to indicate to nurses whether or not the bed is situated at the correct angle.

The Mississippi delegation to the Patient Safety Improvement Corps (PSIC) also focused on reducing VAP rates. One action they took was to ensure that patients' beds were raised to an angle of at least 30°. To facilitate "reliably doing boring things," Darla Belt, an RN on the team, felt that it was important to be able to determine whether the bed was at the correct angle from outside the room in the ICU. Her solution was to apply a label to the bed to indicate the correct angle (Figure 6.34). She reports that staff members have become accustomed to the label's

position. Spotting it from the doorway, they no longer have to walk into the room to check the bed's angle, realizing that a flat or vertical sign is indicative of a less than ideally positioned bed. Consequently, an out of place sign is immediately noticeable to the staff. Now, when they see a bed without a gauge on its railing indicating the angle of the bed, they can judge the correct angle of the bed fairly accurately.[7]

Figure 6.35 could be seen as a slight improvement: staff mount the label at 30° so that it is level when the bed is at the correct angle. Staff will quickly become accustomed to looking at this angle and judging whether or not it is correct.

Figure 6.35. The label on this bed is mounted at 30° so that it is level when the bed is at the correct angle.

Comparable Non-Medical Application

The label in Figures 6.36 and 6.37 is attached to a vibrator bowl (Figure 6.38) that is used to prepare steel tools for chroming. The label helps workers determine if the bowl is operating correctly. It is difficult to tell from the photograph, but in Figure 6.37, the lines labeled 60 and 70 appear to be less blurry. This indicates that the lead angle is between 60° and 70°. The series of circles running horizontally below the fan shaped figure show vibration amplitude. At the circle labeled 2, the two circles created by the vibration do not touch. At 7, the two circles overlap. At 3.5, the circles just touch. This means that the amplitude is 3.5 mm. The label enables anyone to determine how well the bowl is operating.

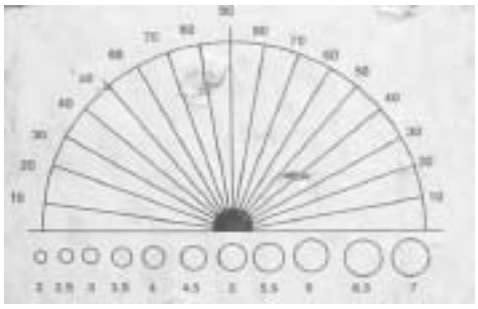

Figure 6.36. A vibrator bowl label with the vibrator turned off.

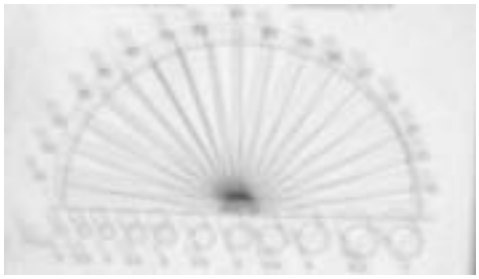

Figure 6.37. A vibrator bowl label with the vibrator turned on.

Figure 6.38. Vibrator bowl.

Example Pair 6.14—Knowledge in the World Equals Knowledge on the Pill

Medical Application

Many phamaceutical companies use color-coding and information printed on the product (Figure 6.39) to inform consumers of the medication and dosage.

Figure 6.39. Color-coded medications with dosage information.

Comparable Non-Medical Application

A color-coding scheme is used for electronic resistors to communicate tolerances and electrical properties from .01 to 10,000,000 ohm (Figure 6.40).

Color	First Band	Second Band	Third Band	Multiplier	Tolerance
Black	0	0	0	1	
Brown	1	1	1	10	±1%
Red	2	2	2	100	±2%
Orange	3	3	3	1k	
Yellow	4	4	4	10k	
Green	5	5	5	100k	±0.5%
Blue	6	6	6	1M	±0.25%
Violet	7	7	7	10M	±0.10%
Grey	8	8	8		±0.05%
White	9	9	9		
Gold				0.1	±5%
Silver				0.01	±10%

Figure 6.40. The color scheme makes differentiation easily understood.

Example Pair 6.15—Don't Reinvent the Wheel, Part I

Medical Application

Often, there is no difference between medical and non-medical applications. In the case of the restaurant pager, the medical application is an off-the-shelf application taken directly from the restaurant industry, not a separate invention.

In St. Joseph's Hospital in West Bend, IL, pagers are distributed to patients in the hospital waiting room (Figure 6.41).

Figure 6.41. The restaurant pager required no changes in order to be useful in a medical environment.

Comparable Non-Medical Application

Staff members saw restaurant pagers (Figure 6.42) and bought them, then began using them to improve patient and health care worker satisfaction.

Figure 6.42. Restaurant pagers have proved useful in different health care environments.

Example Pair 6.16—Coverage Must Be Complete

Medical Application

Chlorhexidine has been shown to be more effective than iodine for the prevention of intravascular catheter-related infections.[8] Yet, its adoption has not been as rapid as some might expect. One explanation is that chlorhexidine is clear (Figure 6.43). It does not leave iodine's telltale, burnt orange stain. The stain gives a visual indication of where it has been applied, and whether or not the coverage is satisfactory. A solution is to add blue-green tint (Figures 6.40 and 6.41) to chlorhexidine for easier visualization.

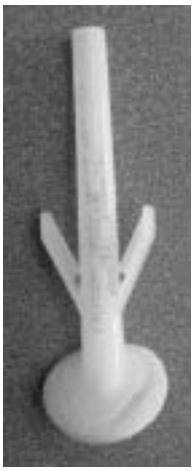

Figure 6.43. Clear chlorhexidine in an intravascular catheter is more effective than iodine in preventing infections.

Figure 6.44. Chlorhexidine with a blue-green tint in an intravascular catheter makes it easier to see if the chlorhexidine has been applied and, if so, determine the thoroughness of the coverage.

Figure 6.45. Tinted chlorhexidine contributes to the prevention of intravascular cather-related infections.

Comparable Non-Medical Application

Ceilings are typically white. The application of a fresh coat of white paint on a surface that is already white makes it difficult to determine where spots have been missed, and whether an adequate amount of paint has been applied for good coverage. A solution is to add pink tint for easier visualization. The specially formulated ceiling paint in Figure 6.46 goes on pink but dries white.

Figure 6.46. This paint is pink when applied, but will be white when it dries.

Example Pair 6.17—Wheelie Bars

Medical Application

The anti-tip wheels mounted to the back of a wheelchair (Figures 6.47 and 6.48) play a very important role. They keep the chair from tipping backward. They also allow the rear wheel to be mounted further forward without the feel of tipping backward. This reduces the weight on the small front wheels, allowing them to turn and roll up and over small obstacles more easily.

Figure 6.47. Anti-tip wheels prevent the wheelchair from tipping backward.

Figure 6.48. Anti-tip wheels also contribute to maneuverability.

Comparable Non-Medical Application

A drag racing motorcycle (Figure 6.49) is equipped with a wheelie bar that keeps its front wheel from coming up too high and prevents the driver from losing control.

Figure 6.49. The wheelie bar helps the driver maintain control of the motorcycle.
Photo by Matt Polito. Used with permission.

Example Pair 6.18—Don't Reinvent the Wheel, Part II

Medical Application

Figure 6.50 illustrates another adaptation of a solution used in retail stores and libraries. Richard Chole, MD, PhD, noted that, even with the "sign your site" policy in place, wrong-site errors (where surgery is performed on a site other than the intended one) still occur and are attributed to one primary cause: the surgical site was not marked. After noting the anti-theft chips attached to items sold at a large hardware chain store last summer, he invented a wristband embedded with a miniature, disposable microchip, and a marker pen with a specialized sticker that deactivates the chip.[9,10] After consulting with the patient or the patient's family, a staff member marks the patient's surgical site, then removes the sticker from the pen and places it on the patient's wristband to deactivate the chip.

If these steps are not followed, the wristband will set off a detector placed in the hallway between the preoperative area and the operating suite. The detector can be set up to give a visual or auditory signal that alerts hospital personnel.

Figure 6.50. A pen, a microchip, and a wristband minimize the chances of wrong-site surgery.
Copyright © CheckSite Medical, Inc. Used by permission.

Comparable Non-Medical Application

Libraries have enacted comparable measures to reduce book thefts. A narrow strip of magnetic material (Figure 6.51) is affixed to each library book. Sensors are placed in front of the exit door (Figure 6.52). An alarm goes off if the book has not been desensitized at the checkout counter.

Figure 6.51. A narrow strip of magnetic material, accompanied by exit door sensors, helps deter library thefts.

Figures 6.53 and 6.54 illustrate alternate configurations. In Figure 6.53, a metallic layer of the sticker desensitizes the article for removal from a library. In Figure 6.54, a commercial product has a sensor strip attached to discourage and catch shoplifters. All three approaches are similar. The advantage of the magnetic material in Figure 6.51 is that it is much harder to find and, therefore, harder to remove.

Figure 6.52. Exit door sensors in a library.

Figure 6.53. The metallic layer desensitizes books so they can be removed from the library without setting off an alarm.

Figure 6.54. The sensor strip can stop a shoplifter.

Example Pair 6.19—Color-Coded Lights

Medical Application

In an effort to make system status obvious even in low-light situations, the IV pole in Figure 6.55 is equipped with LEDs that illuminate the bags of fluid. Colored plastic inserts change the color of the light shining on each channel so that each bag is uniquely identified. Correspondingly colored cyalume lights and stickers are attached to each IV tube (Figure 6.56). This enables the tubing at one end to be more reliably associated with its contents in the IV bag at the other end.

Figure 6.55. LEDs, lights, and stickers uniquely identify each bag of IV fluid.
Image courtesy of Embo-Optics, LLC. Used with permission.

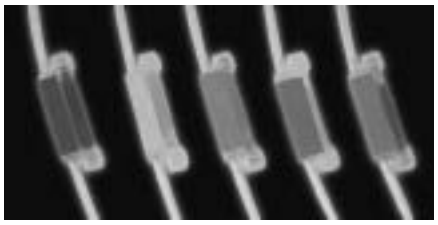

Figure 6.56. Cyalume lights are attached to each IV tube.
Image courtesy of Embo-Optics, LLC. Used with permission.

Comparable Non-Medical Application

The small electronic device on the toilet in Figure 6.57 detects user movement and turns on one of two LED lights. When the red light turns on, the toilet seat is in the up position. A green light indicates that the seat is down.

Figure 6.57. The lights on this toilet enable efficient navigation in the dark.

A Future Mistake-Proofing Wish List

Medical Application—Rolling Bed Table

A participant attending the Patient Safety Improvement Corps, sponsored by the Department of Veterans Affairs (VA) and AHRQ, suggested the need for an overbed table that would not roll when patients used it to steady themselves. No one present knew of such a product. The technology involved to develop such a product, however, could be relatively simple.

Comparable Non-Medical Application

The step stool in Figure 6.58 rolls freely until someone steps on it. The user's weight presses the rim of the stool firmly against the ground so that it will not roll. Perhaps this technology could be applied to solve the hazard of rolling overbed tables. Experimentation of this sort—using creativity to apply existing technology to new problems—has proven to be worthwhile in several examples discussed in this chapter.

Figure 6.58. The user's weight on this step stool prevents it from rolling.

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Chapter 7. Examples of Mistake-Proofing in Health Care

Introduction

This chapter contains 30 examples of mistake-proofing in health care. They range from simple, inexpensive (even hand-made) devices to sophisticated, expensive electronic equipment that can be used anywhere. The creator of one example is a noted expert in graphic displays of quantitative information. Another example has been shown in New York's Museum of Modern Art. All are possible solutions to daunting problems and exemplars of design approaches to solving the problem of human beings making mistakes.[a]

Example 7.1—The Broselow® Tape for Pediatric Trauma

Broselow® Pediatric Emergency Tape is used to reduce errors and increase the speed of treating pediatric trauma patients. The tape is laid out next to the child (Figure 7.1). The tape measure is color-coded according to height. The child is measured along the tape, and the appropriate treatment color is determined. The caregiver then knows that appropriately sized medical devices and appropriate doses of medcations are contained in packets of the same color and can begin treatment immediately.

Dosages of commonly used medications are printed on the Broselow® Tape. Fewer calculations are required, resulting in fewer errors and less time elapsed before treatment actually begins. Supplies are stored in a movable cart or in a satchel (Figure 7.2), each also color-coded according to the Broselow® Tape.

[a] Contributors may submit additional ideas to www.mistakeproofing.com/medical.

Figure 7.1. Use of the Broselow® Tape.
Photo used with permission.

Figure 7.2. A treatment cart color-coded according to the Broselow® Tape.

Example 7.2—Finding the Chart in a Patient's Home

In-House Home Health, Inc. reports that, in the home:

> The patient's home chart becomes lost among the patient's belongings or newspapers and is not available for documentation or continuity of care. Environmental conditions of the patient's home are beyond the control of the agency staff.

Figure 7.3. Hanging the chart on the door helps avoid misplacing it in a home health care situation.
Photo courtesy of In-House Home Health Inc. Used with permission.

The mistake-proofing device in this case is a sturdy bag with the agency's contact information printed on the bag.

> The bag is hung on the bedroom doorknob with the patient's home chart inside (Figure 7.3). Any supplies, equipment, or documentation are placed inside the bag, ensuring that all agency staff will be able to locate the patient's chart when entering the home. The bag also makes it less likely for the chart to get mixed in with newspapers or other clutter that might be in the home.[1]

Example courtesy of In-House Home Health Inc. Used with permission.

Example 7.3—Labeling of Bottled Breast Milk

A hospital risk manager reported that:

> The father of a neonatal intensive care unit (NICU) baby suggested that the previously collected and stored container of breast milk should have some type of seal that would, when broken, indicate tampering. The staff agreed and instituted a system whereby the mother could place a seal on the container after collecting the milk. The seal consists of a paper band placed across the top of the container (Figure 7.4).

Figure 7.4. Mothers will not use this container if the seal is broken.
Photo courtesy of Toledo Children's Hospital. Used with permission.

> The mother is instructed to place the baby's last name on the band on top of the container. A second label designed for breast milk containers, indicating the baby's last name and date/time of collection, is placed around the container covering the ends of the label, which has been placed over the top of the container.
>
> With these labels in place, the container cannot be opened without breaking the seal. The parents and staff are instructed not to use any container that has a broken seal.

Example courtesy of Bill Quinlan, Toledo Children's Hospital. Used with permission.

Example 7.4—Ensuring that Time-Outs Occur

The chief medical officer in Figure 7.5 volunteered to appear on a flyer that is bundled in every sterile surgical kit. Before a surgery, the scrub nurse puts the flyer over the tools to be used in the surgery, blocking the surgeon's access to the tools until the flyer is removed. When the flyer is removed, it reminds the surgical team to perform the required time-out. Although this technique cannot be considered an example of strong mistake-proofing, it is a starting point and is likely to be more effective than the sign usually placed above a door as in Figure 7.6.

Figure 7.5. This chief medical officer emphasizes the use of time-outs. Photo courtesy of Barnes Jewish Hospital. Used with permission.

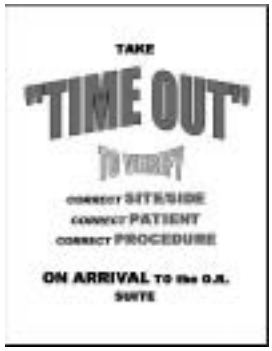

Figure 7.6. The sign reminds surgical personnel in one hospital to take a time-out.

During a time-out, prior to the procedure, the team agrees that they are in possession of the correct information and are about to perform the correct procedure on the correct patient. The sign in Figure 7.6 must be seen to be useful; placing it over the surgical kit would most likely be more effective than hanging it on a nearby wall.

Example courtesy of an anonymous contributor. Used with permission.

Example 7.5—Look-Alike and Sound-Alike Medications

In the absence of planning a change to a robotic pharmacy, a simple job aid can help avoid dispensing the incorrect medication. In Figure 7.7, staff members know that each red bin in the pharmacy contains a look-alike or sound-alike medication. The bins shown contain Celebrex® and Celexa®.

Example courtesy of Elbert Memorial Hospital. Used with permission.

Figure 7.7. Look-alike or sound-alike medications are kept in specially designated bins.

Example 7.6—"Tall Man" Labels

"Tall man" labels also can be used used to distinguish look-alike or sound-alike medications. This technique employs capital letters in unusual places in a word to create larger visual differences between words that are otherwise visually similar. The Food and Drug Administration (FDA) began reqesting tall man labeling in 2001.[1,2]

The effect is more pronounced when the beginning and ending syllables of the drug name are the same.

Normal Text	Tall Man Text
Celebrex	CeleBREX
Celexa	CeleXA
Vinblastine	VinBLAStine
Vincristine	VinCRIStine

Example courtesy of an anonymous participant at a HealthInsight Learning Seminar. Used with permission.

See also: http://www.fda.gov/cder/drug/MedErrors/nameDiff.htm

Example 7.7—High-Risk Medicine Cues

A number of deaths were reported to have been caused by the accidental administration of concentrated solutions. The National Patient Safety Agency (NPSA) of the United Kingdom has been working with manufacturers to ensure the availability of a broader range of diluted products and to help introduce distinctive packaging so that solutions, such as potassium chloride, are easily identified and distinguished from other intravenous products (Figure 7.8).

Figure 7.8. Potassium chloride's distinct packaging helps prevent fatal accidents.

The following "cues" were devised for potassium chloride:

1. The official name (U.S. Pharmacopeia) was changed to "Potassium Chloride for Injection Concentrate." The word "concentrate" in the new name indicates the need to dilute the product prior to use.
2. A requirement that labels contain a boxed warning that reads: "Concentrate: Must be Diluted Before Use."
3. A unique requirement that the cap used in the packaging of this drug be black in color and that it contain an imprint in a contrasting color with the words: "Must be Diluted."[3] See Chapter 8, Example 8.27.

Example courtesy of Holly Ann Burt, NPSF. Current Awareness Literature Alert July #1, 2004 (item #7). Used with permission.

Example 7.8—The Bloodloc™

The Bloodloc™ (Figure 7.9) is a plastic, one-time use padlock that restricts access to a unit of blood. It is opened by a three-letter code that can only be found on the patient's wristband (Figure 7.10).

Use of the Bloodloc™ has been documented in several studies.[4,5,6] Cost is a common concern. AuBuchon[7] reported that the cost of the Bloodloc™ is "between $3 and $4 dollars per unit." His calculation of the cost effectiveness, from the societal perspective (excluding liability costs), was approximately $200,000 per quality-adjusted life year (QALY). Actual values can vary because "Traditional quality-adjusted life year (QALY) cost analysis is complex and assigns arbitrary dollar values to catastrophic outcomes such as death."[7] Nevertheless, in terms of proportional cost, AuBuchon's comments are not unreasonable.

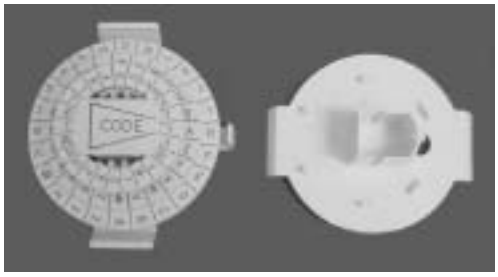

Figure 7.9. The cost effectiveness of the Bloodloc™ is estimated to be very favorable when compared to most transfusion interventions.

Figure 7.10. A patient's wristband contains the unique combination to his Bloodloc™.

AuBuchon[7] stated that at a cost-effectiveness of $200,000 per QALY, the Bloodloc™ is not as cost effective as many medical and surgical interventions, where $50,000 per QALY is generally considered the upper limit. It is much more cost effective, however, than many interventions in transfusion medicine aimed at assuring safe transfusions. The cost-effectiveness of using nucleic acid testing (NAT - to screen whole blood donors for the HIV and hepatitis C viruses), and testing for the p24 protein found in HIV (the p24 test identifies actual HIV viral particles in blood 1 week or more after infection) is more than $1 million each. The cost effectiveness of solvent detergent (SD) plasma is $3 million per QALY.[8] The SD process pools up to 500,000 units of thawed fresh frozen blood plasma and treats it with solvent and detergent to remove viruses such as HIV and hepatitis.

Additionally, factoring in liability payments to a patient's family members make the Bloodloc™ and similar expensive interventions much more desirable from the hospitals' standpoint.

Regarding the Bloodloc™, AuBuchon stated:

> It's a barrier. It prevents the transfusionist from getting to a unit of blood that they are not supposed to get to.

Because the Bloodloc™ may slow the process of administering units of blood in emergent situations, the locks are often opened after the patient arrives in the operating room but before the actual need for transfusion occurs. Since the plastic bag can be cut open, circumventing the Bloodloc™, some hospitals began the practice of putting the Bloodloc™ directly on the tubing that extends out of the unit of blood.

Example 7.9—Child Scale

Using a flat scale, it was easy for children to roll off the scale and injure themselves. The scale in Figure 7.11 is equipped with a seat that provides more security for the child while being weighed. The contributor of this example notes that it "would be more secure if it had a seat belt."

Figure 7.11. This scale with a child's seat prevents injuries during weighing.

Example courtesy of Washoe County District Health Department. Used with permission.

Example 7.10—A Safer Blood Pressure Cuff

In the past, blood pressure cuffs containing mercury posed a risk to patients when they were broken. New blood pressure cuffs containing no mercury (Figure 7.12) are safer.

Figure 7.12. A non-mercury blood pressure cuff poses much less of a risk to patients if broken.

Example courtesy of Washoe County District Health Department. Used with permission.

In a related remark, Trevor Kletz,[9] when listing[10] characteristics of user-friendly chemical factories, pointed out that "What you don't have can't leak."

Example 7.11—Sign Your Site

On July 1, 2004, JCAHO made "sign your site" (Figure 7.13 and 7.14)—the practice of marking the correct site on which a procedure is scheduled to take place—mandatory. Prior to this policy, data suggested that one in four orthopedic surgeons would perform a wrong-site surgery during a 35-year career.[b]

[b]More information on JCAHO's patient safety practices is available at: http://www.jcipatientsafety.org/22782/

Figure 7.13. An advertisement urging health care workers to "sign your site."
Photo courtesy of AOFAS (American Orthopaedic Foot and Ankle Society) and AAOS (American Academy of Orthopaedic Surgeons). Used with permission.

Figure 7.14. The site of the procedure is clearly marked.

Example 7.12—Templates

A mistake or omission on the form in Figure 7.15 will take longer to find than one on the template in Figure 7.16.

A template similar to the one in Figure 7.16 was used in a blood center to ensure that incoming forms were completed. Additional information could be added to the template to indicate valid ranges for numeric entries, further adding to the effectiveness of the job aid.[11]

Figure 7.15. A typical form is inefficient.

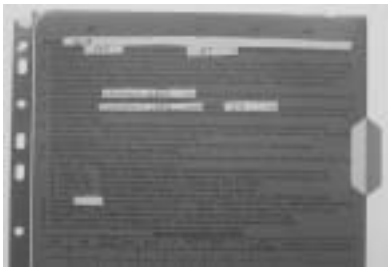

Figure 7.16. A template is more effective than a form.

The template in Figure 7.16, pre-developed to highlight key words and terms, is made using ingredients found at any office supply store: colored plastic pocket dividers and a knife.

Instructions to make the template are simple:

1. Insert the form.
2. Mark the areas to highlight.
3. Remove the form and insert a sheet of cardboard or card stock.
4. Cut out the marked portions.

Cost: $.60.
Time to Completion: 2 minutes.

Example courtesy of Harold S. Kaplan, Columbia University. Used with permission.

Example 7.13—High Risk Medications

The red boxes designate the medication, Retavase®, as a high-risk medication. Administered to cardiac patients who have just had a myocardial infarction, the medication dissolves clots that have blocked arteries. The boxes also contain all items needed for administration of the medication.

Figure 7.17. High-risk medications are stored in red boxes.

> JCAHO defines high-risk and high-alert medications as medications involved in a high percentage of medication errors or sentinel events and medications that carry a high risk for abuse, error, or other adverse outcomes. Examples include medications with a low therapeutic index, controlled substances, medications not approved or recently approved by FDA, psychotherapeutic medications, and look-alike and sound-alike medications. JCAHO requires organizations to identify high-risk and high-alert medications used within the organization.[c]

Example courtesy of Elbert Memorial Hospital. Used with permission.

[c]Available at http://www.medscape.com/viewarticle/482368_11.

Example 7.14—Emergency Defibrillator

The emergency defibrillator in Figure 7.18 is one of many installed in airports, airplanes, and other public places throughout the United States. It has been designed so that anyone can operate it. The device gives its operator verbal instructions during the process. It also employs sensors to deliver a shock, but only when one is necessary.

Figure 7.18. Emergency defibrillators are available in many public places.

Example 7.15—The 5 Gauss Line

The European Magnetic Resonance Forum (EMRF) Web site[10] states that:

> The national regulatory boards decided to limit the threshold for access to MRI areas to 5 Gauss [a measure of the strength of magnetic attraction]. It seems advisable to mark this area by signs or lines on the floor.

Using a line on the floor as a sensory alert (Figure 7.19), a mistake-proofing device in the magnetic resonance imaging (MRI) suite is a start, but its effectiveness is dependent on the constant attention of technicians and patients. Adult patients are required to try to remember relevant events in their medical history, such as the metal plates and screws they received after a skateboarding accident as a 13-year-old. Expecting patients to remember these details is an unreliable safety mechanism. Patients are often unsure of even more recent events. Processes have been redesigned out of concern that patients will forget recent information (see Chapter 5, Example Set 5.20).

Figure 7.19. The lines on the floor indicate the area of magnetic attraction.

The EMRF Web site also states:

> To prevent such accidents, the installation of a metal detector through which everybody has to pass before entering the MRI suite has been recommended, but is rather cumbersome.
>
> Every person working or entering the magnet room or adjacent rooms with a magnetic field has to be instructed about the dangers. This should include the intensive-care staff, and maintenance, service and cleaning personnel, as well as the crew at the local fire station.

It is not clear that a metal detector in its current configuration is the best and final answer to MRI safety. However, it is also not clear that installing a metal detector is a less "cumbersome" solution than the marginal increase in training needed for a large and diverse group of workers that spans organizational boundaries.

Example 7.16—More Color-Coding

The white form on the left in Figure 7.20 is used for a heparin[d] infusion order. The pale blue form on the right is used for a heparin cardiology dosing protocol order. Standard and cardiology protocols differ, so the forms are in different colors. For heparin administration, the mistake-proofing is a subtle sensory alert. The distinction between the white and the pale blue forms could be missed if they are presented to users in close proximity. This is very weak mistake-proofing. Yet, it is better than the confusion generated by two white forms.

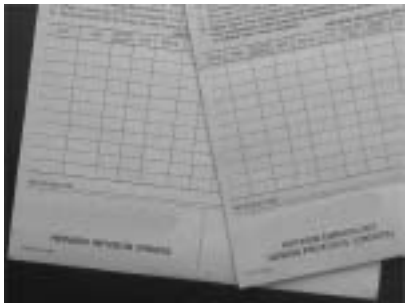

Figure 7.20. These forms are used for different protocols but vary only subtly in color.

Example courtesy of an anonymous Web site contributor. Used by permission.

Example 7.17—Leave Me Alone, I Have to Concentrate

The line around the medication dispensing station in Figure 7.21 provides a visual cue that co-workers should not interrupt the process of retrieving medications. The organization that implemented this sensory alert expects nurses who are in the zone to be allowed to attend to the details of selecting the correct medication and self-checking their work without distractions by others.

[d] Heparin is an anticoagulant, referred to as a blood thinner.

Figure 7.21. Inside the red line is a quiet, no interruption zone.

In another example utilizing visual cues to reduce interruptions,[12] a nurse wore a vest prominently labeled "do not disturb." Interruption rates fell approximately 64 percent.

Example courtesy of Sentara Leigh Hospital, Norfolk, VA. Used by permission.

Example 7.18—What is Normal?

The square in Figure 7.22 measures 1 inch on each side. The figure provides patient data for more than a period of 1 year. It uses the hash marks to indicate the normal range. This figure appears on the first row, third from the left, in Figure 7.23. A large amount of information can be conveyed in a very small amount of space. Comments on the patient's condition and treatment are in the right column of Figure 7.23.

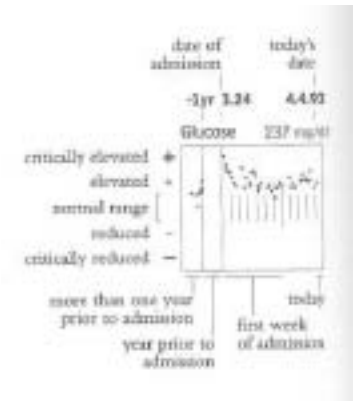

Figure 7.22. A detailed graph of a patient's condition presented in compact form.
From Powsner and Tufte.[13] Used with permission.

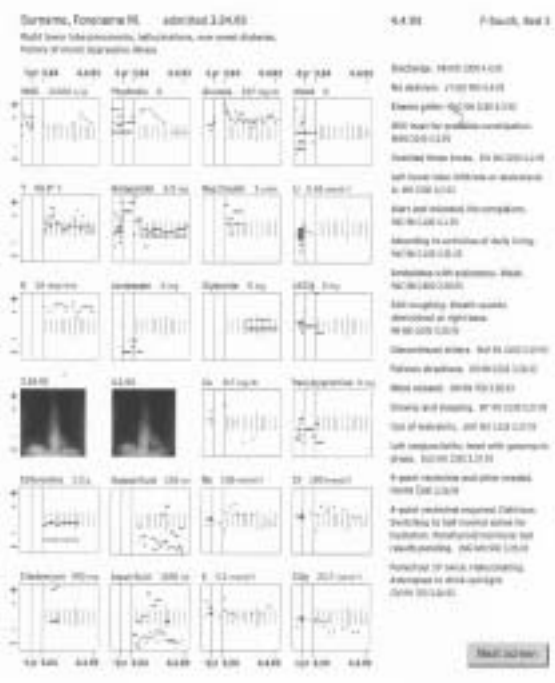

Figure 7.23. More than 1 year's worth of patient information is presented on one page.
From Powsner and Tufte.[13] Used with permission.

Example courtesy of Seth Powsner and Graphics Press. Used with permission.

Example 7.19—Automatically Terminated

In 1993, Leveson and Turner[14] wrote about their analysis of accidents that occurred in 1976 with the Therac-25 (a computerized radiation therapy machine):

> Between June 1985 and January 1987, six known accidents involved massive overdoses by the Therac-25, with resultant deaths and serious injuries. They have been described as the worst series of radiation accidents in the 35-year history of medical accelerators.

Patients died from overexposure to radiation as a result of poor software design and ineffective controls. This failure may have acted as a catalyst for radiology equipment manufacturers to design new equipment. New designs were introduced.[15] The machine in Figure 7.24 detects the amount of radiation that has penetrated a patient and automatically terminates exposure when a predetermined level has been reached. The treatment is optimized by factoring in the variables of patient size and density.

Figure 7.24. One of a new breed of machines that limit patients' exposure to radiation.

Example courtesy of Elbert Memorial Hospital and an Anonymous contributor. Used with permission.

Example 7.20—Blood Sample Traceability

The cassette in Figure 7.25, the complete blood count (CBC) analyzer, and a printout match the cassette number and the patient number.

Figure 7.25. Matching the cassette number and patient number ensures accuracy.

Example courtesy of Elbert Memorial Hospital. Used with permission.

Example 7.21—Leave that Stopper in Place

The blood analyzer in Figure 7.26 accepts tubes without requiring technicians to remove the rubber stopper so that employees are not contaminated with blood. It is also labeled with patient information that matches the printout in Example 7.20, above.

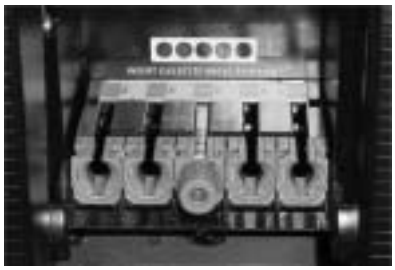

Figure 7.26. The rubber stopper on this blood analyzer is mistake-proofed to prevent contamination of employees.

Example courtesy of Elbert Memorial Hospital. Used with permission.

Example 7.22—Oral Syringes: Two for One

The oral syringes in Figures 7.27 and 7.28 are designed so that they will not fit onto any IV tubing. Oral medication cannot be accidentally administered intravenously. The orange color of the oral syringes in Figure 7.27 provides an additional visual sensory alert, indicating that the syringe is not to be fitted to an IV.

Figure 7.27. These oral syringes will not fit into IV tubing.

Figure 7.28. This syringe prevents the accidental intravenous administration of oral medication.

Example courtesy of Elbert Memorial Hospital. Used with permission.

Example 7.23—Newborn Resuscitation

Two photos of a neonatal resuscitation device are shown in Figures 7.29 and 7.30. The device has two important mistake-proofing features:

1. A pressure relief valve that prevents excessive gas pressure delivery to the lung.
2. A pressure gauge to measure the actual pressure delivered by squeezing the deflatable portion of the bag.

This device protect infants' airways from errors in providing augmented ventilation during resuscitative efforts.

Figure 7.29. A manual neonatal resuscitation device.

Figure 7.30. This neonatal resuscitation device contains a pressure relief valve and a pressure gauge.

Example courtesy of Elbert Memorial Hospital and an anonymous contributor. Used with permission.

Example 7.24—X-Ray-Detectable Sponges

X-ray detectable sponges (Figure 7.31) contain a radio-opaque (impenetrable by x-rays) substance, such as a small embedded flexible strip, or barium sulfate. These sponges are an improvement, but not a perfect solution.[16] X-rays can easily detect the presence of sponges when they are large and "left out in the open" in muscle or fat tissue. When they are small and left near bone, however, they become much more difficult to find in the image. See also Chapter 8, Example 8.10.

Figure 7.31. Sponges containing radio-opaque substances are more easily found after surgery.

Example courtesy of an anonymous contributor. Used with permission.

Example 7.25—Anti-Reflux Valves

A reflux is a backward or return flow. Anti-reflux valves are designed to prevent fluids that have been expelled from returning to the body and leading to varied complications. Anti-reflux valves ensure that there is no return flow after fluids have been expelled, thereby avoiding the "mistake" of a return flow (Figure 7.32).

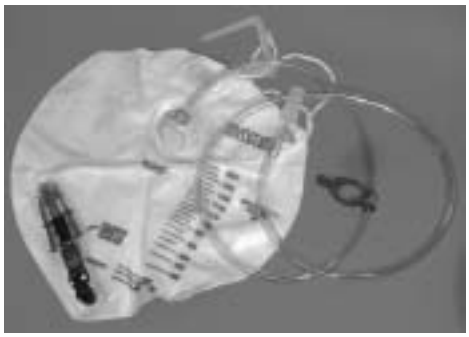

Figure 7.32. The urine bag and catheter have valves designed to allow fluids to flow only one way.

Example courtesy of an anonymous contributor. Used with permission.

Example 7.26—Wristband Checklist

Robert S. Mecklenburg, chief of the Department of Medicine at Virginia Mason Medical Center in Seattle, WA, is designing a bracelet for heart attack patients that uses symbols to track whether they have received the full, universally accepted treatment regimen. The regimen includes receiving beta-blockers within 1 hour of arrival at the emergency department, monitoring cholesterol levels, and counseling on diet and smoking. Patients are not discharged until each item on the wristband medical record is checked off.[17]

Mecklenburg adds:

> The wristband medical record is being tested as part of our work bundles (Institute for Healthcare Improvement) on cardiac care. It is an example of "visual control" that alerts all in the area that the patient is on the bundle pathway and allows the patient and family to follow and audit execution of the components of the bundle. The response of patients, providers and support staff has been positive. We've moved through several versions to maximize its utility.[18]

According to service management theory, this simple mistake-proofing device (Figure 7.33) is very powerful. As a customer mistake-proofing device, it lets the patient and family and other caregivers know the status of the health care process.[19]

Figure 7.33. The author's interpretation of Mecklenburg's design concept.

Example 7.27—Time to Re-Stock

In Japanese, a "kanban" is a "sign" or visual signal. In Japanese manufacturing, a kanban is used to indicate when work needs to be done.[20] St. Joseph's Hospital employs a large sticker to indicate when cabinets are fully stocked (Figure 7.34). This enables the employees who stock the cabinets to know where their attention is needed. When supplies have been used to treat patients, the sticker is torn and employees know that the cabinet needs to be re-stocked.

What Schonberger[20] called "Japanese manufacturing techniques" also has many other names:

- Toyota Production System.
- Just-in-Time.
- Stockless Production.
- Zero Inventories.
- and, most recently, Lean Production.

Figure 7.34. The sticker provides a visual signal that the cabinet has been fully stocked.

There is a standardized supply cabinet in each room. The presence of the stickers enables the staff to rapidly bypass unoccupied rooms as they re-stock the facility.

Example 7.28—Knowledge on the Bottle

The standard medicine bottle reveals some design problems: the bottle must be rotated in order to see the entire label. Recently, Target pharmacies began using a new medicine bottle design.[e]

Good ideas come from many sources. In this case, Target's medication bottle originated when the grandmother of graphic designer Deborah Adler accidentally took another family member's medication. Mistake-proofing features are all over the bottle:

- The bottle is designed to stand on its lid.
- A colored band surrounds the neck.
- The band is color-coded to personalize family members' medications. Each family member can use a different color (yellow, green, blue, purple, or red).
- The bottle has a rounded, rectangular cross section.
- The sides taper toward the top.
- The panels are flat so that all the text on the label is visible at once.
- The typography is larger and more distinct than usual.
- The name of the drug is clearly shown on the front and on the top.
- A patient information card is tucked in the back.[21]

Deborah Adler's bottle was featured at the New York Museum of Modern Art exhibit, SAFE: Design Takes On Risk, October 2005–January 2006.

Example 7.29—Weaving Tangled Webs

The intravenous (IV) pole and infusion pump in Figure 7.35 provide graphic evidence of how IV tubes can become very tangled. This problem can be mitigated through the use of Donald Norman's concept of natural

Figure 7.35. In this configuration it is difficult to tell what is connected to what.

[e]See http://sites.target.com/site/en/health/page.jsp?contentId=PRD03-004033.

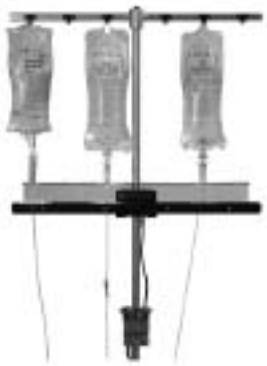

Figure 7.36. It is easy to distinguish a one-to-one correlation between IV tubes and solution bags.

mappings. One possible solution is the use of in-line IV hooks that provide a one-to-one correlation between the IV bags and the infusion pump channels controlling their flow (Figure 7.36).

Example 7.30—What's the Status?

The flat screen panel in Figure 7.37 provides information to families without violating Federal privacy laws. The locator number (indicated by "locator #" on the screen) is the pager number assigned to each family while they wait.

Chase and Stewart,[22] discussed in Chapter 1, would most likely categorize the flat screen display in Figure 7.37 in the following way:

Category: server mistake-proofing device
Subcategory: treatment
Setting function: Information enhancement

Norman,[23] also discussed in Chapter 1, might describe it as providing visibility.

Figure 7.37. The flat screen provides anonymous information to families with pagers.

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Chapter 8. More Examples of Mistake-Proofing in Health Care

Introduction

This chapter features 34 additional examples of mistake-proofing in health care. The examples in this chapter are more expensive and technology-based than those described in Chapters 5-7, although some very simple examples are also included. They are provided as both a catalog and a catalyst for reducing human errors in health care.

Example 8.1-Infant Abduction Prevention

Mistake-proofing often involves electronic sensors to ensure high-quality industrial production. Electronic sensors are also used in health care applications. In this example (Figure 8.1), an electronic device, or "tag," is designed to be clamped to the infant's umbilical cord. The arrow in the photo points to the cord clamp, which secures the tag to the infant. The tag ensures that the infant is not removed from the nursery. If the infant is removed without authorization, alarms sound, specified doors lock, and the elevators automatically return to the secured maternity floor; the elevator doors remain open.

Figure 8.1. An electronic sensor provides robust security to prevent infant abductions.

Example courtesy of Barnes Jewish Hospital and an anonymous contributor. Used with permission.

Example 8.2—Bar Coding

Bar coding is one of the more common and effective information enhancement and mistake-proofing devices. It is particularly useful in ensuring a match between a patient and their treatment, medicines, and supplies (Figures 8.2 and 8.3).

Figure 8.2. Laboratory instruments in the lab read the bar coding on specimen tubes to ensure positive identification of people and procedures.

Figure 8.3. The bar codes are laid out on the wall in close proximity, a design that is inattentive to human factors considerations.

One of the contributors to this example emphasized the importance of radiologists matching the film they are reading to the right patient:

> Bar codes are attached to every order so that the radiologist can electronically identify the patient and

> be sure that the correct patient [information] has been entered into the digital dictation system.

Another contributor stated:

> Each specimen is labeled with a bar code that is specific to that patient and the test that has been ordered. The instruments in the laboratory are programmed to identify the bar code that ensures positive patient identification and to verify that the correct test is performed.

Bar coding, however, is a setting function. Therefore, it is only as effective as the regulatory function to which it is linked. Many of the control methods used with bar coding are warnings or sensory alerts. The control methods of shutdown and forced control are infrequently used.

AuBuchon discussed this shortcoming of bar coding systems for patient identification:

> A disadvantage that we ran into when we began using the system on a trial basis is that the system doesn't have to be used … ultimately, our anesthesiologist said, 'You know, this is a really neat system, but I won't use it. He said [that with] the Bloodloc™, I have got to use it, I have got to do something, we have got to take it off, and that's the whole idea. It's a barrier. It prevents the transfusionist from getting to a unit of blood that they are not supposed to get to.' So we have continued using that older system rather than the new, fancy system.[1]

The use of bar codes does not automatically prevent errors from occurring. Staff should check that assigned bar codes match. In Figure 8.3, a line of red laser light is hovering in the gap between two bar codes, increasing the odds of reading the wrong bar code by mistake.

Given the prevalence of patient identification errors, bar coding is a very promising direction in mistake-proofing.

Example 8.3—Computer-Aided Nutrition and Mixing

Software is used to profile total parenteral nutrition (TPN) solutions (Figure 8.4). A patient's nutritional needs (protein, sugar, fat, vitamins, and electrolytes) are entered into the software application. The software sends a message to an automixer that compounds the ingredients to create the base solution. The software issues a warning if certain concentrations of ingredients are exceeded based on literature values.

Figure 8.4. Software ensures that this automixer optimizes proportions of ingredients for TPN solutions.

Example courtesy of an anonymous contributor and participants of a learning session sponsored by Health Insight.

Example 8.4—Equipment Collisions

In hospital operating suites full of large, expensive equipment, there is always the danger that units of equipment will collide with each other. Equipment requires a wide range of motion while in operation. Collision detection systems warn and, in some cases, can lock if they sense an impending collision. The equipment in Figure 8.5 is situated in an angiographic suite and outfitted with electronic and manual locks to prevent collisions.

Figure 8.5. Equipment with electronic and manual locks.

Example 8.5—Flawless Equipment Setup

When creating x-ray film, it is very important that the tube is centered to the film and is situated the correct distance from the film. The position locks (Figure 8.6) enable the tube to be centered quickly and correctly by only locking at the correct positions.

Figure 8.6. Position locks on x-ray film ensure correct positioning of the tube.

Example 8.6—Mistake-Proof Mistake-Proofing

Transport monitors, which employ flashing and audible alarms, warn all health care workers of high/low heart or breathing rates. A misplaced blood pressure cuff on the lower arm below the elbow, as in Figure 8.7, would result in inaccurate blood pressure readings and trigger flashing and audible misplacement alarms.

Figure 8.7. A misplaced blood pressure cuff gives an inaccurate reading and triggers alarms.

Example 8.7—Private Files

Often, mistake-proofing is accomplished by providing barriers that prevent people from taking the wrong action. In Figure 8.8, a portion of the file cabinet drawer can be locked. This mistake-proofing is neither mysterious nor subtle.

Figure 8.8. A locked portion of this drawer protects against filing mistakes.

Example 8.8—Computer Drug Interaction Checker

Software that checks for drug interactions (Figure 8.9) falls under Shingo's concept of a successive-check.[2] A successive-check is a mistake-proofing device that facilitates checking work previously performed by others and that, in a low-cost, relatively automatic way, notifies the user that something is wrong. Shingo was of the opinion that defect detection and rapid feedback following a mistake are nearly as effective as not making the mistake at all. Even after an initial mistake, staff can recover before substantial harm occurrs. In this case, the pharmacist double-checks the prescriptions submitted by doctors. It is clear that there is no resultant harm if an error can be caught by the pharmacist before the patient receives the medicine, thereby avoiding, at the very least, significant difficulties for the pharmacist, doctor, and patient.

Figure 8.9. Drug interaction software notifies the pharmacist of an incorrect prescription.
Photo: DIT Drug Risk Navigator™, Copyright by DIT Drug Information Technologies, Rockville, MD. Used with permission.

Example 8.9—Computerized Physician Order Entry

According to Poon, Blumenthal, Jaggi, et al;[3]

> Medication errors are the most common cause of preventable injuries in hospitals. Computerized physician order entry (CPOE) systems can reduce the incidence of serious medication errors by 55 percent, but only 10 percent to 15 percent of hospitals use them.

CPOE is computer software that physicians and other health care providers use to issue and record patient orders for diagnostic and treatment services such as medications, laboratory tests, and diagnostic tests. Computers on wheels (COWs) are available throughout hospitals so that staff can enter information without having to go to a central location (Figure 8.10). CPOE provides several mistake-proofing features:

1. Informs providers of common dosages and overdose warnings via drop-down menus.
2. Eliminates the issue of legible handwriting.
3. Conducts drug interaction and allergy checking routines.
4. Employs sophisticated systems that function as a clinical decision support system (CDSS).[a] CDSSs are "active knowledge systems that use two or more items of patient data to generate case-specific advice."[4]

Figure 8.10. CPOE often means doctors must use computers on wheels (COWs).

[a] See http://www.openclinical.org/dss.html#wyatt1991.

Example 8.10—Sponge-Counter Bag

In aviation, significant effort is exerted to ensure that no foreign objects are left inside fighter planes. This is done to prevent foreign object damage (FOD). Changing G forces can make objects weightless. Subsequently, they

could fly through the cockpit and cause serious damage to people and equipment. FOD is also a problem in surgery. Failing to remove foreign objects (tools or supplies) from inside a patient can cause serious harm.

The sponge-counter bag (Figure 8.11) assists in keeping track of sponges removed from a patient. Accounting for the sponges put into the patient is easier because the sponges are not discarded immediately or put in a random pile.

Figure 8.11. A sponge-counter bag.

Example 8.11—Notebook Switches

Galsworth[5] endorses the mantra that workers should be able to "know by looking." The notebooks in Figures 8.12 and 8.13 enable users to do that. The dial on the notebook in Figure 8.12 and the switches on the notebook in Figure 8.13 enable everyone to know the status of the paperwork inside.

Colors indicate when medical staff have made entries that need to be processed by administrative staff. A different color notifies the nurse when the work is finished. No color is displayed when the work is completed, and no further action is needed.

Figure 8.12. The dial on the notebook indicates the status of the paperwork inside.

Figure 8.13. This notebook employs switches to let workers know the status of the paperwork inside.

Example 8.12—Plug Protection

In May 2004, a National Patient Safety Foundation (NPSF) LISTSERV® participant inquired about the safest height for electrical wall outlets in pediatric rooms. In his response, Matthew Rosenblum stated that he believes that other matters are probably more important:

> For example, how the cord is secured to the outlet and to the wall and how the outlet is covered when no devices are plugged in. In this regard, there are numerous products on the market for securing electrical cords to the outlets and to walls. Also, many secure socket covers are available.[6]

When an outlet is used properly, the plug fits without slowing the process. The process is slowed only when an error occurs; then the mistake-proofing device brings the process to a halt. Figures 8.14-8.18 illustrate various mistake-proofing methods employed to make wall sockets safer.

Figure 8.14. Insertion in the outlet of this surge protector is blocked to plugs with less than two prongs.

Figure 8.15A. A screwdriver cannot penetrate the outlet slot because of the shutter.

Figure 8.15B. The shutter is designed to prohibit insertion in either slot.

Figure 8.16. Outlet with correct plug inserted.

Figure 8.17. Secure socket covers prevent accidents.

Figure 8.18. Outlets should be effectively secured to the wall.

Photos courtesy © Koncept Technologies Inc. Used with permission.

Example 8.13—Instructions Getting in the Way

The card shown in Figure 8.19 is not the strongest example of mistake-proofing. It does, however, put knowledge in the world. Also, it is designed to stand out against a noisy background. At a minimum, someone (a patient or family member, perhaps) will have to move it out of the way in order to use the table space.

A card on the overbed table (Figure 8.20) provides information to patients about what patient safety behaviors to expect from staff and encourages them to hold staff accountable for complying with those behaviors.

Figure 8.19. For each admission, a new copy of this piece of folded card stock is placed on the patient's overbed table.

Figure 8.20. St. Joseph's Hospital says "It's OK to ask 'Did you wash your hands?'"

This example is similar to the time-out example (Chapter 7, Example 7.4). It also has some common features with a proxy ballot that was mailed to a retirement fund (Figure 8.21). The ballot was designed so that it would not fit in the envelope until a small portion of the page containing the mailing instructions/checklist was torn off.

Figure 8.21. This proxy ballot will not fit into the envelope until the mailing instructions are torn off.

Example courtesy of Linda Bontrager and the Nebraska State delegation to the VA/AHRQ Patient Safety Improvement Corps, 2005. Used with permission.

Example 8.14—Monitoring Glucose

In the past, glucose monitoring required that patients follow strict clinical procedures to determine their blood glucose levels. Today, most of the precise actions and calculations are designed into a portable glucose monitor that is user-friendly and more mistake-proof.

Example 8.15—Unit Dosing

Robotics, bar coding, and packaging medicines in plastic bags containing a single dose, or "unit dose," form a powerful combination of mistake-proofing devices. Individually, none of them would be very effective. The unit dose package enables the machine to select a single dose to be delivered to a patient. The unit dose package also provides a convenient way to associate bar codes to a specific pill for use in the pharmacy and throughout the medication delivery system. Bar codes make the packages

containing the pills machine readable (Figure 8.22). The machine in Figure 8.23 provides the automation that makes converting bottled medicines into unit doses less expensive, less labor intensive, and more reliable.

Figure 8.22. Unit dose packages associate bar codes to specific pills in a pharmacy.

Figure 8.23. This machine automates the conversion of bottled medicine into unit doses.

Example 8.16—Kits

The Massachusetts team from the Patient Safety Improvement Corps (PSIC) reported their efforts in reducing central line infections.[7] They recommended a variety of changes to the central line insertion process. Included in their recommendations is a customized kit (Figure 8.24) that standardizes available supplies, including drapes and other site preparation materials.

The cost of the custom central line kits is more than twice that of the old methods. Regardless of which method is used, each infection episode has an associated cost of $45,000. Savings will be realized after adoption of the custom kits because the number of infection episodes is expected to decrease by almost 50 percent due to the mistake-proofing built into the kits, effectively more than nullifying the additional cost of each kit. Without the custom kits, the number of expected infection episodes is 145 annually. With the kits, however, the expected annual number of episodes is less than half at 72. Table 8.1 shows the annual savings calculations.

Table 8.1. Cost comparison between two methods of reducing central line infections

Savings will equal the difference in total episodic costs of the two methods:

([B]$6,525,000- [A]$3,240,000
minus the difference in equipment costs
([A]$147,840-[B]$55,552=$92,288)

Method A: Previous Method

Annual equipment cost
2,240 cases x $24.80/kit =$55,552.

Annual infection cost
$45,000/episode x 145 expected episodes = $6,525,000
Total Cost = $6,580,552

Method B: Using Custom Kit

Annual equipment cost
2,240 cases x $66/kit =$147,840

Annual infection cost
$45,000/episode x 72 expected episodes = $3,240,000
Total Cost = $3,387,840

Net Savings = $3,192,712

Figure 8.24. Customized central line kits can significantly reduce the occurrence of central line infections.

According to the calculations in Table 8.1, the annual cost increase is substantial: $92,288. Yet, if the number of infections can be reduced by only 3 episodes out of 145 (a 2 percent decrease), the change will be cost-justified. The team forecasted infection rates would be cut in half, a result that was supported in their preliminary findings. The net savings appeared to be far more substantial than the cost increase.

Example and photos courtesy of an anonymous contributor. Used with permission.

Example 8.17—Bacteria-Detecting Bandages

Benjamin Miller[8] developed the technology to produce "smart bandages" that indicate an infection by changing color (Figure 8.25). The "smart bandage" is in the early stages of development, so actual commercial products may still be years away. In its current form, the technology is in a chip that reveals the existence of different bacteria by changing colors. As a consumer product, a small chip would be embedded in a regular bandage. Computer connectivity is another future posibility.

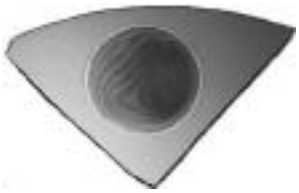

Figure 8.25. Smart bandages may soon be able to reveal the existence of different forms of bacteria. Photo courtesy of Benjamin L. Miller, University of Rochester Medical Center.

Example 8.18—Urinalysis Test Strips

The old method of reading urinalysis test strips required health care workers to make subjective decisions. Timing and color perception were critical to error-free results. The machine in Figure 8.26 analyzes urine test strips and prints out the results. In addition to the obvious mistake-proofing associated with the automatic nature of the machine, the strip can be inserted in only one direction, and the results can be printed out and placed in the patient's medical chart. A transcription of the results is not necessary.

Improperly handled or inadequately maintained samples can result in inaccurate diagnosis and treatment. The sample transport kit in Figure 8.27 maintains urine specimen integrity without refrigeration for up to 72 hours at room temperature.

Figure 8.26. This urinalysis machine can print its results.

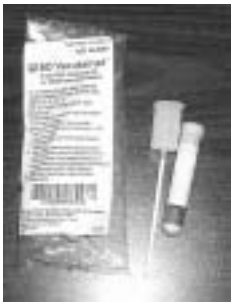

Figure 8.27. The integrity of urine samples can be maintained for 72 hours in this transport kit.

Example 8.19—Controlled by Connections

In Figure 8.28, a benign failure protects patients. Only rubberized specula will fit as attachments to this loop electrosurgical excision procedure (LEEP)[b] machine. Standard metal specula cannot be attached. If a metal speculum could be inadvertently attached to the machine and used, it would result in burns or electrocution.

Example courtesy of Washoe County District Health Department. Used by permission.

[b] LEEP is "a way to test and treat abnormal cell growth on the surface tissue of the cervix. LEEP is prescribed after abnormal changes in the cervix are confirmed by Pap tests and colposcopy." See http://www.clevelandclinic.org/health/health-info/docs/0600/0642.asp?index=4711.

Figure 8.28. Standard metal specula cannot be attached to this LEEP machine.

Example 8.20—Child-Proofing

Child-proofing is mistake-proofing. Since the bottle in the foreground of Figure 8.29 is not child-proofed, it is kept inside a child-proofed medication container when not in use to prevent accidents. In this example, an entire demographic group is unable to open a container, the exact benign failure for which it was designed.

Figure 8.29. The medication container in the background was designed to be unavailable to children.

Example courtesy of Washoe County District Health Department. Used with permission.

Example 8.21—Hemoglobin Testing

Precision in hemoglobin testing is important. Appropriate diagnosis and treatment are based on the results. Automatic hemoglobin testing devices (Figure 8.30), which perform the analyses in under 1 minute, have replaced analyses that relied on visual judgment or time-consuming, complicated methods for their precision.

Figure 8.30. Automatic hemoglobin testing devices do not rely on visual judgments or complicated methods.

Example courtesy of Washoe County District Health Department. Used with permission.

Example 8.22—Auto Shut-Off Treadmills

The treadmill in Figures 8.31 is used in rehabilitative therapy. It is equipped with an emergency stop button and automatically slows to a stop if the patient trips or falls.

Figure 8.31. This treadmill, used in rehabilitative therapy, is equipped with an emergency stop button.

Example courtesy of Jackie Buttacio of HealthInsight and participants in a HealthInsight-sponsored learning session. Used with permission.

Example 8.23—Visual Systems

Figures 8.32 and 8.33 are more examples of how to "know by looking."[5] Visual systems make a system's status visible to all. Norman[9] encourages visibility to reduce errors: "make relevant parts visible." In Figure 8.32, the goal was to encourage employee donations in a workplace. The visibility of the status of the blood supply made a dramatic difference. Employee donations grew 300 percent. The sign served as a simple gauge to indicate inventory levels and mitigated the human perception, or error, of believing that the blood supply was more than adequate. The gas gauge depicted in Figure 8.33 is another visual cue to the status of a machine.

Figure 8.32. A visual cue.

Figure 8.33. The gas gauge is another visual cue.

Example courtesy of Duke Rohe, MD Anderson Cancer Center. Used with permission.

Example 8.24—Needleless Systems

Needleless systems are used throughout the hospital to prevent needle sticks. The display panel in Figure 8.34 informs the nurse if there is air in the system.

Safety-engineered products for intravenous (IV) therapy have proven effective in protecting health care workers from exposure to bloodborne pathogens (Figure 8.35). In a retrospective review, the Exposure Prevention Information Network (EPINet) at the International Health Care Worker Safety Center at the University of Virginia in Charlottesville showed that the rate of

Figure 8.34. A needleless system.

Figure 8.35. Safety-engineered IV therapy products help reduce percutaneous injuries.

percutaneous injuries among nurses declined from 19.5 per 100 occupied beds in 1993 to 9.6 per 100 occupied beds in 2001, a decrease of nearly 51 percent.[10]

Because these figures only include the first few months of legally mandated safety device use, they don't fully reflect the effect of the Needlestick Safety and Prevention Act,[11] which mandated the use of needleless IV systems in all health care settings.

Safety-engineered devices prevent accidental needle sticks in two ways: primary prevention and secondary prevention. The most direct method of preventing needle stick injuries is through primary prevention techniques that eliminate the need to introduce sharps into the workplace, reducing the total number of sharps used.

Example courtesy of Jackie Buttacio of HealthInsight.

Example 8.25—Dress Code Cued by Floor Tile

The patterned tile in the hallway (Figure 8.36) is a sensory alert that surgical attire must be worn past this point. The tile adds a visual cue about what to do, but it only works for those who have been taught what the tiles mean. Patients, visitors, or new staff members will not be aware of this convention, thereby limiting its effectiveness. Fortunately, patients are usually sedated and recumbent in this hall, and visitors are prohibited.

Figure 8.36. Floor tiles provide visual cues.

Examples courtesy of Duke Rohe of MD Anderson Cancer Center. Used with permission.

Example 8.26—Internet–Aware Refrigerator

Undergraduate engineering students at Virginia Military Institute (VMI)—advised by a biomedical engineer, a computer engineer, and a physician—designed a medical, Internet-aware, insulin refrigerator for patients living alone. The small refrigerator (Figure 8.37) is monitored by a microcontroller that is connected to a standard telephone outlet. If the refrigerator door is not opened in a 16-hour period, the microcontroller sends an e-mail or a pager alert to a designated caregiver. The system has battery backup in case of a power outage. The system can be retrofitted to standard refrigerators.

Figure 8.37. This insulin refrigerator sends an e-mail or pager alert if it is not opened during a 16-hour period.
Photo courtesy of Jim Squire, VMI. Example courtesy of Advisors: Jim Squire, Dave Livingston, Joseph Troise, M.D., VMI Department of Electrical and Computer Engineering. Used with permission.

Example 8.27-Resources with Which to Err

Sometimes, mistake-proofing can be thought of as the removal of the materials required to make errors. In the United Kingdom, the National Patient Safety Agency, in its first patient safety alert, warned that potassium chloride solution in its concentrated form should be removed from all general wards and replaced by diluted products. See also Chapter 7, example 7.7.

Example 8.28—Keeping Time

Mistake prevention in the work environment involves reducing ambiguity. As far as time is concerned, variation is ambiguity. Clock systems (Figure 8.38) eliminate variation. A receiver takes signals from global positioning system (GPS) satellites and communicates the signals to other clocks in the system, including those in computers.

Figure 8.38. This clock is part of a system. One receiver communicates wirelessly with each clock in the facility.

The clocks in Figures 8.39, produced by different manufacturers, set themselves accurately. When observed, the variation between them was approximately one-half second.

Figure 8.39. The variation in these clocks by different manufacturers is insignificant.

Example courtesy of John Reiling and St. Joseph's Hospital. Used with permission.

[c] *Information design for patient safety. A guide to the graphic design of medication packaging* is available from the UK's National Patient Safety Agency at http://www.npsa.nhs.uk/site/media/documents/1539_Information_Design.pdf.

Example 8.29—Distinct Labeling

Businesses try to build an image for their product lines by using similar packaging. Figure 8.40 illustrates a consistent image that leads to brand awareness but may also lead to packaging that offers minimal distinctions between products. Figure 8.41 shows that, while patterns and graphics can unify a company's product line, individual product packaging can be visually distinct. Even within the same product line, different dosages can be made distinct.[c]

Figure 8.40. The labeling of different dosages of the same medication can be confusing.

Photos © 2006 and example courtesy of the National Patient Safety Agency, UK. Used with permission.

Figure 8.41. Packaging unifies this product line, but dosages are distinctly labeled.

Example 8.30—Free-Flow/No-Flow Protection

Infusing too much or too little fluid can lead to problems. The free-flow protection on the IV pump in Figure 8.42 causes a benign failure. It is a simple V-shaped piece of plastic (Figure 8.43) loaded on the machine. The flow of medication to the patient stops if a tube is removed from the machine.

Some infusion pumps also offer downstream occlusion alarms that alert staff that the tubes are blocked or that the clamp has not been opened, preventing the fluid from infusing.

Figure 8.42. Infusion pumps regulate the flow of fluids.

Figure 8.43. Close-up of V-shaped plastic tube clamp.

Example courtesy of Elbert Memorial. Used with permission.

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Chapter 9. Summary

Introduction

The examples in this book represent only a fraction of the current mistake-proofing methods and devices in the health care industry and only hint at the possibilities of how mistake-proofing could be applied. The implementation of mistake-proofing does not require starting from a standstill. Instead, existing solutions should be implemented wherever appropriate throughout each health care organization. Where ready-made solutions do not exist, designing, fabricating and installing new devices will be required.

Mistake-proofing is a change of focus, requiring more attention to the detailed design of processes, so that the easy way (or, ideally, the only way) to perform a task is the correct, efficient, and safe way. Mistake-proofing involves changing the physical attributes of a process. Consequently, mistake-proofing devices usually can be photographed.

Implementation of mistake-proofing in health care settings will be accomplished by putting knowledge in the world, designing benign failures, preventing failures in the work environment, detecting errors, preventing errors, and preventing the influence of errors. It will require the employment of devices that mistake-proof the actions of care providers, patients, and patients' family members.

Example Summary

Tables 9.1-9.5 recap the composition of the mistake-proofing examples presented in this book as they were categorized in Chapter 1. Although the selection of these examples was not intentionally biased, a distinct and restrictive definition of what does and does not constitute a mistake-proofing device affects these findings. Mistake-proofing is relatively narrowly defined here when compared with other authors' definitions.[1,2] For example, Godfrey, Clapp, Nakajo, et al, include actions such as "train laboratory technicians to… empower all employees to… encourage patients to… clarify with physicians…"[1] You cannot take a picture of these actions, so, while they may be worthwhile and effective actions, they would not be included here. Therefore, the proportions of examples reported in the tables do not provide a carefully constructed statistical sample that warrants population-wide conclusions. These tables suggest areas that lack medical mistake-proofing examples and call for new contributions to the body of knowledge.

Preliminary data from the example collection process suggest that many of the mistake-proofing examples included here have been broadly implemented in health care. Many device examples were submitted by people from differing organizations and geographical regions, and several were featured on commercial equipment or supplies. No locally developed devices were reported more than once. Further research is necessary to definitively determine if the implementation of certain commercially available mistake-proofing devices is widespread, as the preliminary data suggest. Findings of widespread implementation would be encouraging, suggesting that the health care industry is amenable to these devices.

Table 9.1 shows how the devices from this book are distributed among Tsuda's[3] four approaches to mistake-proofing. One-half of the devices are designed to directly prevent mistakes by prohibiting them from taking place. Another 28 percent represent changes to the work environment intended to prevent mistakes in indirect ways, by removing ambiguity and making correct actions more obvious. Twenty percent of the devices rapidly detect errors, enabling staff to respond quickly and prevent more serious errors. Among those collected, only a few examples of preventing the influence of mistakes were identified.

Table 9.2 shows the distribution of devices that utilize the different setting functions identified by Shingo[4] and Chase and Stewart.[5] More than one-third of the devices, 35.3 percent, are physical setting functions. This percentage would not be unusual for any mistake-proofing application or, for that matter, any industry. The more interesting number is the 36.0 percent of information enhancement setting functions.

Table 9.1. Mistake-proofing devices categorized by Tsuda's[3] four approaches to mistake-proofing

Approach	Count	Percent of total
Mistake prevention in the environment	42	28.0
Mistake detection	30	20.0
Mistake prevention	73	48.7
Preventing the influence of mistakes	5	3.3
Total	**150**	**100.0**

Chase and Stewart wrote about this type of device over a decade ago.[5] They added information enhancement devices to those proposed by Shingo[4] in the belief that this type of mistake-proofing would be needed in services. The fact that over one-third of the devices are in this category supports their belief.

Table 9.3 indicates the distribution of the collected mistake-proofing devices when categorized by control function. Shutdown and sensory alert devices are the most common control functions. The overall distribution of devices is somewhat evenly distributed among the control functions.

(**Note:** Numbers may not total 100 due to rounding.)

Table 9.2. Mistake-proofing devices categorized as setting function

Setting Function	Count	Percent of total
Physical	53	35.3
Sequencing	19	12.5
Grouping and counting	24	16.0
Information enhancement	54	36.0
Total	**150**	**100.0**

Table 9.3. Mistake-proofing devices categorized by control (or regulatory) function

Control function	Count	Percent of total
Forced control	29	19.3
Shutdown	42	28.0
Warning	29	19.3
Sensory alert	50	32.3
Total	**150**	**100.0**

Table 9.4 divides the mistake-proofing devices discussed in this book into the six categories defined by Chase and Stewart.[5] These categories are divided into those concerning errors committed by customers (non-health care personnel) and errors committed by service providers (health care personnel). Of the collected examples, 24.66 percent address errors that would be committed by customers. Of these, almost 90 percent are mistake-proof aspects of the service encounter.

Few examples exist in the areas of preparation and resolution. The remaining 75.33 percent focus on the errors of health care personnel. Not surprisingly, the vast majority of provider devices, 62.50 percent of the total and 84.07 percent of the provider devices, address task performance errors, and 14.16 percent address errors associated with the tangibles delivered to patients. Only two (1.77 percent) devices collected ensure that patients were treated in a respectful and professional manner. This does not mean that patients were treated badly, only that few physical devices aided in providing proper treatment.

This analysis suggests the existence of a broad area of opportunity to identify or create additional mistake-proofing devices that address customer preparation, customer resolution, and provider treatment. The realization of these opportunities will result in a perception of more patient-centered care by everyone involved.

One of the more surprising findings of this project has been the scarcity of locally developed or "do-it-yourself" examples (Table 9.5). Locally developed devices custom-made by process users are pervasive in industrial companies that have implemented mistake-proofing. The relatively few examples in health care may be partially explained by the fact that most industrial companies have a machine shop and tool and die makers readily available to fabricate any mistake-proofing device they need. To compensate, health care providers will need to develop external sources of expertise.

Table 9.4. Devices categorized by areas of focus for service provider and customer mistake-proofing

Type of device	Device count	Percent of devices segregated by customer or provider	Percent of total devices
Preparation	2	5.41	1.33
Encounter	33	89.19	22.00
Resolution	2	5.41	1.33
Customer total	37	100.00	24.66
	Provider		
Task	95	84.07	62.50
Treatment	2	1.77	1.33
Tangibles	16	14.16	10.50
Provider total	113	100.00	75.33
Total	**150**		**100.00**

Table 9.5. Proportion of purchased mistake-proofing devices

Source of device	Count	Percent of total
Locally developed	31	20.7
Off-the-shelf	119	79.3
Total	**150**	**100.0**

Sources of Supply

Although some mistake-proofing devices that will be needed in medicine will be created in-house or in an individual's garage or workshop, others will require more sophisticated design and production help. Competencies in inventive processes, design, fabrication, and assembly will be needed in some cases, and not all medical organizations will have these capabilities. These competencies usually will be found in engineering, maintenance, or biomedical engineering departments. In the absence of these departments, organizations must find other sources of supply.

One place to begin the search for help in developing a prototype for minimal cost is the engineering school at local colleges. Occasionally, engineering students may undertake projects as part of a class. Engineering programs will typically have two types of classes where devices could be designed and fabricated: "senior capstone design" courses and independent research courses. Organizations should expect to provide funding for required materials, but they may be able to avoid labor costs and profit margins. Squire[6] suggests that:

> … the school be physically close … you want to be able to go there and explain the idea...undergraduate engineers have a tendency to go off on their own, and without being available to see the development, you may end up with something very different than you envisioned.

Convincing an engineering school to adopt the project will also depend on the level of difficulty and whether the project requires a combination of competencies that would be beneficial to the students. This approach requires diplomatic treatment of intellectual property issues and commercial contingencies.

Karen Cox, a Patient Safety Improvement Corps (PSIC) 2004 participant, spoke of needing a farmer to weld a piece of equipment to solve a problem in the area of human factors and forcing functions.

The hooks that hold the containers in the infusion pump in Figure 9.1 are randomly arranged. One hook is occupied by a container that is connected to the smaller pump at left. The tubes are thoroughly tangled.

Figure 9.1. This infusion pump can hold and pump up to four medications at once.

Karen Cox wanted a hook immediately above each of the infusion pumps so that it would be clear which medications were running through each of the four pumps (Figure 9.2).

Figure 9.2. The solution. An infusion pump that eliminates confusion.

If a device is not appropriate for an engineering class project, an organization should continue to explore its options. One possibility is to consider networking with local chambers of commerce or with members of civic organizations such as the Rotary Club or Optimist Club in order to develop contacts with local factory engineering managers. Engineering managers are likely to have experience obtaining custom tool design, fabrication, assembly, and installation in the local area. Local machine shops (sometimes listed under "Machinery-custom" in the phone book), metal fabricators, and systems integrators also can help.

Industrial Glossary

Fabrication is an industrial term generally applied to the building of metal machines and structures. Fabrication shops and machine shops have overlapping capabilities, with fabrication shops concentrating on metal forming and welding. See http://en.wikipedia.org/wiki/Fabrication_(metal).

Assembly is the stage of production in which components are put together into an end-product appropriate to the process concerned. See http://www.eyefortransport.com/glossary/ab.shtml.

A machine shop is a workshop where metal is cut and shaped by machine tools.

A systems integrator is an individual or company capable of making diverse components work together as a system. The word system usually implies the inclusion of a computer or microprocessor component to the project. Sources for more information include:

- A Directory of System Integrators in the Medical Industry for Factory Automation, Process Control, and Instrumentation is available at http://www.automation.com/sitepages/pid121.php.
- Medical DeviceLink - a Web site associated with the medical device industry provides a directory of North American Suppliers of Automation and Custom equipment and Software. See http://www.devicelink.com/company98/category/Manufacturing_Equipment_and_Software/AutomationCustom_equipment.html.
- Automation Resources Inc. offers "online resources for industrial automation, process control & instrumentation" at www.automationtechies.com
- The Control and Information System Integrators Association (CSIA) provides a search feature that enables users to search for experienced CSIA member integrators according to industry, application, location, and service. See http://www.controlsys.org/about/member_directory.htm.

The CSIA also provides a free, two-volume guide to selecting and working with a systems integrator that covers most aspects of finding the right systems integrators, and highlights the nuances of navigating a project that otherwise might be initially overlooked. These are available at: http://www.controlsys.org/find/howto_guides.

C. Martin Hinckley's book, *Make No Mistake! An Outcome Based Approach to Mistakee-Proofing*,[7] contains extensive descriptions of, and supplier information about, sensors and other technologies that are useful in mistake-proofing.

A Path Forward

The discussion in these nine chapter has intoduced the concept of mistake-proofing and provided a rationale for using mistake-proofing to reduce errors in health care. It has also delineated a set of concepts, a vocabulary, and tools to assist organizations in taking action. This book contains 150 examples provided by the health care industry, as well as examples provided by manufacturing industries and people in everyday life. Anecdotal evidence indicates that, after they learn about mistake-proofing, readers are more likely to start noticing mistake-proofing examples around them and employ mistake-proofing to develop solutions. Gosbee and Anderson[8] found that root cause analysis (RCA) teams who have been exposed to human factors engineering case studies often change their focus to "underlying design-related factors," such as mistake-proofing, as remedial actions. Initiating this change in focus is the goal of this publication.

As you complete FMEAs and RCAs or witness errors, you will envision new ways to solve problems and create novel mistake-proofing devices. As these ideas are implemented as locally developed mistake-proofing devices, please spread the news of their existence. Submit them as indicated below or publish them in some other venue so that others can benefit from the solution. Modesty, minimizing contributions, or assuming that others have thought of a locally developed solution does not serve the greater good. Some of the best mistake-proofing will be exceptionally simple and inexpensive. All solutions will be developed locally by someone before they become off-the-shelf solutions. Be that someone.

Example Contributions

The examples presented here do not by any means represent an exhaustive listing of devices currently in use. Example contributions are welcome. Contribute mistake-proofing examples by visiting www.mistake-proofing.com and clicking on "Submit Example." Select the preferred submission method and add to the database of mistake-proofing examples. Comments on the devices featured in this book are also welcome.

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Acronyms

AAOS – American Academy of Orthopaedic Surgeons

AFD™ — Anticipatory failure determination

AHRQ – Agency for Healthcare Research and Quality

AOFAS – American Association of Foot and Ankle Surgeons

CBC – Complete blood count

CDSS – Clinical decision support system

CFIT – Controlled flight into terrain

COW – Computer on wheels

CPOE – Computerized physician order entry

CRM – Crew resource management

CSIA – Control and Information System Integrators

DNR – Do not resuscitate

EMRF –European Magnetic Resonance Forum

EPINet – Exposure Prevention Information Network

FDA – Food and Drug Administration

FMEA – Failure Modes and Effects Analysis

FMECA – Failure Modes, Effects, and Criticality Analysis

FOD – Foreign object damage

GPS – Global positioning system

HFMEA – Healthcare Failure Modes and Effects Analysis

IOM – Institute of Medicine

IV – Intravenous

JCAHO – The Joint Commission

LED – Light emitting diode

LEEP – Loop electrosurgical excision procedure

M&M – Morbidity and mortality

MRI – Magnetic resonance imaging

NAT – Nucleic acid test

NPSF – National Patient Safety Foundation

NWWSC – Northwest Wayne Skill Center

PMI – Pulse medical instrument

PSIC – Patient Safety Improvement Corps

QALY – Quality-adjusted life year

RCA – Root cause analysis

RPN – Risk priority number

SD – Solvent detergent

SOP – Standard operating procedure

SPC – Statistical process control

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