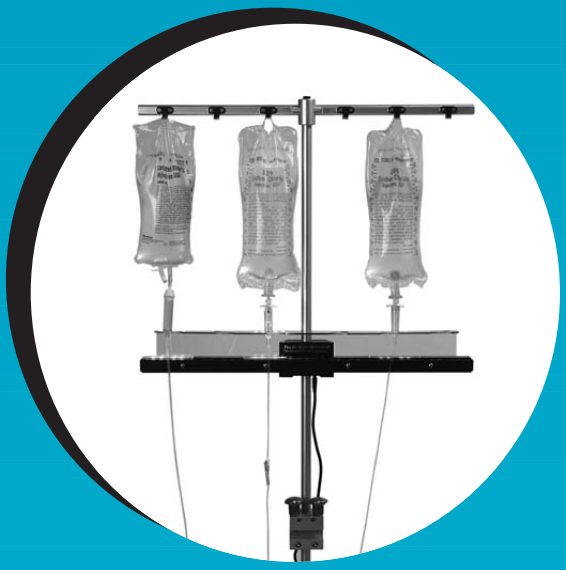

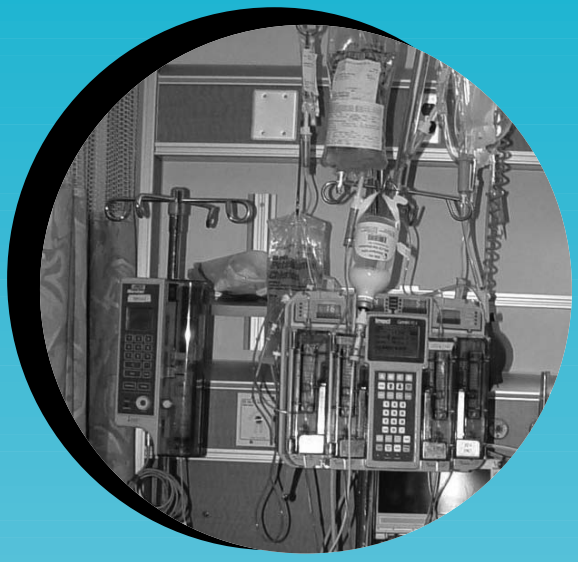

Mistake-Proofing the Design of Health Care Processes

DEPARTMENT OF HEALTH & HUMAN SERVICES • USA

AHRQ

Agency for Healthcare Research and Quality

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PATIENT SAFETY

Mistake-Proofing the Design of Health Care Processes

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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 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.

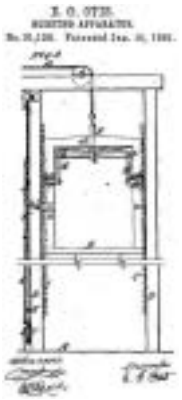


Figure 1.4. Illustration of an elevator brake. Note: Elisha Otis made elevators safe by installing an elevator brake. Otis and his invention are widely credited with making skyscrapers feasible. Photo: © 2003 James E. White, Taletyano Press. Used with permission.

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.

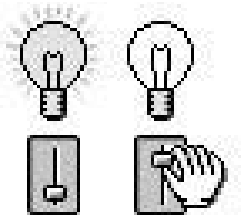


Figure 1.8. No natural mapping here. The right switch turns on the light at left. Illustration Courtesy of BadDesigns.com. Used with permission.

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]

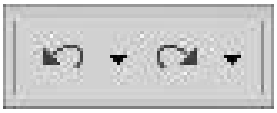
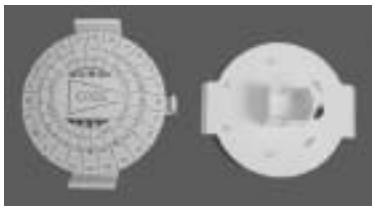


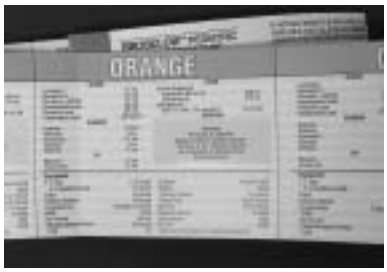
Figure 1.11. "Undo and Redo" allow users to prevent the influence of mistakes.

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		

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.

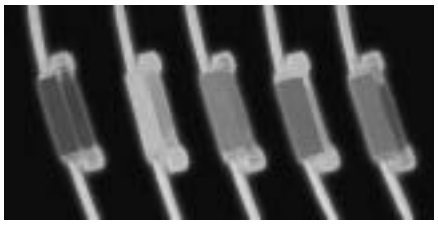


Figure 6.56. Cyalume lights are attached to each IV tube.
Image courtesy of Embo-Optics, LLC. Used with permission.

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.

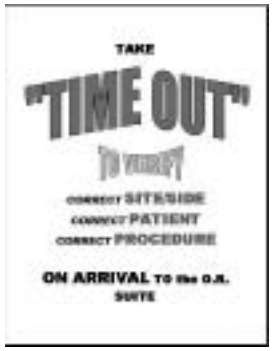

Figure 7.6. The sign reminds surgical personnel in one hospital to take a time-out.

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.

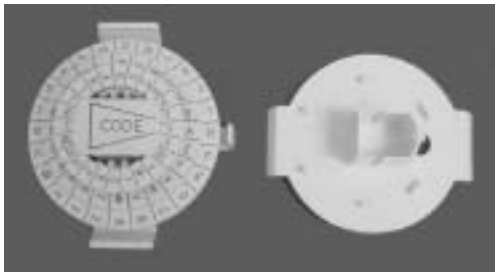

Figure 7.9. The cost effectiveness of the Bloodloc™ is estimated to be very favorable when compared to most transfusion interventions.

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.

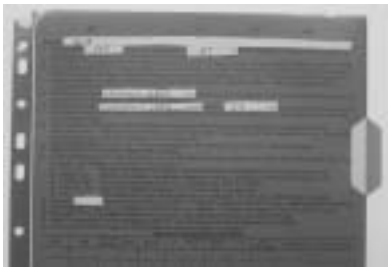

Figure 7.16. A template is more effective than a form.

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.

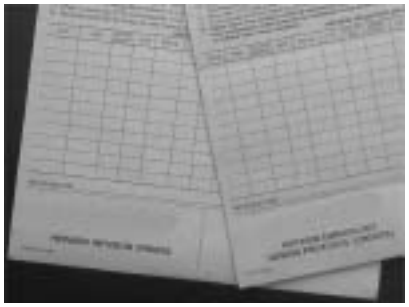

Figure 7.20. These forms are used for different protocols but vary only subtly in color.

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.

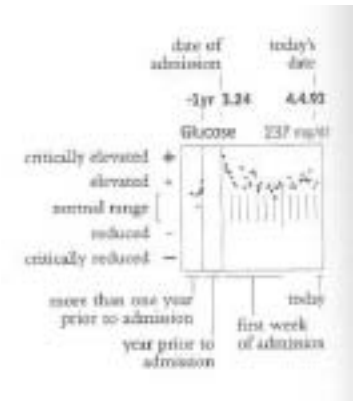

Figure 7.22. A detailed graph of a patient's condition presented in compact form.
From Powsner and Tufte.[13] Used with permission.

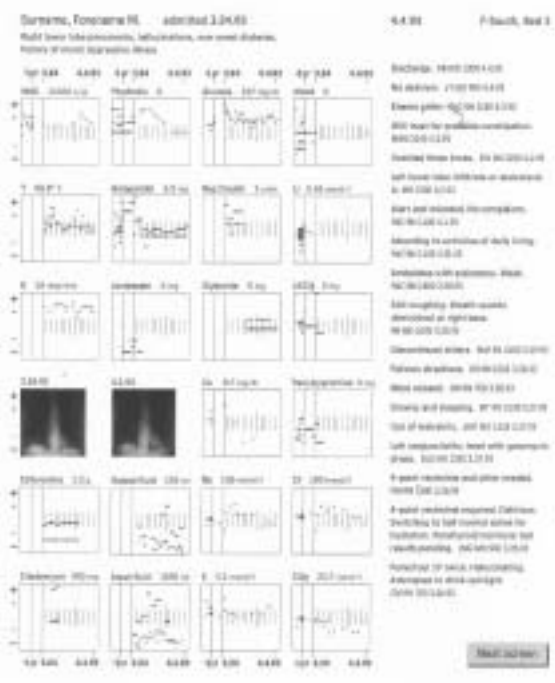

Figure 7.23. More than 1 year's worth of patient information is presented on one page.
From Powsner and Tufte.[13] Used with permission.

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.

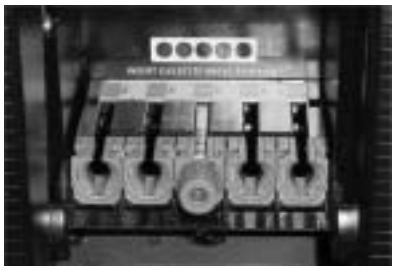

Figure 7.26. The rubber stopper on this blood analyzer is mistake-proofed to prevent contamination of employees.

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.

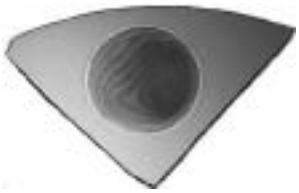

Figure 8.25. Smart bandages may soon be able to reveal the existence of different forms of bacteria. Photo courtesy of Benjamin L. Miller, University of Rochester Medical Center.

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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