

# Mistake-Proofing the Design of Health Care Processes

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.<sup>1</sup>

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)<sup>2</sup> 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<sup>3</sup> 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 pokayokay), Japanese slang for "avoiding inadvertent errors." Shigeo Shingo<sup>4</sup> 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.<sup>5-8</sup>

Shingo,<sup>4</sup> Hinckley,<sup>9</sup> and other authors of books on manufacturing<sup>11</sup> 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 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 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 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-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.<sup>12</sup>

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.

### 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.
2. Executing the action based on that intention. Failure in either step can cause an error.

Norman<sup>13</sup> 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<sup>4</sup> concept of mistake-proofing is more effective on slips than on mistakes. Norman's definition<sup>14</sup> of the term mistake is more precise and narrower than the common usage of the word.<sup>a</sup>

Rasmussen<sup>14</sup> and Reason<sup>15</sup> 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 "autopilot." 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.

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a. Andrew P. Dillon translated Shingo's book. His selection of the term "mistake" might have been different had he read Norman.<sup>13</sup> 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.

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### **Knowledge in the Head vs. knowledge in the World**

Norman<sup>13</sup> 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 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.<sup>16</sup>

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<sup>17</sup> 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.<sup>4,9,10,16,18</sup>

Tsuda's approaches are similar to those recommended by the Department of Health and the Design Council<sup>19</sup> 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<sup>17</sup> 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<sup>13</sup> 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.

**Table 1.1 Summary of Norman's<sup>13</sup> strategies for putting knowledge in the world**

Strategies	Action
Natural mappings	Design one-to-one physical correspondence ( <a href="#">Figure 1.8</a> ) 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.

Another method of mistake prevention in the work environment is the implementation of "visual systems,"<sup>19</sup> 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."<sup>20</sup> 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."<sup>21</sup>

- **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.
- **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<sup>20</sup> 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.<sup>5</sup> 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<sup>5</sup> 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<sup>19</sup> identify four setting functions that are described in Table 1.2.

**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.<sup>22</sup> [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.

**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 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 ( <a href="#">Figure 1.10</a> ).
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## 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<sup>5</sup> 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<sup>13</sup> 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.

**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.

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<sup>25</sup> 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<sup>26</sup> 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 enough. Chase and Stewart<sup>26</sup> 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.

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

Categories	Mistakes
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.
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**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, go to Chapter 7, [Example 7.2](#).)