Mistake-proofing healthcare: Why stopping processes may be a good start

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Abstract Two significant concerns in healthcare are spiraling costs and medical errors. These two concerns are correlated: eliminating medical errors leads to significant cost reductions. We provide an example, ThedaCare Inc., where both problems are improved by providing mechanisms that stop healthcare processes. While businesses often view having their processes stopped as a negative, increasing the stoppages, or creating process failures, is often a precursor to improved performance. A good rule of thumb is: if in doubt, stop. This concept of creating or engineering stoppages in the processes is linked to two “lean” concepts that come from the Toyota Production System: jidoka and pokayoke. A spectrum of methods for stopping processes is discussed, ranging from warnings in the work environment to mechanical devices designed to stop processes and empower humans to stop the process. The preliminary results achieved at ThedaCare demonstrate the financial and medical improvements that may be obtainable from utilizing these methods.

1. On the virtue of inaction

In 1999, the Institute of Medicine (IOM) estimated that between 44,000 and 98,000 people die each year as a result of medical errors. The IOM report further states, “given current knowledge about the magnitude of the problem, the committee believes it would be irresponsible to expect anything less than a 50% reduction in errors over five years” (Kohn, Corrigan, & Donaldson, 2000, p. 4). Ten years later, Consumers Union (2009) gave a failing grade to United States healthcare for its improvement efforts. The Agency for Healthcare Research and Quality (2008) reported that for the 5-year period ending in 2005 patient safety improved by about 1% annually, far short of the goal. The original IOM cost estimate for these errors ranged from $17 to $29 billion annually. However, the President of the United States was delighted to make headlines by announcing an agreement with influential healthcare leaders to curb the growth rate of healthcare costs to 5.5% annually (Bolduan & Liberto, 2009).
The solutions to these problems of safety and cost will be a diverse set of tools that help healthcare workers know what to do differently; to give them a different vocabulary of responses that lead to improvement. Don Berwick (2001), president of the Institute for Healthcare Improvement, says, “The remedy is in changing systems of work. The remedy is in design” (p. 247). Ironically, an effective new change to the system of healthcare work may have its genesis in one of its best-known dictums.

1.1. Primum non nocere: First, do no harm

When in doubt, is the best action no action at all? Though one of the best-known dictums in healthcare, this maxim is not a statement about what to do at all; rather, it is a statement about what not to do. Sometimes it makes sense to cause healthcare processes to stop rather than to let them cause harm. Consider the case of the Blood-LocTM, a plastic padlock that restricts access to a unit of blood by using a three letter combination that is available only on the patient’s wristband (Wenz & Burns, 1991). The following account, provided by James Aubuchon (2002) of Dartmouth Hitchcock Medical Center, demonstrates the necessity of having means in place to shut down healthcare processes:

It was noon in the ICU. Half the nurses go to lunch, the other half take care of two patients rather than one. [A] nurse knew a transfusion had been ordered for her patient, Patient A, and she assumed that the recent unit of blood delivered to the floor was his blood. She went to the bedside of Patient A, was joined by another registered nurse, and the two of them verified all the information on the unit label that said it was really for Patient A, and the medical record number matched, and so forth, and so on. They then went to unlock the Blood-Loc, and it wouldn’t open. We got a call from a very grumpy nurse in the ICU telling us the Blood-Loc won’t open. We said, “What patient are you trying to transfuse?” She said, “Patient A.” We said, “Well, we haven’t sent blood up yet [for] Patient A.” There was a moment of silence at the other end of the phone, and then the nurse was much more cooperative because she realized that we had not only saved her patient a problem, we had saved her a big problem, as well. (pp. 357-359)

When we look for ways to improve healthcare processes, the best approach may be to stop them in their tracks. The recommendation from healthcare and automobile manufacturing is the same: stop the process. Former Toyota executive Alex Warren says:

We give humans the power to push the button or pull what we call the andon cord, which brings the entire assembly line to a halt. Every team member has the responsibility to stop the line each time they see something that is below standard. That is how we put the responsibility for quality in the hands of our team members. They feel the responsibility; they feel the power. They know that they count. (Osono, Shimizu, Takeuchi, & Doron, 2008, p. 135)

Psychologists studying human error and mechanical engineers concur (Norman, 1989; Petroski, 1997). When identical recommendations come from a variety of disciplines, they become all the more credible.

In this article, we describe two ways to stop processes that originate in the body of knowledge known variously as the Toyota Production System, just-in-time, or lean: jidoka and poka-yoke. Each of these terms is described later in more detail. Gosbee and Anderson (2003) find that exposing process improvement (root cause analysis) teams to human factors solutions, similar to jidoka and poka-yoke, enhances the breadth of their approaches to problem solving. Poka-yoke and jidoka techniques are important and effective additions to the vocabulary of healthcare process improvement methodologies.

1.2. Lean

Toyota developed its production system over several decades. It is characterized by continuous process improvement via relentless waste reduction. Waste is very broadly defined, and includes defects, overproduction, transportation, waiting, inventory, motion, and processing. By reducing these forms of waste, firms are able to provide customers with goods and services they value with higher quality, and with less labor, space, and capital investment. Obtaining the same output for less input is the definition of higher productivity.

Rising healthcare costs continue to be a concern. One of the more palatable ways of reducing these costs is through productivity improvements. The implementation of lean production methods is one approach that has been utilized to obtain these productivity increases. The use of these methodologies is spreading from manufacturing into healthcare. Books are becoming available on this topic (Chalice, 2007; Graban, 2008; Zidel, 2006) and successes are being reported (Black, 2008; Grunden, 2007; Zettel, 2007).
1.3. Jidoka

*Jidoka* is “the practice of stopping the process when a problem occurs” (Osono et al., 2008, p. 135). The basic steps of jidoka are to: (1) detect the problem, (2) stop the process, (3) restore the process to proper function, (4) investigate the root cause of the problem, and (5) install countermeasures. As noted previously, each worker at Toyota is empowered to stop the assembly line. Generally speaking, stopping assembly lines can be very costly and is typically avoided. However, Ohno (1988) found that stopping the line and solving problems actually led to better performance in the long run. Initially, lines where workers can stop the process will exhibit lower output. As stoppages lead to problem solving, the line will have fewer stoppages and better quality compared with a line where workers are not empowered to create stoppages. With jidoka in place, the process may be stopped either by a machine using sensors or by a worker pulling on a cord that hangs down in his or her workspace.

Seattle’s Virginia Mason Medical Center has sought to reduce patient safety events by asking all staff members to “be ‘safety inspectors’—empowered to stop the line’ when potential sources of mistakes are discovered, without fear of blame” (Virginia Mason, n.d.). After the line is stopped, and the stoppage is verified as a genuine patient risk, an investigation is initiated to determine the cause and mitigate the risk. In the 5 years ending in 2007, over 8,000 stoppages occurred (Virginia Mason, 2008).

1.4. Poka-yoke

*Poka-yoke* is Japanese slang that is most often translated as “mistake-proofing.” Poka means inadvertent errors. Yoke is a form of yokeru, which means to avoid. Mistake-proofing, then, is the avoidance of inadvertent errors (Shingo, 1986). Mistake-proofing is known by a variety of other names: idiot-proofing (*baka-yoke*), fail-safing, error-proofing, forcing functions, and barriers. Each term has a slightly different connotation, though there is significant overlap in the respective meanings. Forcing functions are a subset of mistake-proofing. The concept of barriers is broader than mistake-proofing. It is not a single approach to reducing inadvertent errors; instead, it includes a wide variety of approaches.

Some approaches to mistake-proofing involve “containment inspections” that merely sort out the defects from among the acceptable product, and keep the defects from going on in the process. Other approaches use data from process outputs to suggest how best to manage the process. A highly effective approach involves inspecting the process prior to action in order to ensure all of the conditions necessary for high quality exist. In each of these approaches, two functions are required: (1) the defect or its cause must be detected, and (2) corrective action must be taken. More details on how these functions can be designed are available (Chase & Stewart, 1995; Shingo, 1986). Most often, the corrective action is to notify a worker that the process is amiss. One of the most effective ways of accomplishing this is by stopping the process. Grout (2007) points out that mistake-proofing often involves the creation of process stoppages, and provides tools and methods for designing them.

Tsudo (1993) created an alternate typology whereby mistake-proofing was divided into the following categories: mistake prevention, mistake detection, preventing the influence of mistakes, and mistake-proofing in the work environment. Mistake prevention is the strongest form of mistake-proofing. It keeps mistakes from occurring. Mistake detection merely alerts workers to the fact that a mistake has occurred. Such alerts are very useful because often mistakes that are detected and corrected rapidly do not actually give rise to defects. Detecting that a surgical sponge has been left in a patient is more easily remedied before closing, and results in a far better outcome for the patient, than if it is discovered after the surgery has concluded. Preventing the influence of mistakes means that the results of the error are mitigated. Mistake prevention in the work environment means reducing clutter, confusion, and ambiguity where work is done. This approach is closely linked with the lean methods of visual systems or 5S (Galsworth, 1997).

2. Approaches to stopping processes

Jidoka and poka-yoke both involve stopping the process. Jidoka involves stopping the line in order to solve problems. Poka-yoke stops the process in order to restore the process to its proper running parameters, or to remove the causes of defects. Poka-yoke can be one of the actions taken in response to problems surfaced by jidoka. In fact, the line between poka-yoke and jidoka is broad and gray. A variety of opinions about these terms could lead one to think of poka-yoke as a subset of jidoka, or vice-versa.

Not only are the distinctions between jidoka and poka-yoke ambiguous, poka-yoke itself is defined in a variety of ways by the various authors who write...
about it. The definitions range from very narrow definitions of physical mistake-proofing, to broad procedural mistake-proofing.

In previous writings, Grout’s definition of mistake-proofing has been quite narrow: the use of process or design features to prevent the creation of non-conformances. A rule of thumb based on this definition is: if you can’t take a picture of it, it is probably not mistake-proofing. Logical checks embedded in software code are the main exception to the rule. Exploring the published examples of mistake-proofing (Grout, 2007; Hinckley, 2001; Nikkan Kogyo Shimbun, 1988; Rajan, 2001; Shingo, 1986) reinforces this rule of thumb since drawings or photographs are provided for nearly every one, or a total of 850 examples, including a modest amount of duplication.

Procedural mistake-proofing involves creating a procedure or habit designed to consistently result in desired behaviors and outcomes. One example of procedural mistake-proofing comes from Dr. Tony Kern, a former B-1 Bomber pilot, author, and instructor at the United States Air Force Academy, who is waging a “global war on error” (Kern, personal communication, 2009). As a military pilot, Kern devised a mistake-proof procedure to avoid a life-threatening error. Sometimes, aircraft need to descend rapidly. This is done with air brakes extended to keep airspeed in check. At the end of a descent, a pilot must remember to retract the air brakes to avoid stalling when the aircraft’s flaps are deployed. Dr. Kern’s procedure involved lowering the tinted visor of his flight helmet halfway to provide a clear visual prompt to disengage the air brakes at the end of the descent. Closer to home, having a habit of placing the long-term parking ticket in your wallet ensures you do not unknowingly leave your wallet in the car and that the ticket is available when you return from your air travel. These kinds of procedures work well once the habit is ingrained into routine behavior; however, creating that habit requires attentiveness and the recollection to do unprompted actions. The broadest definition of mistake-proofing is that used by Stewart and Melnyk (2000, p. 48):

We use the term poka-yoke process to denote any process for which the desired outcome, as defined by the critical customer, is inevitable. That is, by following the process, as designed, the people involved in it should be able to achieve the desired result.

This use of the term poka-yoke is similar to Holnagel’s concept of barriers. “A barrier is something that can either prevent an event from taking place or protect against its consequences. . . . Barriers include signs and indications” (Holnagel, 2004, p. 2). A warning label is very weak mistake-proofing; yet, if workers read the warning, they should be able to avoid the error.

3. Approaches to mistake-proofing in healthcare

The Blood-Loc™ mentioned previously is a good example of a physical form of mistake-proofing in healthcare. The device is a single-use plastic lock that provides closure for a plastic bag that contains a unit of blood. When the patient is admitted, the combination to the lock is placed on the patient’s wristband and reported to the blood bank. The code is conscientiously omitted from the patient’s chart and other information systems. The padlock is set with the patient’s code in the blood bank and the shackled unit of blood is sent to the patient’s location. Those who are administering the unit of blood gain access to it by getting the code from the patient’s wristband, the only place where the code is available to them. Wenz and Burns (1991) report that in a test of 672 transfusions, 3 potential mistransfusions were avoided by using Blood-Loc™ technology. No mistransfusions occurred, nor did any quality checks on the Blood-Loc™ reveal a lock that would open without the correct combination.

Other examples of mistake-proofing in healthcare include automatic wheelchair brakes and central line kits. Automatic wheelchair brakes are designed so that when the chair is unoccupied, the brakes are engaged. Only when the person is seated or a hand lever is pulled will the wheels turn freely (Jerry Ford Co., 2009). This device protects elderly patients from hip fractures that are common when the wheelchair rolls away during entry. In another example, a process improvement project undertaken at Massachusetts General Hospital in Boston revealed that the combined prevention costs and treatment costs of central line infections could be cut by 50% (Grout, 2007). This reduction was accomplished by utilizing a relatively expensive custom kit that contains all the supplies necessary to perform the insertion according to known best practices. A kit that ensures all of the needed supplies are at hand during the insertion is not very innovative mistake-proofing, but it has the desired effect.

Not all mistake-proofing is as effective or strong as the examples cited. But sometimes even mistake-proofing techniques that seem less effective or weak, such as marking the floor, can help. The European Magnetic Resonance Forum (n.d.) advises marking the floor with lines to indicate where the magnet’s strength exceeds five Gauss. One health
system uses a red line on the floor to sequester nurses so that they can retrieve medications from the computerized dispensing machine without interruption. Another facility uses a blue checkerboard pattern of floor tiles to signal the need to don scrubs. Although environmental markers may seem elementary and can be overlooked or overridden, they have been proven to be effective basic techniques for preventing costly and dangerous errors.

Additional weak forms of mistake-proofing include clinicians’ recommendations that patients never accept a handwritten prescription (Meyer, 2006). Another example is the Joint Commission’s (n.d.) speak-up program, whereby patients are encouraged to be more skeptical about their care and to ask questions. The patient is thus cast in the role of the final barrier against healthcare mistakes, a role for which patients and their families are often not ideally suited. Another example of weak mistake-proofing is providing patients with a face sheet that shows names, photos, and positions of every staff member involved in their care. This allows patients to more meaningfully participate with the staff in their care.

Procedural mistake-proofing in medicine might include techniques such as timeouts, sign-your-site, and read-backs. Timeouts involve having a surgical team stop the process for a moment while the team reviews the patient’s identity, the procedure to be performed, and other expectations. Everyone’s concurrence is sought before proceeding. Sign-your-site is a national patient safety goal of the Joint Commission, the main hospital accrediting organization. It requires the doctor to mark the site of an invasive procedure with the patient looking on. A read-back is a procedure where verbal orders received from a doctor are repeated by the person receiving the orders to ensure accuracy.

4. Jidoka at ThedaCare

Several healthcare organizations have demonstrated that the improvement techniques utilized by Toyota can be employed very effectively in healthcare, as well as automotive manufacturing. These organizations include the Virginia Mason Medical Center in Seattle; the Pittsburgh Regional Health Initiative; and ThedaCare Inc. in Appleton, Wisconsin. ThedaCare is highlighted because it has focused on jidoka and pokayoke, and has obtained impressive results from doing so.

ThedaCare’s approach to medical and financial improvements is codified in ThedaCare’s Improvement System (TIS), which is patterned after the Toyota Production System (TPS). TIS includes many of the improvement tools typical in TPS implementations, including the use of rapid improvement events. These events are typically 1 week long, and focus small cross-functional teams’ attentions on one problem that should be resolved by the conclusion of the event. Also, as does Toyota, ThedaCare utilizes impossible goals (Osono et al., 2008). ThedaCare has worked extensively on its metrics. ThedaCare’s impossible goals did not emerge immediately; however, over time the right metrics emerged from an iterative evolutionary process. During this same period, ThedaCare became adept at utilizing week-long rapid improvement events as the means of causing those improvements.

After 2.5 years of iterations refining metrics and methods, ThedaCare converged on decreasing defects, engagement of personnel, and productivity as metrics. Specifically, the goals are: to decrease defects and waiting time by 50% per year, to require the engagement of all physicians and staff in two or more rapid improvement events per year, and to increase productivity by 10% per year. Note that IOM’s 1999 national goal of reducing defects by 50% in 5 years went unachieved (Kohn et al., 2000). Therefore, a 50% reduction on a compounded yearly basis certainly qualifies as an impossible goal.

The results so far have been impressive. Medication reconciliation defects declined from 1.05 defects per chart to 0 defects per chart after 1 year. Productivity has increased almost 3% per year on average, with each 1% improvement yielding $2.3 million in operating income. Thousands of rapid improvement events have been conducted; well over 3,000 employees have been involved in at least one event, with hundreds involved in more than two. In its first year, the Collaborative CareTM unit reduced the average duration of a patient’s stay by 14.2%. Costs have also declined relative to peers. According to Boulton (2008):

An uncomplicated heart bypass, including physician fees, costs $30,400 on average at a ThedaCare hospital, based on what ThedaCare and its independent physicians bill one large health insurer. That insurer pays $42,700 to $71,000 for the same procedure at [other] hospitals in southeastern Wisconsin.

ThedaCare’s assault on defects focuses on improving safety and quality. This approach is based on jidoka. The Collaborative CareTM unit was created as an experiment in making jidoka effective (Toussaint & Gerard, 2009). Rather than hiring a large number of quality inspectors to look over the shoulder of each nurse in order to make sure that nurse was managing
care effectively, those resources and improvement efforts were used to radically redesign the process. Through months of extensive research, experimentation, and prototyping, dramatic reductions in medication errors, falls, and infections were shown to be possible. The resulting process is a new patient-centered vision for in-patient care.

The new process involves completely redesigned roles and division of responsibilities among the individuals providing care. The individuals who care for patients now actually act as a team, tightly linked and working in concert. The doctor, the nurse, and the pharmacist work collaboratively throughout the patient’s stay. This allows for attributes of a high reliability organization to emerge: intra-team mindfulness; preoccupation with failure; and, most importantly for achieving jidoka, deference to expertise (Weick & Sutcliffe, 2001). Deference to expertise means that decision authority migrates to the individual team members with the most expertise in that situation. Rank or status is irrelevant. If the nurse is more aware of the patient’s status, the doctor and the pharmacist should defer to the nurse’s knowledge as they determine how to proceed. Each member of the team has important knowledge and insights to contribute.

The teamwork of the doctor, nurse, and pharmacist starts with a meeting with the patient and the patient’s family within the first 90 minutes of admission to assess the patient and create a care plan. The most dramatic change from a typical care process is that the nurse becomes the “process owner” and is charged with ensuring that the care plan is executed. The nurse acts as the overall care manager, and insures that patients move effectively through the various process “toll-gates” established by the team in the care plan (see Figure 1). The pharmacist does medication reconciliations, writes orders on the chart regarding medications as appropriate, and oversees every aspect of the patient’s medications. The physician’s role is to create the plan in collaboration with the pharmacist and the nurse, but not to manage the care. Therefore, in practice, the nurse or pharmacist often updates or sometimes even reminds the physician that certain care toll-gates have not been met, and seeks orders for tests consistent with the plan. Although having a nurse call a physician to order a test is distinctly different from past practices, most physicians involved in the process report higher satisfaction with nurse performance. These nurses are perceived by physicians to be more helpful than nurses not working in the Collaborative Care™ process.

Mistake-proofing in this process is based on procedural toll-gates intended to prevent defects during the care process. When significant defects do occur, the first step is to provide containment immediately. Containment “stops the line” and determines whether the process should continue, and whether subsequent work can be accomplished safely. It is critical that these determinations be made immediately after a defect is identified. ThedaCare has gone so far as to place a “checker” in every operating room to ensure that the surgeon and staff complete a checklist before every surgery. The checker’s job is to stop the process until the norms of the staff develop to the point where every employee is comfortable in the role of safety-checker. Once stopping the process becomes the accepted norm, one person is given chief responsibility for checking the process and is identified as the process owner.

Figure 1. The patient care process

The process owner checks the criteria for patient progress specified in the care plan. If criteria are not met, the process is stopped and a PDSA problem-solving cycle is performed. The care plan criteria serve as tollgates that ensure proper care occurs. Note that PT is an abbreviation for patient.
Once the process is stopped, long-term solutions are sought. In one case, operating rooms (ORs) were shut down until a complete root-cause analysis was done to determine what had caused a series of surgical-related infections. This shut-down was an expensive decision. The result was a finding that neither physicians nor staff members were properly following hand-washing protocols. The hand-washing process was reviewed with them, and a standard work document was created at the site of the scrub area. The OR manager and supervisors then observed all hand-washing for a period of time to ensure compliance with the standard work. After compliance was achieved, the unit transitioned over time to random assessments that were tracked on the visual tracking board in the operating rooms. The infections stopped.

ThedaCare’s Collaborative Care™ implementation of process improvement and jidoka generated impressive results. The improvement data represents a subset of patients to demonstrate impact of the delivery model. The following data are excluded from both baseline and Collaborative Care™ data: observation patients, ICU patients, and patients with length of stay greater than 15 days. Operations in 2006 are the baseline. Collaborative Care was piloted in 2007. The latest results available are for the period between January and April 2008.

The case-mix index, a measure of how difficult various patients’ cases are, is comparable between 2006 and 2008, rising only slightly from 1.08 to 1.10. Yet, ThedaCare’s length of stay figure dropped from 3.71 to 3.10, a 16.4% reduction. The rate of admission and medication reconciliation defects on charts dropped from 1.05 defects per chart in 2006 to 0 in the 4 months of 2008 where data was available. The percentage of time that pneumonia patients received a well-established set, or bundle, of best-practice treatments rose from 38% in 2006 to 100% in 2008. Patient satisfaction also increased from 68% of patients giving the highest rating to 100% in 2008. From a financial perspective, average cost per case, using a fully-loaded, Medicare ratio-of-cost-to-charges (RCC) method, dropped from $5,669 to $4,964; that represents a 14.2% reduction in costs over 2 years. To put this cost reduction in perspective, a 1.5% industry-wide reduction in the growth rate of healthcare costs, down from a 7% annual increase down to a 5.5% annual increase, is perceived to be a significant improvement (Bolduan & Liberto, 2009).

ThedaCare’s implementation of Collaborative Care™ was not executed without resistance. Nurse ownership of the process and increased pharmacist involvement brought to light a concern often found in stop-the-line or jidoka implementations in medicine. Some doctors resent receiving negative feedback from individuals they perceive to be of lower standing or status. Hospital Health Network (Runy, 2005, p. 47) reports:

[In an all-too-common scenario, a nurse is berated by a physician because she questioned his orders. But, the nurse doesn’t take it quietly. She issues a patient safety alert, which instantly brings the treatment process to a halt. The physician’s orders are examined, treatment is revised and a potential error is averted. After hospital executives and the department head review the incident, the physician is required to take remedial training in the course of treatment in question as well as an anger management class.]

ThedaCare has sought to address these concerns through organizational development and training, and by appealing to outcome data. ThedaCare’s board found the outcome data so convincing that the organization is rebuilding every patient care unit using the Collaborative Care™ process.

5. Final thoughts

The results of ThedaCare’s jidoka implementation are impressive, as are results of the Blood-Loc™ and other mistake-proofing efforts. But, the insight that stopping the process is an improvement is not obvious. However, over the years and from a variety of sources, a consensus has emerged: if in doubt, stop.

This article has suggested a variety of ways in which processes can be stopped. Machines and devices can be designed to stop. Even other people who are empowered to stop the process can significantly improve the quality outcomes of a process. Implementations of these stoppages are in their infancy. Much more needs to be done; however, early results suggest jidoka and mistake-proofing are promising approaches for improvement of process quality and financial results. The results do provide hope that the Institute of Medicine’s 1999 goal (Kohn et al., 2000) of cutting preventable medical errors in half may be achievable using these techniques.

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