Modifying the Toyota Production System for Continuous Performance Improvement in an Academic Children's Hospital

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- CPI (or Continuous Performance Improvement)
- TPS (or Toyota Production System) • Safety
- Efficiency • Waste

Imagine a patient arriving at a clinic and waiting in line for registration, sitting in the waiting room for 30 minutes beyond the appointment time, finding that the previsit laboratory tests were lost and the letter describing the clinic visit never arrived at the referring pediatrician's office. How could this happen? In fact, the above scenarios occur at every interface of our health care system. How did we develop such a tolerance for errors, waste, and poor service? Imagine that the same patient arrived at the hospital's outpatient ambulatory center and after sitting in the waiting room for 5 minutes beyond the appointment time, a yellow light began blinking and the clinic administrator immediately appeared to discuss why the patient was not in the room seeing a physician. If by 10 minutes, the patient was still not in the examining room, the hospital's COO and head of nursing immediately appeared to determine how this could happen and to prevent it from happening to any other patient in the future?

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Is this imaginable? It is the type of response that occurs in a Toyota Production System (TPS) environment for every process step in One Piece Flow. In such a system, there is NO tolerance for errors or waste.

The reports of the Institute of Medicine of the past 10 years on hospital errors and medical quality shortfalls have added substance to the steady decline in public opinion of hospitals and health care professionals. Sadly, the reality of health care in America today, in many respects, is deserving of such low opinion. Clinical errors remain with us and are generally more the subject of debate about definition and data than about how to prevent them. These results are produced at a national cost of $2.4 trillion, which in 2007 equated to 17% of the United States gross domestic product.[1] We've all heard this before. Yet, we also know that the American health care system is composed of very bright and talented people providing the best care they can, but doing so within dysfunctional systems.

Seattle Children's Hospital has embraced the goal of having the "best" quality of care for our patients and families. Being the "best" translates into having a system of care in an academic environment that is unsurpassed in quality. To accomplish this goal, our physicians, nurses, administrators, and staff have adopted the principles of TPS[2] in a program called Continuous Performance Improvement (CPI), as we began a journey to improve the quality of care for our patients. This article describes the principles of CPI and offers examples of how an academic children's hospital has applied these principles in our missions of clinical care, education, and research.

PRINCIPLES OF CONTINUOUS PERFORMANCE IMPROVEMENT

The philosophy of Continuous Performance Improvement (CPI) recognizes that the continuous improvement of an organization's performance is a long-term generational effort. The CPI organization serves its customers first, vigorously supports its people in their work, and with rigor and discipline applies the scientific method to the iterative improvement of its practices. In so doing the organization recognizes the inter-relationship of Quality, Cost, Delivery, Safety, and Engagement. Successfully implemented CPI yields improvement in Quality of care and service, reduction in Cost, improvement in the Delivery of care and service, improvement in patient and staff Safety, and the Engagement of faculty and staff in improving the organization's care and service. A successful CPI program requires tenacity and patience from the organization's leaders. As important as it is for the organization's leaders to espouse and require this philosophical approach, it is more important that the faculty and staff be provided with effective principles and methods (the "tools" of CPI) to enable improvement at the bedside and wherever patient service is provided or supported. The effective use of these tools requires that improvement efforts focus on enhancing the experience of the patient via use of the "Value Stream," and focus on the removal of waste from processes that affect the patient, faculty, and support staff.

The Value Stream

The primary focus of CPI is the patient. The definition of value and conversely the definition of waste are seen through the eyes of the patient. In manufacturing, value for the customer is seen only when an action changes or transforms the shape or character of the product. From the perspective of the customer all other actions are waste. The "Value Stream" is the sequence of actions that occur from the moment the customer orders the product until the customer receives the product. The objective of any company should be to continuously improve its performance to reduce the amount of time between customer order and product delivery by eliminating waste from its processes and systems.

If you watch the flow of products on an assembly line it is relatively easy to see where and how a "product" is being changed and transformed as it moves down the line. You can see how worker movements, worker waiting, and worker searching (for tools, supplies, and so forth) may seem important to the assembly of the product, but in fact are extraneous steps and examples of waste. In health care it is more difficult to see the "flow" of patients through our processes and therefore more challenging to see if our actions are wasteful or provide value. The value stream approach requires that we understand the health care experience from the perspective of the patient. An excellent way to understand the value stream in health care is to map the process of a patient presenting for diagnosis, therapy, and care until medical care is completed—from the patient's perspective. With CPI, value stream maps are drawn by multidisciplinary clinical teams that include patients and families. The results of the mapping effort are complex, confounding, and overwhelming, accurately reflecting our patients' experience.

Once the health care value stream map is drawn, it quickly becomes a remarkable tool for identifying wasteful steps and events a patient experiences in the course of diagnosis and treatment. Examples of waste are identified as "opportunities for improvement" and the tools of CPI are used to reduce and eventually eliminate the waste. Let's use the waste of "waiting" as an example. Without the value stream approach and seeing value and waste from the patient's perspective, waiting is accepted as an unavoidable part of the health care experience. In fact, we design hospital and clinic facilities by building the most welcoming spaces possible to enable restful waiting. Instead, these design efforts should start with the premise that waiting is waste and seek to eliminate it. On the value stream map the reasons for waiting can be clearly seen and addressed through CPI. The value stream map is the tool that gets the improvement process started.

Waste

The definition of "waste" in the context of CPI is often viewed as extreme, and even wrong, by most who encounter the definition—at first. Why? Because the CPI definition of waste shows that virtually 95% of what we do in health care *is waste* from the perspective of the patient. The opposite of waste is value, and value from the patient perspective is defined as "an activity which changes the form or function of a product or service in a way that enhances value from a *patient's perspective*."[3] Expressed in another way, value is "an activity that the patient would be willing to pay for."[3] Waste in health care includes processing, correction (re-work), searching, transportation, underused staff, poorly used space, inventory, complexity, and waiting. The waste of processing is best exemplified by form or signature redundancy; correction is related to any and all errors; searching occurs when information, materials, or equipment are not immediately at hand; transportation involves any unnecessary movement of staff, goods, or patients; the poor or underuse of people and space occurs because of unnecessary peaks and valleys in patient or other activity; excess inventory occurs because of unnecessary variation in activity; complexity relates to the lack of reliable methods and standard work in health care; and waiting is caused by, or is a symptom of, all the other types of waste.

Some waste is *necessary*. Some regulatory requirements are examples of necessary waste. CPI aims to *eliminate* the unnecessary work of no value to the patient, to reduce the necessary work of no value to the patient, and to improve the value-added work we provide patients.

Standard Work

Standard work is required for CPI, although hard to establish in health care. It is impossible to improve any process unless it has been standardized.[4] Creating Standard Work requires identifying the repeatable elements of a process, assessing the best way to perform those elements, developing a reliable method to ensure the performance of those elements, and then performing the reliable method according to a calculated time that meets customer demand. Physicians often express skepticism that because patients are unique and highly variable, standard work is not possible in health care. It is precisely because patients are unique and highly variable that everything else in health care needs to be reliable and standard, so that the variability of a patient's condition can be isolated and not compounded in complexity by the variability in our "system" processes. An example is hospital teaching rounds. When the rounding method is known to all team members and is the same regardless of day of the week or attending physician, the wastes of searching and waiting (for people, information, patients, and so forth) are greatly diminished because physicians and nurses to know what to expect, what to do, and when to do it. With waste reduction, rounds take less time, leaving more time for thinking about the patient, teaching, conducting research, or going home on time.

Just-in-time

Another key CPI principle is "Just-In-Time" (JIT). It simply means that one does one's work only when it is demanded by the customer and, whenever possible, one step at a time (One Piece Flow). Although these two principles are often seen as having to do only with supplies and inventory, there is great application for clinical or administrative practice. When we do not have Just-in-Time or One Piece Flow in clinical practice; we tend to "batch" our work (ie, save up a great quantity of similar work, such as charting or orders), as opposed to doing that work one patient at a time (one piece flow). Going back to rounds, a sound Reliable Method would include the time and means by which all work associated with each patient is completed before the Team moves on to the next patient. When rounds are over, the work is done. The other benefit to one piece flow and JIT is that batching tends to obscure waste and errors. When work is being completed or delivered one at a time the existence of variation or error is easier to spot and prevent from passing on to the next step in the process.

Built-in Quality

The CPI principle of Built-in Quality has its roots in the simple admonition to "do it right the first time." Our challenge is to "error proof" our processes or, failing that, implement self-inspection and other "check" steps to ensure that errors do not get passed on. When variation and complexity are reduced through the development of reliable methods and standard work, process auditing and especially automated fail-proof controls can help prevent errors or at least keep errors from moving to the next step. A good example is the development of reliable methods in automated medication ordering through Electronic Medical Records systems or, short of automation, monitoring and auditing closely in real time. Beyond Built-in Quality, another advantage of reliable methods in order writing (*and* Patient Rounds) is that the pharmacy is better able to project medication inventory and pharmacist workload, aiding in its effort to provide needed materials Just-In-Time.

Rapid Process Improvement Workshop

An excellent CPI tool used for developing and implementing these types of changes is the rapid process improvement workshop (RPIW). RPIWs are designed to educate the participants in CPI principles and methods applicable to the task at hand, and to enable them to redesign and implement a process change in 5 days' time. In many respects it epitomizes the practical application of the scientific method to clinical and administrative practice. To be successful, the RPIW requires data collection and analysis, problem assessment and workshop planning, leadership sponsorship and resource deployment, qualified workshop facilitation and support, and a representative multidisciplinary (including patients and families) workshop team.

In the RPIW, facts and data drive decisions, and opinions and professional titles get "checked at the door." Individuals intent on power plays must be managed respectfully but effectively and quickly. The RPIW Sponsor is responsible for approving the "Charter" (**Fig. 1**) for the workshop, keeping the workshop within scope and on track, and ensuring that barriers and obstacles to the team's success (like power players) are mitigated or eliminated.

An RPIW Team usually includes an executive or faculty leader as Sponsor (one per workshop), key executives and faculty leaders as members of a Management Guidance Team, an "on-the-ground" leader as "Process Owner" (usually only one), and

PROCESS NAME: General Medicine Discharge Criteria SPONSOR: MD	PROCESS OWNER: MD CPI TEAM: (2)	
Boundaries *Starting Point*: Patient admitted *Ending Point*: Patient discharged *Sub-processes included*: Identification and modification of criteria, Documentation/communication of criteria, Incorporation of information into rounds, Education of Residents	**Team Members (10):** **Staff RN** **Staff RN** **Care Coord** **CPI** **R1** **Community MD** **Charge RN** **Sr. Resident** **MD** **Patient/Family rep**	**Management Guidance Team (10):** **COO** **RN** **RN** **MD** **MD** **RN** **RN** **MD** **MD** **MD**
Current Situation *(includes baseline data):* Criteria for discharge inconsistently documented, in various places *85% of charts reviewed did not document discharge criteria • Criteria for discharge inconsistently discussed during rounds *No standard format currently exist for discussing discharge criteria during rounds • Team & Families not always aware of discharge criteria prior to discharge *RN = 1.3 at 24 hours of admission *Family = 3.0 at 24 hours of admission	**Resource Representatives:** Communications MD Pharmacist Social Work Family Resource Health Info and Privacy	**Stakeholders:** **Sub-Specialties** **MCC**
Targets: Discharge criteria will be defined, documented and made visual to Team & Families • (Goal of 65% at 30 Days; 85% at 60 Days w/ Stretch Goal of 100%) Discharge criteria will be communicated to Team & Family within 24 hours of admission Discharge criteria will be updated and communicated daily		
RPI Theme: Reliable method design and implementation, Visual display	**Administrative Support**	**Measurement Specialists**
	Replications Needs & Resources: Sub-Specialties MCC All inpatient units	

Fig. 1. An example of a team RPIW charter.

Team members selected from representative groups affected by the process under consideration. The RPIW Team that redesigned General Medicine patient rounds included the Hospital COO as Sponsor; the Pediatrics Chairman, the Chief Nursing Officer, and Chief Medical Officer as members of the Management Guidance Team; the chief hospitalist and hospital nurse leader as Process Owners; and faculty, nurses, residents, parents, and unit coordinators as team members.

RPIW Teams are expected to develop proposed design changes (ie, hypotheses) and then share them with affected "stakeholders" during the workshop week. By the end of the week a new design is implemented after which it will be audited on a 30-, 60-, and 90-day basis to determine both whether the new process is being followed and whether it is having the desired result. This is the stage at which the application of the "Deming Cycle" of Plan Do Check Act (PDCA)[2] is important to the organization in the short and long term. In the short run, PDCA provides the means by which improvement work is evaluated in real time, and for the long term it is the means by which the organization remains credible in its commitment to continuous improvement. Through the RPIW tool and its evaluation with PDCA, an organization can bring the practical application of the scientific method to the improvement of clinical and administrative practice.

CONTINUOUS PERFORMANCE IMPROVEMENT PRINCIPLES ADAPTED TO CLINICAL PRACTICE

Many of the process changes are designed and implemented using the RPIW methodology. During the workshop, the team goes to the actual clinical site and watches the actual process. To expose the many forms of waste it is important to follow a series of standard steps when looking at a process. The team maps and quantifies the actual steps involved, the time for each step, and the distance traveled with each step, then determines which steps add value and designs and implements the improved process during the week. While the ideal state is identified, our philosophy is that 50% improvement in a process, continued measurement, and further cycles of improvement are more important than attempting perfection. The following examples will illustrate how CPI methodology was used to improve quality, remove waste, and improve flow.

Central Line Process Improvements

We used the CPI methodology in a multipronged set of improvements aimed at reducing central line infections. These interventions were specifically targeted at the overuse and complexity in the use and ordering of peripherally inserted central catheters (PICC).[5] Overutilization in itself is a form of waste and contributes to an increased risk of infection. Our existing ordering process was nonstandard, confusing, error prone, and wasteful. Orders for PICC line placement could be sent to interventional radiology, anesthesia, or the registered nurse (RN) line placement team. There also were no specific criteria to determine the need for the PICC or the method of placement. These issues were the basis of a RPIW.

A series of three RPIW events for line placement were completed over a 9-month period. Participants in this RPIW included a multidisciplinary group of MDs, RNs, residents, and nurse practitioners. Workshops occurred over 3 to 5 days with participants being relieved from all other duties. The first workshop identified the elements of standard rounding to ensure that central lines are included as part of the daily discussion during morning patient rounds. This work was started on the medicine service (model line) and then replicated to surgical and other services and was dubbed the "6th Vital Sign." The subsequent workshops identified the criteria for

PICC line placement and the design of the vascular access service to centralize the process. To error proof these design elements (and avoid the waste of complexity and rework), the steps were "hard wired" in an RPIW event to use our computerized provider order entry (CPOE) system with order sets and linked electronic forms. The new process required steps to screen for appropriate need of the line placement and to ensure that the vascular access service had the necessary information (avoid rework) to schedule placement. The electronic order form also served a secondary purpose by supplying information at the point of use for the provider. This is both a mistake-proofing adjunct and a JIT teaching moment for our residents. These last steps were not put in place until the prior three workshops had standardized the process steps. This is an important concept—do not leap to automation until the process is worked out.

Each event also had a series of outcome measures that included provider satisfaction and the use of PICC lines.[5] Following the workshops there has been a sustained drop in PICC line use for over 3 years, as well as improved provider satisfaction. Although it cannot be shown to be causally related, this probably has also been a factor in our institution's decrease in central line infections during the same time period. The PICC line work illustrates multiple CPI concepts: reduce unnecessary variation, mistake/error proof, reduce waste (complexity, rework-correction, search time), multiple iterative improvements, and reliable methods (order set and form make it easy to do the right thing).

Surgical Site Infections

Prevention of surgical site infections is a national priority. Prior efforts at Seattle Children's had not led to a reliable method for dosing and re-dosing of antibiotics during surgical procedures. Our infection rates were above 4/100 high-risk procedures (cardiac and spine cases). Using CPI methodology we developed and implemented the following interventions: created cardiovascular and spinal surgery guidelines of care for perioperative antibiotic usage, which included antibiotic choice, dosage, timing, and accountabilities (standard work); added antibiotic orders to the preop order set; ensured correct doses go with the patient and chart to the OR (reliable method); designed standard preop bathing processes that included chlorhexidine bath at home by families and a chlorhexidine wipe down the morning of surgery by families (standard work); updated inpatient order set to include preop bathing (reliable method); and removed all razors from the facility so that preop hair removal, if done, must be done with clippers (error-proof, reliable method).

Following the above set of interventions we have sustained dosing and re-dosing (> 97%) and infection rates below 2 of 100 cases. Although these are neither perfect nor adequate, they do show the concept of at least 50% improvement with a commitment to return, reevaluate, and improve the process.

Emergency Department Throughput

The emergency department (ED) at Seattle Children's has used CPI methods for a number of years to improve the quality of care and specifically to address wait time to see a provider, length of stay, and the number of patients leaving without being seen (LWBS). Early RPIWs mapped the movements of the providers against an architectural room layout of the ED creating a "spaghetti" diagram. The time required to travel in the ED was also quantified. These measurements of movements and times allowed the providers to see the waste of movement. This waste did not mean the providers were not working hard, but were wasting their time and skills on movement.

The RPIW and subsequent workshops led to formation of work units designed to more closely match the ability of the team to match the patient arrival demand and to begin to institute a system that pulls patients into the ED. The ED LWBS rate, which fluctuated as high as 4.5%, has now remained below 1% for 3 years.

A more recent ED RPIW used a multidisciplinary team to look at flow and charting to redesign the ED chart into a multidisciplinary chart that also encourages charting at the patient bedside. Charting at the bedside is an example of one piece flow as opposed to traditional charting, which is often batched away from the patient, sometimes long after the patient is gone. Traditional workflows have been based on the belief that running from patient to patient is more efficient and moves patients faster. Using the CPI methodology and strict measuring of time, distance, rework, handoffs, seek time, and other forms of waste actually shows the work is completed more rapidly and with higher quality using one piece flow (complete each task as you go).

CONTINUOUS PERFORMANCE IMPROVEMENT IN THE ACADEMIC TEACHING SETTING

As described previously, a culture of CPI with participation of the entire hospital community is required for success. In a teaching hospital, clinical care is provided in a supervised educational process with a team of resident physicians and medical students. The daily teaching rounds have been described as a mobile one-room school house. Early in our journey with CPI, we developed a philosophy of including a resident or residency director in most clinical improvement processes. This approach prevented us from creating improvements that would diminish our outstanding education programs. To ensure that sufficient numbers of residency representatives were available for this program, we increased the number of chief residents from two to three and provided CPI leadership training for each of the three chiefs. Having residents participate as members of improvement workshops provided essential knowledge of the daily clinical processes, as well as opportunities for residents to feel ownership of changes in the daily work at the hospital, and pride in achieving improved patient outcomes.

Selected examples of improvement workshops and targets for improvement in which residents provided essential guidance were: reducing errors in total parenteral nutrition orders, creating a model of care in the ED, reducing errors in formula orders, reducing pharmacy order turnaround time, ensuring medication reconciliation, eliminating dangerous abbreviations, improving transfer of patients from the ED to the inpatient service, and designing the medically complex child inpatient service. Many of these improvement processes required changes in how residents did their daily work. The residents who participated in these improvement workshops facilitated acceptance of change within the residency program by communicating the rationale for the changes and providing positive leadership.

Teaching rounds have been a continuing focus of our CPI program. The introduction of the 80-hour work week, a growing patient census, implementation of the electronic medical record, and moving into a new inpatient hospital wing offered many challenges to the teaching and clinical care programs. CPI proved invaluable in meeting these challenges. As a result of our CPI work, teaching rounds moved out of the conference rooms and became truly family centered. Team communication with families by the entire team, including nurses and interpreters, occurred at the bedside. Parent satisfaction has increased dramatically with each new improvement in our teaching rounds. Surprisingly, after 3 years of CPI focus on the inpatient teaching rounds, we discovered from our regular residency satisfaction surveys that what had been the most popular resident hospital experience—the senior inpatient resident team—had become the least popular resident rotation. This discovery provided us a unique opportunity to apply CPI principles to a teaching process.

A Unique Rapid Process Improvement Workshop: Improving the Experience of the Senior Inpatient Resident

First we had to ascertain the causes of resident dissatisfaction with this rotation. We learned that with the time constraints in the existing resident schedule, the senior resident was able to examine only approximately 25% of the patients on the service and had to rely on the intern and attending examinations to make patient decisions. Another concern was that family-centered rounds were becoming so lengthy that there was insufficient time to discuss all the assigned patients before the noon conference and departure of the residents to continuity clinics. This situation seemed to be an outstanding opportunity for CPI. A 5-day RPIW was planned. The Chair of the Department of Pediatrics served as the sponsor and supported the Process Owners, the residency directors, and a chief resident. The CPI office staffed the initial design discussions and began to measure the problem by collecting data to inform the goals of the RPIW.

Pre-RPIW work found that residents actually spent 3 to 4 hours rounding, when the block of time allotted for teaching rounds was 2.5 hours. During the mean 3 to 4 hours of rounding, 17% to 20% of the time was spent waiting for attendings and 12% to 13% of rounding time was spent traveling around the hospital. Each team received an average of 20 phone call interruptions during the teaching rounds and 45% of the senior residents examined fewer than 25% of their patients each day. The senior resident satisfaction score for the inpatient team was 2.85 out of 5.00, with 5.00 being most satisfied.

The RPIW sponsor and leadership group concluded that the desired outcomes for the event were to reduce phone call interruptions during rounds, increase the percentage of patients examined by the chief residents, increase attendance at morning report and noon teaching conferences, and increase resident satisfaction. In addition to the sponsor, process owners, and the CPI staff, the RPIW project team included three residents, a unit clerk, a patient care coordinator, a floor nurse, an attending hospitalist, a pediatric specialty attending, a patient's family representative, and a community physician. The management group that offered feedback during the RPIW included more residents, the floor nursing supervisor, the hospital Chief Operating Officer, the Chief Nursing Officer, and hospital medical leadership.

One of the most unique aspects of this project was that unlike **every** other RPIW, it was not the patient and family who were seen as the customer, but rather the senior resident. This different focus was actually somewhat uncomfortable for the residents, and the conversations during the event continually came back to what was best for the patients. Many of the participants in this project did not have experience with CPI methods. For this reason, the core concepts of standard work, waste reduction, and error proofing were provided during the first day of the event. The second day was spent observing team rounds with stopwatches, pedometers, and evaluation forms. The number of phone interruptions were recorded, as well as the distance in team walking, the average time required to complete family-centered rounds and answer parent questions, and the time and reasons for waiting or revisiting patient rooms. A process map of where the team traveled was created. The findings were eye-opening. The team traveled over a mile during rounds. The path that the teams traveled was redundant and chaotic; the average time to meet with families, discuss patient findings, and create the daily plan was 8 minutes. Telephone calls were a constant source of interruption and distraction and rounds were almost never completed by noon.

On day 3, changes were proposed based on the data and input that the team received. What were the interventions? Nurses and consultants agreed not to phone during rounds unless it was an emergency, and phone calls during rounds were converted to text messages. This had an immediate and profound positive effect on rounds. A new 30-minute team work time was created at the beginning of the morning. Part of this work time was used to determine how many patients needed to be seen and if there was sufficient time for the entire team to see all the patients during rounds, using the average cycle time of 8 minutes. A visual board was set up to alert the team of excessive census and the team would divide in order to see the patients, with one team being led by a senior resident. Noon conferences were changed to start at 12:15 PM rather than noon so that residents could more predictably attend. Morning report was moved to 8:00–8:30 AM. Attendings agreed to be available promptly at assigned times and specialty service attendings were assigned specific times to interface with the team on their patients. These changes were implemented on day 4.

The new system was generally well received and tolerated by residents and faculty. PDCA cycles made selected changes for one team owing to the nature of the specialty patients, and the timing of morning report was moved to 8:30 to allow the 30-minute team work time to occur at 8:00 AM. The introduction of the new system was delayed for a week so that all teams initiated the new system on the day that the new attendings assumed responsibility for the services. The head of the hospital service held a special preparatory session for the new attendings to explain the new design.

One week following the implementation of the new design, phone call interruptions had declined by nearly 50% (**Fig. 2**). The average number of patients examined by the senior residents increased from 43% to 53%. Attendance at morning report increased by 15%, at noon conferences by 30%, and at Grand Rounds by 20%. Senior resident satisfaction increased from 2.87 to 3.46 with these changes. Minor modifications of these changes have been required, but the gains in the metrics have been sustained and increased over a 2-year period. Residents who participate in CPI activities become enthusiastic advocates for change and improvements. This has led to

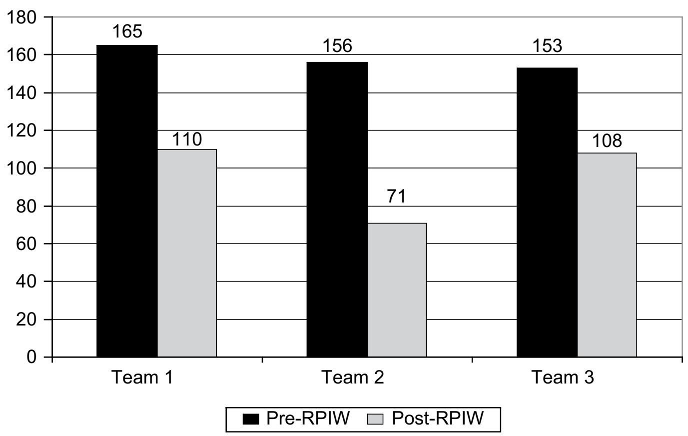

Fig. 2. Phone interruptions during rounds before and following the RPIW.

improved morale during heavy workloads, as the organization has confidence that solutions will be developed to ensure patient flow, safety, and quality care.

RESEARCH APPLICATIONS

The past decade has been marked by rapid advances in technology that have transformed the conduct of biomedical research and accelerated the pace of scientific discovery. These advances have been fueled largely by funding from the National Institutes of Health (NIH). Having doubled between 1998 and 2003, the NIH budget has stagnated in recent years. The current economic crisis exigencies threaten the NIH budget, and with it, the pace of scientific discovery. Rather than implementing cost-reduction strategies aimed solely at "weathering the current storm," it is time for research institutions to adopt a long-term, sustainable approach to cost control. When applied rigorously and throughout the research enterprise, CPI can have a dramatic affect on productivity, cost, and quality.

Because the scientific method is embedded in the tools and techniques of CPI, it is particularly amenable to the research enterprise. Despite this fact, the leadership of Seattle Children's Research Institute (SCRI) recognized that creating a lean culture would require a strong commitment from investigators. To secure that commitment, it was decided to focus initial efforts on maximizing value and eliminating waste from core processes (value streams) in which the investigator was considered the "customer." This initial focus on supporting business lines included Institutional Review Board approvals, animal care services, and other core services.

Institutional Review Board

Institutional review boards (IRBs) are generally regarded by investigators as a "necessary (albeit important) hurdle" to conduct clinical research. IRB requirements are considered overwhelming, and the review process unnecessarily slow. IRBs face unwieldy federal requirements, mountains of paperwork and a burgeoning workload, and suffer from high levels of work-in-progress, a volatile workload, long and variable lead times, and the absence of standard work. These characteristics provide a burning platform for change.

The tools of the CPI Management System make it possible to examine the IRB review process as a set of action steps, each of which must be accomplished in such a way to attain the key value step—application approval. Lean methodologies relentlessly focus on the customer; however, identifying the primary customer may prove difficult. In the IRB CPI implementation, investigators viewed themselves as the IRB's primary customer, whereas the IRB community viewed prospective research participants as their customer. The IRB community viewed the IRB as serving the interests of research participants, not facilitating the work of investigators. They were concerned that defining the investigator as customer could compromise the independence of the IRB. Research leadership emphasized the distinction between the IRB and the staff that support the IRB application process. IRB support staff are charged with moving applications through the review and approval process, working as a conduit between investigators and the IRB. Because support staff are not voting members of the IRB, the staff serves investigators as the primary (external) customer and the IRB as a secondary (internal) customer. Reaching consensus on this issue helped to establish roles for future CPI workshops. The administrative director of Children's Office of Institutional Assurances was appointed workshop leader. Workshop teams consisted of investigators and IRB support staff.

The first RPIW was conducted in early 2006. As the first step in CPI, in fiscal year (FY) 2004, the IRB began collecting turn-around-time (TAT) data for several rate-limiting steps identified in a full-review process analysis (**Fig. 3**A). As shown in **Fig. 3**B, the average TAT for full IRB review was 70 days in FY 2004 and 86 days in

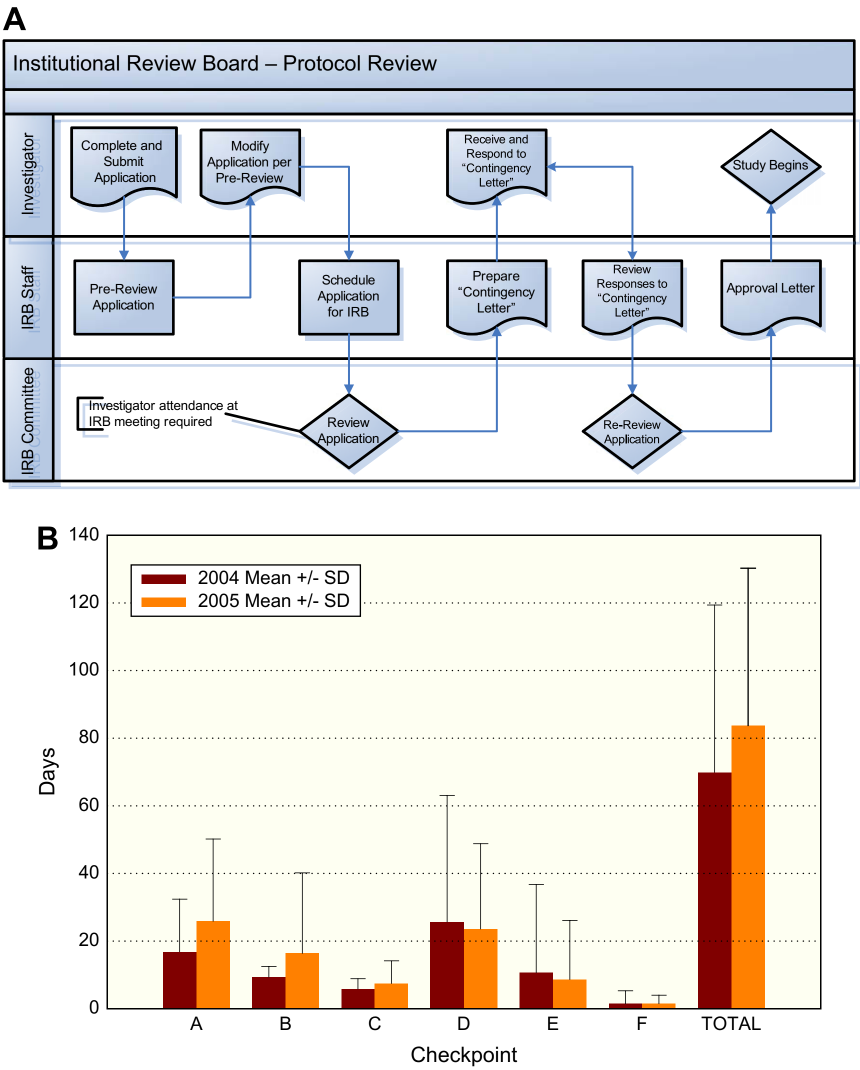

Fig. 3. Assessment of "current state" for full IRB review process. (*A*) Process analysis to identify rate-limiting steps involving investigator, IRB support staff, and the IRB committee. (*B*) Checkpoint summary for full IRB review in FY 2004 and FY 2005. Checkpoint A, date of application receipt to date pre-review completed; checkpoint B, date pre-review completed to date of first IRB meeting; checkpoint C, date of first IRB meeting to date Investigator notification of contingencies; checkpoint D, date investigator notification of contingencies to date response received by IRB; checkpoint E, date response received from Investigator to date contingencies finally removed (may involve subsequent IRB meetings); checkpoint F, date contingencies removed to date IRB chair signs approval letter.

FY 2005. The greatest contributors to the total TAT time were checkpoints A (date of application receipt to date prereview completed) and Checkpoint D (date investigator notification of contingencies to date contingency response received). The workshop was led by a member of Seattle Children's CPI Department and involved a team consisting of two IRB staff members, two investigators, the IRB Chairman, and an IRB manager from a partner institution. The workshop team began by mapping the IRB review process in its current state, including the flow of information and people throughout the process. Each step of the process was evaluated for value from the perspective of the customer, as well as waste. **Table 1** shows process data that came out of the RPIW for the current and future states. A total of 22 steps were eliminated from the process. Significant reductions in the waste associated with handoffs, check-steps, and queues were also achieved. Target TATs for each checkpoint were established, along with a target total TAT of 60 days. In an effort to notify management of potential process problems, a visual management signboard listing days in process for each application was prominently displayed in the IRB office. Any application exceeding the target approval time for each checkpoint in the process activated a formal troubleshooting review. As a result of the RPIW, the total TAT for full-review applications was reduced from 86.0 days to 46.5 days. This reduction has been maintained for more than 2 years.

Animal Care Services

Animal research facilities provide a centralized resource for the efficient delivery of high-quality humane animal care. Under cost principles set forth by the Office of Management and Budget, all costs associated with animal research must be recovered as direct costs on grants and contracts. Animal research facilities develop animal per diem rates based on cost accounting data. Although most research institutions subsidize per diem rates to some extent, biomedical research inflation requires frequent revisions to the animal per diem rate. In multiyear research projects, these revisions can prove problematic if the institution is unable to increase its subsidy. In the current economic climate, cost containment has become a priority. The tools of CPI provide a strategy for reducing costs without compromising quality, and can be applied effectively to animal research operations.

We conducted several CPI events aimed at improving efficiency and reducing waste in its operations. These events have focused primarily on equipment processing and material handling.

Good animal husbandry practices require the frequent washing and sanitation of cages. SCRI processes an average of 230 cages per day in its murine-specific pathogen-free animal facility. This represents a significant volume of work, and has proven

Table 1
Institutional Review Board process data collected during the rapid process improvement workshop for current and future state of full review by the Institutional Review Board

Measure	Current State	Future State
No. steps	57	35
No. value-added steps	5	5
% Value-added steps	9%	14%
No. handoffs	54	19
No. check-steps	28	8
No. queues	25	8

a useful target for CPI efforts. As published elsewhere,[6] an RPIW focused on cage washing activities resulted in a 34% reduction in processing time and increased staff safety by reducing repetitive bending and twisting motions. Significant reductions in processing times contributed to reduced costs, improved production predictability, and increased customer service.

In traditional "batch" animal operations management, a cage buffer inventory is maintained to offset variation in cage processing caused by demand forecast inaccuracies and machine downtime. In CPI JIT animal operations management, however, customer demand dictates production, reducing the need for inventory. The SCRI animal facility implemented a simple visual management system as a customer demand signal. The signal for cleaning consisted of a cart onto which dirty cages were placed by the staff. The wall behind the cart was taped off at a level consisting of 72 cages, the maximum capacity of the cage washer. As soon as the cart was filled, cage-washing production was initiated. By implementing this system, the animal facility was able to decrease its buffer inventory by 51%.[7] A small buffer inventory was maintained in the event of equipment failure.

In an RPIW focused on further reductions in the frequency of cage changes, the workshop team suggested using rodent feces as a "biologic signal." The team noted that all cages were changed at 7 days regardless of the number of occupants. The team initiated an Institutional Animal Care and Use Committee (IACUC)-approved trial designed to measure bedding conditions in cages containing from one to five mice

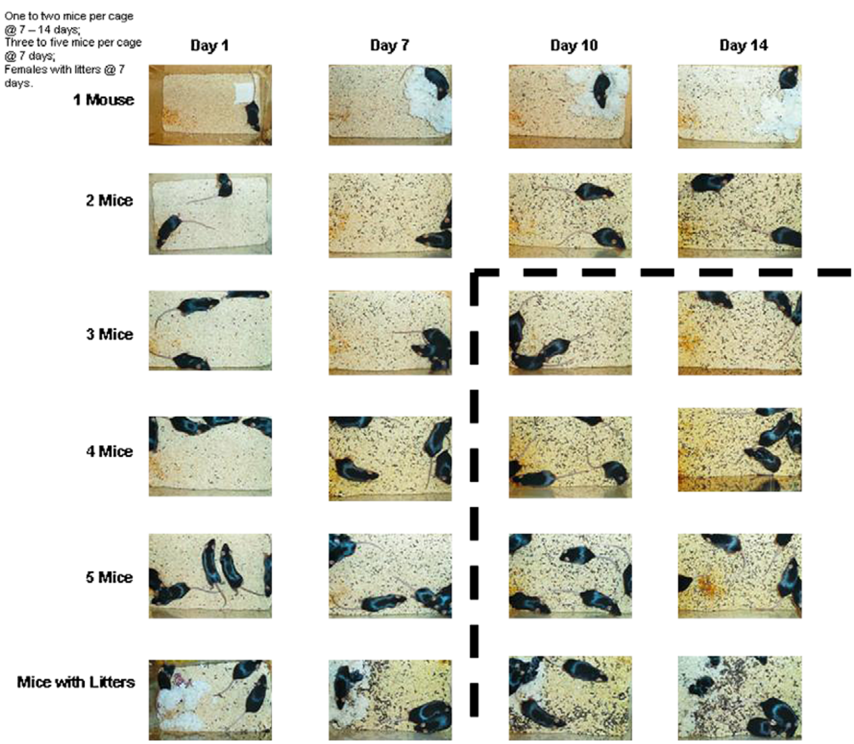

Fig. 4. Effect of murine cage occupancy and on change frequency: a biologic kanban system. A photographic record of bedding conditions over a 15-day period based on the number of cage occupants.

maintained for a period of 14 days without a cage change. A photographic record of bedding conditions at days 1, 7, 10, and 14 are shown in **Fig. 4**. Based on this study, the team concluded that cages containing a single mouse could be changed at 14 days; cages containing two to three mice could be changed at 10 days, and cages containing four to five mice or litters must be changed at 7 days. By matching the frequency of cage changes with the number of cage occupants, our animal facility was able to further enhance operating efficiencies aimed at reducing costs.

SUMMARY

Continuous performance improvement based on the principles of the Toyota Production System can be successfully adapted to improve the quality of medical care and academic processes. Seattle Children's has been evolving along this journey for a number of years. We believe the improved quality, safety, efficiencies, and cost savings examples shown in this article are the tip of the iceberg for clinical, administrative, and academic programs. Since 2005, there have been well over 200 CPI events using these tools at our institution that have improved nearly every aspect of our academic health environment. Patience, persistent education, and commitment from the administrative, academic, and clinic leadership is critical to fully engage faculty and to reach the tipping point of a cultural change in which mistakes, waste, and planning silos are eliminated.

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