Case Study

Texas health system taps into Six Sigma for ways to implement and improve N95 reprocessing project

Recycling Safety

Topic
Six Sigma tools

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The COVID-19 pandemic created a global health emergency in 2020. An influx of infectious patients followed, leading to increased demand for personal protective equipment, including disposable N95 respirators. The World Health Organization warned of shortages due to severe disruption in the global PPE supply.[1]

Imminent N95 shortages prompted the U.S. Centers for Disease Control (CDC) to allow for the decontamination and reuse of these respirator masks as a crisis capacity strategy.[2] A 2016 U.S. Food and Drug Administration report reviewed the use of vaporized hydrogen peroxide (VHP) to decontaminate N95s to mitigate constrained supply chains in a pandemic.[3] As transmission became widespread, a large academic medical center in Texas identified the need to extend N95 inventory within CDC guidelines.

A multidisciplinary team formed to implement N95 decontamination based on Duke University's use of VHP,[4] in conjunction with the hospital's existing experience with VHP. The pandemic, as well as increasing patient census across the health system, imposed time constraints on the team.

The project team had five calendar days to test and implement the reprocessing center before it began decontaminating N95s for hospitals across the health system. The team had three additional days before the reprocessing demand increased to more than 2,000 N95s per day. This article outlines the Six Sigma tools and methodology used to minimize the cycle time of the N95 reprocessing center and support the health system's N95 demand.

Reducing the cycle time: define and measure

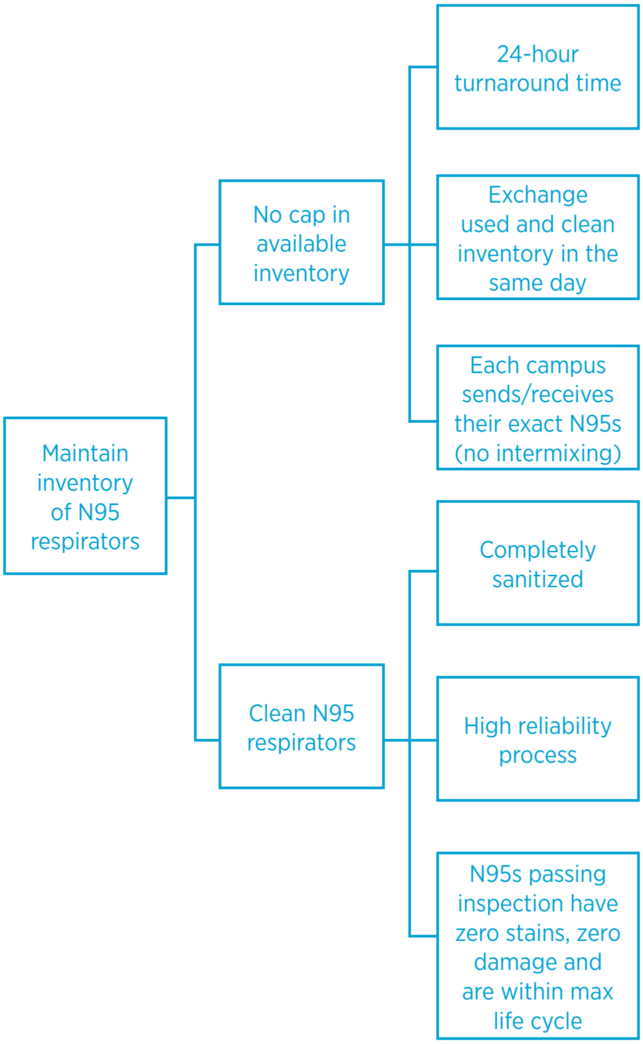
The project team defined elements critical to quality (CTQ) for the N95 reprocessing center. The CTQs defined six key process characteristics—shown in Figure 1—that guided the team's decisions to develop goals, revise processes and ensure outcomes were successful in meeting the health system's needs.

To prevent gaps in available inventory, the team used the projected patient census and frequency of staff interventions to anticipate the daily demand for N95s. Using this calculation and current inventory volumes, the team forecasted reprocessing demand of about 2,000 N95s per day. The CTQs and anticipated demand defined the reprocessing center's high-level goal to sanitize and inspect a minimum of 2,000 N95s per day within a safe, high-reliability process.

The reprocessing center process was divided into "clean" and "dirty" sections (separated by a dashed line) and mapped using a suppliers, inputs, process, outputs and customers (SIPOC) diagram, shown in Figure 2 (p. 12). The SIPOC diagram provided a high-level overview of the process, identifying the relevant elements within the process that required cycle-time measurements. The project team created a more detailed process map that highlighted the complexity of the "dirty" section process. This complexity, combined with the CTQ's focus on sanitizing the N95s, led the team to evaluate this section of the process' cycle time.

The team created a measurement system and a standardized N95 log to capture the cycle times per daily volume. The mean cycle time of four samples was 12.95 seconds/N95 with a standard deviation of 1.396. The maximum capacity per cycle was 768 N95s, taking an estimated 2.76 hours to load. Using one staff shift per day, this cycle time limited the department to run two cycles per day at a maximum capacity of 1,536 N95s.

Figure 1 **CRITICAL TO QUALITY**



The baseline time and capacity reflected an inability to support the anticipated demand of more than 2,000 N95s while controlling staff costs and meeting the 24-hour turnaround time identified in the CTQs. A goal was set to reduce the cycle time to 10 seconds per N95 and increase volume capacity to 3,000 N95s in two cycles per day.

Reducing the cycle time: analyze and improve

To combat the challenging time constraints, the project team completed the analyze and improve phases in *gemba*. The team observed the initial process of hanging used N95s on baker's racks with paper clips, which required N95s to be hung individually—as shown in Photo 1 (p. 12). This method contributed to prolonged cycle times and capacity limitations.

The team's observations and work in *gemba* promoted the use of "trystorming" possible solutions. Trystorming uses rapid cycles to actively develop, test and adjust ideas.[5] Successful solutions quickly became apparent through this method because the team tested each solution in real time. Trystorming led to implementing a pole system built of

Figure 2 **SIPOC DIAGRAM MAPPING THE PROCESS**

SUPPLIERS	INPUTS	PROCESS STEP	OUTPUTS	CUSTOMERS
External hospitals/ clinics	Used N95s	1. Don PPE	Sanitized N95s	Couriers
Couriers	Reprocessing staff	2. Move N95s to "dirty zone"	Inspected N95s	Frontline staff
	Bakers racks	3. Hang N95s on racks, separated by location	Paper records	Leadership
	BioQuell machine	4. Start BioQuell cycle		
	Hydrogen peroxide	5. Complete environmental cleaning		
	Sanitized N95s	6. Move sanitized N95s to "clean zone"		
	Documentation logs	7. Mark/inspect N95s one campus at a time		
	Standardized operating procedure	8. Complete documentation		
		9. Package inspected N95s with paperwork		

SIPOC = suppliers, inputs, process, outputs, customers
PPE = personal protective equipment

Photo 1 **PAPERCLIP METHOD**

Photo 2 **POLE METHOD**

PVC pipe, as shown in Photo 2. This increased the speed and ease of hanging multiple N95s at a time.

Using the pole method, four PVC pipes were placed on each shelf of the baker's rack with multiple N95s hung on each pipe—increasing the maximum capacity from 768 N95s to 1,440 N95s per cycle. This method reduced the mean cycle time of five samples by 1.47 seconds/N95 (from 12.95 seconds to 11.48 seconds) with a standard deviation of 4.655.

Although an improvement, the reduced cycle time did not meet the goal of 10 seconds per N95. After reviewing the control chart in Figure 3—which compares the trystormed cycle time improvement data to the baseline—the team identified two samples with lower times per N95 than the other three samples. This finding revealed potential variation in the process, requiring further analysis.

During this time, leaders completed observations of the revised process using the pole method and noted two different reprocessing teams completed the process differently: Team A worked together on the three days with higher cycle times (observations one, four and five) and Team B worked together on the two days with lower cycle times (observations two and three).

The cycle time data was separated into groups: baseline, improvement samples for Team A and improvement samples for Team B. The interval plot (Figure 4) was created to evaluate the difference in cycle times between the three groups:

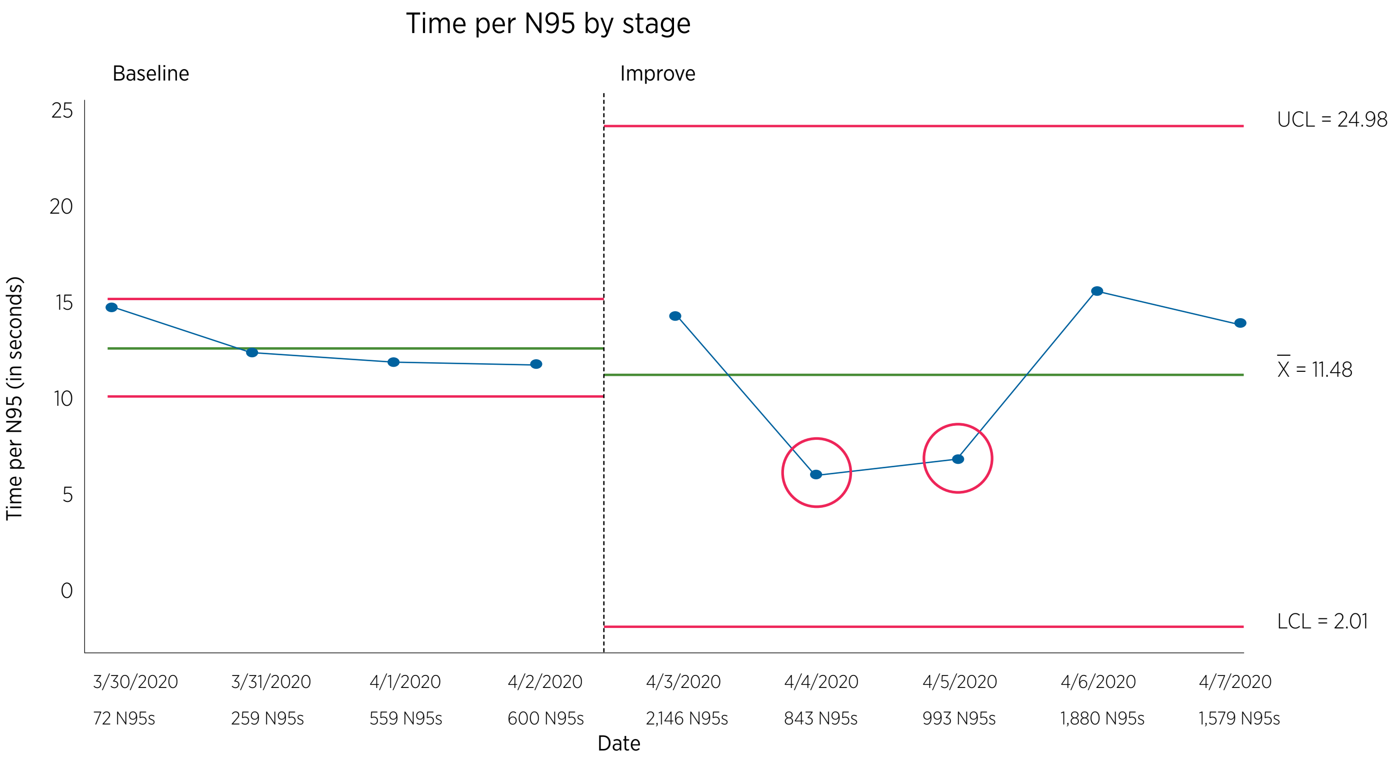
- Observations from Team B had the lowest mean cycle time.
- The confidence interval for Team B did not overlap the other confidence intervals, indicating the difference in mean cycle times may be significant.
- The confidence intervals of Team A and the baseline overlapped, indicating the difference between these cycle times is likely not significant.

The team used a one-way analysis of variance to confirm the interval plot's depiction, showing the effect of team grouping on time per N95 was significant: F (2, 6) = 33.2, p = 0.001. The significant difference between observation groups led the project team to analyze this variation further.

The leaders observed the teams that completed spaghetti diagrams of their observations to identify how the process characteristics differed between the two teams. Figure 5 (p. 14) illustrates how staff in Team A completed the process steps from beginning to end individually, while staff in Team B delineated specific roles for each person and completed the process as a team. The spaghetti diagrams visually highlighted the differences between the teams' workflows.

The project team and staff compiled a cause and effect diagram to identify potential contributing factors in not achieving the 10 seconds per

Figure 3 **CONTROL CHART**



LCL = lower control limit $\bar{X}$ = mean UCL = upper control limit

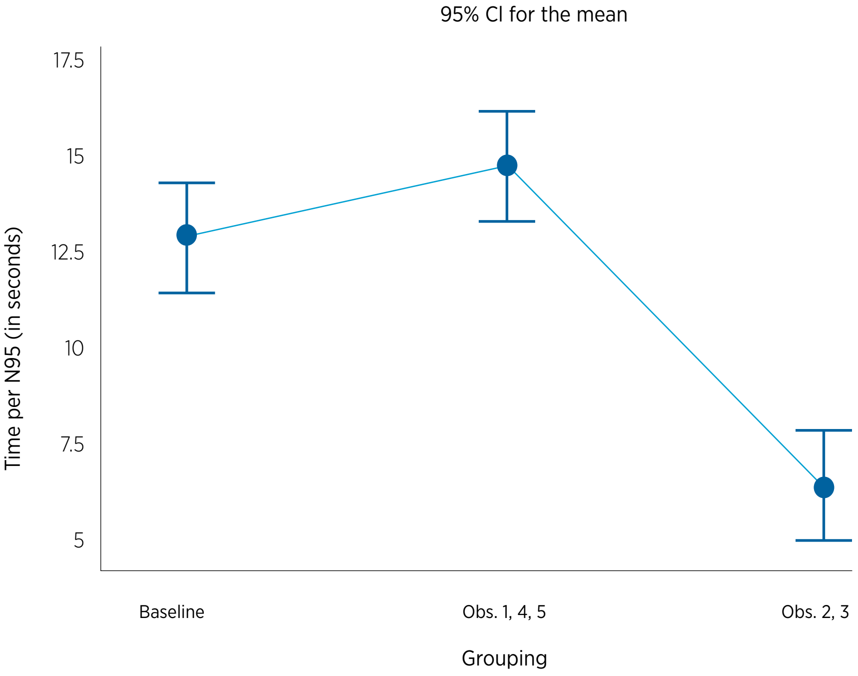
N95 goal. Three categories of contributing factors were identified as personnel, process and equipment.

In reviewing the completed diagram, Team A identified contributing factors in all three categories, whereas Team B only identified causes under the equipment category. Using the spaghetti and cause and effect diagrams together enabled the team to understand how variation in workflow resulted in different factors contributing to not achieving the goal. The teams discussed these findings and agreed the future state should align with Team B's process.

To narrow the causes further, the team discussed what actions helped achieve or hindered the future state. Due to the time constraints, the team stayed in *gemba* to brainstorm solutions to target each helping and hindering opportunity.

Through brainstorming, staff proposed hanging similar N95 styles next to each other for space efficiency, placing N95s with plastic straps on racks instead of poles, and implementing standardized work with staff training. The staff also recommended designating four roles:

Figure 4 **INTERVAL PLOT OF TIME PER N95 BY GROUPING**



The pooled standard deviation is used to calculate the intervals.

CI = confidence interval Obs. = observation

The trystorming revealed all of the brainstormed solutions were successful in increasing the team's speed and efficiency when applied together.

1. One person moving bins to the hot zone.
2. One person opening and separating N95s.
3. One person preparing N95s to be hung.
4. One person hanging N95s.

The staff trystormed possible solutions during N95 loading, and team leaders documented feedback provided during the exercises. The trystorming revealed all of the brainstormed solutions were successful in increasing the team's speed and efficiency when applied together.

The implemented solutions in the second process revision reduced the mean cycle time to 6.19 seconds/N95 with a standard deviation of 0.911 as shown in the control chart in Figure 6. A two-sample t-test showed a significant difference in the time per N95 for the baseline ($\mu = 12.95$, standard deviation = 1.4) and the improved ($\mu = 6.19$, standard deviation = 0.32) processes; $t(6.763) = 8.8$, $p = 0.001$. In addition, the maximum capacity increased to 2,520 N95s/cycle, exceeding the goals and promoted adherence to the CTQs within one shift per day.

Reducing the cycle time—control

To sustain these improvements, the team updated the standard operating procedure and created competency checklists to validate training for new and existing staff. As part of the control plan, the team implemented daily timing goals and an escalation pathway. Staff discussed the anticipated volume and schedule at the beginning of each shift to adjust the timing goals as needed.

These goals were updated on a dry-erase board to create a reference and visual reminder for the staff. If any concerns arose for achieving the goals, staff used the escalation pathway to trigger a huddle between staff and the leadership team. During the huddle, the team evaluated the remaining volume, staff availability and other factors to determine an action plan to accomplish the goals and adhere to the CTQs.

Leaders audited the process through direct observations, timing of critical time points, and daily review of volume and timing. Leaders used direct observations and the timing of critical time points to ensure compliance with the process and timing outcomes were sustained.

Staff submitted daily volumes to leadership at the end of each shift. This time-stamped documentation provided data of the processes' overall cycle time and other information for tracking and

Figure 5 **SPAGHETTI DIAGRAM BY TEAMS**

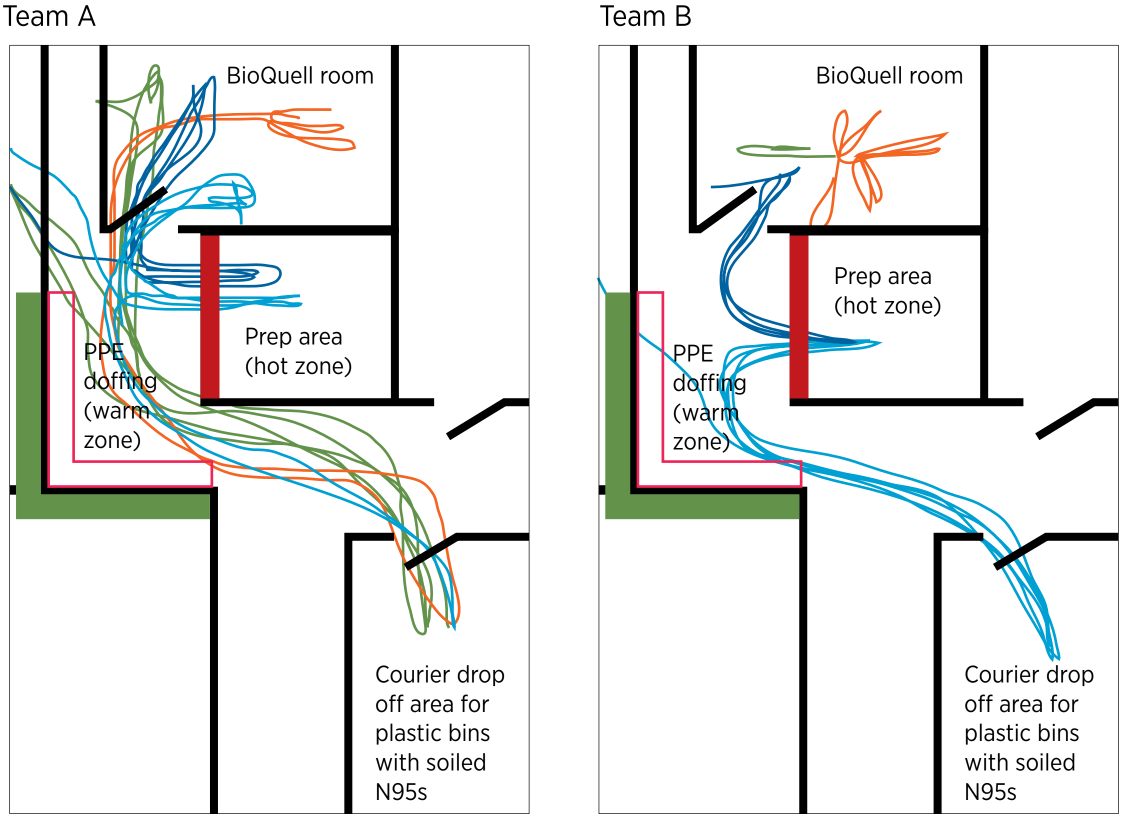
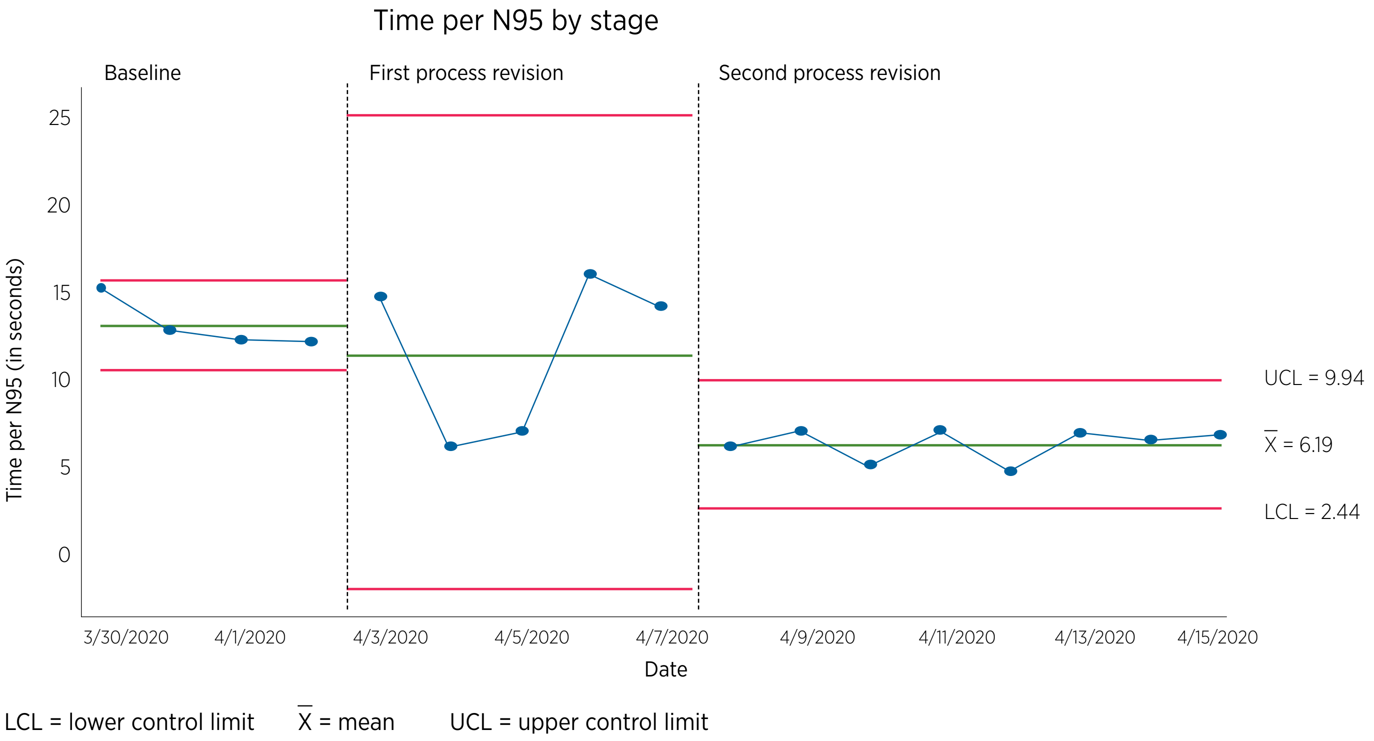


Figure 6 **CONTROL CHART SHOWING IMPROVED CYCLE TIME BY STAGES**



trending purposes. Staff and leaders used daily huddles to review the previous day's data, compliance in meeting the established goals and any needed adjustments based on these findings.

Messy at times, but rewarding

The N95 reprocessing center implementation and cycle time reductions occurred in a two-week period with daily N95 reprocessing starting on the fourth day.

The N95 reprocessing center successfully met the health system's CTQs and N95 demand by reprocessing 200,000 N95s in a six-month period. Defining the CTQs at the beginning guided decisions in the measure, analyze and improve phases.

Proactively developing a measurement system and collecting baseline data enabled the team to recognize the 24-hour turnaround time CTQ would not be met and begin cycle time reduction efforts.

Time constraints provided an opportunity to achieve rapid improvements by applying define, measure, analyze, improve and control, and Six Sigma tools in real time as processes occurred. The team's use of basic but effective Six Sigma tools such as CTQs, SIPOC, process maps, spaghetti diagrams and cause and effect diagrams enabled the achievements to be accomplished in *gemba*.

Using these tools away from conference rooms increased the team's engagement and idea generation. Rapidly testing and adjusting these ideas through trystorming further reduced the time it took to narrow, select and implement possible solutions. Embracing constraints and bringing tools to *gemba* may be messy at times, but it is richly rewarding in rapid process improvement. &

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