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An Experiment with Lean Methods in Clinical Research

By Andrew Snyder and Virginia Cosgriff

Toyota originally developed the Toyota Production System (TPS) to maximize value for customers (internal and external) while improving quality and eliminating waste in its automobile manufacturing business. TPS-based methods, because of their focus on eliminating waste and superfluous activities, are now known as "lean," and have been applied in many industries across the world.

Starting in 2006, the HealthEast Care System began using lean tools in small projects. In 2013, HealthEast launched a system-wide lean program called "Value Based Improvement" (VBI) and the "Frontline Management System" (FMS) to over 300 teams.

FMS empowers all employees to make continuous small-scale improvements to simplify their work and increase the value they provide to their customers every day with a five-step methodology:

1. **Process.** Understand the work we do and what success looks like.
2. **Measure.** Measure our performance toward targets and identify opportunities for improvement.
3. **Analyze.** Track and analyze the causes that prevent us from meeting our targets.
4. **Huddle.** Come together as a team to brainstorm ideas, share progress and celebrate wins.
5. **Improvement Board.** Manage, track and communicate the progress of improvement ideas.

To date, FMS has generated over 125,000 process improvement ideas at HealthEast.

Clinical Research Example

HealthEast's Clinical Trials Office (CTO) provides turnkey research support to any investigator in the HealthEast network. The CTO can provide research nurses, regulatory experts, compliance expertise, budget and contract negotiation, business development, and patient recruitment activities.

In 2015, enrollment results were not meeting stated goals. In lean terms, if actual results do not meet desired results, a problem exists. The CTO therefore launched a lean project to improve the process for recruiting clinical study participants.

We started by characterizing the existing process by asking questions like:

- What recruitment methods are available?
- When are the various methods being used?
- How do patients respond to the methods?

We quickly discovered that data was not available to answer these questions in a definitive manner, so we created a database to help everyone involved document 100% of their patient contacts (e.g., a phone call following a letter).

After several months of data collection, we observed that, in one department, the primary recruiting method was to obtain a report from the EMR system, send out an IRB-approved letter to a batch of 500-600 patients that met a study's primary eligibility criteria, and then field incoming telephone calls. Study coordinators struggled with the high volume of phone

calls from patients, losing potential study participants due to slow follow-up. They would enroll several patients over the subsequent few weeks, and then enrollment would cease until the next letter months later.

Lean methods assume that a period of experimentation might be required to find the best way — or ways — to improve a process. For example, instead of sending out 500 letters in a single batch, we rolled them out at the rate of 30 per week. The first few weeks went well, with a small increase in enrollment, but we then discovered that the list degraded over time, as patients moved, changed doctors, experienced other healthcare issues, etc.

After several more experiments, we realized that the source of our problem was a "batch" mentality. The solution lay in classic lean methodology, which has also been called "just in time." In other words, we needed to generate and mail the letters in a more continuous process, tied to the patient's next visit, so the information would be current. In addition, the follow-up step would be a brief face-to-face interaction with a trusted physician, rather than a telephone call with an unknown study coordinator. We initiated an experiment with a process that met the following criteria:

- Maximize the number of eligible patients contacted.
- Level recruitment work by eliminated inefficient batches.
- Communicate with patients when they are most receptive.
- Employ brief physician-patient interactions.

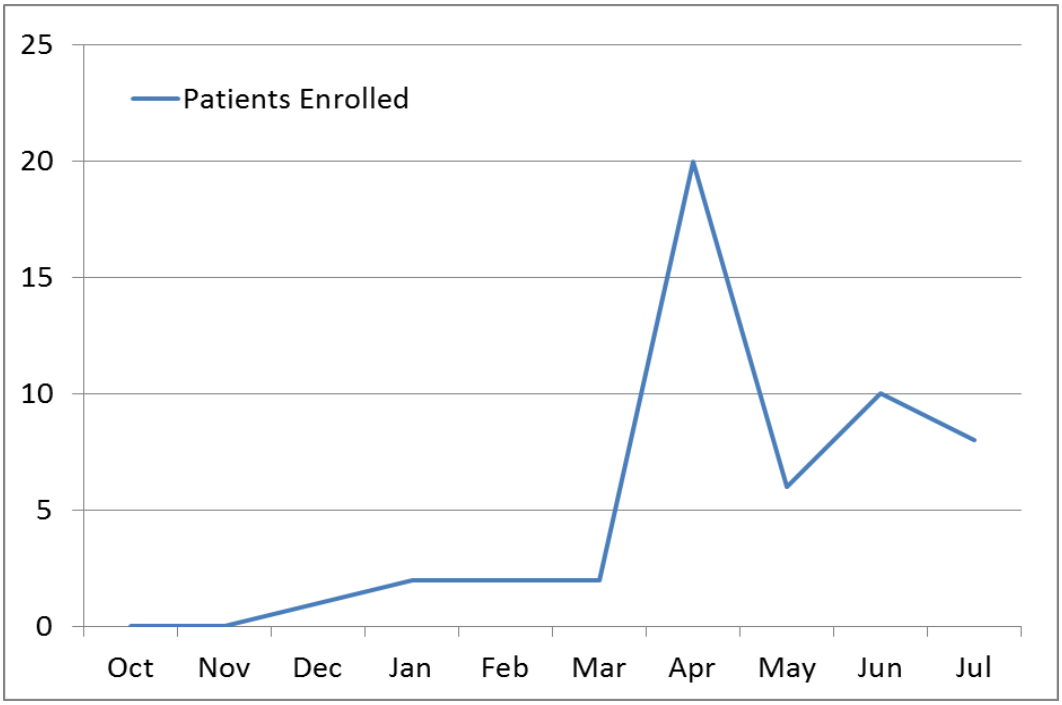
To meet the first criterion, we expanded the search from the 23 physicians in the cardiology department in the single clinic conducting the study to 150 physicians in cardiology, internal medicine, family practice, etc., across all four HealthEast hospitals and 14 clinics.

To meet the second and third criteria, we searched the EHR for qualified patients scheduled to see their physician within the following two weeks. We then mailed 60-80 letters to patients the week before their appointments. We used the customized patient database to track all letters, eliminating duplicate letters and letters sent to patients who had previously asked not to be contacted concerning research studies.

To meet the third and fourth criteria, we trained all 150 physicians to engage in two-minute conversations with appropriate patients, based on study summary sheets provided to the physicians one day prior to the appointments via a message in the EHR. With management support, the physicians understood that these conversations were not optional and had to fit into their current scheduling parameters. The main points of the conversations were to engage both the physicians and patients, and to ask the patients to talk to a member of the research staff about the study.

Based on the success of this experiment, the process has been rolled out system-wide. Chart 1 shows how the enrollment numbers changed for an outpatient medication study from an average of less than two patients per month during the pre-experiment period to over eight patients per month after implementation of the enhanced recruitment process.

Chart 1. Patient Recruitment Performance over Time (2015-2016)



Conclusion

Lean methods, now ingrained in the HealthEast culture, are yielding steady improvements for the CTO and across the entire organization.

Authors

Andrew Snyder, MBA, PMP, FACMPE, CRCP, is the Director of the system-wide Clinical Trials Office at HealthEast Care System. Contact him at atsnyder@healtheast.org.

Virginia Cosgriff, MS, is a Senior Improvement Advisor in the Value Based Improvement division at HealthEast Care System. Contact her at vecosgriff@healtheast.org.

