The Journey of Applying Quality Improvement to Clinical Trials

GUEST EDITOR'S MESSAGE
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Quality improvement is a formal approach for the analysis of performance and systematic efforts to improve it. In the world of manufacturing, it has been applied widely and has reached a state of maturity. In the service industry, quality improvement is in an earlier stage of being adapted from manufacturing principles.

The first question is, "What are we trying to achieve?" Once that answer is established, quality improvement's second question is, "Are we achieving what we want to achieve by doing what we are doing?"

Quality improvement is distinct from quality control and quality assurance, as explained here:

- ***Quality control*** involves the systematic inspection of every product. Quality control asks the question, "Are we doing what we are supposed to do?" When you see an "Inspected by No. 15" notice in your clothing, it is quality control. When we draft a consent document or protocol, and are required to submit that document for review by others for accuracy and completeness, we are performing quality control.
- ***Quality assurance*** is an application of statistical methods to reduce the effort of quality control in which a sample of a product is tested. Auditing a subset of a site's records for completeness and regulatory compliance is a common form of quality assurance.
- ***Quality improvement*** takes a different approach. The first question is, "What are we trying to achieve?" Once that answer is established, quality improvement's second question is, "Are we achieving what we want to achieve by doing what we are doing?"

Quality control and quality assurance are retrospective and reactive to detecting and correcting errors. These efforts tend to have a policing mentality that attempts to focus upon the behavior of people.

Quality improvement is prospective and forward thinking. It first considers the designed outcome and what can be done to prevent errors. A mantra of quality improvement is, "It's faster to take the time to do things right the first time than to have to do everything twice." Quality improvement tends to be a blame-free undertaking, because the focus is on the design of the system rather than the behavior of individuals.

Many Approaches to a Common Goal

An article solicited for this issue that had to be held for appearance later due to time and space considerations discusses applying quality improvement principles to the clinical trial process.[1] Instead of using a rigid quality assurance process, what can we achieve by first deciding on what we need to achieve (quality data and compliance), and then asking, "What are the best processes to achieve quality data and compliance?"

Quality improvement has many schools of thought—among them, Total Quality Management, Lean Six Sigma, Continuous Quality Improvement, the Plan-Do-Check-Act Cycle, and the Balanced Scorecard. The terminology is often confusing to initiates, but the truth is that they are all about the same aforementioned principle: "Are we achieving what we want to achieve by doing what we are doing?" In a more fundamental sense, they all apply the scientific method to the delivery of a service.

Just like scientific schools, the schools of quality improvement emphasize different tools, but also borrow from each other. Managers know that that there are many management tools, including project management, planning, active listening, and change control. Most managers start by learning a few, applying them, and then learning more, until by the time they are seasoned managers, they might have difficulty listing all their tools. Quality improvement tools and the schools of quality improvement are the same way.

And So it Begins…

To start the journey of quality improvement, it is best to learn a few tools and then move on from there. Two tools that are familiar to those experienced in clinical trials are "standard work" and "root cause analysis."

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Standard work refers to objective descriptions of the actions that are required from an individual to ensure consistency and quality. Quality specialists often refer to a process being "in control"—meaning that everyone is consistently performing the same task in the same way. In the world of clinical trials, standard work is often referred to as "standard operating procedures."

The principle of root cause analysis is to look at errors from a systems approach, while the methods of root cause analysis peel away the layers of a process to find the fundamental flaw that needs to be corrected. In this issue, Borasky's and Kim's article discusses applying ISO 9001 to the institutional review board process, which is largely the development of a standard work and corrective action processes to the delivery of a service.

Meanwhile, "value stream mapping" derives from the Toyota Production Method. Value stream mapping starts by developing a visual description of a workflow, and then determining what steps provide value or waste resources. In the context of clinical trials, value includes many facets, such as regulatory compliance, accuracy of data, speed, and minimization of costs. In the conduct of clinical trials, waste often includes waiting (being ready to process subjects, but waiting for advertisements to be run), over-processing (monitoring data not critical to the study endpoint), over-production (studying more subjects than necessary), and correction (repeating tests not correctly performed the first time).

From a value stream map, one can redesign an ideal process and take steps to move from the current state to the ideal state. Two articles in this issue specifically look at waste in the clinical trial process. Opler's article looks at how the process of administering a clinical outcomes assessment can bias or add random variation to the endpoint being assessed. This leads to the waste of over-production, because more subjects need to be studied due to random noise in the data. By introducing standard work, the variation can be reduced and over-production controlled. Leinfuss's and Bullock's article analyzes the importance of eliminating errors early in the process of drug development by better applying clinical pharmacology to the choice of the best drug candidate.

A tool closely related to value stream mapping is "kaizen," which is the Japanese word for quality improvement. Kaizen refers to a series of tools for implementing value stream mapping and analysis. The article here by Kim, Patel, and Choi embodies the principles of kaizen by taking a decentralized value stream and using the principles of the scientific method to discern an ideal state that maximizes compliance. Similarly, Dass's article discusses how to redesign information systems to extract maximum operational value.

For Your Reading Pleasure

Those who are interested in advancing their quality improvement skills might consider reading some of the major works in the field. Senge's *Fifth Discipline*[2] is an introduction to the concepts of systems thinking and the learning organization, both of which need to be part of a corporate culture for effective quality improvement. Liker's *The Toyota Way*[3] describes the quality improvement principles of the Toyota corporation, whose management processes are highly emulated. Robinson and Schroeder's *The Idea-Driven Organization*[4] discusses why quality improvement must be driven from both top-down and bottom-up perspectives. This book also addresses a common problem in clinical trials, which is that we don't have control over many things we would like to change, and we often don't have the resources to change everything we would like to change. On the other hand, hundreds of small changes can lead to major improvements.

Goldratt's *The Goal*[5] is a novel illustrating the theory of constraints, which is a frequent problem in clinical trials. We are waiting for the contract to be signed, we are waiting for drug to be shipped, we are waiting to identify participating investigators, and we are waiting for the investigator meeting. Sometimes the constraints are subtler. Goldratt explains how to identify and correct the most important constraints.

Finally, since almost everyone involved in clinical research understands the importance of statistics to the scientific method, a reference on statistical process control,[6] from which we get the "t-test" of time-series data from processes, is a useful addition to one's library.

I hope that the articles presented and the references provided here are inspiring and useful to help all of us improve the important endeavor of clinical trials.

References

1. Jose N, Padbidri R, Cody S. Blind spot in clinical trial operations: who is watching? Accepted for publication in a forthcoming issue of *Clinical Researcher.*
2. Senge PM. 1990. *The fifth discipline: The art and practice of the learning organization.* New York: Doubleday/Currency.
3. Liker JK. 2004. *The Toyota way: 14 management principles from the world's greatest manufacturer.* New York: McGraw-Hill.
4. Robinson E, Schroeder DM. 2014. *The idea-driven organization: unlocking the power in bottom-up ideas.* San Francisco: Berrett-Koehler Publishers, Inc.
5. Goldratt EM, Cox J. 2004. *The goal: A process of ongoing improvement.* Great Barrington, Mass.: North River Press.
6. Wheeler DJ, Chambers DS. 1992. *Understanding statistical process control.* Knoxville, Tenn.: SPC Press.

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