Introduction and Evolution of the Continuous Quality Improvement Concept

The past few decades have seen a change in perception in the health care system and among the public of patient safety, quality, and cost of health care. Regardless of whether their position is laboratory director, manager, or a trainee, patient safety and quality improvement (QI) are terms that the reader will need to be familiar with and use in daily practice. This chapter is an introduction to the world of quality and patient safety; hopefully, with this introduction, the reader can more confidently embark on the process of QI. This chapter focuses on approaches to QI and how to apply the principles of QI in the laboratory. A basic tenet is that “every system is perfectly designed to achieve the results it achieves.”1 Poorly designed systems generate inefficiency and waste, poor health care quality, and negative health outcomes. The emphasis of QI should be on systems and processes of care instead of the individual laboratorian. To achieve better laboratory quality we must change the system.

Historic Perspective

QI methods were first applied to health care in the United States in the early 20th century in the form of professional licensing and standards-based external evaluations of hospitals and medical schools.2,3 Avedis Donabedian, a mid-20th century academic physician with a special interest in public health and healthcare quality, is considered by many to be one of the founders of the contemporary health care quality movement.4 Donabedian describes 7 pillars of quality in medicine: Efficacy, Efficiency, Optimality, Acceptability, Legitimacy, Equity, and Cost. To measure these goals, he described three types of metrics for evaluating quality in health care, the domains of quality of care: structure, process, and outcome. Structure includes the environment in which care is provided; the facilities, equipment, services, and manpower available for care; the qualifications, skills, and experience of the healthcare professionals; and other characteristics of the hospital or system providing care. The process consists of the activities and steps involved and the sequence of these steps when patients receive health care. For the laboratory, process refers to how the specimen is moved into, through, and
out of the system, which equates to the preanalytical, analytic and postanalytic steps in the process of a laboratory test. Process measures of quality can be developed and monitored around any of these steps.

After this groundbreaking work, a body advising the government on issues regarding social, economic, and political aspects of health care and medicine evolved, and the Institute of Medicine (IOM) was founded in 1970. To Err is Human brought the patient safety perspective in health care to the forefront. Six domains of healthcare quality were described by the IOM in 2001 in the report “Crossing the Quality Chasm.” These domains include safety, timeliness, effectiveness, efficiency, equity, and patient-centeredness. For example, laboratories generally aim to be efficient without waste and timely with reports. The exact indicators to measure in a QI plan can be determined using the frameworks of the Donabedian triad and the IOM’s quality domains. Local priorities, local patterns of practice, ease of access to data, and resources required to collect, analyze, and display data, etc., will also play a role in determining the measures that are established.

Shewhart, Deming, and Juran are often considered to be the three founders of the QI movement. Two of Shewhart’s contributions continue to influence the daily work of quality: control charts and the Plan–Do–Study–Act (PDSA) cycle. The Shewhart cycle or Shewhart learning and improvement cycle combines management thinking with statistical analysis. The constant evaluation of management policy and procedures leads to continuous improvement. This cycle has also been called the Deming cycle, the Plan-Do-Check-Act (PDCA) cycle, or the Plan–Do–Study–Act (PDSA) cycle. While Deming marketed the cycle to the masses—a cycle, which he called the Shewhart cycle—most people refer to it as the Deming cycle.

The basic tenet of Shewhart’s work was to reduce variation and bring processes into statistical process control (SPC), defined as the use of statistical methods to measure and analyze the quality of a production process. Shewhart identified two categories of variation which he called “assignable cause” and “chance-cause” variation. Others call the two categories “special cause” and “common-cause” variation, respectively. He devised the control chart as a tool for distinguishing between the two. The various control charts that Shewhart proposed for variables and attributes include mean, range, np, p, c, and u charts. Shewhart reported that bringing a process into a state of statistical control—where there is only chance-cause (common-cause) variation—and keeping it in control is needed to reduce waste and improve quality. Variation in these processes follows predictable statistical laws. In contrast, processes not in statistical control suffer from assignable-cause variation. In Shewhart’s own words, “While every process displays variation, some processes display controlled variation, while others display uncontrolled variation.” Special cause is a factor that intermittently and unpredictably induces variation over and above what is inherent in the system. It often appears as an extreme point (such as a point beyond the control limits on a control chart) or some specific, identifiable pattern in data. Common-cause is a factor that results from variation inherent in the process or system. The risk of a common-cause variation can be reduced by redesigning the process or system. For over 50 years, clinical laboratories have embraced Shewhart’s ideas and incorporated statistical process control into standard
operating procedures for clinical laboratory quality control and external quality assessment (EQA). Total Quality Management

Total quality management (TQM) is a practical philosophy of excellence. It arose with the postwar renaissance of Japanese industry and was mostly shaped by two American advisers, W. Edwards Deming and Joseph Juran, and the president of the Japanese Union of Scientists and Engineers, Kaoru Ishikawa. TQM involves how best to organize a business to apply SPC to quality and productivity. However, TQM is more than statistics: Fundamentally, it is about how to enable an organization and its employees to pursue a statistical approach to quality instead of using traditional management approaches, which TQM’s founders considered ineffective.

The Toyota Production System

The Toyota Production System (TPS) does not represent a distinct philosophical approach to managing quality. Instead, TPS provides a particularly salient example of TQM applied within an individual company. The TPS has been studied in detail by a number of authors, and the application of TQM at Toyota over the course of more than half a century has resulted in the development of production methods and an organizational culture that have relevance for the clinical laboratory industry today.

The lean production approach was applied to Toyota’s methods by three enterprising business authors who published several well-written and widely read analyses of Toyota’s production methods in the 1990s. Today, the term lean production refers to any production process based on the methods applied at Toyota. The TPS has some unique characteristics, but many TPS elements can be found in other organizations within and outside of Japan. For example, just-in-time inventory management is well developed at the Dell computer corporation, and continuous flow practices are being applied in many industries, including histopathology laboratories.

Models for Improvement

QI in health care has developed in the past three decades by using the above-described principles, tools, and techniques from other industries regarding improving product quality in order to meet their customers’ needs and expectations; QI is now an established movement in health care. The basic premise of QI in health care is that improvement in patient care and outcomes can be achieved by making intentional and systematic efforts using a defined set of scientific methods and by constantly reflecting on and learning from the results of attempts to improve care. QI is based on systems thinking and therefore it emphasizes the organization and systems of care. Although there are multiple QI models and frameworks—IMPROVE, Model for Improvement, Lean or Lean Six Sigma (define, measure, analyze, improve, and control; DMAIC), the Toyota Production System, Rapid Cycle Improvement, four key habits (VON), Advanced Training Program of Intermountain Healthcare, and the Microsystems approach—they are all broadly similar in their approaches. The Model for Improvement, which was formalized by Langley, Nolan, and colleagues, is a simple and effective approach that can be used to improve the quality of care. A brief description of some of the key QI frameworks is included in this chapter.

Six Sigma and DMAIC

Motorola developed the philosophy for QI, based on SPC, which is called “Six Sigma”. Sigma is the Greek letter used to denote the standard deviation
Chapter 1

Figure 1-1. Model for Improvement

<table>
<thead>
<tr>
<th>DMAIC</th>
<th>Aim</th>
<th>Measurement</th>
<th>Change</th>
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<tbody>
<tr>
<td>Define – The sponsors and team members define who the customers are and the processes, scope, goals, and financial and performance expectations.</td>
<td>What are we trying to accomplish?</td>
<td>How will we know that a change is an improvement?</td>
<td>What change can we make that will result in improvement?</td>
</tr>
<tr>
<td>Measure – Data are gathered that provide measurements of the current state that will be used to identify the primary causes of the problem.</td>
<td>Act</td>
<td>Plan</td>
<td>Study</td>
</tr>
<tr>
<td>Analyze – Analysis of the data collected is performed to identify or verify the root cause(s) of the problem that resulted in unacceptable performance or barriers to improved performance.</td>
<td>Cycle for Learning and Improvement</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Improve – Potential solutions to the problem are developed and prioritized; then, implementation of the selected solutions occurs.</td>
<td></td>
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</tr>
<tr>
<td>Control – There is a process to check the effectiveness of the change and a process to periodically check that improvements are sustained over time with defined actions to take if performance is unacceptable.</td>
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of a population. In 1988 Motorola won the US Baldrige National Quality Award and this brought the six-sigma concept to public attention. Several other organizations started using six sigma, and General Electric, under Jack Welch’s leadership, popularized the six sigma method.

Six Sigma is the term for population standard deviation; it is considered “virtual perfection”. In statistical measurements, 99.9997 percent of data points lie within six standard deviations of the mean. The concept of Six Sigma is that customers’ needs should be met and provided within the time-frames they expect, 99.9997 percent of the time.

Six Sigma is a systematic methodology that seeks to improve the quality of process outputs by identifying and eliminating the causes of defects and by eliminating or reducing variation in the process. Six Sigma methodology seeks to improve laboratory processes, test results, and services continuously and proactively. It incorporates strong leadership commitment and empowerment of employees who work in the process.

Six Sigma improvement methodology incorporates the DMAIC principle which is an acronym for “define, measure, analyze, improve, and control” (see text box).
Continuous Quality Improvement in the Clinical Laboratory

**Lean**

Lean is a systematic approach that laboratories are adopting from industry to identify and eliminate waste (non-value-added activities) in order to deliver a quality product or service to the customer. Laboratories that incorporate Lean continuously review their processes to evaluate where wasted effort and incidental tasks that do not add value can be eliminated.25,26

There are six main principles of Lean: value, value added activity, value stream, flow, pull and perfection. **Value** is the worth of a product or service as judged from the customer’s perspective. A **value-added** activity has three characteristics: the customer recognizes the value and is willing to pay for it; it changes the product; and it is done right the first time. **Value stream** is the set of all activities, both value added and nonvalue added, which are required to complete an order or provide information, treatment, or service as requested by the internal or external customer. A value stream includes product, information, and material flow. **Flow** is the process of getting the product (or pathway of the sample) to move without stopping, thus eliminating wasteful or unnecessary steps. **Pull** is the ability to provide customers with what they need when they need it. **Perfection** is the process of improvement and re-evaluation.

**Lean Six Sigma**

Lean Six Sigma, also known as Lean Sigma, is the combination of attributes of both Lean and Six Sigma to form a more balanced methodology.27 The four key concepts of Lean Six Sigma are delighting customers, improving processes, teamwork, and data-driven decisions. By combining Lean’s focus on reducing waste to improve process speed and increasing value to the customer with Six Sigma’s focus of bringing a process under statistical control by reducing variability and increasing efficiency, process capability can be improved.

**Visual Management-5S** application can be used to create a workplace suited for operation visual control, resulting in a leaner operation and higher efficiency. This business approach utilizes the 5S - Sort, Straighten, Shine, Standardize and Sustain- to make the normal and abnormal conditions and all wastes visible, so standards can easily be followed by employees; flow of materials, people, and information are self-evident, and waste can be eliminated to prevent it from recurring in the future. With this approach, each employee can see when an error occurs in the process, ask for assistance, and perform any required corrective actions.28,29

**How to design and implement a QI project**

QI is an intentional change that is done in a methodical and systematic way. It can be applied to any step of a laboratory process: preanalytic, analytic and postanalytic.

**Identifying the opportunity for improvement**

Opportunities for improvement may arise from a need to make a process more efficient, to meet accreditation standards, or to change processes after the occurrence of a near-miss event or error. The Clinical and Laboratory Standards Institute (CLSI) defines improvement actions as **preventive** (proactive —to eliminate the cause or causes of a potential nonconformance), **corrective** (reactive—to remove the root cause of a problem to reduce or eliminate recurrence) or **remedial** (Immediate—to rectify a recognized nonconformance).30 Opportunities for
improvement can be identified using information generated along a continuum of sources that extend beyond the symptomatic (e.g., “incident reports”) to the asymptomatic (e.g., SWOT strengths, weaknesses, opportunities, and threats analysis—see text box).

**SWOT Analysis example for a clinical laboratory**

**Strength**
- Open 24 hours
- Offers a wide range of tests

**Weakness**
- Outdated IT system
- Time taken to report results
- Need to send out some tests
- No quality management team to follow up on complaints

**Opportunities**
- Adding molecular tests
- Faster report than university hospital
- Increased capacity of analyzers

**Threats**
- Competition
- Decreased reimbursements
- Staffing shortages

Many organizations use a performance monitoring tool like a “scorecard” to capture primary performance indicators, which, when outside the acceptable level, can be helpful in identifying a QI opportunity. The *Balanced Scorecard*—measures that drive performance—was initially described by Kaplan and Norton during a year-long research project with 12 companies at the leading edge of performance measurement. They devised a set of measures that give top managers a fast but comprehensive view of the business. The balanced scorecard includes financial measures that tell the results of actions already taken and operational measures like customer satisfaction, internal processes, and the organization’s innovation and improvement activities; the selected operational measures may become the drivers of future financial performance. This tool is widely used in many industries including healthcare. It can be used for measuring laboratory performance using a set of *key performance indicators* (KPIs). Priority is often given to any project that could adversely affect patient safety, issues that impact most customers and cause the most problems, issues needed for laboratory accreditation, benchmarked metrics, etc.

Often there is at least one champion in the laboratory who wants to make an improvement and to change the system. However, QI cannot be done alone. It is a team effort which requires support from leadership to provide adequate time, resources, and personnel. The QI project needs to align with the vision and mission of the organization for success. The availability and capacity of existing personnel, equipment, supplies, and information management capabilities all need consideration as improvement projects are prioritized. Time is a valuable resource and getting “buy-in” from leadership will help allocate time away from duties to do the QI project.
Continuous Quality Improvement in the Clinical Laboratory

The QI Team
A QI team of at least 3-4 individuals is usually comprised of personnel from multiple disciplines. QI teams may include physicians, laboratory technologists/technicians, supervisors, and other stakeholders who are directly or indirectly involved in aspects of the topic that is targeted for improvement. Since time and resources are limited, the team must be used efficiently and effectively.

The members of the QI team must become skilled in how to have productive meetings. They must also learn how to work together as a team, how to deal with barriers to improvement, and how to collect, analyze, and display data. Having a team leader who is trained in QI methods is advantageous. Effective teams should have an aim, an agenda with time for each item that is strictly adhered to, and a timekeeper. The team should list action items and assign responsibilities for team members to work on. All team members should participate, listen, and disagree constructively in the meetings. Each meeting should also be evaluated to see what went well and what could be improved upon for the next meeting.

Aim of the QI Project
The improvement project should start with a clear aim of what needs to be accomplished: This is called the global aim. An example of a global aim would be to improve adequacy of FNA material for molecular testing. This is followed by a specific aim statement (Fig. 1-2). A specific aim statement defines a goal, a population, and a time period. Aims should be specific, measurable, attainable, relevant, and timely (SMART). Before writing the specific aim statement, a statement of problems or opportunities for change is made in two to three sentences followed by a statement regarding why the current system or process needs improvement. This should include baseline data and relevant benchmarks from the published literature or other sources. Examples of specific aim statements are given below:

“Increase the percentage of critical values called to the clinician or designee to 100 percent by June 2022”
“Decrease the percentage of mislabeled specimens by phlebotomy to 0 by July 2022”
“Improve turn-around-time for flow cytometry reports from 2 days to less than 12 hours by July 2022”

Measurement: What is Improvement
Improvement is change from the current system to a system that is more effective, patient-centered,

**Figure 1-2. Specific Aim Statement**

<table>
<thead>
<tr>
<th>We aim to ____ (the change you wish to happen - increase/decrease/improve/etc.)</th>
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<tbody>
<tr>
<td>the _________ (measure - number/percentage/score/etc.)</td>
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<tr>
<td>of ___________ (name the exact thing to be improved)</td>
</tr>
<tr>
<td>by/from ____ (exact amount of improvement e.g., by x% or from x to y%)</td>
</tr>
<tr>
<td>by___________ (time - enter the month and year)</td>
</tr>
</tbody>
</table>
timely, efficient, equitable and safe. The acronym STEEEP can be used to remember this. Measurement tells you whether you are making improvement or not. QI teams should use measurement to monitor their performance in order to make mid-course adjustments as they move forward with improvements.

Measurement serves three purposes:

- Indicates the current state
- Informs QI teams whether they are actually making an improvement or not. It removes reliance on guesswork and opinions (which can be misleading).
- Helps teams learn from successes and failures

Measurement has a conceptual definition and an operational definition. A conceptual definition is broad and tells what you want to measure. This definition can be relatively vague, unlike the operational definition, which is a clearly specified method for reliably identifying, sorting, and classifying a variable. It tells you how a variable should be measured.

The operational definition answers three important questions:

- What is the phenomenon?
- What aspect will you measure?
- How do you know the measure reflects the phenomenon faithfully?

Before determining what process changes may result in an improvement, it is essential that the QI team understands the current situation since for every problem there are potential causes, facilitators, and barriers to change. A review of published literature and benchmarking helps with perspective on what one should or could aim for.

Tools to Use for QI

Though this is not an all-inclusive list, some of the commonly used tools for QI include brainstorming, cause-and-effect diagrams, flow chart/process mapping, Pareto chart, Five whys and root cause analysis, failure mode effect analysis, and 5S/ workplace organization.

Process Mapping

Process mapping, which is a detailed analysis and mapping of the current process, can be obtained using a flow chart. A flow chart is a pictorial representation of sequential steps and the directional flow of those steps in a process. It can be a 30,000-foot view of the process or a highly detailed map. Fig. 1-3 shows some basic concepts on symbols to use and how to make a flow chart for a hemoglobin A1c (hbA1c) test in the laboratory. When creating a process map, clearly define where the process you are mapping begins and ends, determine the steps in the process and sequence the steps.

Ishikawa Diagram

An Ishikawa/fishbone diagram offers a useful outline for brainstorming and to identify possible causes that contribute to a single effect. The fishbone diagram was described by Kaoru Ishikawa who led the committee of Japanese Union of Scientists and Engineers in 1968. The structure of the fishbone diagram is composed of a spine and attached bones. Big bones attached to the spine denote major categories of causation- process, equipment, materials, people, environment, etc. Smaller bones attached to the bigger bones denote specific causes and contributing factors. This demonstrates the complexity of the problem and helps organize categories logically. Fig. 1-4 shows an example of
a fishbone diagram showing causes for inadequate material for molecular studies in cell blocks of FNA samples.

**Pareto Chart**
A Pareto chart is a bar graph that can be used to rank categories from most significant to least significant. A simplified way to look at the Pareto principle is that 80 percent of problems are produced by 20 percent of the possible causes (80/20 rule), and the Pareto chart is a visualization of this. In the form of a histogram, the Pareto chart is able to show the number of times (y-axis) the process failure occurs when the potential contributing factors (x-axis) are present. Fig. 1-5 shows an example of a Pareto chart looking at the type of errors in specimens sent for testing to the chemistry laboratory.

**Collecting Data for QI**
Data for QI is different from data we collect for classic research projects where we collect as much data as possible and control for every bias possible.