15.   Process improvement

15-1: Continual improvement concept

Role in quality management system

Process improvement, one of the 12 quality system essentials, establishes a programme for helping to ensure continual improvement in laboratory quality over time. This continual improvement of the laboratory processes is essential in a quality management system.

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Organization	Personnel	Equipment
Purchasing and inventory	Process control	Information management
Documents and records	Occurrence management	Assessment
Process improvement	Customer service	Facilities and safety

Historical basis

W. Edwards Deming is one of the originators of the concept of continual improvement, the primary goal of a quality management system. Beginning in the 1940s, he worked with manufacturing and industrial processes, and introduced many of the tools used in quality improvement efforts; his ideas and concepts are used today to produce reliable, quality laboratory results. Deming outlined 14 points for quality, many of which can easily be applied to the laboratory. For the purposes of this discussion, two of his points are particularly important:

1. **Create constancy of purpose for improvement**. The message here is that there is a need to be constantly working toward making the process better.
2. **Improve constantly and forever**. This statement points out that continual improvement will always be a goal. Perfection is never achieved, but we try to get as close to it as possible. Process improvement is something that is never finished, but rather continues on "forever".

Deming's PDCA cycle

The Deming Plan-Do-Check-Act (PDCA) cycle shows how to achieve continual improvement in any process.

- **Plan**—identify the problems and the potential sources of system weakness or error. Decide on the steps to be used to gather information. Ask the question, "How can you best assess the current situation and analyze root causes of problem areas?" Using the information that is gathered through these techniques, develop a plan for improvement.
- **Do**—implement whatever plans have been developed—put the plan into action.
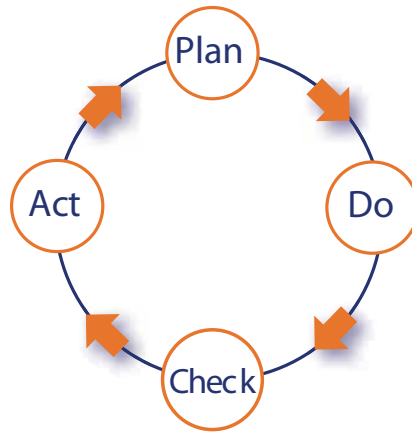
- **Check**—this refers to the monitoring process. It will be important to assess the effectiveness of the action taken, using focused review and audit processes. If the system weakness is complex, a pilot study may be needed in order to understand all the complexities. After "checking", revise the plan as required to achieve the improvements needed.
- **Act**—Take any corrective action that is required, and then recheck to be sure that the solution has worked. This cycle is a continuous process, so the laboratory will begin again with a planning process to continue the improvements.

This is the continual improvement process and, in the laboratory, this process is applied to all procedures and processes that are a part of the path of workflow.

ISO process for continual improvement

ISO 15189 [4.12] describes a very similar set of activities for achieving continual improvement in the laboratory. These are outlined as follows:
- identify potential sources of any system weakness or error;
- develop plans to implement improvement;
- implement the plan;
- review the effectiveness of the action through the process of focused review and audit;
- adjust the action plan and modify the system in accordance with the review and audit results.

15-2: Tools for process improvement

A process is a series of actions or operations contributing to an end. In every case, inputs (patient samples) are turned into outputs (patient examination results) because some kind of work, activity or function is carried out. Process improvement is a systematic and periodic approach to improving laboratory quality and the inputs and outputs that glue these processes together. It is a way of solving problems. If there is a problem, however hard to describe, one or more processes needs to be improved.

Many useful techniques have been developed to use in process improvement, and some have been discussed in other chapters of this handbook. For example, both **internal and external audits** will identify system weaknesses and problem areas. Participation in an **external quality assessment** is another useful tool; it allows for comparing laboratory performance to that of other laboratories.

Management review of all information gathered through these activities should be conducted. In addition, there should be management reviews of the laboratory records on a regular basis; for example, quality control, inventory management and equipment maintenance. These reviews will provide useful information about areas for improvement.

Quality plan

Monitoring Monitoring Monitoring

Internal audit   External audit   Quality assessment   Quality control

Opportunities for improvement

Quality goal

Using information from these reviews and from audits, and through the process of monitoring the organization's customer complaints, worker complaints, errors, near errors or near misses, **opportunities for improvement (OFIs)** will be identified. These OFIs will be the focus for corrective action.

When conducting audits or evaluating laboratory records, it is important to have a goal or standard of performance. Therefore, **quality indicators** will be needed and will have an important role to play.

The plan leads to the goals; OFIs, which are the result of monitoring, lead to the creation of a new plan, with the process leading to continual improvement.

Newer tools

New ideas for tools to use for continual improvement continue to come from the manufacturing industry. Two of these new tools are now being used in laboratory quality improvement.

1. **Lean** is the process of optimizing space, time and activity in order to improve the physical paths of workflow. This tool of industry is applicable to laboratories, and many laboratories are currently engaged in creating a lean system. Lean analysis may lead to revised processes and changes in laboratory floor plans. This should save time and financial resources, as well as help to reduce errors in the path of workflow.

2. **Six Sigma** is also a concept that has come to us from the manufacturing industry. This consists of a formal structure for project planning in order to implement change and improvement. In Six Sigma, the focus is to move toward reducing error to very low levels. The processes that are described in Six Sigma are define, measure, analyze, improve and control. These are similar ideas to those already discussed. The Six Sigma concept applies a very structured method for achieving these processes. (This chapter will not explore Six Sigma in depth; it is included here so that participants will become familiar with the term. See Chapter 15 reference list for sources of Six Sigma information.)

15-3: Quality indicators

It is often useful to consider a number of definitions in order to make very clear what is meant by a term such as quality. Philip Crosby, in his essays on quality management from the 1960s, defined quality as "conformance to requirements, not as 'goodness' or 'elegance' ".

Established measures used to determine how well an organization meets needs and operational and performance expectations is a good working explanation of a quality indicator.

Quality indicators are addressed in ISO 9001 and ISO 15189 documents.

ISO 9001 [5.4.1] requires that quality objectives should be measurable. Thus, the objectives or indicators must be quantifiable or otherwise capable of analysis, allowing for an assessment of the success of the quality system.
ISO 9001 [8.4] more specifically requires collecting and analyzing specific information or data upon which one can determine effectiveness and continual improvement. Some of the indicators that are required to be considered include customer satisfaction, conforming to customer requirements for products, counting the number of preventive actions addressed, and ensuring that suppliers are providing materials that will not adversely affect quality.

ISO 15189 [4.12.4] states that the laboratory shall implement quality indicators to systematically monitor and evaluate the laboratory's contribution to patient care. When the programme identifies opportunities for improvement, the laboratory management shall address them, regardless of where they occur. Also, it is stated that laboratory management shall ensure that the medical laboratory participates in quality improvement activities that deal with relevant areas and outcomes of patient care.

Quality indicators are information that is measured. The indicators:
• give information about the performance of a process
• determine quality of services
• highlight potential quality concerns
• identify areas that need further study and investigation
• track changes over time.

15-4: Selecting quality indicators

General guidelines

In selecting quality indicators for measuring performance, Mark Graham Brown, a leading expert on performance measurement, suggests the following useful guidelines.[1]

- Fewer are better; that is, do not try to have too many quality indicators, as tracking becomes difficult. Few laboratories can effectively address more than five or six indicators at a single time.
- Link the indicators to the factors needed for success. Choose the quality indicators that relate to areas that need correction in order to achieve good performance; select those that will be most meaningful to the laboratory.
- Measures (indicators) should be based around customer and stakeholder needs.
- Measures should look at all levels of the laboratory; if possible, include indicators that will evaluate function at the top management level, but also flow down to all levels of employees.
- Measures should change as the environment and strategy changes. Do not stick with the same indicators over long periods of time.
- Base the targets and goals for the measures on rational values, rather than values of convenience. They should be established on the basis of research rather than arbitrary estimates.

Developing successful indicators

Quality indicators—also called metrics—are the specific targets that are regularly examined using objective methods, in order to determine if the goals of compliance are being met. When developing quality indicators an organization should ensure the following.

- **Objective**—the indicators must be measurable, and not dependent on subjective judgements. It must be possible to have concrete evidence that the event (or indicator) either occurs or does not, or that the target is clearly met.
- **Methodology available**—be sure that the organization has the tools needed to accomplish the necessary measurements. The laboratory must have the ability to gather the information. If the data or information collection requires special equipment, then make sure the special equipment is available before starting.
- **Limits**—the laboratory will need to know the acceptable value, including the upper and lower range, before starting measurements. Determine in advance the limits of acceptability, and at what point a result causes concern. Also consider what action will be required. For example, how many delayed reports per month would be considered acceptable? How many would be considered as requiring corrective actions? How many would require immediate revision of the action plan?

1   Brown MG. *Baldridge award winning quality: How to interpret the Baldridge criteria for performance excellence*. Milwaukee, ASQ Quality Press, 2006.

- **Interpretation**—decisions must be made as to how indicator information will be interpreted before beginning measurements. Know in advance how to interpret the information that has been collected. For example, if you are monitoring completed requisitions to see if they are correct, you need to know how many samples you have examined, if they have come from multiple sources or all sources, and whether they are for only one type of sample or all sample types.
- **Limitation**—the organization should understand exactly what information is being provided by the indicator, and be clear on what is not being determined by the measurement of a particular indicator. For example, if collecting the number of accidents or errors, do you know if all are being reported?
- **Presentation**—the organization must decide how to present the information in order to fully display its value. Some information is best presented in a table, whereas other information might be best shown by a longitudinal graphic bar or in text. Presentation of information is important when looking for trends that predict future outcome.
- **Action plan**—before beginning the use of an indicator, the laboratory should have some idea of what to do if the indicator shows that there is a problem. Also decide how to collect the information, who will collect it, and how long it will be collected.
- **Exit plan**—because making these measurements takes time and resources, there should be a plan as to when to stop using a particular indicator and replace it with another. Generally, this is done when the original indicator shows that the operation is working and stable.

When developing quality indicators, be sure to engage the bench-level staff— those who do the work have a clear understanding of the tasks and outcomes. The planning process is best done in groups rather than by the quality manager alone. By engaging the people who actually do the work, the opportunity for success improves.

Characteristics of good quality indicators

Good quality indicators (also called metrics) have the following characteristics:
- measurable—the evidence can be gathered and counted;
- achievable—the laboratory has the capability of gathering the evidence it needs;
- interpretable—once it is gathered, the laboratory can make a conclusion about the information that is useful to the laboratory;
- actionable—if the indicator information reports a high or unacceptable level of error, it is possible to do something about the problem identified;
- balanced—consider indicators that examine multiple aspects of the total testing cycle in the pre-examination, examination, and post-examination phases;
- engaging—indicators should examine the work of all staff, not just one group;
- timed—consider indicators with both short-term and long-term implications.

The laboratory produces much information, but all the things that can be measured are not necessarily informative. As an example, a computer can analyze data in a variety of ways, but this does not always mean that the information is useful for continual improvement activities.

Mark Graham Brown warns, "Many organizations spend thousands of hours collecting and interpreting data. However many of these hours are nothing more than wasted time because they analyze the wrong measurements, leading to inaccurate decision making".[1]

Some examples of quality indicators

All laboratories should consider implementing a process for using a set of indicators which cover pre-examination, examination, and post-examination issues, as well as patient care systems.

A 2005 study of medical laboratories carried out in the United States showed the most commonly monitored indicators in use at that time were related to proficiency testing, quality control, personnel competencies, turnaround time, and patient identification and its accuracy.[2]

Most common indicators tracked (%), 2005
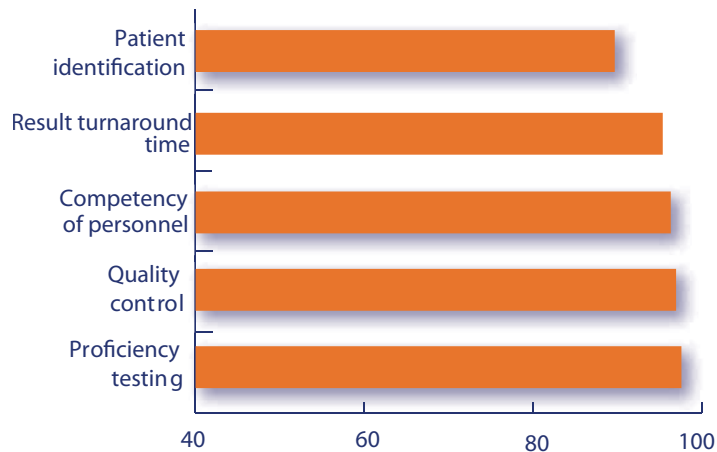
It is important to note that, ideally, quality indicators used in health care should be linked to patient outcomes. However, this is very difficult with laboratory indicators because patient outcome is dependent upon a complex set of circumstances, including age and underlying illness, stage of illness, stage of diagnosis and stage of therapy. Therefore, laboratories often use quality indicators other than health outcomes of patients.

1 Brown MG. *Using the right metrics to drive world-class performance*. New York, American Management Association, 1996.
2 Hilborne L. Developing a core set of laboratory based quality indicators. Presented at Institute for Quality in Laboratory Medicine Conference, Centers for Disease Control and Prevention, Atlanta, GA United States, 29 April 2005 (http://cdc.confex.com/cdc/qlm2005/techprogram/paper_9086.htm).

15-5: Implementing process improvement

Regardless of the technique used, continual improvement requires action from the people within the organization. Some of the necessary steps are important management roles, and others require the entire laboratory staff for success. These essential factors and steps include:

- Commitment from all levels of the laboratory staff. Improvement requires continual awareness and activity. This is a full-time task and requires dedicated staff time .
- Careful planning so that goals can be achieved. Before action plans are implemented, there is much to consider: root causes of error; risk management; failures, potential failures and near misses; costs, benefits and priorities; and the costs of inaction.
- An organizational structure that supports the improvement activities.
- Leadership—top management must be engaged and supportive.
- Participation and engagement of the people that normally perform the tasks being addressed. These are the staff most likely to know and understand what is done on a regular and daily basis, and without their participation, improvement programmes have little opportunity for lasting success.

When undertaking and implementing action plans for quality improvement, there are a number of factors to consider.

- What are the root causes of error? In order to correct errors, it is important to identify the root causes, or underlying causes, of the problem.
- How will risk be managed in the laboratory? Risk management takes into account the trade offs between the risk of a problem, and the costs and effort involved in fixing it.
- Failures, potential failures and near misses are categories into which laboratory problems fall. Failures are most commonly identified, as a failure in the system will usually be immediately obvious. Failures need to be addressed as a part of continual improvement. However, a good process improvement programme will try to identify potential failures, which are not so obvious, as well as near misses (those situations where a failure has almost occurred).
- Any process improvement programme must take into account the costs of making changes, the benefits of making the changes and the priorities for action. These decisions relate to the concept of risk management.
- Finally, it is important to consider the cost of inaction, or failure to take action. What will be the cost, in money, time or adverse effects, of not correcting a problem in the laboratory quality system?

Early on, Deming observed that quality managers working without the clear, active, and open participation of top management cannot succeed in implementing continual improvement. Sustained leadership must come from the top.

Good leadership fosters the culture for improvement, including:
- openness—the process must be understood by all and there must be a recognition that all laboratory staff will have good ideas to help with improvements.
- commitment—it must be clearly communicated that there is support for the process and that improvements will occur.
- opportunity—a good leader will ensure that all staff have the opportunity to participate in the process.
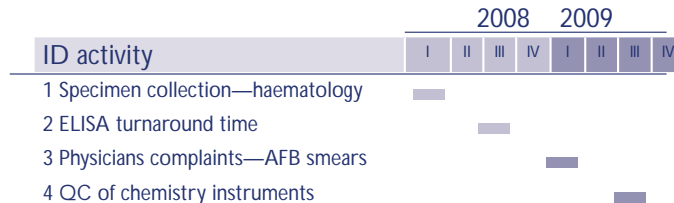
Participation in the process

Always remember that top management, quality managers and consultants do not know everything that the bench-level staff know, and often are not aware of all of the staff's tasks. It is vital to engage all bench-level staff in the process improvement programme, as their knowledge and support are also essential. Furthermore, when staff know they can make a difference, they will benefit the laboratory by pointing out potential problems that can be avoided.

Continual improvement requires both leadership and engaged team participation.

Quality improvement activities

The following steps show how to plan quality improvement activities:
- use a timeline and do not take on more than can be accomplished within a timeframe;
- use a team approach, involving bench-level staff;
- use appropriate quality improvement tools;
- implement corrective or preventive actions;
- report quality improvement activities, findings and corrective action progress to management and also to laboratory staff.

ID activity	2008				2009			
	I	II	III	IV	I	II	III	IV
1 Specimen collection—haematology	▬							
2 ELISA turnaround time		▬						
3 Physicians complaints—AFB smears				▬				
4 QC of chemistry instruments						▬		

If possible, design a study so that results can be statistically measured. Use available information to select a topic for study, for example:
- customers' suggestions or complaints
- identified errors from occurrence management programme
- problems identified in internal audits.

Consider as a guideline to have no more than one project every six months.

Retiring a quality indicator

Use a quality indicator only as long as it provides useful information. Once it is indicating a stable and error-free operation, select a new quality indicator.
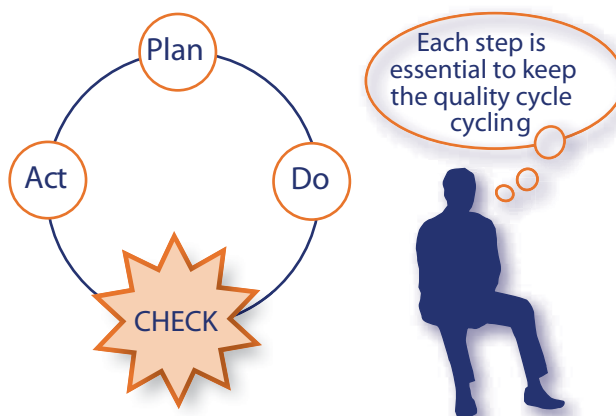
15-6: Summary

The process for continual improvement includes:
• identification of the problem;
• analysis of the data and the processes;
• determination of the root cause of the problem;
• generation of ideas for solutions.

The quality cycle

Continual improvement is the core of quality management, but it requires commitment, planning, structure, leadership, participation and engagement.

• Quality counts—it is a very important goal for any laboratory.
• Continual improvement is an outcome of an active laboratory quality management system.