6. Quality management in the clinical laboratory

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Abstract. The concept and principles of total quality management have now become the basis for managing the seemingly contradictory demands of cost reduction and improved quality in the clinical laboratory. Quality, which is understood as conformance to the requirements of the customer or end-user, can only be attained within a quality management system. This quality management system is built on a framework of quality planning; quality processes; quality control; quality assurance; and quality improvement. These five components work together in a feedback loop and illustrate how continuous quality improvement is accomplished. Every laboratory is encouraged to design, develop, document, validate, implement, monitor, and improve its work processes and management infrastructure elements (quality system essentials). Collectively, the management infrastructure elements and work processes comprise the laboratory’s quality management system. Traditionally, management principles of the clinical laboratory have been based on the concepts of Quality Control and

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Quality Assurance. Quality management is a continuously evolving concept and newer initiatives are being developed and adopted into the clinical laboratory. Lean Production is another quality initiative that is focused on creating more value by eliminating activities that are considered waste. Quality improvement reduces waste and leads to improved productivity, which in-turn reduces cost and provides a competitive advantage.

1. Introduction

The clinical laboratory has progressively become an essential component of the healthcare delivery system all over the world. High-quality laboratory testing is critical for patient care, disease prevention, and outbreak investigations (Gershy-Damet et al, 2010). Functionally, the clinical laboratory transforms a request from an authorized healthcare professional, into a tangible report of results and interpretations in support of patient care. This transformational process involves a series of complex work processes and interaction amongst a host of healthcare personnel with varying backgrounds – physicians, nurses, couriers, laboratory assistants, laboratory scientists and pathologists (Berte, 2004).

The laboratory’s work processes may be completely, partially or not at all computerized and analytical methods may be completely, partially or not at all automated. This makes it imperative for the work processes to be managed and controlled in such a way to conform to the requirements of the customer (physicians and their patients) at all times. This is done by applying a systematic approach to the laboratory’s work processes – carrying on from quality planning; process design, development, and implementation; quality control; quality assurance and; quality improvement.

Such an approach not only greatly increases the likelihood of the laboratory’s consistent and predictable contribution to patient care, but also reduces errors, and inefficiences that waste resources.

1.1. Principles and concepts of quality management

Quality is defined as the totality of characteristics of an entity that bear on its ability to satisfy stated or implied needs (ISO; 8402:1994). It is also defined as conformance to the requirements of users or customers and the satisfaction of their needs and expectations (Burtis et. al., 2008). In the clinical laboratory, quality has the following attributes:

(a) **Accuracy**: The agreement between the best estimate of a quantity and its true value. It is expressed by the term inaccuracy. Numerically, it is the difference between the mean of a set of replicate measurements and the
true value. Other words synonymous with inaccuracy are bias and systematic error.

(b) Precision: Agreement between replicate measurements. It is expressed by the term imprecision. This is the standard deviation or coefficient of variation of the results in a set of replicate measurements. Random error is sometimes used for imprecision. A reliable analytical method should have very minimal imprecision.

(c) Specificity: This is the ability of an analytical method to determine solely the component(s) it purports to measure.

(d) Sensitivity: This is the ability of an analytical method to detect small quantities of the measured component. It is expressed by the term detection limit, i.e., the smallest single result which, with a stated probability (commonly 95%), can be distinguished from a suitable blank.

Total quality management (TQM) provides the management philosophy for organizational development and a management process for improvement of quality in all aspects of the work. This concept of TQM was first adopted in industry; however, many healthcare organizations (including clinical laboratories) have adopted the concepts and principles. The universal principles of TQM are: (1) customer focus, (2) training, (3) management commitment, (4) process capability and control, and (5) measurement using quality improvement tools (Westgard et al., 2003). The focus on users and customers is important, particularly in service industries such as healthcare.

An understanding of quality and costs leads to a new perspective of the relationship between these two concepts. If quality improves, waste is reduced, which in turn reduces cost. The architect of this fundamental concept was the late Edwards Deming, who developed and promulgated the idea that quality improvement reduces waste and leads to improved productivity, which in turn reduces cost and provides a competitive advantage (Deming, 1987). The principles and concepts of TQM have been formalized into a quality management process.

### 1.2. Framework for managing quality in the clinical laboratory

Quality goals in the clinical laboratory can only be achieved within a well-functioning quality management system. A framework for managing this quality system must be established. Each clinical laboratory must design, develop, document, validate, implement, monitor, and improve its own work processes and management infrastructural elements (quality system essentials). These work processes together with the management infrastructural elements make up the laboratory’s quality management system.
(Berte, 2004). The framework for this quality management system has five components (as shown in Figure 1) – quality planning, quality processes, quality control, quality assurance and quality improvement - working together in a feedback loop.

Of the five interdependent concepts, quality control and quality assurance have traditionally been the basis for quality management in industry, business and the clinical laboratory. This section focuses on these two concepts.

**Appendix 1**

![Quality Management Framework](image)

**Figure 1.** Total quality management framework for management of quality in a healthcare laboratory (Westgard et al, 1990).

### 1.2.1. Quality control

Quality control is defined as the operational techniques and activities that are used to fulfill the requirements of quality (ISO; 8402:1994).

Quality control is product oriented and is used to verify that a product (test result in the case of the clinical laboratory) is of acceptable quality. Its prime objective is to determine defects and minimize them. As a result, it is described as a reactive intervention as opposed to a proactive one.

There are two types of quality control schemes: (1) internal quality control and (2) external quality control. Internal quality control is a set of procedures undertaken by laboratory staff for the continuous monitoring of operation and the results of measurements in order to decide whether results are reliable enough to be released (ISO;8402:1994). It involves the use of control charts such as the Levey – Jennings (Figure 2). Control rules such as
Figure 2. Levey –Jennings Chart for AST Control Data (Courtesy Central Laboratory, Korle-Bu Teaching Hospital, Accra, GHANA). The above chart shows control values plotted on a Levey-Jennings chart. Control lines are drawn at +/- 1SD, 2SD, and 3SD. These are colour-coded green, yellow and red respectively. The +/- 2SD line is a “warning limit” and should prompt investigation into pre-analytical and analytical procedures or equipment checks. The +/- 3SD line represents an outright rejection due to random or systematic error.

Westgard’s multirule (Table 1) are applied to control data as part of the internal quality control process.

It is important to emphasize the need for the control specimen to be treated in the same way as the specimen to be analyzed. Only then can meaningful deductions be made from the control data.

The Levey – Jennings chart is a simple control chart that can be used even in the most resource – constrained laboratories.

External quality control

External quality control (EQC) involves the use of results of many laboratories analyzing the same specimen of known composition and value, supplied by an external agency, for quality control purposes (Lewis, 1988). EQC uses a statistical methodology. The recognized external agency can be a national or an international body. This agency supplies specimen for analysis by different participating laboratories on a regular basis; for e.g. fortnightly.
Appendix 2

Table 1. Westgard’s multirule.

<table>
<thead>
<tr>
<th>Rule</th>
<th>Interpretation</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 2s</td>
<td>One control observation exceeding the mean ± 2s.</td>
<td>It is used only as a “warning” rule that initiates testing of the control data by other control rules.</td>
</tr>
<tr>
<td>1 3s</td>
<td>One control data observation exceeding the mean ± 3s.</td>
<td>Rejection. Method is primarily sensitive to random error.</td>
</tr>
<tr>
<td>2 2s</td>
<td>Two consecutive control observation exceeding the same mean +2s or mean – 2s limit.</td>
<td>Rejection. Method is sensitive to systematic error.</td>
</tr>
<tr>
<td>R 4s</td>
<td>One control observation exceeding the mean + 2s and another exceeding the mean – 2s</td>
<td>Rejection. Method is sensitive to random error.</td>
</tr>
<tr>
<td>4 1s</td>
<td>Four consecutive observations exceeding the mean +1s or mean – 1s</td>
<td>Rejection. Sensitive to systematic error</td>
</tr>
<tr>
<td>10x</td>
<td>Ten consecutive control observations falling on one side of the mean (above or below, with no other requirement on size of deviations).</td>
<td>Rejection. Sensitive to systematic error</td>
</tr>
</tbody>
</table>

The laboratories then return their analyzed result to the organizing agency, which later provides feedback to the participating laboratories. This whole process requires a high level of central organization (Lewis, 1988).

For proper assessment and grading, all participating laboratories are grouped according to the analytical method and equipment used. The mean and the standard deviation are usually calculated from the group result. This is referred to as the consensus mean. The mean from individual laboratories can then be compared against the “consensus” mean and standard deviation and a determination is made as to acceptable level of quality of results. The acceptance criteria are solely determined by the organizing agency. Unfortunately many countries in sub-Saharan Africa lack external quality control organizations and most laboratories that operate in this region are not registered with any international external quality control scheme provider such as the International Organization for Standardization (ISO) (Gershy-Damet et al; 2010). South Africa is the only country, in sub-Saharan Africa that has accumulated significant experience in this regard, boasting a national agency – South Africa National Accreditation Service – and a network of several
hundred clinical laboratories which participate in external quality control schemes (Dhatt, 2002). The benefits of participating in external quality control schemes are invaluable. The organizing agency will benchmark current performance, evaluate the distance remaining to achieve international standards and also establish a mechanism for tracking progress towards these goals.

1.2.2. Quality assurance

The attainment of quality objectives and goals in the clinical laboratory requires a comprehensive quality assurance programme. The essential elements of the quality assurance programme are also known as quality system essentials (QSEs). Quality assurance is defined as “all those planned and systematic activities implemented to provide adequate confidence that an entity will fulfill requirements for quality” (ISO; 8402:1994). Quality assurance is process oriented and focuses on defect prevention.

The quality system essentials

(a) **Organization** – the clinical laboratory must have a core management and an organizational structure which is headed by the medical director. This management needs to commit to comply with all governmental, accreditation and organizational requirements and to design the quality system essentials and work processes in a way that these administrative requirements and the needs of the patient are met. The core management needs to develop policies and processes for all the quality system essentials, provide facility, human and material resources in support of the quality system essentials. They also need to remove all barriers to implementation. The core management should also conduct periodic reviews of the quality management system.

(b) **Personnel** – high-quality personnel are essential for high-quality services. The educational background and experience of all personnel are important. The clinical laboratory has personnel with diverse academic qualification and experience – laboratory assistants, technicians, laboratory scientists, pathologists etc. The laboratory’s core management needs to clearly define qualifications for each job title and provide each member of staff with a job description.

(c) **Purchasing and inventory** – the laboratory needs to identify the critical supplies and support services it requires to operate and define the criteria to be met by vendors for each critical supply and service. It is imperative for the laboratory’s management to collaborate with the organizations purchasing unit to ensure a continuous supply of logistics. All processes,
from raising a purchasing order through to receipt and storage of purchased items should be documented.

(d) **Process Control** – all laboratory-based disciplines follow the same overall sequence of technical work processes – pre-analytic, analytic and post-analytic. Every laboratory should provide a flow – chart detailing its technical work processes. This flow – chart should also identify persons responsible for each activity. This will communicate important requirements that ensure consistency and successful performance. Quality control programmes ensure that test systems and methods work as expected and provide accurate results.

(e) **Equipment** – all equipment purchased must be installed by certified personnel and followed through with calibration, maintenance and operation in accordance with manufacturer’s instructions. Records of installation, calibration, operation, service and repair should be kept as a “life-history” of the equipment.

(f) **Documents and records** - policies, process descriptions and procedures must be documented as they communicate important organizational and operational information to the laboratory’s staff. Documents are management’s communication to staff about what is to be done, how it is to be done, and the effect it has on the overall work process. There should be established processes for creation and approval of new documents; periodic review of unchanged documents; removal of obsolete documents; and storage of archived documents. Records are completed paper or electronic worksheets that capture source information obtained, activities performed and results achieved when performing procedures.

(g) **Information management** – the flow of information within the clinical laboratory; between the laboratory and other parts of the healthcare organization; and between the laboratory and external agencies is vital if the laboratory is to achieve its quality goals. The clinical laboratory deals with private and confidential information thus the handling of this information must be secure at all times irrespective of the form it takes – paper or electronic.

(h) **Occurrence management** – adverse events such as errors, accidents and customer complaints, have the potential of ruining the reputation of the clinical laboratory. Thus such events need to be detected, documented and analyzed to determine which work processes are related to the event. This enables management to design and develop an effective risk management plan as well as patient and employee safety programmes.

(i) **Assessment: External and internal** – regulatory bodies such as International Organization for Standardization (ISO), World Health Organization – Africa Region, College of American Pathologist (CAP)
and South Africa National Accreditation Service (SANAS), are international providers of accreditation and assessment. These assessments provide a measure of the extent of compliance with published requirements. Internal assessment takes the form of the laboratory’s own quality performance indicators – turn- around-time, test utility, equipment down-time, and stock out.

(j) **Customer service and satisfaction** – every organization needs to continuously assess employee satisfaction as well as satisfaction of customers who use the service.

(k) **Facilities and safety**– both the internal and external environment of the laboratory should be safe to staff, visitors and patients. Laboratory design should conform to published standards such as is contained in the World Health Organization’s ‘Laboratory Bio-safety Manual’. Routine maintenance and good house-keeping are necessary to keep the facility in a functional, reliable, clean and safe condition. Disposal of hazardous waste should meet national, international or regulatory standards. To correct unsafe conditions, laboratory management must teach safety, be disciplinarians, set good examples of safety practices and be authoritative leaders (Ederer, 1968).

Implementation of all of the above quality system essentials will generate the needed confidence among users, that the clinical laboratory will satisfy requirements for quality.

### 1.3. New concepts in quality management

Quality management is a continuously evolving concept and several new quality initiatives have been developed and adopted in the clinical laboratory. Two notable initiatives are (1) Six Sigma Process Control and (2) Lean Production. The principles of Six Sigma were developed by Motorola in 1986 as their answer to implementing total quality management (Tennant, 2004). The performance goal under this concept is that 6 sigmas or 6 standard deviations of process variation should fit within the tolerance limits for the process (Burtis, et al, 2008).

Lean production is a quality process that is focused on creating more value by eliminating activities that are considered waste.

### Summary

The attainment of quality objectives and goals in the clinical laboratory is the responsibility of all members of staff. It requires leadership, time,
attention, resources and a continuous commitment to evaluation and improvement. The clinical laboratory functions through a series of complex work processes and the interaction of a host of healthcare professionals.

These work processes need to be controlled at all stages by applying a systematic approach in a quality management system. The design, development and implementation of a quality management system reduces waste and leads to improved productivity.

1.4. Glossary of definitions

The IFCC-Expert Panel on Nomenclature and Principles of Quality Control in Clinical Chemistry, henceforward referred to as the IFCC-EP, has published a series of provisional recommendations (Buttner et al. 1978). These include a glossary of recommended terms and their definitions.

**Analytical method**: is a set of instructions which describe the procedure, materials and equipment necessary to obtain a result.

**Result**: the final value obtained for a measured quantity.

**Calibration**: the process of relating the value indicated on the scale of an instrument or analytical device to the quantity being measured.

**Standard**: the material or solution with which the sample is compared in order to determine the result.

**Arbitrary standard**: calibration standard containing an unknown quantity of the specified substance. The content is assigned by convention and expressed in arbitrary units e.g. international biological standards.

**Internal standard**: a substance, not normally present in the specimen and clearly distinguishable from the substance to be analyzed, which is added in known amount to the sample, or to both the sample and the standard, for the purpose of correcting results for inaccuracy.

**Definitive method**: a method which after exhaustive investigation is found to have no known source of inaccuracy or ambiguity.

**Reference method**: a method which after exhaustive investigation has been shown to have negligible inaccuracy in comparison with its imprecision.
References

1. Berte, M.L. Managing Laboratory Quality – A Systematic Approach. LabMedicine, Vol. 35; No.10