OUTLINE OF QUALITY INDICATOR IN CLINICAL LABORATORY

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ABSTRACT

While quality in healthcare is an essential concept, the methodology to measure the quality is in preliminary stage. Developing quality indicators seems to be inspiring concept in measuring quality in healthcare system. Clinical laboratory being the inseparable part of health care system, we have made an attempt to through a light on quality indicators in clinical laboratory. Developing key performance indicators and monitoring, auditing and improving those parameters is a dynamic process which requires standardization, improvement and innovation – the three arms of any improvement process, may it be in industry or in service scenario. While standardization means removing the outlier's i.e. reducing the standard deviation, improvement denotes gradual bettering of a parameter from the previous level with a degree of irreversible consistency. Innovation is however, sporadic and often it requires a thinking cap which, while maintaining the speed of standardization and improvement, quickly takes the parameters to a new level.

Keywords: Quality Management System, Measurement of Quality, Analytical, Pre-analytical, Post-analytical, Goals, Monitor, Safety, Inaccuracy

INTRODUCTION

Quality of care is now not just a concept in a health cares industry. It has become essential to patient well-being and financial survival. Also due to increase pressure from society and medico-legal concerned quality stands as a sole solution to all these problems. With increasing awareness, the impact of medical errors can be seen on patient's safety. Medical errors can result into annoyance and inconvenience such as time lost or necessitated patients revisits, but can result into more serious consequences of diagnostic delay or error, increased cost, inappropriate therapy and worse, increased risk of patient illness, debility, and sometimes death. Medical errors occur throughout the health care industry may it be clinical setting or diagnostic laboratory. Laboratory testing and services have an important role in the provision of health care and in utilization and reimbursement.

Total Quality Management (TQM) is a specific approach to the art of management in a company that aims to provide its customers with products and services that fully meet their needs (Westgard *et al.*, 1990). Implementing TQM means introducing the quality management system, defining the quality policy and procedures which are essential for quality assurance and quality control instruments. Successful implementing TQM also requires commitment and full participation by all employees in continuous quality improvement activities, by continuously improving effectiveness and reducing the errors, defects and waste. This required process for monitoring and addressing these types of errors. This is done by defining some quality indicators in quality management system of clinical laboratory. Here we have summarized information on quality indicators related to laboratory testing to assess current gaps with respect to stages of the laboratory testing process.

Measurement of Quality

A quality indicator is defined as an objective measure evaluating critical health care domains as defined by the Institute of Medicine (IOM) (patient safety, effectiveness, equity, patient centeredness, timeliness, and efficiency). In other words, a quality indicator is a tool enabling us to quantify the laboratory's performance by selecting a certain comparative criterion. Any potential quality indicator needs to fulfill primarily two inclusion criteria: it must be an indicator of laboratory functioning and it must cater to at least one IOM health care domain. In recent years, laboratories have used varying methods to develop quality indicators to comply with the requirements of accreditation standards and to monitor and improve

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quality and patient safety based on data obtained over time. However, the quality indicators selected should be designed to identify those events that reflect the actual situations in question, are user friendly, are easy to measure, provide the information for improving performance, are understandable, and encourage prompt and suitable corrective or preventive action.

Taking into account everything that has just been said about the continuous monitoring and improvement of the system as a whole, it should be emphasized that the main goal is to achieve the maximum quality with minimum waste and minimal error rate. As of clinical laboratory, it means to offer a right patient, right service in the right moment; i.e. to provide the reliable result from the best available sample with appropriate interpretation and in the most cost-efficient way. The biggest challenge is how to measure your own performance and how to assess your performance compared to other laboratories. That is what quality indicators are used.

Quality Indicators

Quality indicators are measurable, objective, quantitative measures of key system elements performance (Shahram and Snyder, 2009; Ana-Maria and Elizabeta, 2008). They indicate the extent up to which a certain system meets the needs and expectations of the customers. Every clinical laboratory accredited according to the current standard for medical laboratories (EN ISO 15189) shall systematically monitor and evaluate its quality indicators (Price, 2005). Some of the organizations that are involved with quality indicators: College of American Pathologists, Centers for Disease Control and Prevention, Institute for Quality in Laboratory Medicine, Joint Commission on Accreditation of Healthcare Organizations, Centers for Medicare & Medicaid Services, and others.

Quality indicators can either be measures of processes, outcomes or contribution of the laboratory to the patient care. They can indicate the quality of the key, strategic (organization and management), and support (external services and supplies, maintenance, environmental safety) processes (Westgard,6). It is of utmost importance that quality indicators address all three key processes in the laboratory: preanalytical, analytical and postanalytical (Ricos *et al.*, 2008; Kirchnner *et al.*, 2007).

Number of quality indicator to be monitored varies depending on the size of the laboratory, workload and test volume. Small laboratories usually monitor less whereas larger laboratories monitor more indicators. Number of indicators can change with time. Certain indicator should be monitored as long as it provides useful information on the system performance. This can be done by monitoring certain quality indicators over a period of time and evaluating their performance periodically. When the goals set for particular quality indicator are achieved it can be removed from the list of quality indicator and routine follow up can be done for it. If the set goals are not achieved necessary corrective and preventive action needs to be taken and the performance is again evaluated for the compliance. Whereas a new quality indicator can be defined to replace the previous one and again certain goals can be set for it which is to be monitored over a period of time and to be evaluated. This cycle needs to be carried for the continual improvement of the quality management system of the laboratory.

Quality indicators are useful not only just for self evaluation but also for identifying opportunities for implementing corrective action; performing a root cause analysis; developing a quality improvement strategy; modifying targets or action thresholds; reporting to interested parties; and deciding to continue monitoring or stop monitoring the indicator. Quality indicators should have clear and unambiguous definition and interpretation, whereas the ability to measure the indicator is a prerequisite for its successful implementation, reproducible application, monitoring and evaluation.

Defining Quality Indicators in Clinical Laboratory

Quality indicators for key processes in clinical laboratories can assess preanalytical, analytical and postanalytical phases of laboratory activity. Quality indicators can be defined using criteria mentioned in Table 1.

Laboratory operations are divided into three major phases: Pre-analytical; Analytical; Post analytical. While choosing the appropriate quality indicator all the three phases should be taken into consideration so as to cover the all areas of the laboratory operations (Table 3).

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In addition to key processes in laboratory operations strategic and support processes are also important for successful functioning of a laboratory. Those processes refer to the laboratory organization, communication, education, environmental safety, resolving of complaints and nonconformities, etc. All those activities have a substantial effect to the overall quality of laboratory processes. It is therefore also important to monitor some indicators of those strategic and support processes. Ricos *et al.*, (2008) have recently published a comprehensive review on strategic and support processes in laboratory medicine (Westgard) (Table 6). Though having quite different meanings, efficiency and effectiveness are often mistakenly used synonyms. Efficiency refers to resources (time and money) spent by a certain process, while effectiveness defines the extent to which a process or a product meets its purpose and fulfills customer needs. Efficiency is therefore a measure of productivity whereas the effectiveness is a measure of quality.

Implementation of Quality Indicators

Implementation of quality indicator requires precise definition of quality indicator with effective monitoring and measurement. For successful implementation of a specific quality indicator, the dimensions of the specific indicator that are to be clearly defined are mentioned in Table 8. Implementation of quality indicator should follow the Deming PDCA quality cycle. (Plan, Do, Check, Act; Figure 1) The sample plan for operating indicators of quality is mentioned in Figure 2.

Presenting - Quality Indicator Information

Measurement of quality through quality indicator monitoring generates data that is to be interpreted and represented in some graphical form. This date statistically analyzed data can be represented in the form of simple tables bar diagram, histogram, line diagram, pie charts. Presentation of data should be self explanatory and informative from which some conclusions can be drawn which could serve as input for further plan of action.

Difficulties in Definition and Implementation of Quality Indicators

Defining a quality indicator take a lot of effort. While setting feasible goals for a defined quality indicator literature data is to be put forward. The dimensions of the quality indicator are taken into consideration and should be defined. For example, if turnaround time is to be implemented as a quality indicator, following are the dimensions that are to be defined

- > Turnaround time for each laboratory parameter
- Procedure for monitoring of turnaround time
- Corrective and preventive action to reduce the turnaround time
- Representing the data

Turnaround Time refers to the percentage of specific laboratory tests that do not meet a reporting dead-line. (Bonini et al., 2002) There are no widely accepted turnaround time (TAT) goals for specific laboratory tests. Laboratories most commonly (41%) defined TAT as time of specimen receipt in the laboratory to time of results reporting (Steindel, 1995). However, order-to-reporting TAT is the most common clinician definition for TAT (Steindel and Howanitz, 2001; Howanitz et al., 1993; Jones and Novis, 2001; Jones et al., 1999; Kilgore et al., 1998; Novis et al., 2004; Steindel, 1995; Steindel and Jones, 2002; Steindel and Novis, 1999; Valenstein and Walsh, 2003). Timely reporting of laboratory tests may improve patient care efficiency, effectiveness, and satisfaction (Valenstein and Walsh, 2003). In particular, the speed of diagnosis of acute myocardial infarction using cardiac troponin tests in the ED may determine the type of therapy and patient outcomes. Many stat tests are not used for urgent clinical decisions; therefore, faster results may not impact outcomes (Kilgore et al., 1998). Some studies have shown shorter TATs can shorten LOS in certain ED situations, (Steindel, 1995; Bluth et al., 1992; Lee-Lewandrowski et al., 2003; Holland et al., 2005; Singer et al., 2005; Holland et al., 2006) but the impact on other outcomes is unclear. Except for implementation of point-of-care testing (Lee-Lewandrowski et al., 2003; Fitch et al., 1999; Lewandrowski, 2004) no published studies were identified on any intervention that was consistently effective in improving laboratory TAT.

The importance of continuous monitoring and trend analysis of quality indicators has already been emphasized, as well as the concept of continuous system improvement. Accordingly, turnaround time

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should be continuously monitored and potential causes for failure analyzed. If quality goals are not met, following corrective actions can be implemented:

- Staff education.
- Separate requisition form with colour code can be introduced for emergency samples
- > Pneumatic pipe system for transportation of samples can be introduced in high throughput laboratory
- Modular automated analyzer can be introduced for fast processing of samples.
- > Heparin plasma samples can be used instead of serum samples for selected chemistry analysis

As already previously mentioned, choice and number of indicators monitored in a laboratory may vary. Indicator should be closely monitored after corrective preventive actions are undertaken, in order to appraise the effect of the implemented changes. Indicator can be monitored either for a certain period of time or permanently, depending on its nature and what it refers to. After some major process redesign, a laboratory can even stop monitoring an indicator and introduce another one if proven to be more representative of the system performance (Entry - Exit of Indicator).

Table 1: Criteria to set Quality Indicator

RELEVANCE:

> area is of interest and financially and strategically important to stakeholders

clinically important aspects of health, defined as high prevalence or incidence and significant effect on disease burden

- Can differentiate between biological variations among population
- \blacktriangleright need for the measure
- > Contribution for overall improvement in health care system

TECHNICAL IMPORTANCE

- > indicated to be of great importance to improving quality of care
- > Repeatability and reproducibility of the results

PRACTICAL FEASIBILITY

- > Should be statistically measurable and comparable
- > timeliness and possible utilization as a measure of laboratory improvement

Table 2: Indicators of	Good Indicators
Maagurahla	Can you o

Measurable	Can you count it, time it, record it?
Achievable	Can you actually capture it?
Interpretable	When you've got it, what does it mean?
Actionable	Can you do something about it?
Timed	Does your set cover both the short and long term?
Engaging	Does your set involve all laboratory personnel?
Balanced	Does your set cover the full cycle of events

Table 3: Quality Indicators Distributed According To Laboratory Activity Quality indicators for pre analytical laboratory activity

Erroneous request;

Error in patient identification;

Test order appropriateness;

Inadequate sample (hemolytic, lypemic, clotted etc.);

Missing sample (sample lost or not received)

Needle sticks injuries.

Quality indicators for analytical laboratory activity

External quality assurance results;

Internal quality control results;

Imprecision;

Inaccuracy

Total error.

Quality indicators for postanalytical laboratory activity

Number of tests completed, but not requested by the clinician;

Number of tests not completed

Reports with erroneous patient or physician data;

Hard copies of reports given out

Average time for critical results reporting

Number of critical results successfully reported

Reports exceeding tat (10);

Customer satisfaction (patients and clinical staff);

Number of reports corrected or withdrawn;

LIS downtime episodes;

Technical staff errors.

Table 4: Laboratory Medicine Quality Indicators by Stage of the Total Testing Process		
Stage	IOM Domains	
Test ordering		
Test order appropriateness	Effectiveness, efficiency, timeliness	
Patient identification/specimen collection		
Inpatient wristband identification error		
Patient satisfaction with phlebotomy	Safety	
	Patient-centeredness	
Specimen identification, preparation, and transport		
Specimen inadequacy/rejection Blood culture contamination	Effectiveness, efficiency, safety, timeliness	
Specimen container information error	Efficiency, safety	
Analysis		
Proficiency testing performance	Safety	
Gynecologic cytology-biopsy discrepancy	Effectiveness, efficiency, safety	
Result reporting		
Inpatient laboratory result availability	Patient-centeredness, timeliness	
Corrected laboratory reports	Efficiency, safety	
Critical values reporting	Safety, timeliness	
Turnaround time	Timeliness	
Clinician satisfaction with laboratory services	Effectiveness, timeliness	
Result interpretation and ensuing action		
Follow-up of abnormal cervical cytology results	Effectiveness, timeliness	

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Table 5: Selected Quality Measures and Guidelines for Recommended Laboratory Tests by Disease and Condition in the Agency for Healthcare Research and Quality National Quality Measures and Guideline Clearinghouses (2)

Disease/Condition	Sources
Anemia	CMS (2004)
Breast cancer	American Society of Clinical Oncology/College of American Pathologists (2007), Breast Health Global Initiative (2006), ICSI (2005)
Cardiovascular disease	American College of Cardiology (2003), American Heart Association (2003), BMA (2006), CMS (2007), European Society of Cardiology (2005), ICSI (2006), NCQA (2003), PCPI (2003), The Joint Commission (2008), USPSTF (2008), VHA (2002)
Cervical cancer	American Cancer Society (2002), CMS (2007), ICSI (2005), Kaiser Permanente Care Management Institute (2006), NCQA (2003), The Joint Commission (2008), USPSTF (2008), VHA (2002), Wisconsin Department of Health (2006)
Chlamydia infection	NCQA (2005), USPSTF (2008)
Diabetes	BMA (2006), Health Disparities Collaboratives (2006), ICSI (2005), NCQA (2003), National Diabetes Quality Improvement Alliance (2003), VHA (2002), Wisconsin Department of Health (2002)
HIV infection/AIDS	CDC (2006), New York State Department of Health (2005), USPSTF (2008)
Lead poisoning	Wisconsin Department of Health (2006)
Pneumonia	CMS (2007), The Joint Commission (2008)
Prenatal conditions	CDC (2006), PCPI (2002), USPSTF (2008), Wisconsin Department of Health (2006)
Renal disease	CMS (2005), Renal Physicians Association (2002)
Sepsis	CMS (2007), The Joint Commission (2008)
Upper respiratory infection	ICSI (2003), NCQA (2006)
Urinary tract infection I	CSI (2004)
Venous thromboembolism	ICSI (2006)

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Table 6: Quality Indicators Not Related To Laboratory Activity (7)

Indicators for the strategic processes:

· Goals reached;

- · Referred tests for;
- · Projects carried out.

Indicators for the support processes

- · Physician satisfaction;
- · Patients satisfaction;
- · Written complaints;
- · Verbal complaints;
- · Corrective maintenance of instruments;
- · Non-conformities to providers;
- · Evaluation of training (number of hours received/number of hours worked)

Financial indicators (indicators of laboratory effectiveness)

- · Efficiency (defined as the cost per test);
- · Productivity (defined as the workload per staff member);
- · Total number of working hours;
- Preventive maintenance cost;
- \cdot Number of clinical trials, number of accredited tests.

Table 7: IQLM Indicators

- Diabetes monitoring (system)
- Hyperlipidemia screening (system)
- Test Order Accuracy and Appropriateness
- Patient Identification (pre-analytic)
- Adequacy and Accuracy of Specimen Information (pre-analytic)
- Blood Culture Contamination (pre-analytic / system)
- Accuracy of point-of-care testing (analytic)
- Cervical cytology/biopsy correlation (analytic)
- Critical Values Reporting
- Turnaround time (postanalytic)
- Clinician satisfaction (system/postanalytic)
- Clinician followup (system/postanalytic)

Table 8: Developing Indicators

Objective	What are you trying to measure
Methodology	1. How to capture the data
	2. Who (or what) to capture the data
	3. How often to capture the data
Limits	Acceptable, Concern, Unacceptable Critical
Presentation	Graphic or Text
Interpretation	What does it mean?
Does it reflect on YOUR quality?	
Limitations	Unintended variables
Action Plan	What will I do if it indicates acceptable performance?
What will I do if it does not?	
Exit Plan	When can I stop measuring

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Figure 2: Plan of Operation of Quality Indicators

Current Gaps

There exist considerable gap in implementation of quality indicator due to lack of evidence base for some of the indicators; focus on patient outcomes; inadequate coverage of the total testing process (TTP). Some of them mentioned here as: many laboratory test orders are not supported by guidelines or are unnecessary duplicate tests; (Merlani *et al.*, 2001; Ozbek *et al.*, 2004) turn around time is not standard for all test at all places, the turn around time goals are set according to clinicians requirement which impose more of subjective variation; except for transfusion medicine, no direct evidence was found relating patient misidentification to any adverse impact on clinical, health, or cost outcomes; false-positive blood cultures lead not only to unnecessary repeated tests, but also to unnecessary drug use with potential harm to patients and significant downstream patient care costs; (Schifman *et al.*, 1998; Bekeris *et al.*, 2005) the lowest satisfaction scores have been related to poor communication, including timely reporting, communication of relevant information, and notification of significant abnormal results; (Zarbo *et al.*,

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2003) type of specimen collection personnel impacted specimen rejection rates; nonlaboratory personnel were 2 to 4 times more likely to be associated with rejected specimens compared with laboratory personnel; (Novis *et al.*, 2003; Renner *et al.*, 1993) patient satisfaction with phlebotomy services has not been related to any other outcomes; although PT performance has been positively correlated with performance in blind PT and with routine patient testing, there is no direct evidence that improved PT performance positively impacts actual test performance or any other outcome; (Parsons *et al.*, 2001; Reilly *et al.*, 1999; Jenny and Jackson, 1993; Keenlyside *et al.*, 1999) no studies were found relating critical values reporting to any outcomes however, critical values have been found to influence patient care (Keenlyside *et al.*, 1999).

Conclusion

Clinical laboratories play a significant role in patient safety because timely and accurate laboratory-test results are a cornerstone of effective diagnosis and treatment of patients. The use of quality indicators in the clinical laboratory to assess and monitor its quality-control systems is an extremely valuable tool for keeping the total testing process under control in a systematic and transparent way while ensuring accurate and precise laboratory-test results. The critical areas that can affect the quality of test results are the preanalytical phase (Novis and Dale, 2000; Lippi *et al.*, 2006) which comprises the patient identification, sampling, sample handling and transport to the laboratory. That extralaboratory segment has the major potential for improvement.

As previously pointed out, clearly defined and easily comparable quality indicators are needed in order to quantify defects and limitations of system segments as well as to register and continuously monitor improvements resulting from system redesign and corrective actions. With the information we read out of the quality indicators, we can analyze our own trends, conceive changes over time and rank our own position on the national and international level.

Analytical part of the diagnostic laboratory processes is highly standardized and surely presents the negligible source of the total volume of laboratory errors (Lippi *et al.*, 2008; Plebani, 2007). Majority of errors occur outside of the laboratory. Proficiency testing and interlaboratory comparison are well established for the external independent evaluation of analytical phase of laboratory processes.

For some 20 years ago, there have also been some preanalytical and postanalytical external quality assurance programs. First such programs for preanalytical external quality assurance were launched in 1989 (Q-probes) and 1998 (Q-tracks) (Novis, 2004; Zarbo *et al.*, 2002) by College of American Pathologists (CAP). Those programs refer to the issues of patient identification, sample quality and appropriateness, TAT, critical values reporting, corrected and withdrawn reports, test request errors and some other. Several years later, Spanish Society of Clinical Chemistry and Molecular Pathology has also launched a similar external quality assurance program for preanalytical phase of laboratory diagnostics (Alsina *et al.*, 2008).

External quality assurance programs for postanalytical phase have also been widely introduced and run in several countries, such as Italy (Sciavolli *et al.*, 2003; Falbo *et al.*, 2008), Australia (Lim *et al.*, 2004; Challand and Vasikaran, 2007) and United Kingdom (Hastings *et al.*, 2008).

Contemporary laboratory medicine envisions a laboratory with high quality standards, laboratory based on knowledge, competences and skills; built on the philosophy of continuous improvement. Because there are so many processes involved in laboratory testing, there is considerable challenge in identifying, defining, and, ultimately, implementing indicators that cover the various stages of the total laboratory testing process, in general and specific to different diseases and conditions, that address the IOM domains, various testing environments, and multiple relevant stakeholders.

Laboratory accreditation and implementation of the quality management system is inevitable. Such concept implies the existence of a reliable and independent external quality assurance system for all phases of laboratory processes, using evidence-based quality indicators.

Eventually, every such step forward is for the patient benefit and for the satisfaction of all users of the laboratory services.

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