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The Need for Quality for Better Laboratory Performance, Alexandria University Experience

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1. Introduction

Quality means meeting the pre-determined requirements of the users for a particular service. ⁽¹⁾ The quality of laboratory services depends upon many characteristics, such as painless acquisition of a specimen, specimen analysis, correctness of the test result, proper documentation and reporting, quick turn-around time for the test, and reasonable cost. To achieve good laboratory quality; the lab has to establish the following, qualified and experienced staff, calibrated and maintained equipment, standardized methods, adequate checking, and lastly accurate recording and reporting. ^(2,3)

Total quality management (TQM) means that every variable that could possibly affect the quality of test results has been controlled. ^(2,4) The traditional framework for TQM in a laboratory emphasizes the establishment of Quality Laboratory Processes (QLP), Quality Control (QC), and Quality Assessment (QA). Also to provide a fully developed framework of a good TQM system, Quality Improvement (QI), and Quality Planning (QP) must be established. ⁽⁵⁾ The purpose of QA in laboratory practice is the right result, at the right time, at the right specimen from the right patient, with result interpretation based on right reference data, and at the right price.

2. Quality assessment activities

2.1 Pre-analytical activities

From the moment a test is ordered, quality becomes an issue critical to the outcome. The pre-analytical phase of testing is complex and is prone to the most variation and the highest proportion of mistakes, as it is not under the full control of the laboratory and involves doctors, nurses, porters and other ancillary staff. The definition of mistake in the pre-analytical phase is "any defect during the pre-analytical phase, which results in failure of further laboratory processes". This indicates that active monitoring and feedback of all defects generated by non-laboratory personnel are essential to enable the inclusion of steps outside the laboratory, in the QA program of the laboratory. ⁽⁶⁾

Accreditation agencies require that laboratories should consider all aspects of pre-analytical variation as part of their quality assurance plans, including effective problem solving and documentation. Pre-analytic Quality assessment activities extend to the following areas ;⁽⁷⁾ Test selection and ordering, Patient preparation, Patient identification and specimen collection procedures, Specimen transport, handling, and storage. Each laboratory should

have its pre-analytical quality manual, that should be distributed to all nursing units and, therefore, be available to all medical personnel. Additionally, easy-to-understand patient handouts must be available for outpatients. ^(7, 8) Pre-analytical quality manual should include the following:⁽⁹⁾

1. Instructions to the patient in preparation for specimen collection, including fasting hours, refraining from exercises, etc.
2. Minimum sample volume needed for a laboratory test.
3. Equations to calculate sample volume for the number of tests requested for a patient.
4. Instructions for blood sample collection, order of specimen collection, and sample identification guidelines.
5. Sample processing, transportation and storage guidelines.
6. Regulations for unacceptable specimens, and how to avoid causes of rejection.
7. Guidelines for the collection of other body fluids, like 24 hours urine samples, CSF, synovial fluid, peritoneal and pleural aspirate.
8. Listing of analytes and notation on the effect of at least commonly encountered interfering factors, also drug interferences should be included.

Although the "pre-analytical quality manual" and the strict criteria for rejection of inappropriate specimens may represent useful approaches in controlling the pre-analytical variables, still laboratories need more control. Knowledge dissemination, training and education are also important key points to improve the performance. Certification of phlebotomists, including training curricula for all collection staff, preferably developed by the laboratory, is another essential part of this crucial process of standardization.

2.2 Analytical activities

Quality design in a laboratory must begin with analytical quality because it is the essential quality characteristic of any laboratory test. Although the pre-analytical and post-analytical mistakes account for 46% and 47% of the total laboratory incidents respectively; the laboratory must first be able to produce a correct test result before any other quality characteristic becomes important. For example, turnaround time is an important quality characteristic, but it doesn't matter how fast the result is reported if the result is wrong. ⁽¹⁰⁾

Management of the analytical phase involves reducing inaccuracy and imprecision of test methods as much as possible. Attention to standardize test procedures and monitor method performance with a well-designed quality control system are the key elements meeting this management goal. Analytic quality assessment procedures guide and monitor all related activities, including the following: Instrument maintenance and operation, Method selection and evaluation protocol, Documentation of analytical protocols, Test calibration, Quality control, including internal and external quality control, Reagents, Supplies and Personnel.

The analytical activities that should be monitored during laboratory assessment include the following :

2.2.1 Instrument maintenance

The director must define a program that monitors the proper calibration, function check, and preventive maintenance of instruments. A schedule of daily and monthly preventive maintenance is essential; these routinely done checks should be detailed in the procedure manual. Records of routine maintenance, unscheduled maintenance, should be kept for an

appropriate period of time, usually instrument maintenance records must be kept for the lifetime of the instrument and transferred with the instrument. ⁽¹¹⁾

2.2.2 Method selection and evaluation

Selection of a good laboratory method depends upon many characteristics;

Application characteristics: General factors that could affect method or instrument selection include; type of specimen required, sample volume, run size, turn around time (TAT), throughput, population tested, personnel skills, safety (chemical hazards), utilities (ionized water requirements, waste disposal), reagents storage and stability, opened versus closed system, capability of random access, instrument cost per year (calculated from the average life span of the instrument), cost per test, and space requirements. ^(12, 13)

Methodology and performance characteristics: These are factors that contribute to best performance, they include; calibration, sensitivity and specificity of the method, linear range of analysis, interferences, precision, and accuracy, as well as types of internal and external quality control measures applied. Both the application and performance characteristics affect method selection decisions. ⁽¹⁴⁾

After selection of the method, the laboratory should validate the performance specifications for such method. College of American Pathologists (CAP) requires the validation of all the methods used by the laboratory. ⁽¹¹⁾

The following is an approach for formulating a plan for method validation. . First, establishment of the analytical quality goal should be done. Then the lab should select the appropriate experiment to reveal the expected types of analytical errors, collect the necessary experimental data, and perform statistical calculations on the data to estimate the size of analytical error. Finally, compare the observed errors with the defined allowable error, and judge the acceptability of the observed method performance. Method validation is an error detection process, the aim of all experiments performed to verify the performance specification is to detect different types of errors; either random error (RE) or systematic error (SE).⁽¹⁴⁾

2.2.3 Calibration

Calibration is a process of testing and adjusting an instrument or test system, to establish a correlation between the measurement response and the concentration of the substance that is being measured by the test procedure. The substance used for calibration is known as calibrator.

Calibration verification; refers to 2 distinct processes: confirming that the current calibration settings remain valid for a method, and validation of the analytical measurement range (AMR). ⁽¹¹⁾

All of these processes: calibration, calibration verification, and AMR validation, are required to ensure the continued accuracy of a test method.

Calibration verification is done through assaying of materials of known concentration in the same manner as patient samples to confirm that the assay system will accurately recover the activity of the analyte over the reportable range, it must be performed at least once every six months. Materials for calibration verification must have a matrix appropriate for the clinical specimens assayed by that method, and target values appropriate for the measurement system. Materials used for calibration verification may include, but are not limited to: ⁽¹¹⁾

1. Calibrators used to calibrate the analytical measurement system.

2. Materials provided by the analytical measurement system vendor for the purpose of calibration verification.
3. Previously tested unaltered patient specimens.
4. Standards or reference materials with matrix characteristics and target values appropriate for the method.

How to perform calibration verification? ⁽¹⁵⁾

1. Prior to starting calibration verification, all routine quality control procedures should be performed at first to assure that the equipment and reagents are performing correctly.
2. A minimum of three standards must be tested, low or zero standard, mid-range standard, high standard, they should cover the range of clinical values reported using standard procedures for the test. Each standard should be tested at least three times, preferably five to six times.
3. The mean and SD for each standard are calculated, the mean for each standard must fall within the target range specified by the standard manufacturer.
4. If no target range is specified by the standard manufacturer, then the value for the standard must fall within ± 2 SD units from the lab established mean.
5. A graph of the results is drawn by plotting the expected values on the "x" axis and the observed values on the "y" axis then plotting the upper and lower range for each observation as determined by (mean ± 2 SD). Then a straight line is drawn which passes through the upper and lower ranges for each point.

Calibration is considered verified when:

1. The mean of each standard falls within the specified range of the manufacturer or within ± 2 standard deviation units of the observed mean.
2. A straight line can be constructed between the upper and lower ranges for each standard that covers the entire reportable range of the instrument or test procedure.

Successful calibration verification certifies that the calibration is still valid; unsuccessful calibration verification requires remedial action, which usually includes recalibration and AMR revalidation.

Recalibration should be performed in the following situations;

- a. A complete change of reagents that affects the range used to report patient results or QC values.
- b. When QC fails to meet established criteria, after major maintenance or service.
- c. When calibration verification data fail to meet laboratory acceptance criteria.
- d. When recommended by manufacturer and at least every six months.

2.2.4 Quality Control (QC)

Quality control may be defined as the control of the testing process to ensure that test results meet their quality requirements. QC may be practiced prospectively and provide information about the acceptability of the most recent analytical runs, or may be practiced retrospectively and provide information about past performance. Any QA program should comprise two key components: ⁽¹⁶⁾

1. Internal quality control (IQC): includes appropriate measures taken during day-to-day activities to control all possible variables that can influence the outcome of laboratory results. This is a continuous process that is operated concurrently with analysis. IQC is used in the decision to accept or reject results on patients' samples and enables the laboratory to describe and monitor the quality of its work.

2. External quality assessment scheme (EQAS): This component is necessary to ensure comparability of results among laboratories. It is carried out retrospectively and is conducted by an independent agency.

3. Internal Quality Control (IQC)

Internal Quality control means monitoring the analytical process to determine conformance to predetermined specifications, and taking any necessary corrective actions to bring the analytical process into conformance.

QC material is the daily analyzed sample with known values stated by manufacturer. This material is commercially prepared, stabilized in liquid, frozen, or lyophilized form, packaged in small bottles suitable for use on a daily basis. Ideally, control materials should have the same matrix as the specimens being tested, so that they will behave the same as the real specimen. Certain test methodologies may also influence the selection of control materials. For example, a bovine-based control material will usually give low results with a bromocresol purple albumin method, which has been optimized for human albumin. ⁽¹⁷⁾

Measuring the concentration of analytes contained in QC material usually detects any deviation from the expected performance. Results of QC material must fall within "confidence limits", ie, must be at least 95% of the values stated by manufacturer, or can be graphically represented by ± 2 SD of the mean for each value in question. Deviation of an analytical measurement from expected; could be either a shift in the mean (an accuracy problem), or an increase in the SD (a precision problem). If the result measured from the QC specimen deviates significantly as defined by QC rules, routine analysis is suspended and the analytical run is investigated, and corrective action should be taken. ⁽¹⁸⁾

The laboratory must establish the number, type and frequency of testing QC materials that monitor the analytical process. A minimum QC accepted is two levels per day rather than per run (8 hour's period). ^(30, 54)

The chance of detecting an analytical problem will depend on the size of the error occurring, the number of controls used to monitor method performance, and the sensitivity of the statistical rules being applied. In laboratories, medically important errors should be detected (Probability for error detection), and false alarms should be minimized (Probability for false rejection).

Probability for error detection (P_{ed}), describes the probability of getting a rejection signal when there is a change in the precision or accuracy of the analytical method.

Probability for false rejection (P_{fr}), describes the probability of getting a rejection signal when there is no change in method performance.

Ideally, P_{ed} should be high, near 1.00 to provide a 100% chance of detecting a medically important analytical error. And P_{fr} should be low, near 0.00 to provide a 0.0% chance of false rejections that would otherwise waste time and effort and slow the reporting of patient test results. A practical design objective is a P_{ed} of 0.90, which means there would be a 90% chance of detecting an analytical problem and P_{fr} of 0.05 or less, which means there would be only a 5% or less chance of false rejection. ⁽¹⁹⁾

Analytical errors are determined by the imprecision and inaccuracy of the method evaluated, errors are classified into;

Random error (RE) or imprecision: is the lack of reproducibility or repeatability, it occurs by chance and fluctuates about the mean. It is attributed to factors affecting the reproducibility of the measurement including; instability of the instrument, variations in

temperature, and variability in handling techniques such as pipetting, mixing and timing, variability in operators.

Systematic error (SE) or inaccuracy: it is a measure of the agreement between a measured quantity and the true value. It is subdivided into, constant and proportional errors. When the error stays the same over a range of concentrations, it is called constant systematic error, and when it changes as the concentration changes, it is called proportional systematic error. Causes of systematic errors include; poorly made calibrators or reagents due to the use of bad quality distilled water or non- calibrated pipettes; failing instrumentation (lack of frequent calibration, preventive maintenance of equipment and photometer check); improper preservation and storage of reagents and calibrators; and lastly poorly written procedures. ⁽²⁰⁾

Total error (TE): represents the overall error that may occur in a test result due to both the imprecision (random error) and inaccuracy (systematic error) of the measurement procedure ($TE = SE + RE$). The intended use of total error is to describe the maximum error that might occur in a test result obtained from a measurement procedure, if it is less than the maximum allowable error according to the CLIA, then the method over-all performance is acceptable.

4. Make it right the first time

According to Feigenbaum; Total quality control is an effective system for integrating the quality development, quality-maintenance, and quality improvement efforts of the various groups in an organization so as to enable marketing, production, and service at the most economical levels which allow for full customer satisfaction.⁽²¹⁾ In a simple word it is the state of the art of finding defects early which will be much less costly than those found later in the product life cycle i.e "Make it right the First Time".

TQM as a philosophy states that Quality is a TOP Management responsibility with Customer Satisfaction as the primary target, continuous improvement as the credo, and the way of action being based on FACTS and not opinions, while every employee must be involved. ⁽²²⁾

It was our challenge in the Alexandria University Hospital (AUH) to dream for such an ideal performance; which is nowadays a daily practice this is indeed cause and effect of a well organized Support from the top level of the organization, as our TQM involves all persons in the organization starting from the dean of the faculty of Medicine to the junior staff in the lab which conform with our internal regulatory requirements. The strategy is to concentrate on simplification and improvement of processes and organizing action around the medical laboratory service offered. Use of inter-disciplinary teams for improvement and problem solving. We are continuously benchmark ourselves; train all employees in the philosophy of TQM. ⁽²³⁾

How do we achieve excellent performance in the AUH LABORATORY?

- Ensure quality of overall process
- Detect and reduce errors
- Improve consistency within and between laboratories
- Contain costs

This is achieved through our commitment through ISO 9001 Quality Systems on the managerial level as well as the ISO 15189 Quality management in the clinical laboratory of AUH for the technical specifications and support.

The importance of achieving good organizational quality system

1. **Quality costs:** as we have a limited resources compared to the service offered which serves a large of population in our area; we had to minimize the cost. The cost of wrong or incorrect calibration test decisions can be significant. This task is well achieved by better quality practice. ⁽²⁴⁾
2. **Analytical Quality specifications or goals:** Which involves the lists of procedures for setting analytical quality specifications for laboratory methods. However, analytical goals related to biological variations have attracted considerable interest. It was suggested that the analytical SD should be less than half the intraindividual biological variation. If a subject undergoing monitoring of an analyte, the random variation from measurement to measurement consists of both analytical and biological components of variation. The total SD for the random variation during monitoring then is determined by the relation

$$A^2/T = \alpha^2 \text{ within } \beta + \alpha^2 A$$

where the biological component includes the preanalytical variation.

In addition to imprecision, goals for Bias should also be considered. The allowable bias can be related to the width of the reference interval, which is determined by the combined within and between subject biological variation in addition to the analytical variation. On the basis of considerations concerning the included percentage in a interval in the presence of analytical bias, it has been suggested that

$$\text{Bias} \leq 0.25 (\alpha^2 \text{ within } \beta + \alpha^2 \text{ between B})^{0.5} \text{ (20)}$$

Analytical quality specifications for laboratory methods includes: ⁽²⁵⁾

- I. Evaluation of the effect of analytical performance on clinical outcomes in specific settings.
- II. Evaluation of the effect of analytical performance on clinical decisions in general.
 - a. Data based on components of biological variation
 - b. Data based on analysis of Clinician's opinions
- III. Published professional recommendations:
 - a. From national and international expert bodies
 - b. from Expert local groups or individuals
- IV. Performance goals set by:
 - a. Regulatory bodies (CLIA)
 - b. Organizers of EQA schemes
- V. Goals based on the current state of the art:
 - a. Data from EQA & proficiency testing
 - b. Data from current publications on methodology
3. **Verification & Validation:** All quantitative procedures require a calibration of the tests using reference materials. The laboratory results are calculated via calibration curve. Semi quantitative procedures do not belong to this category ⁽²⁶⁾. These results are calculated by using a so called cut off calibrator leading to an index or are obtained as titter steps.
 - a. **Checking the precision and accuracy** is done by the aid of :
 - I. Control material: Control materials preferably covering the three concentration ranges are used to determine or check the precision and accuracy of the

method. The concentration of the controls should be in the lower, middle and higher range of the calibration.

The following materials are used:

- Purchased control samples with known values with references methods or with known values.
- Patient pool sera may be used.

II. Calculation :

Mean and Standard deviation are calculated by using known statistical methods ; while the Coefficient of variation (CV) and the inaccuracy (INA) are calculated by using the following formulae:

$$\% \text{ CV} = \text{SD} / \text{Mean} \times 100$$

$$\% \text{ INA} = \text{Measured value} - \text{target value} / \text{target value} \times 100$$

b. Checking the linearity or Analytical Measurement Range (AMR)

Range of values that instrument can report directly (Less accurately called linearity). Done every six month or after major maintenance as we should verify that your test results cover the span of the analyzer claimed AMR.

c. Limit of Detection (LOD) or Verification of Analytic Sensitivity Also called lower detectable range.

Done by Running 20 blanks; if <3 exceed stated blank value, accept that blank

Run 20 low patient samples near the detection limit; if at least 17 are above the blank value, the detection limit is verified

d. Validation of Reference Ranges

The laboratory must verify that the normal values in use are appropriate for patient population served

Once or when introducing new test; if at least 18 of 20 specimen falls within recommended reference range then the run is valid. If >2 falls outside the ranges then select a new 20 samples. If greater than five specimens' falls outside the recommended ranges, the QC ranges must be corrected according to the in house mean not the manufacturer claim ones.

4. Quality Assurance / Management

Alexandria University Hospitals serve a huge community that consists not only of inhabitants of Alexandria, but the hospitals are a referral center for the northern part of Egypt and the surrounding northern coastal regions. The laboratories are located on three campuses and include the various specialties of laboratory medicine; clinical chemistry, hematology, immunology and molecular diagnostics. Most tests are performed on automated machines throughout the day. Over 80,000 routine clinical chemistry tests are performed every month and a slightly lower number of hematological tests including complete blood picture and coagulation studies are performed. Laboratory staff includes faculty staff members, interns and laboratory technologists. Being the largest reference laboratory in the north of Egypt, we felt the urge and the responsibility towards our patients to provide them with the best laboratory services possible. ⁽²⁷⁾

5. Challenges

The major challenge to introducing a quality system was, and still is, financing. The hospitals' services, both diagnostic and therapeutic, are mostly free of charge. Only a few

highly specialized tests are paid for and even these are priced at a very low level that barely covers the actual cost per test. We could not increase the prices because most of our patients come from a financially disadvantaged sector of the society. Funding is mainly provided through the annual budget of Alexandria University. The tight budget means that spending areas must be prioritized and any new introductions to the existing system of laboratory management must be carefully assessed as regards the cost.

Spreading a “culture of quality” was one of the top priorities. Educating personnel and changing their attitude was one of the toughest jobs on hand. All levels of employees needed this type of education. Besides day-to-day work and collaboration, an annual workshop was organized since 2005 on laboratory management and quality assurance. These workshops focused on the introduction of the concepts of total quality management, quality assurance, laboratory safety and benchmarking among other topics. The official language of these workshops was English because medicine is taught in that language in Egypt. However, most laboratory technologists do not master the language very well, most of them are not university graduates but hold a 2-year degree from a polytechnic institute. All technologists were encouraged to attend the workshops but in addition, satellite workshops were held in Arabic for them where they attended in smaller groups and had a better chance for group discussions. Besides continuous education, annual and periodic appraisals were also effective in motivating all staff members of the laboratory to embrace the new culture.

Other challenges included a dilapidated infrastructure, lack of a laboratory information system, a very disorganized documentation system among many others.

6. Overcoming financial obstacles

Total quality management requires a considerable flow of money to ensure proper documentation, proper implementation of internal quality control and external quality assessment programs, adherence to laboratory safety procedures, not to mention the huge task of renovating the infrastructure of the laboratories.

1. Internal quality control:

Due to the high cost of quality control material, two levels of quality control were run once per day instead of with every run. This was done only in the clinical chemistry unit in the 3 hospitals. In the hematology and immunology units, no quality control material was purchased due to the very high cost. These units depend on regular inter-laboratory comparisons. They also perform the same tests on randomly chosen samples in different shifts to assess the intra-run variations. Plans are underway to introduce a proper internal quality control system in the hematology unit by the end of 2010.

2. External quality assessment:

Alexandria University laboratories started to participate in the bi-weekly external quality assessment scheme (EQAS) for clinical chemistry by BioRad since November 2006. In order to compare our lab results with the correct peer group, it was essential to provide Bio-Rad with accurate information on the methods we are currently using. Upon enrollment into the program, a Method Questionnaire was completed using the appropriate Method Classification Guide, and returned back to Bio-Rad. Every 6 months a set of 12 numbered lyophilized serum specimens were delivered to our laboratories. Every 2 weeks, the appropriate sample was reconstituted following the manufacturer's instructions and assayed for 22 different biochemical analytes. Results were emailed to Bio-Rad. Within 3

working days of each Results Receipt Date, a user-specific statistical report was sent to our lab. These reports provide statistical analyses that include specific peer group and overall comparisons. In the report, each laboratory is provided with a numerical indicator of its competence, a performance index or score, together with information on the performance of the group as a whole, enabling its proficiency relative to the group to be compared and evaluated by means of three measures. The following data were included in the report:

- Mean of Comparator: This is the mean value of the category, either 'method', 'group' (assay technology) or 'mode' (collection of methods giving similar results) against which my own result was compared for the determination of the value plotted on the Levy-Jennings chart.
- Accuracy or Z scores: The 'Accuracy Score's a measure of the percentage difference of our result from the selected 'Comparator', converted into an integer of '0' up to '10', with '0' being minimal deviation.
- Standard Deviation index (SDI) this is the number of standard deviations my result differed from the selected 'Comparator'. $\text{Group Mean-Lab Result SDI} = \text{Group SD}$
- A comprehensive end of cycle report was also sent to the lab.

In 2009, owing to the global financial crisis, we felt the economic strain that the bi-weekly program was exerting on our financial resources. Consequently, we shifted to a less expensive monthly EQAS program.

External quality assurance for hematological tests was done through periodic inter-laboratory comparisons.

Other measures to ensure quality assurance included appointing a quality officer in each unit whose job was mainly to evaluate accuracy and precision of automated system periodically (photometer check, pumps and pipettes i.e. ABS) and to check the daily performance with QC materials. Standard operating procedures (SOPs) were written for all lab procedures in an easy to understand language and kept in easily accessible places in each lab. All personnel received training in lab safety procedures. A lab information system (LIS) was installed in 2009 and is now operational. Transcriptional errors have been considerably reduced. A hospital information system is expected to operate in 2011.

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The rich palette of topics set out in this book provides a sufficiently broad overview of the developments in the field of quality control. By providing detailed information on various aspects of quality control, this book can serve as a basis for starting interdisciplinary cooperation, which has increasingly become an integral part of scientific and applied research.

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