QUALITY MANAGEMENT

The principles of quality management, assurance, and control have become the foundation by which clinical laboratories are managed and operated.

FUNDAMENTALS OF TOTAL QUALITY MANAGEMENT

Public and private pressures to contain healthcare costs are accompanied by pressures to improve quality. Seemingly contradictory pressures for both cost reduction and quality improvement (QI) require that healthcare organizations adopt new systems for managing quality. When faced with these same pressures, other industries implemented *total quality management*, or TQM.

TQM may also be referred to as (1) total quality control (QC), (2) total quality leadership, (3) continuous quality improvement, (4) quality management science, or, more generally, (5) industrial quality management. TQM provides both a management *philosophy* for organizational development and a management *process* for improving the quality of all aspects of work.

Fundamental Concepts

quality is defined as conformance with the requirements of users or customers. More directly, *quality* refers to satisfaction of the needs and expectations of users or customers. The focus on users and customers is important, particularly in service industries such as healthcare.

Fundamental Principles

Quality improvement occurs when problems are eliminated permanently. Industrial experience has shown that 85% of all problems are process problems that are solvable only by managers; the remaining 15% are problems that require the action and improvement in performance of individual workers.

This emphasis on processes leads to a new view of the organization as a system of processes (Figure 8-2). For example, physicians might view a healthcare organization as a provider of processes for patient examination (A), patient testing (B), patient diagnosis (C), and patient treatment (D).

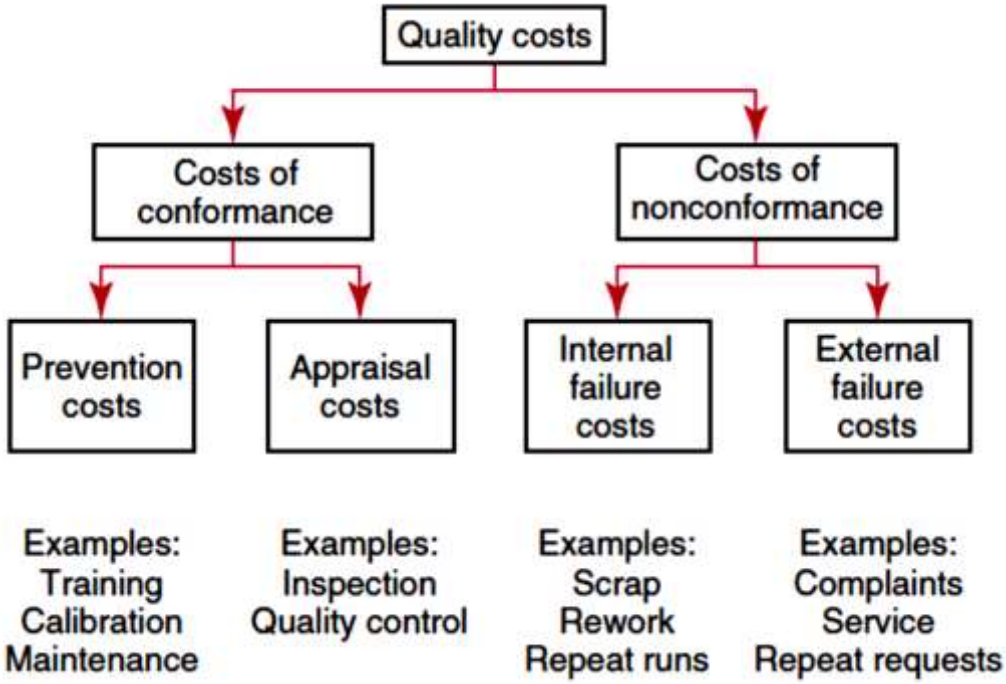

Figure 8-1 The cost of quality in terms of the costs of conformance and the costs of nonconformance with customer requirements.

The importance of empowerment is easily understood if a problem involves processes from two different departments. For example, if a problem occurs that involves the link between process A and process B in Figure 8-2, the traditional management structure requires that the problem be passed up from the line workers to a section manager or supervisor, a department director, and an organization administrator.

The administrator then works back through an equal number of intermediaries in the other department. Direct involvement of line workers and their managers should provide more immediate resolution of the problem.

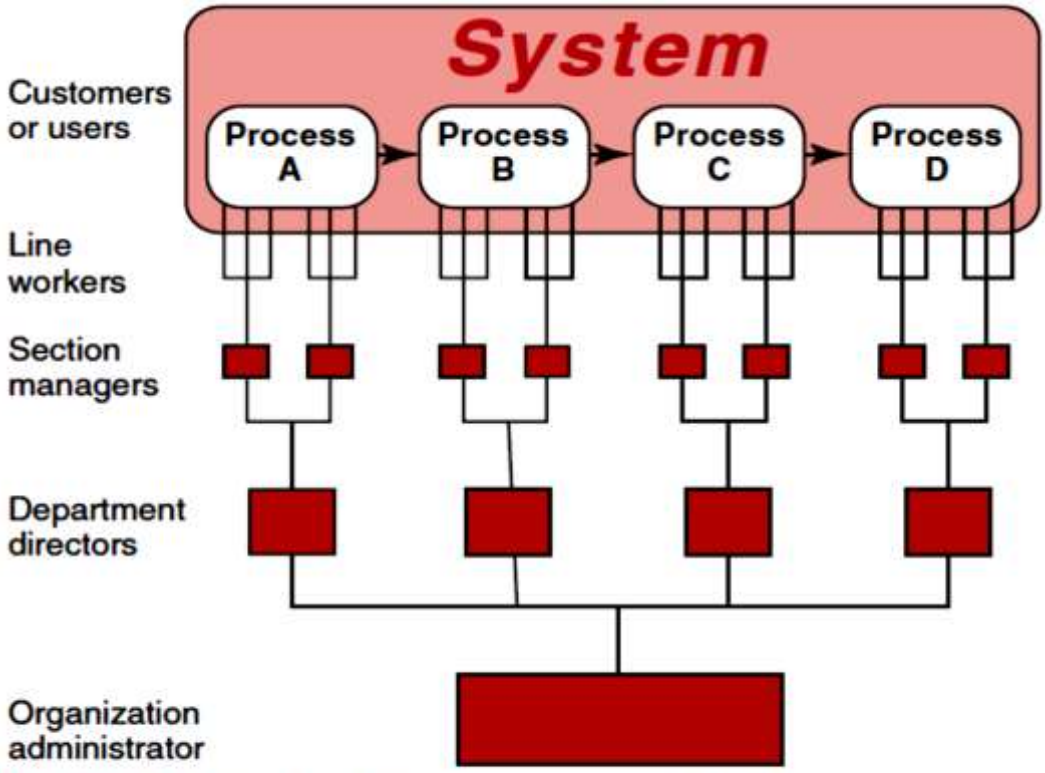

Figure 8-2 Total quality management (TQM) view of an organization as a system of processes.

TOTAL QUALITY MANAGEMENT OF THE CLINICAL LABORATORY

The principles and concepts of TQM have been formalized into a quality management process (Figure 8-3). QA, as currently applied, is primarily concerned with broader measures and monitors of laboratory performance, such as (1) turnaround time, (2) specimen identification, (3) patient identification, and (4) test utility. Quality "assessment" is the proper name for these activities rather than quality "assurance."

Measuring performance does not by itself improve performance and often does not detect problems in time to prevent negative outcomes. Quality assurance requires that causes of problems be identified through QI and eliminated through quality planning (QP), or that QC be able to detect problems early enough to prevent their consequences.

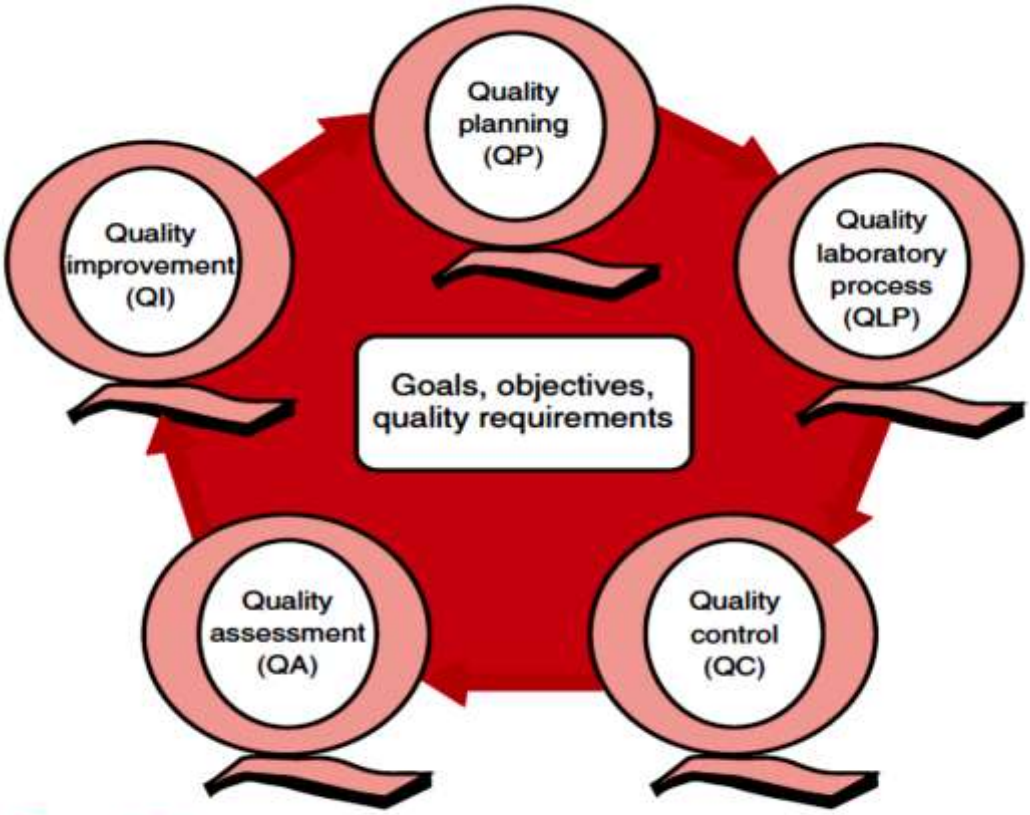

Figure 8-3 Total quality management (TQM) framework for managing quality in a healthcare laboratory. *(From*

LABORATORY ERROR AND THE SIX SIGMA PROCESS

The magnitude of laboratory errors and the use of the Six Sigma process in controlling them are discussed in the following sections.

Number of Errors Made in the Clinical Laboratory

A study of 363 incidents captured by a laboratory's quality assurance program in a hospital enumerated the sources and impact of errors. Incidents included those in which:

(1) physicians orders for laboratory tests were missed or incorrectly Interpreted.

(2) patients were not properly prepared for testing or were incorrectly identified.

(3) specimens were collected in the wrong containers or were mislabeled or mishandled.

(4) the analysis was incorrect.

(5) data were entered improperly.

(6) results were delayed, not available, or incomplete, or they conflicted with clinical expectations.

ELEMENTS OF A QUALITY ASSURANCE PROGRAM

Attainment of quality goals in a clinical laboratory requires a comprehensive quality assurance program. *Quality assurance* is used here to represent practices that are generally recommended for ensuring that desired quality goals are achieved. It is a broad spectrum of plans, policies, and procedures that together provide an administrative structure for a laboratory's efforts to achieve quality goals.

The term *quality control* is often used to represent those techniques and procedures that monitor performance parameters. Generally, these are quantitative techniques that monitor particular sources of errors, estimate the magnitude of the errors, and alert laboratory personnel when indications suggest that quality has deteriorated. A quality assurance program involves virtually everything and everybody in the clinical laboratory.

An error in any one step during the (1) acquisition, (2) processing, (3) analysis of a specimen, and (4) reporting of a laboratory test result affects the quality of the analysis and causes the laboratory to fall short of its quality goals.

Facilities and Resources

Laboratories must have the administrative support necessary to provide the quality of services desired. This means having (1) adequate space, (2) equipment, (3) materials, (4) supplies, (5) staffing, (6) supervision, and (7) budgetary resources.

These resources provide the basis upon which quality services are developed and maintained.

Technical Procedures

Technical procedures necessary for laboratory services include the following:

1. Control of preanalytical conditions or variables, such as test requests, patient preparation, patient identification, specimen acquisition, specimen transport, specimen processing, specimen distribution, preparation of work lists and logs, and maintenance of records.
2. Control of analytical variables, which include analytical methods, standardization and calibration procedures, documentation of analytical protocols and procedures, and monitoring of critical equipment and materials.
3. Monitoring of analytical quality through the use of statistical methods and control charts.
4. Control of postanalytical conditions or variables.

CONTROL OF PREANALYTICAL VARIABLES

Systems Analysis

The operation of the clinical laboratory consists of a series of processes, each of which has potential sources of error. Table 8-1 shows the processes that take place from the time of the physician's initial request for a test to the time of final interpretation of the test result.

This *systems analysis* identifies the critical processes for a typical laboratory; however, each laboratory situation is somewhat different, and additional processes and additional sources of error may be identified. It is important for each laboratory to perform a systems analysis of its own laboratory testing system to identify those areas where errors are likely to occur.

TABLE 8-1 Laboratory Testing Processes and Their Potential Errors

Process	Potential Errors
Test ordering	Inappropriate test
	Handwriting not legible
	Wrong patient identification
	Special requirements not specified
	Cost or delayed order
Specimen acquisition	Incorrect tube or container
	Incorrect patient identification
	Inadequate volume
	Invalid specimen (e.g., hemolyzed, too dilute)
	Collected at wrong time
	Improper transport conditions
Analytical measurement	Instrument not calibrated correctly
	Specimen mixup
	Incorrect volume of specimen
	Interfering substance present
	Instrument precision problem
Test reporting	Wrong patient identification
	Report not posted in chart
	Report not legible
	Report delayed
	Transcription error
Test interpretation	Interfering substances not recognized
	Specificity of test not understood
	Precision limitations not recognized
	Analytical sensitivity not appropriate
	Previous values not available for comparison

Types of Preanalytical Variables

It is difficult to establish effective methods for monitoring and controlling preanalytical variables because many of these variables are outside of traditional laboratory areas. Monitoring of preanalytical variables requires the coordinated effort of many individuals and hospital departments, each of which must recognize the importance of these efforts in maintaining a high quality of service.

Patient Identification

Correct identification of patients and specimens is a major concern for laboratories. The highest frequency of error occurs with the use of handwritten labels and request forms.

One method for checking identification is to compare identifiers such as the patient's name and his or her unique hospital number. The identification on the specimen label should also correspond with the identification supplied with the test requisition.

Turnaround Time

Delayed and lost test requisitions, specimens, and reports have been major problems for laboratories. An essential feature in monitoring the cause of delays is the recording of actual times of specimen collection, receipt in the laboratory, and reporting of test results.

This has been done manually by placing time stamps in key locations such as blood-drawing centers, specimen-processing stations, result-reporting areas, and wards or chart-posting areas. It also has been done more effectively by programming computer systems to automatically

document the times of test requests, specimen acquisition, processing, analysis, and reporting.

Turnaround time has been monitored like any other QC variable, and limits established to flag "out-of-range" specimens. Lists of delayed specimens also provide a powerful mechanism for detecting lost specimens or reports.

Resolution of problems in this area is aided by a systems analysis of laboratory operations, which helps to identify those steps and areas that cause delays and disruptions in service. A good system for monitoring patient, specimen, and information flow may be obtained through integration of the light wand and/or bar code or optical character identification system with a computer that could automatically track each specimen at each of the steps from test request to result posting.

Transcription Errors

In laboratories where electronic identification and tracking have not been implemented, a substantial risk of transcription error exists is associated with manual entry of data, even with double checking of results.

Patient Preparation

Laboratory tests are affected by many factors such as recent intake of food, alcohol, or drugs, and by smoking, exercise, stress, sleep, posture during specimen collection, and other variables.

Specimen Collection

The techniques used to acquire a specimen affect many laboratory Tests. For example, prolonged tourniquet application causes local anoxia to

cells and excessive venous back pressure. The anoxia causes small solutes (such as potassium) to leak from cells, and the venous pressure concentrates cells, proteins, and substances bound to proteins (such as calcium).

Specimen Transport

The stability of specimens during transport from the patient to the laboratory is seldom monitored; however, this aspect may be critical for some tests when performed locally and for most tests when sent to regional centers and commercial laboratories.

Documentation

When the serum aliquot tubes arrive in the laboratory, various logging and monitoring systems are necessary. In laboratories without computerized reporting, a request and/or report form generally accompanies the specimens. The specimen should be inspected to confirm adequacy of volume and freedom from problems that would interfere with the assay, such as lipemia or hemolysis.

Specimen Separation and Aliquoting

Separating and aliquoting blood specimens are directly under the control of the laboratory. The main variables are the centrifuges, the containers used, and the personnel.

Centrifuge Performance

For QC purposes, centrifuges should be monitored by checking the speed, timer, and temperature.

Container Monitoring

Evaporation can substantially alter test results; therefore all containers should be sealed or the surface area of the liquids contained in them protected. Collection tubes, pipettes, stoppers, and aliquot tubes are sources of calcium and trace metal contamination. Also, glass beads and other materials added to blood specimens to aid in the separation of serum from cells may cause contamination.

Clerical Errors

An elegant system for monitoring manual clerical functions was developed to detect errors in blood banking records. In this system, known errors are discretely introduced into the system using fictitious patients. The types of errors introduced are chosen to represent errors likely to occur or errors that cause major problems.

CONTROL OF ANALYTICAL VARIABLES

Reliable analytical methods are obtained by a careful process of selection, evaluation, implementation, maintenance, and control.

Certain variables: water quality, calibration of analytical balances, calibration of volumetric glassware and pipettes, stability of electrical power, and the temperature of heating baths, refrigerators, freezers, and centrifuges—should be monitored on a laboratory-wide basis because they will affect many of the methods used in the laboratory.

In addition, certain variables will relate more directly to individual analytical methods, and these require that procedures be developed to deal specifically with the characteristics of those methods.

- **Choice of Analytical Method**
- **Reference Materials and Methods**

Role of International Organization for Standardization (ISO)

ISO is a worldwide federation of national standards bodies from more than 150 countries (http://www.iso.ch) accessed March 22, 2011. The work of the ISO results in international agreements, which are published as international standards.

CONTROL OF ANALYTICAL QUALITY USING STABLE CONTROL MATERIALS AND CONTROL CHARTS

In the routine operation of clinical laboratories worldwide, the performance of analytical methods is routinely monitored by analyzing specimens whose concentrations or activities are known, followed by comparing observed values with known values.

Known values are usually represented by an interval of acceptable values, or upper and lower limits for control (control limits). When observed values fall within the control limits, the analyst is assured that the analytical method is functioning properly. When observed values fall outside the control limits, the analyst should be alerted to the possibility of problems in the analytical determination.

Control Materials

Specimens that are analyzed for QC purposes are called *control materials*. They are required to be (1) stable, (2) available in aliquots or vials, and (3) amenable to analysis periodically over a long time.

Little vial-to-vial variation should occur, so that differences between repeated measurements are attributed to the analytical method alone. The control material preferably should have the same matrix as the test specimens of interest.

General Principles of Control Charts

The most common method of comparing the values observed for control materials with their known values is the use of control charts. Control charts are simple graphical displays in which the observed values are plotted versus the time when the observations were made.

The known values are represented by an acceptable range of values, as indicated on the chart by lines for upper and lower control limits.

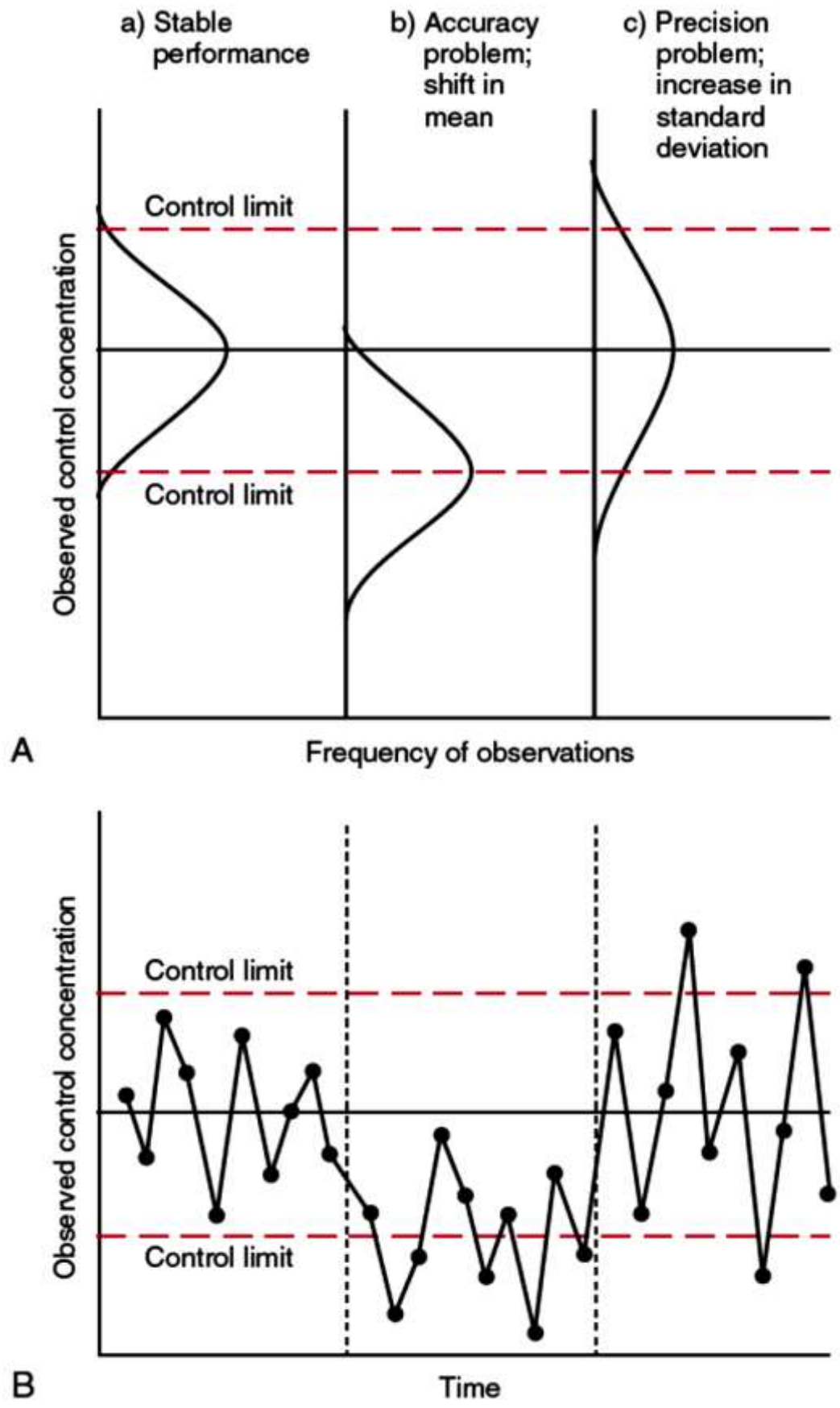

Figure 8-9 Conceptual basis of control charts.

EXTERNAL QUALITY ASSESSMENT AND PROFICIENCY TESTING PROGRAMS

All of the control procedures described earlier in the chapter have focused on monitoring a single laboratory. These procedures constitute what is called *internal quality control* to distinguish them from procedures used to compare the performance of different laboratories, the latter being known as *external quality assessment.*

The two are complementary activities, internal QC being necessary for the daily monitoring of the precision and accuracy of the analytical method, and external quality assessment being important for maintaining long-term accuracy of the analytical methods.

Quality Assurance in the biochemistry laboratory is intended to ensure the reliability of the laboratory tests. The objective of quality assurance is to achieve reliable test results by

- Accuracy
- Precision

Accuracy

This refers to the closeness of the estimated value to that considered to be true. Accuracy can, as a rule, be checked only by the use of reference materials which have been assayed by reference methods.

Precision

This refers to the responsibility of the result, but a test can be precise without being accurate. Precision can be controlled by replicate tests and by repeated tests on previously measured specimens. And the test result or value which we get should be closer to the previous one.

DIAGNOSTIC ACCURACY OF TESTS

The extent of agreement of test results with accurate patient diagnosis is represented in several ways, including (1) sensitivity and specificity, (2) predictive values, (3) receiver operating characteristic (ROC) curves, and (4) likelihood ratios.

Sensitivity and Specificity

The *sensitivity* of a test reflects the fraction of those with a specified disease that the test correctly predicts. The *specificity* is the fraction of those without the disease that the test correctly predicts. Table 3-1 shows the classification of unaffected and diseased individuals by test result. *True positives (TP)* are those diseased individuals who are correctly classified by the test. *False positives (FP)* are nondiseased individuals misclassified by the test. *False negatives (FN)* are those diseased patients misclassified by the test. *True negatives* (*TN)* are nondiseased patients correctly classified by the test.

$$\text{Sensitivity} = \frac{TP}{TP + FN}$$

$$\text{Specificity} = \frac{TN}{TN + FP}$$

Both high sensitivity (few FN) and high specificity (few FP) are desirable characteristics for a test, but one is typically preferred over the other, depending on the clinical situation. By design, some tests have only positive or negative results and provide qualitative results. These tests, which are termed *dichotomous*, have a single sensitivity and specificity pair for a designated assay cutoff. If a cutoff value is selected to produce high sensitivity, the specificity often will be compromised. Likewise, cutoffs that maximize specificity lower sensitivity.

An example of a dichotomous test is the human immunodeficiency virus (HIV) screening test. This test detects HIV antibodies, producing results that may be nonreactive (negative) or reactive (positive). False positives occur owing to technical errors such as mislabeling or contamination and the presence of cross-reacting antibodies found in individuals such as multiparous women and multiply transfused patients.28 False negatives occur because of technical errors such as mispipetting and sampling determinants such as testing in early infection (3 to 4 weeks) prior to antibody production. Reported sensitivities and specificities for the HIV screening test vary widely,16 but reasonable estimates are 96% and 99.8%, respectively. Thus, 4 of 100 HIV-infected subjects will test negative. Only 2 of 1000 noninfected subjects will test positive.

As opposed to dichotomous tests, *continuous* tests are those that produce quantitative results. Continuous tests have an infinite number of sensitivity and specificity pairs, as the cutoff varies from lowest to highest decision value.

Figure 3-1 is a dot plot of the performance of a continuous assay for prostatic-specific antigen (PSA) in patients with benign prostatic hyperplasia (BPH) and in those with established carcinoma of the prostate (stages A through D).8 Often continuous tests are used in a dichotomous fashion by choosing one or more decision cutoffs. Note the two dashed lines crossing the graphs that represent two diagnostic cutoffs.

Both tests A and B are PSA tests, but they have different decision cutoffs, namely, 4 μg/L and 10 μg/L. When test A is compared with test B, the decision cutoff of 4 μg/L for test A produces increased sensitivity but at

the cost of a decrease in specificity. Thus increased true-positive detection has been traded for an increase in the number of false-positive results.

This tradeoff occurs in every test performed in medicine. Not only does it affect the interpretation of quantitative laboratory results, it also affects the opinions of surgical pathologists and radiologists and of the care provider who performs a physical examination.

TABLE 3-1 Classifications of a Test Result Applied to Unaffected and Diseased Populations

	No. of Patients With Positive Test Result	No. of Patients With Negative Test Result
No. of patients with disease	TP	FN
No. of patients without disease	FP	TN

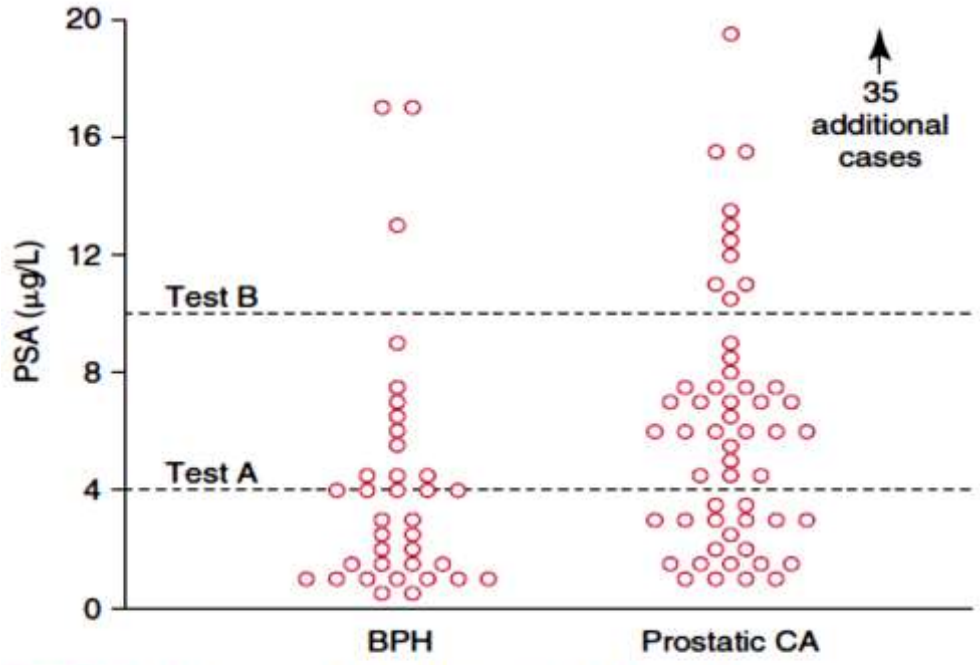

Figure 3-1 Prostate-specific antigen (PSA) concentrations for patients with benign prostatic hyperplasia (BPH) and known prostatic carcinoma (CA) are shown with two decision-level cutoffs.

Figure 3-2 illustrates a hypothetical test that shows higher results in patients who have a disease compared with those who are unaffected. As the decision cutoff is increased, FP decrease and FN increase. At extremely low and extremely high cutoffs, sensitivity and specificity are 100%.

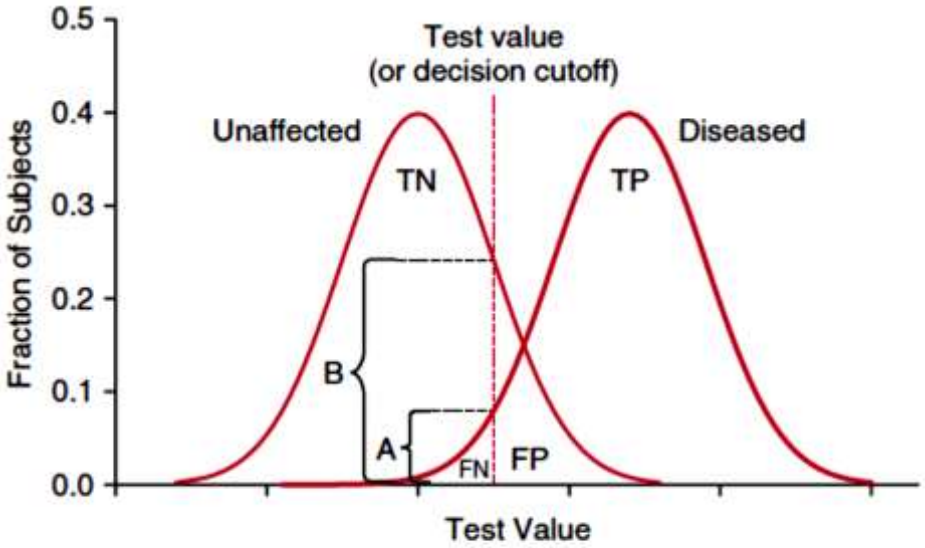

Figure 3-2 Simulated distributions of unaffected and diseased populations. Note that the ratio of diseased patients to healthy patients, A to B, is less than 1 and is very different at the point of decision (the likelihood ratio) from the ratio of TP to FP, which is much greater than 1. *FN*, False negatives; *FP*, false positives; *TN*, true negatives; *TP*, true positives.