PART 1

General Quality Program

1 General quality planning in the hemostasis laboratory

John D. Olson[1,2]
[1]Department of Pathology, University of Texas Health Science Center, San Antonio, TX, USA
[2]University Health System, San Antonio, TX, USA

Introduction

Quality:
Invisible when it is good.
Impossible to ignore when it is bad.

"So," you might ask, "What is quality, anyway?" The word quality repeatedly infiltrates our discussions and interactions as we work to produce or choose a product. The *Oxford English Dictionary* devotes more than 3000 words in its effort to define the many variations on the use of this word [1]. We may all have difficulty with a definition, but we do know what we mean. The customer of the product or service defines many aspects of its quality while those who are producing define many others. Stated in its simplest terms, quality is the condition or state of a person, thing, or process.

The principles

As early as the middle of the 1400s, boat makers in Venice, Italy, introduced the principle of "mass production" with the manufacture of boats in the sequential assembly of preproduced parts. This assembly line process was refined in the modern sense by Henry Ford between 1900 and 1910. The scientific elements of quality management systems began in the 1930s with the publication of Shewhart in 1931 [2], providing a scientific and statistical basis for quality processes. He stated:

> A phenomenon will be said to be controlled when, through the use of past experience, we can predict, at least within limits, how the phenomenon may be expected to vary in the future. Here it is understood that prediction means that we can state, at least approximately, the probability that the observed phenomenon will fall within given limits. [1]

The evolution of quality management systems was influenced by experiences in World War II. During the war, individuals involved in the production of reliable products for the consumer (soldier) to effectively do their job tied the entire system from raw material to the use of the finished product in a unique "team" from start to finish. Few circumstances can link the person in production so directly to the importance of the outcome. The success of the soldier was tied to the long-term well-being of the person making the tools used by that soldier. This ability to build the tight kinship and team performance on the part of people in production to the quality of the product is the goal of quality programs in all sectors of the economy today. It is, of course, very difficult to achieve this attitude in the workplace in the same way that it could be when the outcome could so directly benefit the producers.

Following World War II, the effort of reconstruction of the industry and economy of the affected countries became a major international effort and

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Table 1.1 Comparison of Deming and traditional management principles

Common company practices	"Deming" company practices
Quality is expensive.	Quality leads to lower costs.
Inspection is the key to quality.	Inspection is too late. If workers can produce defect-free goods, eliminate inspections.
Quality control experts and inspectors can ensure quality.	Quality is made in the boardroom.
Defects are caused by workers.	Most defects are caused by the system.
The manufacturing process can be optimized by outside experts with little or no change in the system afterward.	Process is never optimized; it can always be improved.
Little or no input from workers.	Elimination of all work standards and quotas is necessary. Fear leads to disaster.
Use of work standards, quotas, and goals can help productivity.	People should be made to feel secure in their jobs.
Fear and reward are proper ways to motivate.	Most variation is caused by the system.
Employees can be treated like commodities, buying more when needed and laying off when needing less.	Buy from vendors committed to quality and work with suppliers.
Rewarding the best performers and punishing the worst will lead to greater productivity and creativity.	Invest time and knowledge to help suppliers improve quality and costs. Develop long-term relationships with suppliers.
Buy one supplier off against another and switch suppliers based only on price.	Profits are generated by loyal customers.
Profits are made by keeping revenue high and costs down.	

Source: From Reference 6.

influenced the evolution of quality programs. The work of Deming [3] and Juran [4, 5], both associates of Shewart, extended his work. In 1951, Juran published a seminal book [4] that proposed the key elements for managing quality: quality planning, quality control (QC), and quality improvement. Following World War II, Deming presented a significant departure from the "standard" thinking about quality. He proposed a modification to the real relationships of quality, costs, productivity, and profit. The different approach to quality espoused by Deming is compared to the "standard" thinking in Table 1.1 [6]. Thus, anything that improves the product or service in the eyes of the customer defines the goals of the quality program.

Organizations that follow Deming principles find that good quality is hard to define, but the lack of quality is easily identified. In the "standard" management of a system, the workers ultimately pay for management failure because labor costs are reduced when profits fall. In contrast, moving quality programs as close to the worker as possible will ultimately lead to lower cost and improved consumer and worker satisfaction.

The clinical laboratory has three "consumers" of their product: (1) the patient who benefits from the best possible quality of care; (2) the ordering clinician who depends upon the right test, at the right time with an accurate result in order to make a clinical decision; (3) the hospital, clinic, or other entity that depends upon the laboratory for a positive margin when comparing cost with revenue. All three consumers benefit when the quality program drives the best possible practice.

Elements of quality in the hemostasis laboratory

When a clinician orders a laboratory test, he/she sets in motion a complex process that involves many individuals. More than two dozen individual actions, involvement of sophisticated instruments, and multiple interfaces of computing devices encompass the

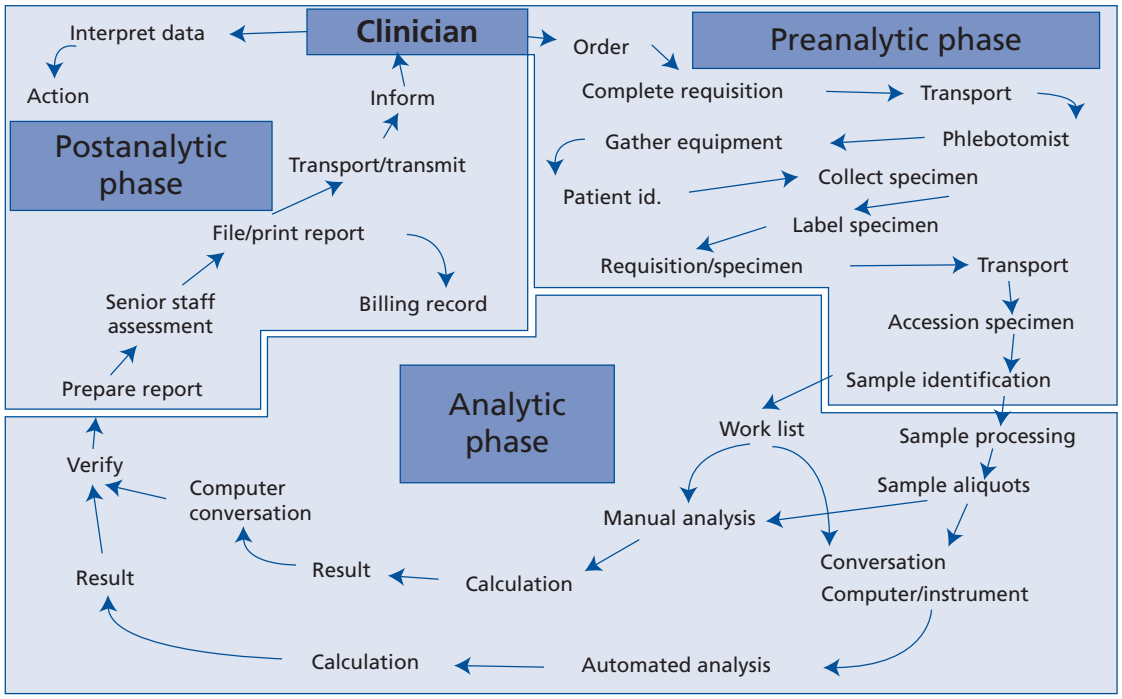

Figure 1.1 The laboratory cycle: depicted are the steps needed to complete a laboratory test, beginning with the ordering clinician and ending with the response of the ordering clinician to the result. Preanalytic, analytic, and postanalytic parts of the process are indicated. More than two dozen steps (arrows) are involved, each of which may be the source of an error. Monitoring all steps by a quality program is required.

three phases: the preanalytic phase (order, collection, and transport); the analytic phase (making the correct measurement); the postanalytic phase (formulating and delivering the data and the action of the clinician in response to the result). Figure 1.1 is a graphic depiction of the laboratory cycle. Examining the figure, one might think that each arrow represents an opportunity for error that could affect the final result. A quality program must encompass all of these events including processes to prevent and detect errors, should they occur.

The tools

Many different quality practices/programs have evolved in the decades since the early work of Shewhart, Juran, and Deming. They all have their acronyms (i.e., TQM, CQI, ISO, IOP, ORYX, SIX SIGMA, Lean, TOC, and others) and a common goal of improving the quality of the performance (and product) of an organization. The discussion of all these individual programs is beyond the scope of this chapter, but many of the principles are addressed below and in other chapters of this book. All programs have great strength, but they also suffer from being proscriptive, an issue that will be discussed later in this chapter.

Currently, *Six Sigma* and *Lean* are programs that are in use in laboratories and merit some description.

Six Sigma

Many industries and some laboratories have adopted control processes that focus on quantifying and reducing errors called *Six Sigma*® [7]. *Six Sigma* was developed by an engineer (Bill Smith) at the Motorola Company and the company began using the program in the mid-1980s. *Six Sigma* is a registered trademark of the Motorola Corporation. Application of the process has become very popular among companies internationally. *Six Sigma* processes can be applied to

Table 1.2 Six Sigma metrics

Measure outcomes	Measure variation
Inspect outcomes and count defects	Measure variation of a process (SD)
Calculate defects per million	Calculate Sigma process capability
Convert DPM to Sigma metric	Determine QC design metric

Source: From Reference 7.

discrete events (mislabeled specimens, clerical errors, etc.) and to variable events (i.e., variance of a method like the fibrinogen assay). Elements of these activities are depicted in Table 1.2. Discrete elements are expressed in defects per million events (DPM). Achieving the Six Sigma goal means that defects are less than 1:1,000,000, a level achieved in the airline industry. Errors in the healthcare industry are much more frequent with errors causing injury to hospitalized patients at 10,000 DPM (3.8σ), errors in therapeutic drug monitoring 244,000 DPM (2.2σ), or errors of laboratory reporting much better at 447 DPM (4.8σ) [8]. Other aspects of the laboratory activity rely on analysis of the variability of data. This variability can be measured at several levels. The greatest variability is seen in External Quality Assessment (EQA) data regarding the all method variance, referred to as the National Total Quality (NTQ). EQA programs also report data for an analyte comparing many laboratories using the same method, referred to the National Method Quality (NMQ). NMQ is frequently significantly better because variability is only among laboratories using the same methods, but not among methods. The lowest variability is seen with a single method in a single laboratory, referred to as the Local Method Quality (LMQ) [9]. Greater variability occurs with method-specific interlaboratory testing with the greatest variability being observed when all methods are compared. Thus, the degree of variability is best controlled at the local level.

Examples of this degree of variability are shown for prothrombin time, international normalized ratio (INR), and fibrinogen assay in Table 1.3 [9]. The data in Table 1.3 are very specifically based on the data from the 2004 EQA data of the College of American Pathologists, as reported by Westgard [9]. Should a number of different EQA data sets be analyzed, there would be a range of sigma statistics of a similar magnitude. The low sigma values shown mean that adequate control will demand more rigorous attention to control procedures, often necessitating multiple control rules. Common goals in industry are to strive for 6σ processes and to accept 3σ. At 3σ or below, effective error detection could not be achieved, even with as many as six QC rules. There is much progress yet to be made in the quality of many coagulation procedures.

Table 1.3 Sigma metrics for common coagulation tests

		Sigma metric		
Test	TEA (%)	NTQ	NMQ	LMQ
Prothrombin time	15	na	1.77	5.35
INR	20	na	2.39	3.52
Fibrinogen assay	20	1.78	2.01	3.24

TEA, total acceptable error; NTQ, national total quality (all methods); NMQ, national method quality (within method); LMQ, local method quality (single laboratory); na, not available.

Source: From Reference 9.

Lean

Concepts of *Lean* appear to have originated with Henry Ford and his assembly line production. He actually sent engineers to the automobile junkyard to examine automobiles that could no longer function. Two types of information were gathered: first, to determine which parts failed, leading to the failure of the automobile, information used to develop improved parts in order to increase the usable life of the automobile; second, to determine those parts that were not worn out at all (or minimally), information used to examine whether alternative parts of lower cost could suffice. In the latter case, the motive is to provide sufficient performance of the part at the lowest cost to the customer. Representatives of the Toyota Motor Company visited Ford in the early 1930s. They applied and refined the principles, developing the Toyota Production System, later to be known as *Lean* [10]. *Lean* is a business management system designed to improve productivity and quality by elimination of

waste. Goals are customer satisfaction; employee satisfaction; increased workplace safety; long-term working relationships with suppliers; improved quality; reduced cost; elimination of waste. Any activity, no matter how trivial, that does not offer benefit to the product (and the customer) is a candidate for elimination. Companies involved with *Lean* are continually examining every process for opportunities to save time and improve quality. Several common activities used in other business models rarely add value. Examples include approval (delegate as much as possible); batching (delay results as little as possible, balance this with cost); searching and walking (keep all supplies immediately at hand, locate tasks as few steps as possible from each other); waiting (work with suppliers for delivery "just in time"). Thus, *Lean* aims to make processes simple enough to understand, do, and manage by the worker.

Organizations using Six Sigma and Lean rely on the common structured problem solving strategy used in business called DMAIC (**D**efine the problem; **M**easure events; **A**nalyze and understand the data; **I**mprove the process; set up **C**ontrols that maintain the improvements). The strategy can be applied to all problem solving; however, more complex issues, such as restructuring a process, require the assembly of a team, the setting of clear goals, and a planned timeline for completion. Further details regarding application of Lean and Six Sigma can be found in George et al. [11].

Error detection and correction

McGregor contrasted two theories of company management that he referred to as X and Y [12]. A company following theory X assumes that the worker prefers to be directed and wants to avoid responsibility. In contrast, a company that is following theory Y assumes the workers enjoy what they do and, in the right conditions, will strive to do their very best. In general, the company that follows theory X manages from the "top down" with dependence of the worker upon management as he/she performs tasks. A hallmark of theory X is toughness, the rules are laid out, and every employee must "obey." The workplace has an element of fear that an error might occur and a reprimand will result. The style of the company that follows theory Y is different. Management works from the "bottom up." The workplace is configured to satisfy the worker and to encourage commitment to the organization. Workers are encouraged to be self-directed and the management/supervisory style is supportive. Theory Y has been described as operating with a "velvet glove." Stated in another way, management under theory X strives to "drive" the organization and the workers to success, while the management under theory Y strives to "lead" the organization and the workers to success. The goal in both cases is essentially the same, but the means to the goal are very different. This brief description of diverging management styles can impact process improvement within the laboratory.

A later chapter in this book (Chapter 3) addresses the causes of medical errors and reemphasizes the need for a system in the quality program for capturing and categorizing errors. In order for any method, process, or laboratory to improve, it is paramount to correct and understand the cause of the errors that interfere with performance. The laboratory needs a system for capturing and categorizing errors. Such a system becomes the infrastructure for improvement in a quality program. It is obvious that for a system to be successful, there needs to be an aggressive program to identify all errors, optimally at the time of the occurrence. The ideal process is one that looks prospectively at activities seeking to prevent errors. Deming [6] pointed out that inspection is too late. Once again the airline industry provides an example. Considerable effort is applied to understanding what causes the big error, an airplane crash. However, major efforts are now actually directed at the near misses both in the air and on the ground, a proactive effort to understand the "close call" to help prevent the major event. The laboratory needs a similar aggressive approach that must begin with each individual owning their part of an activity and identifying the problems as they occur, or seeing ways to prevent problems by changing procedures. In order for such a process to be most efficient, the worker should not be threatened by the mechanism to report errors. The following examples regarding the differing approaches may be useful.

First, a technologist has just completed a run on an automated instrument using expensive reagents and producing many patient results. He/she notices that two required reagents were placed in the wrong position, causing them to be added in the wrong order. The error caused erroneous patient results, but not to the degree that it would be easily detected. The consequence of repeating the run is twofold: the cost of

the reagents and time of the technologist are expensive and the delay in completing the testing results in complaints from clinicians. In this scenario, management under theory X results in a reprimand from the supervisor and a letter being placed in the technologist's personnel file for negative consideration at the next performance evaluation. The consequences may be severe enough for the technologist to consider not reporting the error. In contrast, management under theory Y would result in the supervisor complimenting the technologist for detecting the problem and engaging the technologist in an investigation of the reason that the error occurred. The supervisor and the technologist understand that the goal is to prevent this from happening in the future, whether this person or another performs the procedure. The assumption is that the process contributed to the error.

Second is a case in which the error that occurred above was not detected by the technologist performing the test, but at a later time during the supervisor's inspection of reported results. Managing under theory X, the supervisor will confront the technologist with the data and, just as in the prior example, will issue a reprimand and a letter. Managing under theory Y, the supervisor will present the information to the technologist and ask the technologist to assist in understanding how the problem occurred and how it might be avoided in the future.

Errors like those described that are detected and investigated are most frequently found to be problems in the process, not exclusively with the individual doing the procedure at the time. Improving the process to help workers prevent errors is the goal and can only succeed if errors are detected and investigated. Contrasting the approaches, one can see that punishing the worker and failing to examine process will not improve the quality and the worker will not be enthused about reporting future errors. The second approach engages the workers and rewards activities that improve quality in the laboratory.

Internal quality control

The control of the testing procedure (QC) evolved with the transition of research testing into the clinical arena. In general, internal QC provides a method to verify the imprecision of a test. To be confident that the method returns the correct result requires that steps be taken to ensure all elements are within the control of the operator. Technologists are taught that instruments/methods are designed to fail and that they can rely upon results only if the entire method performs within defined limits with specimens of known value. The frequency of these control events are method specific and a function of the stability of all of the elements (reagent, specimen, instrument) and must be driven by historical data from the method itself. Internal QC is the grandfather of quality programs in the laboratory and is detailed elsewhere in this book (Chapter 6).

Quality assurance

During the 1980s, laboratories began looking beyond the analytic procedure with quality programs called Quality Assurance. QC remained a part of the Quality Assurance program, but the program expanded to consider such items as laboratory orders, requisitions, collection techniques, and other issues directly impacting the result of the test but not always directly in the control of the laboratory. Preanalytic issues are detailed elsewhere in this book (Chapter 5). Postanalytic issues also became a part of quality initiatives this same era: such issues as reporting formats, verification of calculated results, timely reporting, and even action taken as a result of the data reported. It was during this period that computer applications in both the laboratory and the clinical environments began to grow, requiring the validation and continued verification of computer function and interfaces for electronic result reporting between computers as well as between instruments and computers. Encouraged (or demanded) by accreditation and/or regulatory agencies, laboratory professionals also began asking questions of and listening to clinicians regarding the quality of service and needs to provide new tests shown to have clinical value and to remove antiquated tests that no longer offer added clinical information. These activities started the interaction of the quality programs in the laboratory with similar programs in the rest of the healthcare institutions.

External quality assessment

In the 1930s [13], the need for interlaboratory standardization for public health programs (a method to verify accuracy) led to early efforts at External Quality Assurance. The concept of an unknown specimen

being sent from a central EQA agency to the laboratory for testing with the results sent back to the agency for evaluation added an important new level of assurance for the quality of analysis. In addition, results were reported in a way that allowed a laboratory to compare their performance to other laboratories using the same or similar methods. Laboratory participation in EQA programs grew rapidly in the 1950s and 1960s. In large part this growth was due to the development accreditation and regulatory programs requiring EQA; however, the recognition by unregulated laboratories that EQA was vital to the quality of their own programs has also led to widening acceptance.

EQA is generally viewed as a process to examine the analytic phase of testing, offering little or no information regarding the pre- and postanalytic phases. Described below is a method to examine a portion of the preanalytic process and all of the postanalytic process if the laboratory uses a laboratory information system (LIS) with electronic reporting to an electronic medical record (EMR).

Within the LIS and the EMR, one can create an additional floor on the hospital, or clinic in the outpatient department. Doing so allows for development of as many "beds" or clinic visits as necessary to handle all EQA challenges. Next, the Medical Records and/or billing departments assign a block of medical record numbers for laboratory use only. The laboratory then assigns a medical record number and name to each of the EQA challenges to which it subscribes (coagulation limited, coagulation special, etc.). Each challenge may have several analytes.

Having created this for each challenge, when the specimen arrives, the specimen is accessioned into the computer with the same method as a patient, the testing is performed in the same manner as a patient, and the reporting into the LIS and the EMR will occur in the same manner as a patient. The data reported to the EQA provider can be that reported to the EMR.

The advantage of such an approach is that all instrument/computer interfaces are validated and the evaluating, accessioning, and reporting process becomes a part of the EQA program. In addition, with time, the laboratory can query the EMR by the name and medical record number of the EQA challenge to see the longitudinal data reported by analyte.

Detailed discussion of EQA programs is addressed elsewhere in this book (Chapter 7).

The application of the tools in the laboratory

Quality system essentials

Development and maintenance of a quality program in a laboratory requires that there be an infrastructure of support in order for internal and external QC and quality assurance to be successful. The field of hemostasis provides an excellent example of this issue. The hemostasis laboratory has the entire spectrum of testing from the highly automated to the complex manual tests that are time-consuming and demand a different skill set. Thus, in addition to a good QC program, there is need for an effective program for development and continuing education of the staff. The same can be said of a host of essential activities in the laboratory including such things as acquisition and maintenance of capital equipment; supply inventory; safety of staff and patients; and others. In the late 1990s and early 2000s, recommendations began to appear for the comprehensive management of the quality of all aspects of the laboratory operations. International Standards Organization (ISO) developed the ISO 17025 (primarily a laboratory management program) [14] and ISO 15189 (a program specifically for clinical laboratories) [15]. The Clinical Laboratory Standards Institute (CLSI), at the time named NCCLS, published the Quality System Essentials (QSE) [16]. The ISO programs have achieved acceptance in Europe and internationally, while the QSE programs are more commonly in use in North America. Both approach the issues of quality with a very broad perspective, covering all elements of laboratory operations.

The list presented in Table 1.4 is an example of the QSE for a given laboratory. The list is not intended to be the list for use in every laboratory. Each laboratory needs to develop its own essentials, formulated to help manage issues within their own laboratory. The list is ordinarily 9–12 items in length and the types of issues to be addressed are encompassed in Table 1.4. Each of the items on this list will be controlled by a set of three levels of documents:

Policies: Statement of intent with regard to rules and requirements of regulations, accreditation, and standards. Each QSE will have one or a small number of policies that will provide the framework for all activities within the QSE. In the case of test

Table 1.4 Quality system essentials (CLSI—1999)

Purchasing and inventory	Information management
Organization	Deviations, nonconformance
Personnel	Assessments: internal and external
Equipment	Process improvement
Document and records	Customer service
Process control	Facilities and safety

Source: From Reference 14.

development, policies may address such things as validation, QC, EQA, and others.

Process descriptions: This is a description of how the policies are implemented. Process descriptions will often cross more than one department, section of departments, and procedures within a section. Flowcharts and tables are often used to describe processes. An example of a process requiring control is given below.

Procedures and related forms: The standard operating procedure (SOP) is a step-by-step description of how to perform a method or task.

The Policy and the SOP are documents commonly used in all laboratories; however, the process description may not be as familiar. An example is shown in Figure 1.2. The purpose of this process is to provide the surgeon and anesthesiologist with information needed to manage blood transfusion therapy in the rapidly bleeding patient. The data needed are the Prothrombin Time, Fibrinogen, Hemoglobin and Platelet count. The process needs an order, specimen collection, transport, laboratory receipt/accession, testing in two separate sections of the laboratory, reporting, and delivery of the data to the clinician. Ownership of the various steps in this process is in the control of the physician, nurse, and three different sections of the laboratory. In order for this to occur in a meaningful time frame in the clinical setting (less than 15 minutes), there must be well-understood coordination among all of those involved. Each step in the process described has its own SOP for the action taken. In this case, there are at least ten SOPs supporting a single process.

Implementation of a program can be challenging. Most laboratories have a quality program that can provide the beginning for the development of QSE. Most laboratories also have most of the essentials that they will define in their QSE; they are just not under the umbrella of the program and not easily identified. Thus, an initial step in changing the program will be gathering key individuals with knowledge and energy for the process to identify the QSE for the organization. Technologists should also be represented in this process. Once the QSE are identified, teams can be formed to begin drafting of policies. Leadership from the highest levels, supporting the changes that need to be made, and leading the infrastructure of a management structure base upon McGregor's theory Y are crucial elements.

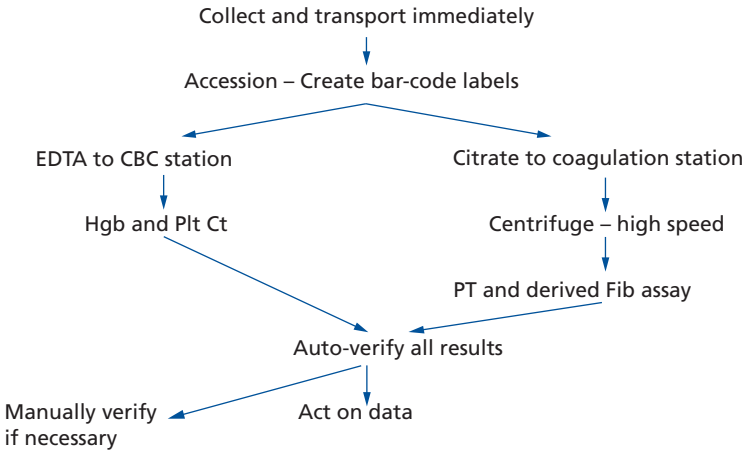

Figure 1.2 Process for the Bleeding Profile: This process for reporting the results of the Prothrombin Time (PT), Fibrinogen Assay (Fib Assay), Platelet Count (Plt Ct), and Hemoglobin (Hgb) involves the activity of at least four different units in the health system and execution of as many as ten SOPs. As a part of the QSE, a process description would be needed to ensure return of results rapidly enough for clinician action when managing an actively bleeding patient.

Possibly the most important issue is putting reality into fault-free reporting of errors, followed by an investigation to improve process to prevent future occurrences.

For many laboratories, instituting the concepts that are described in this chapter would necessitate significant change in the quality program, the perspective of the manager, and the attitude of the employee. Such a change in the culture is difficult. It is tempting to try to "buy, install and run" a program from a quality vendor. Such an approach is likely to meet with resistance from workers who view it as "just another of those quality things that the administration is going to force on us." In the past two decades (or more) most laboratories have instituted more that one new quality program in an effort to find a solution that works well in their setting. One possible difficulty in such an approach is the proscriptive nature of the process. They provide everything that is needed, policies, forms, SOPs, and so on. What they do not provide is the personal ownership that can come from the internal development of the quality process. Managers may find a smoother and more lasting solution in providing policies that allow for each unit to develop their own approach to the gathering of data, the identification of errors, and the many other elements of the quality program.

Summary

Over the course of the past 70 or more years, elements of the quality program have evolved in a somewhat stepwise fashion, beginning with internal QC and progressing to more comprehensive programs that encompass all activities in the workplace. In the remainder of this book you will find information regarding quality in all aspects of the hemostasis laboratory. Experts provide information regarding the highest level of development of standards (both methods and materials) to the finest details of the nuances of selected methods. Integrated into a comprehensive quality program, similar to that described above, the information should help in the development of a "QUALITY HEMOSTASIS LABORATORY."

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