Chapter 2
Quality Control and Quality Assessment

A difference to be a difference must make a difference.

Gertrude Stein

Quality

The word "quality" is thrown about so frequently that is has lost meaning in general and in cytology in particular.[1] It's not what you say, it's what people hear.[2] Examples abound: "death tax" instead of "estate tax," "affordable health care act," "drilling for oil" instead of "exploring for energy," "quality outcomes." I have zero tolerance for loose language (e.g., referring to random rescreening as QC).

"Quality" is derived from the Latin *qualitas*, meaning "of what sort." The set of attributes that allows a product to be used for its intended purpose *defines* its quality. In short, therefore, quality means useful for its intended purpose. That having been said, one must define the purpose, and go on from there, one logical step after another.

Cytopreparation allows cytotechnologists and cytopathologists to get the right answer by not being the limiting factor. "Right answer" means finding abnormal cells when present and interpreting them in ways that guide the clinician in patient management. Note, I did *not* say reproducibly and reliably interpreting the cytologic changes so they correlate with the underlying histology.

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Variation is normal.[3–6] After all, clinicians want to know whether cytology has identified a lesion that requires follow-up.

To make cytology specimens useful for their intended purpose, cytopreparation must include and display the cells-of-interest, so they make sense visually. Period. Simply, cytology preparations must include cells that are a representative sample of the raw specimen, well-preserved, flattened, fixed, stained to promote the visibility of nuclear chromatin and differentiation of cell types, and coverslipped to promote optimal imaging by microscope objectives.

Quality Control

Quality control activities look *forward*. They define the product's quality, imparting to it the credibility needed for its intended purpose. QC activities are the result of planning and are applied prospectively to everything that contributes to the final product, thereby impacting the outcome. QC activities are deterministic (i.e., lead to expected results when followed). Quality control is mentioned 26 instances in CLIA '88, but it is not defined and is not mentioned once in the context of cytology.

Quality Assessment

On January 24, 2003, CLIA '88 was finalized, which was 5,198 days after President Reagan signed it into law on October 31, 1988. That's more than 14 years! Among the changes, quality assurance became known as quality assessment. Properly implemented, quality assessment leads to quality assurance.

Quality assurance is mentioned 6 times in CLIA '88; quality assessment, 23 times. Unlike quality control, quality assessment is defined: "The laboratory's quality systems must include a quality assessment component that ensures continuous improvement of the laboratory's performance and services through ongoing monitoring that identifies, evaluates, and resolves problems." Quality

TABLE 2.1. Quality control is any material or method used routinely to promote useful outcomes.

Differential feature	Quality control	Quality assessment
Purpose	Defines quality	Measures success
Timing	Prospective	Retrospective
Application	All processes	Sample outcomes
Impact	Outcomes	Processes
Nature	Deterministic	Probabilistic

Quality assessment samples outcomes to see whether they "measure up," and if not, why not?

assessment is defined identically in preanalytic, analytic, and postanalytic systems. Note that CLIA '88 tells laboratories what they must do, but not how to do it. Therefore, implementation is unavoidably uneven, and at times, questionably effective. The word quality, not paired with control or assessment, is not mentioned once among the 1,327 words that constitute **§ 493.1274 Standard: Cytology** in CLIA '88.

In contrast to QC, QA looks *backward*. QA measures the degree to which desired outcomes are successful (i.e., their impact). QA activities, therefore, retrospectively sample outcomes. Discrepant findings should be investigated to learn the cause(s), if possible. The findings should be incorporated into the processes that contribute to the final product in an effort to prevent recurrences of the same types of discrepant results (e.g., did the patient have cancer as reported,and if not, why?). As a practical matter, quality assessment activities are probabilistic (i.e., have attendant uncertainty relative to reliability), as it not possible to review all product outcomes.

To decide whether an activity qualifies as QC or QA, see Table 2.1:

Differential Features of Quality Control and Quality Assessment

To implement an *effective* QC/QA program, laboratory personnel must first understand the *differences* between the two sets

of activities. Otherwise, documentation of such activities to meet regulatory requirements becomes primarily an exercise in paperwork compliance, rather than one that makes a real difference in how work is done. Judging by how often QC and QA are used interchangeably in conversations, quality control and quality assessment appear to be considered synonymous. Usually, it's "I'm going to QC this or QC that," and never "I'm going to QA this." When the terms are used as though interchangeable, the user obviously perceives no difference. When a distinction between the two terms is perceived, it is often applied incorrectly. In either case, the recipient of such information is misinformed. As a result, the planning of QC/QA activities is often confused; the implementation, suboptimal.

Is 10% Random Review of Negative Pap Tests QC?

No, it's QA. The random rescreening of at least 10% of negative gyn cases as required by CLIA '88 is universally referred to as "QC." While performed prospectively relative to the final reporting, rescreening is performed retrospectively relative to the activity it is intended primarily to measure, that is, the performance of the cytotechnologist. "(c) *Control procedures.* The laboratory must establish and follow written policies and procedures for a program *designed to detect errors in the performance of cytologic examinations* [italicized for emphasis] and the reporting of results."

The rescreening samples outcomes; the findings impact the process of screening. The 10% of negative gyn cases that are rescreened is a random sample, which means it is probabilistic. Such a set of differential features is characteristic of quality assessment. On the other hand, routinely rescreening all high-risk gyn cases as a matter of laboratory policy is quality control, as it is applied prospectively to all such cases, and is intended to prevent false negatives.

Total Quality Management

QC activity without associated QA activity is half-action. Documentation per se simply constitutes paper compliance with regulations that fails to satisfy the intent. QC and QA activities must be practiced continuously to monitor and maintain the performance of the two sets of contributory processes, recognize problems as they arise, identify corrective actions to be taken, and improve quality. Taken together, these two sets of activities constitute a program of total quality management.

Analyzing Quality Control and Quality Assessment Activities

In the broadest possible sense, QC activities cease and QA activities begin when the laboratory product, the cytological interpretation or consultation, is complete. In other words, everything that precedes sign-out is quality control and everything that follows is quality assessment. Specifically, that point is the moment in time when the cytological interpretation is committed to the laboratory report. That definition is too broad, however, to be instructive at the levels where QC/QA activities are most useful.

Cytopreparation constitutes the *processes* that determine the outcome. Successfully detecting abnormal cells is the outcome of a series of interdependent samplings of successively diminishing size. The specimen collection technique samples the biologic process, the cytopreparatory technique samples the specimen, the screening process samples the preparation, and the diagnostic interpretation samples the cellular features. A quality laboratory increases the sensitivity of its cytological method by optimizing and standardizing its materials and methods of specimen collection and preparation.

The relation of cytopreparation to the whole process of detecting abnormal cells is depicted as the left side of the CytoTect Triangle (Fig. 2.1).

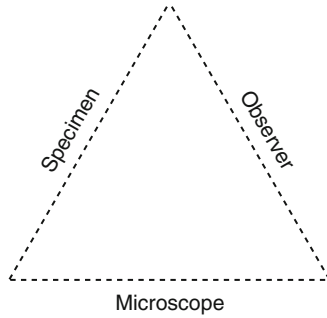

FIG. 2.1. "CytoTect Triangle" is a portmanteau for "cytodetection triangle." The CytoTect Triangle relates the interdependent roles of the specimen, observer, and microscope usage in the detection of abnormal cells.

Numerous physical, psychological, and physical factors must converge in time and space to promote the likelihood of perceiving the presence of abnormal cells. Relating this model to familiar language used in electronics, the specimen is the signal; the observer, the receiver; and the microscope, the transmitter. The many variables that impact the process can introduce noise. By optimizing and standardizing the three processes, the signal is strengthened and the noise is reduced.

Optimized processes increase the probability of abnormal cell detection (i.e., high sensitivity) and reduce the incidence of missed abnormal cells (i.e., false negatives). In Fig. 2.1, the probabilistic nature of the entire process is represented by dashed lines, rather than solid lines, as would be the case for a deterministic process such as the fire triangle.

The fire triangle, also known as the combustion triangle, illustrates simply the relationship among three elements essential to starting and sustaining fire: heat, fuel, and atmospheric oxygen. When present in suitable proportions, these elements will *always* result in combustion. To extinguish a fire, take away any 1 of the elements. The probabilistic CytoTect Triangle connotes the concept that abnormal cells will usually, but not always, be detected during the complex process of screening.

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