2 • DESCRIPTION OF THE NUCLEAR DIAGNOSTIC SYSTEM

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Modern technology itself has provided a mechanism whereby we can by-pass the dilemma caused by the indefinability of quality. The technique comes from operations research. In this practical approach, quality is defined operationally in terms of the final product or the objectives of the system. In our case, these are the nuclear medical services themselves. Using this mechanism, the first step is to establish the goals. The second stage is to make measurements of outcome and compare the two. Corrections at regular intervals improve the match between the outcome and the goals, which can be routinely updated to match the objectives of the overall health care delivery system. This approach to quality allows us to continuously change our expectations for nuclear medicine and to continually improve the system, without requiring an arbitrary definition of quality.

The use of this approach to achieve quality in nuclear medicine begins with a description of nuclear medicine using the terminology of the systems analyst. Once the parts are identified, standards can be devised and quality control tests established to compare day-by-day performance with the accepted standard. Feedback loops can then be created to correct the performance of each part. Examples of feedback loops that work very well in nuclear medicine include the initial film reading by the staff required before the technologist is allowed to release the patient. If the physician finds the film quality to be less than he expects, he may suggest changes in technique and request additional films. In this situation the standard is a hypothetical film existing in the mind's eye of the physician. This standard is usually an evolving image that changes as the understanding and experience of the physician increases. Feedback is often immediate and provides a constant impetus for improving the image-acquiring procedures. Another feedback loop occurs at the same time. If the distribution of the tracer in the patient, as revealed by the image, deviates from the expected distribution, this information is usually relayed directly back to the radiopharmacy, along with a request to correct the radiopharmaceutical preparation before a dose is prepared for the next patient. These feedback loops are useful on a day-to-day basis to maintain and improve the performance of individual components of the system. These might be termed as the first level of quality control.

The second level of quality control focuses on the interrelated functions of the component parts, such as matching the tracer to the collimator and the nuclear detection device. The third level is the selection of an optimized set of operating parameters for all the component parts. The final level is matching the performance of the whole nuclear medicine clinic to the requirements of the hospital, the community, and the national health care delivery system. Again, evolving standards, quality control procedures, and feedback loops are essential. However, at these higher levels they are not as easy to specify and institute as they are at the basic level.

A basic principle of quality assurance in a system is that it is not enough to check out the performance of each component part or individual worker. Rather, a random sample of final products must be taken from the end of the line and tested against standards. A failure to use outcome measures of quality means a failure of quality control in the overall system. A system not managed or directed by objectives tends to become inefficient and to maximize secondary objectives. Thus, the system tends to focus on factors that affect one outcome in a thousand, such as record keeping of radioactive inventory, while neglecting factors that may affect one outcome in ten, such as physically examining each patient prior to administration of the tracer. Another potential system failure results in ineffective linkages of the nuclear medical clinic to other parts of the overall health care system. An example of this would be failure to ensure that patients from our clinic find their way to the next specialist and failure to ensure that information we have obtained follows the patient to the next station within the system. A significant long-term failure often results when a system cannot learn from itself. The feedback loops, at all levels, allow for the system's self-learning process. Nuclear medicine often accomplishes self-learning in the area of acquiring images and of correcting radiopharmaceutical failures. What are needed, however, are feedback loops that will allow corrections at higher levels.

System evaluation and adjustment

The following are steps necessary in a system analysis[5] to adjust outcomes to achieve quality in nuclear medicine:

1. Determine the objectives of the system.
2. Identify outcome measures that can be used to test the effectiveness with which the objectives are achieved.
3. Identify input variables and classify them as controllable and uncontrollable.
4. Develop strategies, for example, configurations of controllable variables.
5. Design apparently effective strategies using experiment or analysis.
6. Implement one or more strategies.
7. Evaluate strategies using outcome measures.
8. Loop back to step 4 when objectives remain constant or to step 1 when objectives are changed.

OBJECTIVES OF NUCLEAR MEDICINE

The overall objective of nuclear medicine clinics is to provide diagnostic radiotracer tests and radiotherapeutic administration of isotopes. In addition to these clinical services the unit often provides training for technologists, residents, and perhaps graduate students. Research projects may also be carried out in conjunction with the routine clinical activities.

The clinical diagnostic services are designed to provide information that will make a contribution to overall patient care. Usually the objective includes improvement and updating of services to provide the latest and most effective technological advances, upgrading the sensitivity and specificity of diagnostic tests, and increasing the availability of the test while holding down costs. At times this means instituting a tracer test to replace an invasive procedure such as a biospy or using a tracer to screen patients for arteriography, as when using a kidney scan to select candidates for surgery prior to the preoperative renal arteriogram. At other times it means selecting or developing a tracer test in which radiation exposure is minimized without compromising on the required diagnostic information. Minimizing risks also means avoiding the use of toxic levels of ingredients in the tracer formation. It may also mean avoiding long or traumatic experiences for the patient.

The training and research objectives are also important to the long-term quality of patient care. Training is usually aimed at increasing individual effectiveness and at providing adequate numbers of trained personnel. Research is carried out to improve and update nuclear medical practice, specifically, and to increase our overall understanding of health and disease, generally. The research may also be designed to obtain objective evaluations of other components of the health care system. An example of this is the use of gallium-67 whole body scans to evaluate the results of cancer therapy.

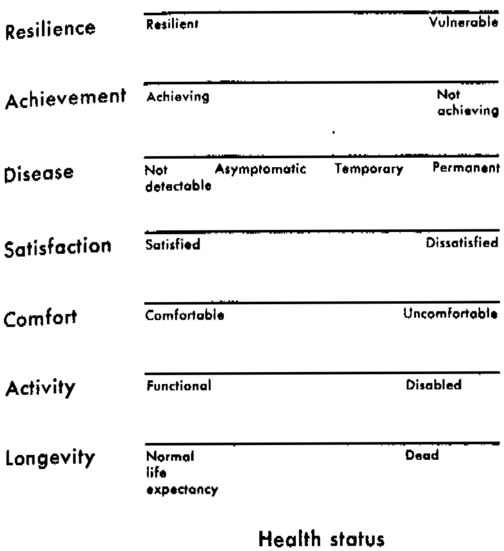

Fig. 2-1. Dr. Starfield recommended that we consider these seven criteria when we measure outcome. Resilience is the ability of patients to cope with adversity on a long-term basis. Achievement is measured by objective tests, which determine if our system has really improved the health of the patients in terms of what they can do. Another unique aspect of nuclear medicine is that its physiologic measurements can provide objective tests to measure the achievements of other parts of the overall program of health delivery. The old standard measurements of outcome were of whether the amount of disease in the population actually decreased. Satisfaction is measured from the patients' point of view. Are they satisfied with their states of health as a result of what we have done? Another measurement is of comfort. In the long run have we done something to reduce the pain or reactions that the patients have to their diseases? Activity, or the long-term functional capacity of the individual, and how it is affected by going through our clinic is also measured. Longevity is expressed in terms of changes in life expectancy.

OUTCOMES AND THEIR MEASUREMENT

The systems analysis approach requires identification of outcome measures that express the effectiveness with which the objectives are achieved. Starfield[18] (Fig. 2-1) has proposed seven categories of outcome that are classified as vectors because they have both direction and magnitude. The qualities are measurable but require costly long-term follow-up studies done with parallel control studies. For example, we could design, in theory, a study to determine if patients with the diagnosis of cancer who have periodic bone scans to identify bone metastases live longer than a control group of patients matched with respect to symptoms, treatment, age, and so on, who do not receive bone scans. These kinds of studies are indeed useful; however, from the practical point of short-term decision making less involved measures should be available.

Measures of the progress of care[4] outlined below can be used to evaluate achievement of objectives on a short-term basis. Thus, both the measurements of process in addition to measurements of outcome are needed.

1. Inclusiveness
   a. Proportion of population reached
   b. Proportion of health problems covered
2. Content
   a. Completeness of services
   b. Rationality of services
   c. Appropriateness of services
   d. Humaneness of services
3. Productivity
   a. Volume of services rendered
   b. Health productivity
   c. Costs of services

PROCESSES AND THEIR MEASUREMENT

The process of care can be quantified using three types of measurements. First, there are measurements of inclusiveness. What proportion of the population is actually reached by our procedure? Are all of their problems recognized and met? We realize that the general public does not feel we are giving quality medical care when we have great procedures that can be carried out only for a few patients. Then there are measurements of content. How complete is our service? Is the service part of a logical and necessary process from the standpoints of patient and referring physician? Are our services appropriate to the problem at hand? Finally, are the services humane? Do the patients have a human experience when they pass through the clinic? The answers to these questions are given by measures of content of care. The third measurement of process answers questions of productivity of the system. What volume of services are rendered? What is our consumption of resources in rendering these services? What is our productivity in terms of the overall health of the population in general?

The following is an outline of specific objectives and measures in the nuclear diagnostic system that can be made to determine how well the system is functioning:

I. Objectives of the system
  A. Service objectives
    1. To provide information that will improve patient care by:
      a. Increasing the specificity and sensitivity of diagnosis
      b. Increasing speed of recovery and patient satisfaction
      c. Decreasing morbidity and mortality
      d. Decreasing risks of exposure to unnecessary nonnuclear procedures
      e. Decreasing cost of patient care
    2. To minimize risks to the patient due to:
      a. Exposure to radiation
      b. Exposure to toxic materials
      c. Exposure to long or traumatic procedures
  B. Training objectives
    1. To increase personal effectiveness
    2. To provide adequate numbers of trained personnel
  C. Research objectives
    1. To improve and update the nuclear diagnostic system
    2. To increase our understanding of health and disease
II. Evaluation of system performance
  A. Service function
    1. Benefits
      a. Structural measures
        (1) Number of nuclear procedures completed
        (2) Number of higher risk procedures eliminated
        (3) Number of referring physicians using service
      b. Process measures
        (1) Inclusiveness
          (a) Proportion of patients utilizing service
          (b) Proportion of physicians utilizing service
          (c) Proportion of diagnostic problem covered
        (2) Content
          (a) Proportion of definitive nuclear diagnosis
          (b) Proportion of services performed when requested
          (c) Proportion of tests performed on time
          (d) Proportion of tests requiring repeat studies
          (e) Proportion of patients having a positive experience during the study
        (3) Productivity
          (a) Number of diagnostic decisions influenced
          (b) Number of therapies altered
      c. Outcome measures
        (1) Longevity
        (2) Activity
        (3) Comfort
        (4) Satisfaction
        (5) Disease
        (6) Achievement
        (7) Resilience
    2. Costs
      a. Dollars spent
      b. Financial restructuring
      c. Number of therapies misdirected
      d. Radiation exposure
      e. Number of patient experiences
        (1) Trauma
        (2) Adverse reaction
        (3) Discomfort
        (4) Dissatisfaction

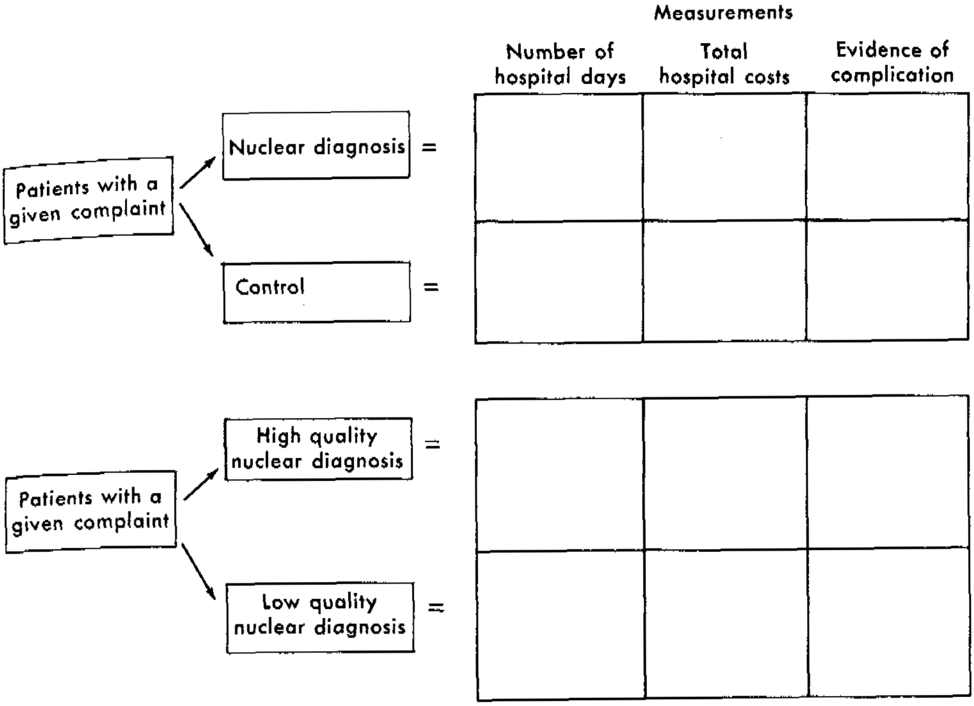

Fig. 2-2. This is a rough outline of an evaluation scheme that can be applied to a nuclear diagnostic system. For example, patients with a complaint such as acute abdominal pain are admitted and randomly sorted into two pathways, one of which goes through the nuclear clinic and one that does not. Measurements of the entire hospital system's output are taken. Several measurements are required; examples of three are listed here. If the values for each of these measures are compared, the contribution of the nuclear diagnostic system to the quality of patient care becomes measurable. This scheme can also be applied to the problem of optimization of the nuclear system. If similar patients are randomly put into the system, half of them having one configuration and half the other, the groups can be compared using identical measures of output. In this way, any differences between the two configurations of input variables become measureably apparent.

B. Training function
   1. Benefits
      a. Levels of personal competence
      b. Number of trained personnel
      c. Improvement in service and research functions
   2. Costs
      a. Dollars spent
      b. Losses in service or research functions

C. Research function
   1. Benefits
      a. Improved service and training functions
      b. Increased understanding of health and disease
   2. Costs
      a. Dollars spent
      b. Losses in service or training functions

The techniques of decision theory are applied to formulate optimum decision strategies to problems of medical diagnosis and therapeutic schemes.[11-16] This approach is theoretically applicable to decision making in which configurations of controllable variables produce optimal designs of nuclear diagnostic systems. Often a cost-benefit analysis such as that outlined in Fig. 2-2 is useful. For a more detailed discussion of diagnostic strategies see Chapter 10.

INPUT VARIABLES

Many factors influence the nuclear diagnostic system. These variable inputs to the system are broadly classified as controllable or uncontrollable. In reality, however,

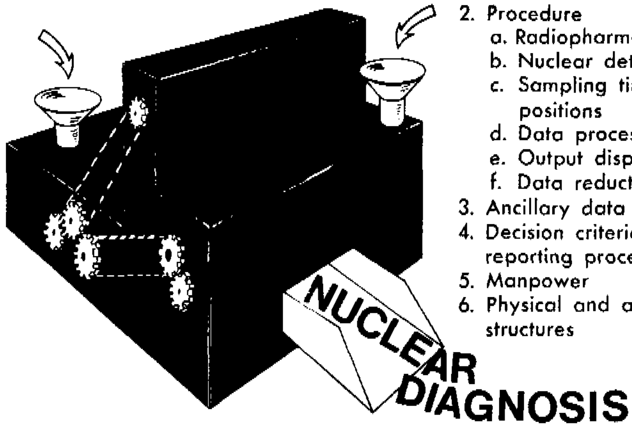

Fig. 2-3. In system analysis the system is represented as a black box. What goes in and what comes out of the black box are measured. Testing is accomplished by changing inputs and measuring the resultant effects on the outputs.

the inputs are rarely totally controllable or totally uncontrollable. For example, when a new clinic is being designed, the floor plan is controllable within certain limits. Later, as the building is completed, the ability to control the floor plan is greatly reduced.

Uncontrollable inputs

Fig. 2-3 contains an outline of most of the input variables we deal with in nuclear medicine. To be workable, the system must be flexible enough to accommodate the ranges of values for the uncontrollable variables. An example of such a variable might be the request for three emergency lung scans at midnight. The timing and frequency of requests is perhaps the easiest of the uncontrollable variables to recognize. Other random phenomena with which the system must be able to cope are inherent patient variability coupled with the range of pathology associated with various diseases, hidden interferences, unpredictable component failures, human error, and various forms of statistical noise.

Controllable inputs

PATIENT SELECTION. Usually it is considered good practice for patient selection to be a controllable variable. This is not a requirement of the system, however, since the clinic may test any patient for whom a study has been requisitioned. In cases of certain in vitro assays the nonselection of patients may be cost effective. More often, carefully followed selection criteria prove beneficial. Thyroid workups are good examples of this, since many treatment regimens may alter the test results. Hence, a review of the history and patient interview are vital in deciding which tests should and can be performed to provide meaningful data. This topic is explored in more depth in Chapters 7 and 10.

PROCEDURES. Selection of the best radioactive tracer, imaging device, display, and so on is the subject of much of the scientific literature in nuclear medicine. These components are discussed individually in subsequent chapters. Also it is important that the different components are properly matched. For example, collimators are changed depending on which radiopharmaceutical and which organ are being imaged.

ANCILLARY DATA. Ancillary data are obtained from the requisition, the patient's medical record, the patient interview and examination, and the referring physician.

This data is useful in patient selection and in the selection of decision criteria and may also influence reporting procedures. It is economically important to get all the essential facts rapidly. Efficient use of physician time is directly related to how this variable is controlled.

DECISION CRITERIA AND REPORTING PROCEDURES. It is probably characteristic behavior of nuclear physicians to use ancillary data to help move up and down the receiver operator characteristic (ROC) curve. If a 20-year-old woman with a generalized severe headache of three years' duration and no neurologic signs has a brain scan, the decision criteria may be appropriately biased in favor of calling the scan normal. On the other hand, if a patient with multiple myeloma and visualized bone density changes has a bone scan, the physician may change his bias in favor of calling the scan abnormal. The study and the use of ROC analysis to adjust observer bias and make it a controllable variable is a recent innovation in nuclear diagnosis. This is discussed more fully in Chapter 13.

MANPOWER. The number of personnel and their backgrounds and levels of training are obviously major determinants of quality. The current trend is to establish minimum requirements of accredited training programs and to provide certifying examinations for personnel. The optimum configuration of people to provide quality services and acceptable costs is a major administrative problem (see Chapter 12).

PHYSICAL AND ADMINISTRATIVE STRUCTURES. The importance of physical and administrative structures is so central to quality that they come under the scrutiny of hospital accreditation programs. Maintenance of sufficient flexibility to keep these factors as controllable variables is a major part of the management of nuclear medicine clinics.

OUTPUTS: COSTS AND EFFICIENCY

Nuclear medicine outputs, in simplest terms, are two pieces of paper. The first paper is the report that is sent to the referring physician telling him the results of the study; the second is the bill sent to the patient or third party payers. Efficiency, defined in these simple terms, is the value of the report compared to the cost of getting that report to the referring physician. Evaluations of the quality of system performance include efficiency, but this is by no means the total story, since quality involves much more than having an efficient operation.

The medical output of the nuclear medical clinic is characterized by the sensitivity and specificity of the reported diagnosis. These are related to the controllable inputs; thus they can to a certain extent be controlled by how the constellation of input variables is arranged. For example, we may change the decision criteria and as a result alter the specificity and sensitivity of the diagnosis. We can also change things such as the detection devices or the tracer; these also change specificity and sensitivity. Each change also has its associated cost and change in the level of productivity. In addition to dollar costs there are the risks associated with radiation exposure and the other hazards of the test procedures, including patient discomfort.

Quality control

Quality control has three essential ingredients: standards, surveillance, and responsiveness, or corrective action. When surveillance indicates substandard products or performance, the quality is restored by taking the appropriate corrections. Standards for quality control checking of radiopharmaceuticals and nuclear instrumentation performance are still evolving. Standards for intercomparing radioactivity measurements are well established and traceable to national and international standards.

Standards come from different sources —research, group judgment, or observation of practice. In nuclear medicine there are usually a few well-documented tissue distribution or follow-up studies. For example, the paper, "Pharmacodynamics of Some Technetium-99m Preparations," published by Harper, Lathrop, and Gottschalk in 1966,[8] has served as the key reference data to which many subsequent biodistribution studies of technetium radiopharmaceuticals can be compared. Another example is follow-up studies to evaluate the accuracy of brain scanning. This initial study revealed a diagnostic sensitivity of around 80%.[2,7] Subsequently, with the introduction of new tracers, instrumentation, or procedures, diagnostic sensitivity has often been remeasured and the results compared to the earlier reports.[21]

What is done when the surveillance program indicates that performance is not up to standard? If quality is to be controlled a corrective action must be taken. Four levels of corrective action have been recognized: education, procedural changes, reinforcement and encouragement, and intervention. Often the recognition that the result is substandard is sufficient motivation for making the adjustment. A technologist looks at the film and sees that the contrast is not right, readjusts the instrument, and takes new film. This type of response is dependent on education. If the technologist is aware of the required levels of quality, can evaluate the quality of his films, and is well aware of what adjustments can be made to improve quality—in other words, is well educated—often this is sufficient to control quality.

Sometimes standard quality can be restored only by making procedural changes. When ^{99m}Tc-albumin was being labeled by the tedious iron-ascorbate method, preservative-free ascorbic acid was a key reagent. When this ingredient became commercially unavailable, substitutions were made, but quality of the tracer remained unsatisfactory until appropriate procedural changes were instituted.

Motivation is very important to quality. Reinforcement by appreciation of high quality work and by providing encouragement to improve and maintain quality is a major contribution to the sustained practice of quality nuclear medicine.

Finally, poor quality can be stopped actual intervention. Local hospital comn tees or administrators, state boards a licensing agencies, federal regulat agencies—the Nuclear Regulatory Co mission (NRC), the Food and Drug A ministration (FDA), and others—have tl authority to intervene when the practi of nuclear medicine fails to meet leg standards. This is rarely necessary in nuclear medicine because poor quality is often immediately and visually apparent. If a physician gives a patient an aspirin that for reasons of poor quality fails to provide the standard response, how does he know that this has occurred? If a physician gives a patient a bone scanning agent that does not accumulate in the bone, he has within about three hours a picture revealing that problem and also indicating the cause of the failure. Corrective action is almost always taken. Also medical ethics and financial considerations are powerful forces operating to assure high quality in nuclear medicine.

In current practice, nuclear medicine is overregulated to a point of loss of quality. High expenditures of efforts and talent to meet governmental requirements take attention away from the patient and the supporting staff. John McAfee[10] has expertly focused our attention on the negative aspects of the current "regulatory jungle" and its waste of public funds. A most obvious example of this is to see someone standing by a radiation source filling out legally required documents. The purpose of the initial regulation was to limit radiation exposure, but the user is unnecessarily exposed to radiation in order to provide proof to a regulatory agency that he has complied with the letter of the law. In following the letter of the law, the spirit of the law is violated. *We must encourage governments to invest in education, the first level of corrective action. This is more cost effective in improving quality than investments in regulation, the final level of corrective action, where intervention is often more harmful than helpful.*

Standards and standardization

Standardized radioactive sources are widely available. Standardized radiopharmaceutical preparations are not. Standardized animal models and procedures for determining biodistributions are not. Individual specifications are established for each NDA-approved radiopharmaceutical; however, these specifications are not public information. Standardized performance characteristics for nuclear instrumentation are under development, and some instrumentation testing procedures are available. Standardized diagnostic procedures are not available. Thus, some components of the system can be standardized; other parts cannot.

While standardized evaluations of system components are essential to quality in nuclear medicine, standardization of the whole procedure may not be. Watts[19] has argued that the art and science of medicine as practiced by an individual physician is a unique thing. He notes that a patients' response to his disease and to the medical system is also highly individual. A third unique part also exists; this is the process of interaction of the patient with the system; that is, each experience that the patient has with the medical system is also unique. Consequently, three independent, unique factors are involved when a patient comes for medical care. Watts' argument, in brief, is that to have high quality care, these three unique processes must be carefully considered. Standardization of the whole process ignores the uniqueness of these three human interactions. Watts' conclusion is that quality is lost roughly to the extent that standardization takes place.

Thus, it appears that on the one hand we are saying that standardization is a good thing, and on the other hand we are saying that standardization may indeed be the opposite. But it should be clear that we are calling for use of quality control standards for system components, being sure that each component of the nuclear diagnostic system has been compared to the appropriate standard, and that each procedure has been controlled by comparison to reference procedures. If this is done, and if the physician and patient are assured that this is done, then they are free to interact in their own unique and individual way.

Summary

The essentials of quality assurance in nuclear medicine depend upon system and component performance standards, surveillance, and corrective actions. Assessment of the quality of overall performance is based on measurements of structure, of process of care, and of outcome. The evaluation of quality must take into account the values and objectives of the patient, the physician, the health care system, the third party payers, and society at large.

The dilemma and difficulties inherent in quality assurance program design include (1) societal demands for a guarantee of highest possible quality for all patients at all times, coupled with the difficulties of amassing quantitative measures that demonstrate this guarantee has been fulfilled; (2) the possibility of an inverse relationship between quality and rigidly standardized procedures; (3) the diminished responsiveness to change imposed by standardization; and (4) the conflict posed if those responsible for the service are the same as those responsible for its evaluation.

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