

# *An Introduction to Quality Assurance with an Application for Perfusionists*

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## **Abstract**

Cardiovascular perfusionists have always been interested in quality assurance (QA), most often in the form of equipment maintenance and record keeping. However, these activities have tended to be fragmented. In an attempt to define a more global approach to QA, basic concepts are identified and the steps used to start a formal QA program are illustrated.

In the usual approach to QA, three areas are commonly assessed: Structure, Process, and Outcome. Structure evaluates the adequacy of facilities and personnel. Process involves review of the

activities concerned with the management of patients. Outcome represents evaluation of the end points of care.

In starting our formal QA program, five steps were delineated. These were planning the program, setting up an administration, assessing preexisting activities, initiating the program, and finally evaluating results. A QA specialist helped to define a number of concerns about perfusion from perfusionists, surgeons, anesthesiologists, and nurses. Using a standard approach to QA, these areas were defined according to Structure, Process, and Outcome.

## **Introduction**

What is the relevance of quality assurance (QA) to the practice of cardiovascular perfusion? On a day-to-day basis, a QA program provides an organized method of evaluating and improving the various activities of a perfusion department. On a larger scale, many factors force continued search for the optimal use of increasingly limited healthcare resources. These factors include rapid advances in medical technology, increased consumer expectations, rising costs of medical care, and limitations in government funding. Programs such as the "Agenda for Change" of the Joint Commission on Accreditation of Healthcare Organizations reflect this trend.<sup>1</sup> In response to these pressures, institutions have turned to QA programs. Quality assurance has been extensively reviewed, but little of this material has been applied directly to the practice of perfusion.<sup>2</sup> The purpose of our review is to clarify the terminology and approach used in QA, and to show an application of it to a fledgling perfusion department.

### **Quality Assurance — What is it?**

Quality assurance has been defined as "a program to

evaluate and improve patient care through identification, evaluation, and correction of problems in the patient care delivery system."<sup>3</sup> Some may view QA as a means of performing risk and utilization management. While QA can serve as a means of coordinating these activities, they are only secondary aims of any system, the goal of which should be to provide excellence in patient care.

The most widely used model of QA was described by Donabedian in 1966.<sup>4</sup> In this approach, the study of patient care is categorized into three major components: Structure, Process, and Outcome (see Table 1).

Structure is the environment in which health care is administered. It is composed of factors related to human resources (for example, the qualifications of the perfusionists), including their organization (for example, reporting policies), and the material resources themselves (for example, the cardiopulmonary bypass machine, bypass circuits, etc.).

Process represents the actual activities performed by the perfusionist in the provision of patient care (for example, the selection of circuitry, pump flows, maintenance of equipment, etc.) These may be defined as interpersonal tasks and technical tasks.<sup>5</sup>

Outcome is the evaluation of the end point of patient care. An example of an Outcome measure from cardiac surgery might be the ability of the patient to return to work after coronary artery surgery. In perfusion, ex-

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amples of Outcome assessments are the temperature of the patient on arrival in the Intensive Care Unit, or the acid-base status at the end of cardiopulmonary bypass. Recently, patient satisfaction has become an important consideration in some areas of health care. To this end, patient satisfaction can be considered part of Outcome, after mortality and morbidity.

In general, Structural concerns are more easy to identify and to quantify than are Process problems. Measures of Outcome are also difficult to obtain. For this reason, most accreditation activities are centered on the Structural components of a program. Implicit in this assessment is the assumption that good Structural components will lead to good Outcome measures. Unfortunately, there is little evidence that this is the case.<sup>5</sup> Similarly, the relationship between technical care (Process) and Outcome, while firm in some areas of medicine where extensive clinical trials have been conducted, has not been explored in the area of perfusion. An example of this type of issue is the controversy over pH management while on bypass (pH-stat versus alpha-stat).

Once problems have been categorized, it is essential to decide how to study them. Two approaches have been used: implicit and explicit review.<sup>5</sup> Implicit review uses "experts" to assess the quality of care in a particular circumstance. Experts, working as individuals or as committees, can judge the quality of a particular Structure, Process, or Outcome using their knowledge of the area. While little preparation is necessary to have a problem reviewed in this way, it is expensive and time consuming.

In comparison, explicit review requires careful preparation of accepted standards of practice. Once there is agreement on these standards, review is rapid and inexpensive. In fact, nonprofessionals can be trained to rate the care using prepared data sheets. While this method is clear and objective, the developed standards may oversimplify clinical care, and may introduce rigidity into practice. In an effort to prevent this, the California Medical Association and California Hospital Association developed a guide for criteria formation which asks the question: Can the criteria RUMBA?<sup>6</sup> Criteria developed in this fashion are Relevant, Understandable, Measurable, Behavioral and Achievable.

In both implicit and explicit review, there remains the problem of how to select cases. If numbers are not large, then all cases of a particular type can be reviewed. Otherwise, cases may be stratified and random sampling may be used to ensure proper selection. Finally, only cases of certain type may be reviewed. Selection is easier if sentinel cases are used for analysis. This approach is used in traditional morbidity and mortality rounds, where cases are identified by their obvious poor results. Detailed analysis is then undertaken using either an

**Table 1**  
The Components of Quality Assurance with Examples

**Structure**

Personnel (Who?)  
Qualifications and training  
Numbers

Equipment (What?)  
Types and numbers

Environment (Where?)  
Office space  
Space for equipment storage

**Process**

Tasks (Which duties?)  
Maintaining record of equipment maintenance  
Attending continuing education courses  
System of reporting critical incidents

Methods (How are duties carried out?)  
Using blood gas results without temperature compensation  
Rewarming patients to 37.5 ° C before weaning from bypass

**Outcome**

Objective  
Usual measures: Morbidity and Mortality

Subjective  
Dissatisfaction of patients or health workers?

Comparative  
Results similar to other institutions?

implicit or explicit approach. Critical incident reporting is also an example of sentinel case analysis.

## **Goals of a Departmental QA Program**

Any activity which maintains or improves quality of care can be defined as "quality assurance." To group these activities systematically, a number of tasks need to be carried out as outlined below. While all QA programs encourage the identification, evaluation, and resolution of clinical problems, they can also draw attention to newer trends in clinical practice and serve as educational tools for department members. However, it must be remembered that the primary aim of a QA program is to provide excellent patient care and optimal working conditions for the care providers. Secondary aims encompass cost containment, also known as effective budget control (which includes risk management).<sup>7</sup>

## **Setting up a Quality Assurance Program**

Starting a QA program involves a number of overlapping steps: 1) planning the program, 2) setting an administrative structure, 3) assessing activities which already exist, 4) setting the plan in motion, and 5) evaluating the results.<sup>8</sup> Each of these steps will be described below, with samples from our experience.

### **1. Planning**

Our perfusion department is located in a major teaching hospital which recently opened a small cardiac surgical unit (approximately 300 cases per year). When starting our program, we felt that the incident reporting form used by the Department of Nursing in most areas of the hospital was not applicable to perfusion. We decided that an incident form specific for perfusion services was necessary. This led to discussions with the QA Specialist who was working in the Department of Anaesthesia. We also realized that a QA program would provide us with a way to develop and use a specific incident form, as well as give us a general review of our practice.

### **2. Administrative Structure**

It was decided that the best course of action would be for the QA specialist to consult the groups who work closely with perfusion, namely, anesthesiologists, surgeons, and nurses. Since our practice was new to the institution, it was difficult to find agreement on which areas should be monitored. Nevertheless, a small working committee was established which included the chief perfusionist, the quality assurance specialist, a cardiac surgeon, and an anesthesiologist. These first steps can be

initiated by a nucleus of the QA committee, with representation from both within the department and from other allied areas (for example, anesthesiology, surgery, and the hospital quality assurance committee). Ideally, the director of the perfusion department should be on the committee.

### **3. Assessing Activities**

The first phase of the program is critical. Formal interviews with individuals within the perfusion department and those closely associated with it (for example, cardiac surgeons and anesthesiologists) will identify areas of concern and will increase the credibility of the program. In these interviews, existing quality assurance activities can be identified and their effectiveness assessed. A number of questions should be asked: Who is being assessed? What activities are being assessed? Are there criteria which describe how those activities are supposed to be conducted? What are the activities supposed to accomplish? In most hospitals, there are individuals with experience in QA whose experience can guide these activities.

### **4. Setting the Plan in Motion**

Once the committee is established, its role will be to select the initial problems to be tackled, and to set up a system of periodic review to ensure the QA activities are effective.

Problem areas may be identified from information gathered from both inside and outside the hospital. The medical literature, continuing education of perfusionists, communications from manufacturers and adoption of upgraded standards by accrediting bodies are all factors requiring continuing changes in practice. In the hospital, additional problems may be identified by surgeons, anesthesiologists, O.R. nurses or I.C.U. personnel. Within the department, incident reports, comments or complaints by perfusionists, or morbidity and mortality conferences may help to identify significant problems. By forming a committee responsible for QA, the department identifies individuals who can be approached by perfusionists and coworkers about significant issues.

Once a problem has been identified, the QA committee must have a systematic way of solving it. Items to be considered include: 1) the goal of the assessment (Is the objective to document the existence of the problem, or to look for an immediate solution?); 2) the breadth of the assessment (Is the problem related to a specific perfusionist or the whole department?); 3) the duration of the assessment; 4) the standards to be used (implicit or explicit); and 5) sources of information about the assessment (e.g. medical record, or medical literature).

The committee should also have the responsibility of

screening certain types of incidents; for example, cases where the activated clotting time fell beneath 400 seconds while on bypass, or where adequate pump flows or oxygenation were not be maintained. This type of screening can give useful information about the overall function of the department. Over time, some specific items may be changed, and others introduced. Early in the development of a QA committee, the question of which types of incidents to screen must be answered. Specific screening forms or work sheets can be developed to allow tabulation and computer entry of data for easier follow-up.

In our program, three initial objectives were identified: 1) to develop and use an incident report form; 2) to establish a continuing education program for perfusionists; and 3) to develop equipment maintenance schedules and programs. While the first objective relates to Structure, the other two objectives are related to Process. Initially, no Outcome objectives were considered.

Each of these overall objectives was expanded to include a number of enabling objectives to achieve the desired goal. The implementation of these objectives frequently required revision. For example, an incident report form was developed by the perfusion department and was implemented in a draft version. After being used for reporting various incidents, it was evaluated and changed until there was general satisfaction with the form. Concurrently, the information that was collected on the form was evaluated by the QA committee and used to direct the actions of the committee. The other overall objectives were treated in an analogous manner.

Plans for future expansion of this QA program include the development of screening of Outcome events, such as termination of bypass prior to adequate rewarming.

### ***5. Evaluating the Program***

Finally, it should be noted that the committee should not function in isolation. Reports summarizing the problems encountered, the actions taken and the follow-up planned should be included in periodic department business meetings. This type of communication serves to encourage staff members, as well as to allow continuing identification of new problems.

### ***Conclusion***

Quality assurance is usually viewed from three perspectives: Structure, Process, and Outcome. This framework enables problems to be identified and managed efficiently and effectively. We have shown how these principles can be applied to a small perfusion department, using readily available resources.

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