A Quality Assurance Program for Perfusion

B.A. Winn, M.B. Hurdle, J.B. Riley, and K.P. Riley
Extracorporeal Technologies, Inc.
Indianapolis, IN

Abstract

The Quality Assurance Program for Perfusion (QAPP) is designed to minimize injury to a cardiac patient through risk management.

The QAPP is a flexible manual that includes guidelines for managing human resources and contains several universal forms for use in documenting pre-pump patient status, equipment maintenance, durable and disposable equipment and justification for their use, product failure CPB procedural audits, and staff development. The QAPP contains tables outlining the risks, hazards and accidents associated with ECC equipment; protocols for routine ECC preparation; special and emergency CPB procedures; and an extensive bibliography.

The periodic audit of the QAPP contents will allow common team knowledge of protocols and physicians' orders to meet hospital accrediting body requirements and to reduce risks and hazards associated with ECC.

Introduction

Physicians have long been accountable for the results of care which they have provided. Until recently hospitals were protected from liability by the doctrine of charitable immunity which implied that hospitals were considered shells within which physicians could treat their patients. This notion gave hospitals almost complete protection from potential liability.

The legal concept of charitable immunity and the corporate practice doctrine, however, have each helped to limit hospital liability. There was actually an organizational separation between the governing body of the hospital and the medical staff. Hospital management was responsible for financial and housekeeping chores while the practice of medicine was the role of the medical staff.

As hospitals began to play more of a role in patient care through provision of laboratories and diagnostic procedures, charitable immunity status was gradually lost and hospitals were liable for patient care.

As hospitals began to assume an organizational structure similar to any corporation, they were forced to accept corporate liability. Many physicians, nurses, perfusionists, and other medical practitioners now became employees of these new corporate entities. Because perfusionists may practice as independent contractors, hospitals can be somewhat insulated from liability for the malpractice of these professionals.

The hospitals' duty of care was expanded to include the following:

1. The hospital must establish and enforce guidelines for patient safety.
2. There must be some form of risk management and/or incident reporting system to constantly evaluate and alleviate any dangers to patient safety.
3. The hospital has a duty to supervise all independent contractors and employees, professional and non-professional.

The hospital must strictly enforce the standards of medical care used by all practitioners, including perfusionists. In the event that neglect in duty of care occurs, a suit may be brought against the hospital, its employees, or an independent contractor. Malpractice suits are divided into two categories of civil law. The first category is breach of contract which occurs when a specific result or cure has been promised but the hospital, the employees, or independent contractors have failed to deliver the promised result. The other category of civil law is a tort. A tort is any wrongful act that does not involve a breach of contract.

In order for a plaintiff to recover in a medical malpractice suit based on negligence, he must demonstrate that there was a particular standard of care or duty owed that was not upheld.

Over 90% of all medical malpractice suits in the U.S. have been filed since 1964. The National Association of Insurance Commissioners (NAIC) estimates that over two million patient injuries occur per year, 35% of which appear to be due to negligence. Perfusion accidents appear to be responsible for approximately 100 injuries or deaths per year worldwide since the mid-1970s.
The current medical malpractice crisis has forced hospitals to develop risk management departments, the responsibilities of which are to predict patient injury, avoid liability exposure, and minimize malpractice claims. Unfortunately, this is normally a general function of the hospital and is not specific to any particular department, such as perfusion services.1

Stoney and Kurusz, in the 1970s and 1980s respectively have quantitated and eloquently reported the most common cases of injury and death during CPB. The most common accidents are:

1. Arterial line air embolism
2. Disseminated intravascular coagulation
3. Electrical failure
4. Mechanical failure
5. Oxygenator failure

Kurusz repeated this survey on the topic of perfusion accidents in order to determine if there had been a deterioration or improvement in the number of perfusion-related accidents. The total caseload included in the Kurusz survey was over 550,000 CPB cases.6

The two most significant results obtained from Kurusz’s survey are that safety device use is limited and that human error is responsible in greater than 70% of perfusion accidents.

Materials and Methods

The Quality Assurance Program for Perfusion (QAPP) was developed to identify, analyze, and reduce risks and hazards associated with product and equipment choice and the set-up and operation of the extracorporeal circuit. A risk management approach was developed to insure objective evaluation of all disposable components, durable equipment, and procedures utilized during extracorporeal circulation.

The performance requirements of each extracorporeal component are discussed along with suggested selection criteria to be utilized by the perfusion technician.

Education, one the most powerful tools used to reduce risks and hazards during extracorporeal circulation, is stressed throughout the Quality Assurance Program for Perfusion (QAPP). The QAPP bibliography includes articles extracted from twenty years of surgical and perfusion practice literature.

Results

The Quality Assurance Program for Perfusion (QAPP) provides the institution and the perfusion technician with a tool to objectively identify ECC risks and hazards and to document their control. The Quality Assurance Program for Perfusion is divided into five primary sections. These sections are:

1. Human Resources
2. Patient Documentation
3. Durable Equipment
4. Disposable Equipment
5. Procedures

Discussion

The Quality Assurance Program (QAPP) is now being utilized successfully in cardiac surgical centers worldwide. The medical malpractice crisis has heightened the awareness that all medical practitioners have to manage risks associated with duty of care to our patients. The application of a risk management approach to technical medical practice areas such as perfusion technology will decrease risks associated with CPB and our practice as perfusionists.

References