DEFINITIONS IN QUALITY ASSURANCE AND QUALITY MANAGEMENT

C.Th. Smit Sibinga, W.P.A. van der Tuuk Adriani

Introduction

Like in many other fields there is in the concept of Quality Assurance (QA) much confusion because of a lack of understanding and an inappropriate communication due to absence of definitions of key-terminology. Where QA in transfusion medicine is concerned with every aspect of transfusion practice and applies to all activities of a blood transfusion service or blood bank, from identification of potential donors, collection of blood and preparation of blood products to ensuring the best, safest and most appropriate use of blood and blood products in the clinic [1], there are many key-issues and terminologies involved which deserve a clear and unequivocal definition.

The conceptual starting point is a Quality System (QS) based on Organization Wide Quality Assurance (OWQA) or Total Quality Management (TQM). OWQA/TQM reflects the institute’s or organization’s quality policy dealing with personnel, facilities, equipment, safety, product design, purchasing, good manufacturing/laboratory and clinical practice, quality control, quality assurance, storage, distribution, optimal use, consultative services, administration and all related functions.

Such a QA should be based on well defined and accepted standards [2]:
- Standards for procedures and processes;
- Standards for quality control;
- Standards for services.

Examples of such standards are:
- NEN-ISO 9000 series;
- Current Good Manufacturing Practice guidelines;
- Current Good Laboratory Practice guidelines;
- Current Good Hospital/Clinical Practice guidelines;
- Standards for Blood Banks (AABB, USA);
- Normen voor Bloedbanken (NVBlFederatie, NL).

The main elements of an OWQA/TQM based QS are:
- Personnel, trained and motivated;
- Standards;
- Documentation;
- Quality control;
- Quality monitoring;
- Quality assurance;
- Error policy;
- Evaluation and audit.

They key element, however, is dedicated, motivated and professional leadership. Whatever is instituted, implemented and evaluated, personnel will determine whether a quality system or QA program will be effective and successful. Attitude and mentality are of paramount importance, where errors will occur and therefore need attention for prevention leading to improvement in quality. If we accept that errors in the field of transfusion medicine are the primary cause of morbidity and mortality and implicitly reflect a deviation from a standard procedure, then the necessary elements of a QA program are readily apparent and will provide means for error control (prevention and an efficient quality management system.

Focused on the objective of a safe and effective transfusion practice, these necessary elements are:
- Standards and Standard Operating Procedures (SOPs);
- Job descriptions;
- Teaching and training;
- Control of equipment (Equipment Operating Procedures (EOPs)) and reagents;
- Monitoring and evaluation of performance of personnel, equipment and reagents;
- Monitoring and evaluation of efficacy (including safety) of end products.

Definitions

When written up, agreed upon and accepted in consensus, definitions will provide a workable basis for mutual understanding, communication, evaluation and exchange of information and expertise.

**Quality**: The consistent and reliable performance of services or products in conformity with specified standards.

**Quality assurance**: The creation and operation of standards, programs and effective management systems to ensure quality, to be achieved by application of Good Manufacturing/Laboratory/Clinical Practice (GMP/GLP/GCP).

**Standards**: Criteria against which processes, products and services can be measured qualitatively and/or quantitatively.

**Policy**: This comprises the stated aims, objectives or standards adopted by an institution or organization. These may be determined institutionally, locally or regionally, professionally, nationally or internationally.