QUALITY ASSESSMENT AS AN ESSENTIAL TOOL FOR THE ACHIEVEMENT OF TOTAL QUALITY

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INTRODUCTION

The pursuit of the highest quality is one of mankind's most noble activities in that, in so doing, we are seeking to approach perfection in our endeavours. Though the explicit concept of quality is of recent rigorous definition, the original concept must have originated from beyond the mists of prehistory. Who can view the relics of antiquity or the artistic masterpieces of the Renaissance and not appreciate these products of artisans, craftsmen and artists for their intrinsic quality?

Whilst in many fields, this pursuit could be related mainly to personal satisfaction, peer acclaim and success in general, quality in healthcare-associated activities has all to do with people's lives and well-being. In this paper, the subject of Quality Assessment is examined as an overview by reference, firstly, to the fundamental and global concepts of quality and, secondly, to the variety of tools available for Quality Assurance. Finally, an example of a local Quality Assessment Scheme for haemoglobin levels in blood donors is then reviewed.

QUALITY CONCEPTS

One of the inherent difficulties in developing and implementing quality-related activities is that of definition of the commonly used, and often misused, terms used when discussing the various aspects of quality. For example, it is common to find the terms Quality Control (QC) and Quality Assurance (QA) used interchangeably, when in reality they refer to different but complementary activities. Similarly, modern use of language has resulted in the misuse of the word **quality** as referring to the best attainable, not as it should be, a mere description of the property of an object.

According to the International Standard ISO 8402[1], **Quality** is defined as *'the totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs'*. This definition has an important bearing on the formulation of quality policy as it injects realism and attainability and puts quality in the context of the needs of a product or service.

In tracing the development of the formalised concept of quality, one finds that the earliest forms of investigation consisted largely of Inspection and/or Testing; the former refers to

observation of product, e.g. visual inspection, whilst the latter is normally based on a more quantitative procedure. These somewhat disparate and independent activities were later incorporated into **Quality Control** which ISO defines as *'the operational techniques and activities that are used to fulfil requirements for quality'*. Thus QC Units were set up in many organisations with specific responsibilities for ascertaining product quality through appropriate inspection and testing regimes. It should be noted however that all such initiatives were product related, not service related. Where laboratory services were concerned, the practice of using controls was established, in order to monitor variations within a particular laboratory. These practices come within the scope **Internal Quality Control** which assesses the performance of a laboratory or testing site, over real time, usually through the use of control samples.

All the quality related activities referred to so far have been reactive in nature and hence, while preventing customers from receiving a defective product or poor service, they did not address the root cause. This aspect was to be covered by **Quality Assurance**, defined as *'all those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality'*. For the first time, a proactive approach was being put forward whose main objective was to tackle the cause of defects rather than the effect. This approach has proved to be so successful that most organisations nowadays possess a QA unit of some sort.

With increasing regulation and legislation, the promulgation of various codes of Good Manufacturing Practice (GMP), the laboratories' equivalent Good Laboratory Practice (GLP), and various certification and accreditation schemes, as well as the rapid growth in quality concepts based on management and scientific principles, the QA concept has developed into **Quality Systems** which consider the organisational structure, responsibilities, processes and resources for implementing quality management. These developments are now covered by such international certification schemes as those based on the ISO 9000 series of broadly based quality systems standards and the more specific accreditation schemes, e.g. NAMAS and Clinical Pathology Accreditation in the UK.

The culmination of the development of the quality concept is **Total Quality Management** (TQM). The fundamental principles of TQM may be summarised as[2]:

- Quality is not the monopoly of particular persons or units within an organisation, but is the responsibility of everyone within it.
- Quality must be an intrinsic part of all processes and procedures from the start rather than inspecting, testing, or controlling it out at the end.
- The quality ethos is subscribed to by everyone within an organisation, including top management who must declare its commitment and provide appropriate resources.

- Quality is about inter-relationships not only outside an organisation but also within the organisation; hence the concept of the *internal customer.*

QUALITY TOOLS

A wide variety of tools is used in order to accomplish quality related tasks; each has its place and its particular relevance for one or more of the quality disciplines. The particular selection that follows is comprehensive but not necessarily exclusive:

Observation is the most basic of the tools available for Inspection and QC. Much can be learnt about the quality of a product by simple but informed observation of characteristics. Similarly in a service environment, observation can often be the first indicator of potential problems.

Monitoring is an important generic function when related to process quality. In its widest sense it can be used to describe any surveillance procedures, but there are instances where it has a more specific application. One such is in the Transfusion Service where quality monitoring is an activity akin to QC, but not carried out as a pre-release procedure.

Measurement is the fundamental tool of QC activities that are based on quantitation. This tool provides an admirable basis for the application of various appropriate numerical techniques for further interpretation.

Analysis is another fundamental tool of QC, applicable particularly on less quantifiable procedures, such as the testing of raw materials. The development of a more defined quality culture saw many Analytical Departments converted into QC Departments.

Trend Analysis is one of the newer tools that uses established mathematical techniques to monitor product or service quality over time, provided that quantitative data are available. Typical parameters used are means, medians, $\pm$nSD, maxima and minima. A particular development of this tool is **Statistical Quality Control** (SQC) which seeks to refine the technique by linking data collected with particular knowledge of a process.

Quality Audit is a means of monitoring compliance with a particular standard or guideline. Current variants include GMP audits, certification audits to ISO 9001, accreditation audits, etc. By their very nature, these are qualitative tools, but particularly powerful and influential if carried out properly by able auditors.

Quality Assessment in its widest sense includes any activity that elucidates the quality status of a product or service. It has sometimes been used in the past to indicate less than precise procedures that were not easily quantified, but nevertheless provided an accurate assessment. Nowadays, the term as used in the laboratory sciences is largely synonymous with External Quality Assessment Schemes, which form the remainder of this paper.

QUALITY ASSESSMENT

The approach that we know as Quality Assessment first developed out of a need for peer comparison of similar procedures carried in geographically disparate locations. As such, this technique lent itself well to the monitoring of performance of analytical, and later clinical laboratories

External Quality Assessment (EQA) is concerned with examining and reporting the differences between different sites testing the same analyte. Typically, one or more identical specimens are distributed to participants at regular intervals for assessment under the normal test conditions used by each particular test site. Results are returned to the Organiser by the due date and are then processed to evaluate a consensus result, spread, and method differences. Reports are sent to all participants and poor performers are highlighted and notified. Persistent poor performers may have further action taken in an effort to effect improvements.

The purpose of this paper is not to examine the schemes in detail, but to examine the basis and principles of EQA in the context of Total Quality. EQAS Organisers often publish detailed annual reports for their schemes and these should be consulted for more detailed information.[3]

INFLUENCES ON EQAS PARTICIPATION

As in most endeavours to improve quality, there are positive and negative reasons for progressive adoption of new practices.

On the positive side, one can cite that the past few decades have seen a significant increase in the level of quality awareness in laboratories. This has been driven by the need to demonstrate competence both to external bodies and customers. The development and imposition of Good Manufacturing/Laboratory Practices and the later introduction of laboratory accreditation schemes have assisted in this trend.

On the more negative side, the introduction of product liability legislation and the general global increase in litigation have established the need to continually assess performance against an independent benchmark and to have such data available for any eventuality.

WHAT EQAS MAY MEASURE

By their very nature, not all EQAS offer the same level of quantitation or analysis. However they will normally measure/detect the following:

- Accuracy and precision of method: some methods or procedures may show bias or be inherently less precise.

- Changes in reagents/instruments: may show a change in reagent batch although this is more usefully identified from a laboratories own internal QC.

- Changes in environment: some methods may be temperature sensitive, and differences may show in an uncontrolled working environment.

- Changes in personnel: this can be a useful indicator in the EQAS testing policies of some laboratories where the best person may be allocated the duties of testing EQAS samples. This then is tantamount to being a proficiency test of the worker not the laboratory, certainly not in keeping with the ethos of EQAS.

- Changes in methods: often but not always the case when a new method is introduced. Unfortunately, the nature of EQAS is such that if a new more accurate method is introduced and used only by few participants, it will show a bias because of the weighting effect of the many using other methods.

CRITERIA FOR EQAS

The following are some of the criteria that should be considered in using an EQAS fully an to best advantage:

- The parameter being measured must be appropriate to the method.

- Degree of quantitation and frequency of assessment must be compatible with work carried out in the laboratory. Thus a scheme distributing samples at two-weekly intervals would be less useful to a laboratory carrying out the test every three months.

- Variables associated with assessment must be known and understood.

- Presentation and communication of results must be clear, informative and timely. Late or irregular dispatch of results often bring discredit to the scheme and appear to diminish its authority.

- The scheme's limitations must be known and understood.

- The extent of coverage (whether international, national or local) may have an important influence on its usefulness. Truly international schemes tend to be commercial in origin and should analyse data not only in method groups, but also in national groups. National schemes predominate and an example is the UK NEQAS which has a very good and consistent track record and includes participants from outside the UK. Local schemes are certainly the most variable in quality and reliability, but they also provide the means of tackling situations that often cannot be covered by the bigger schemes.

EQAS IN THE UK (NEQAS)

EQAS in the UK has been in existence for some 25 years, and has grown consistently over this time in serving the needs of clinical laboratories. At the present time there are some 58 schemes registered with the NEQAS Executive:

Schemes	Number
Autoimmune serology & special immunochemistry	12
Blood coagulation	1
Blood group serology	1
Clinical cytogenetics	1
Drug assays	6
General clinical chemistry	7
Haematology	2
Histopathology	5
Human leucocyte antigens	5
Hormones	8
In vitro allergy testing	2
Leucocyte immunophenotyping	3
Medical microbiology	3
Trace elements	2

A LOCAL EXTERNAL QUALITY ASSESSMENT SCHEME 'LEQAS' FOR HAEMOGLOBIN SCREENING OF BLOOD DONORS AT THE NORTH LONDON BLOOD TRANSFUSION CENTRE (NLBTC)[4]

In 1991, it was perceived at NLBTC that there was a need to assess the performance of each blood collection team at screening donors' haemoglobin (Hb) levels, prior to donation. According to established guidelines, men with Hb levels below 13.5 and women below 12.5 g/dL cannot donate whole blood. The screening of donors' Hb levels by the copper sulphate method, where a drop of blood from the donor's finger is observed sinking through the solution, is in routine use. Ambiguous or low results lead to a retest by HemoCue haemoglobinometer in order to obtain a quantitative result on site.

A pilot local quality assessment scheme was introduced in order to assess the machine/operator performance as well as influencing motivation. All teams were sent aliquots

of the same six selected and pooled blood samples at monthly intervals; these were also assessed by two cell counters and a standardised haemoglobinometer by the Quality Department. Each team tested these samples by both copper sulphate and haemoglobinometer techniques and returned results for analysis at NLBTC. The pilot was run for 10 sample distributions and the results were most promising as shown in Figure 1. The scheme permitted the identification of poor performers in the use of the haemoglobinometers.

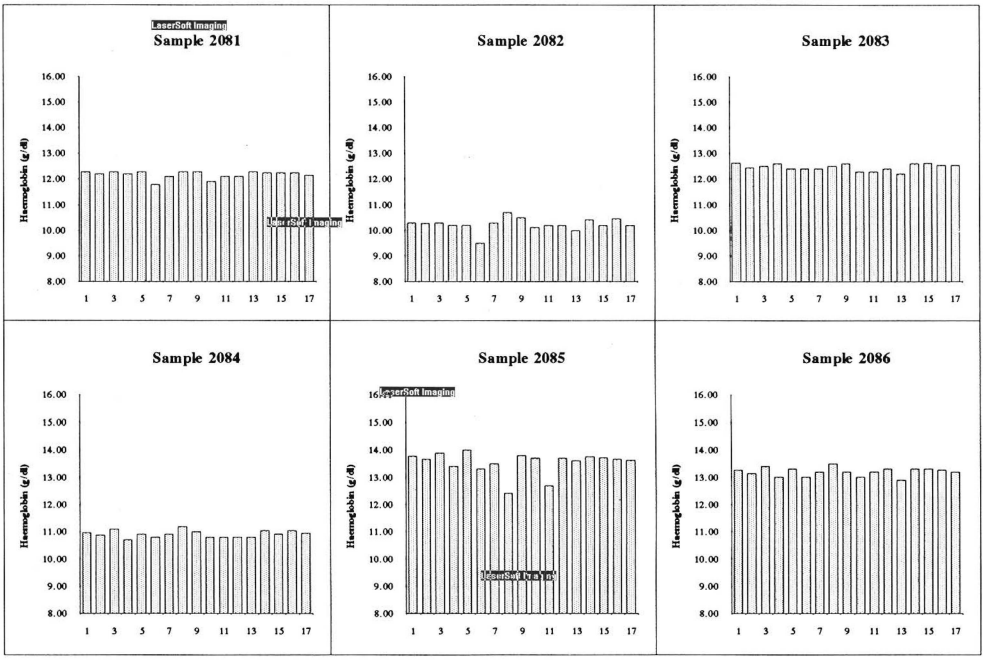

Fig 1. Haemoglobin LEQAS - Samples measured by haemoglobinometer at different sites

By further manipulation of the data accumulated over the all the monthly returns, it was also possible to compare the qualitative results by copper sulphate against the quantitative results obtained from the cell counter, as shown in Figure 2.

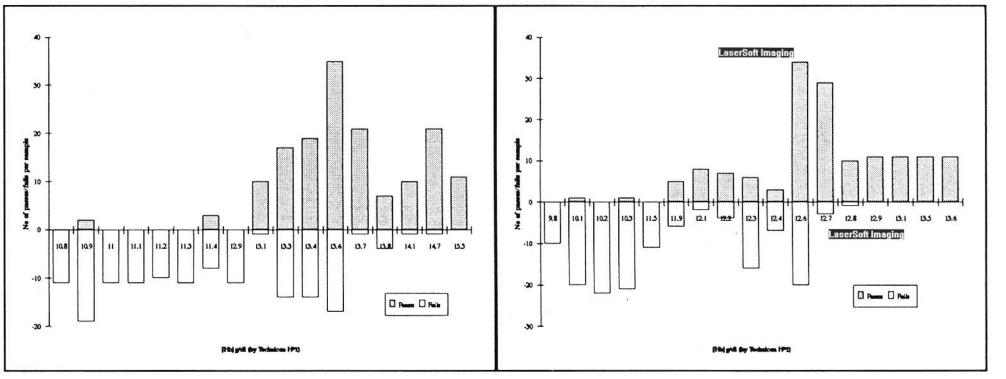

Fig 2. Haemoglobin Screen of Male (left) and Female (right) Donors by Copper Sulphate

CONCLUSION

The author recently came across the following statement which clearly enunciates the true meaning of quality in stark terms and should be understood without further comment:

"Quality . . . was a concept that was not rigorously taught or a principle to which we consecrated our hearts and souls. It was simply understood that patients could die if we made mistakes."

In this commitment to quality, it is clear that Quality Assessment plays a very important role as a tool both for monitoring and improving quality.

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