QUALITY MANAGEMENT IN MEDICAL LABORATORIES; FACTS AND FABLES

J. G. Loeber
CCKL and CCKLtest, P.O.Box 392, 3720 AJ BILTHOVEN, The Netherlands

SUMMARY — In this paper development of quality management in medical laboratories in the Netherlands is described. The following topics are discussed: concept of total quality, code of practice, training of quality managers and laboratory accreditation.

Key words: quality management, medical laboratory

INTRODUCTION

It has long been recognized that medical laboratories form an integral part of the health care system devoted to cure and care of patients. Nonetheless, medical laboratories are not a homogenous group of laboratories. They vary in size and number of disciplines (clinical chemistry, hematology, microbiology, etc.) and may be independent or part of a larger (hospital) organization, private or public funded. It is therefore difficult to fit them all into a general set of rules and regulations concerning quality management in health care. On the contrary, it is justifiable that medical laboratories claim their own specific place within the health care environment, though keeping close links to the other parts of this environment.

In 1981 the Coordination Committee for Quality Assurance in Health Care Laboratories in the Netherlands (CCKL) was founded. It has a tripartite structure consisting of various laboratory professions (including clinical chemistry, microbiology, pathology, immunology, hospital pharmacy, nuclear medicine and others), the industry, and health agencies, and resembles the U.S. National Committee on Clinical Laboratory Standards (NCCLS).

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Already in 1984 the CCKL started to get very much involved in the matter of development and implementation of quality systems, inspection, accreditation and certification. Five years later, in 1989, the subject of "quality in the health care" became a political issue in the Netherlands when a conference was held in Leidschendam, near the Hague, where all the parties concerned, i.e. patients, insurers and professionals, agreed on a time schedule for implementation of quality systems. A letter of intent was signed to have quality systems implemented by the end of 1995 in all health care units, i.e. hospitals, paramedic centers, nursing homes, etc. In line with the general governmental policy of deregulation, the Ministry of Health decided to remain at the side line, though keeping an eye at the process. In 1995 during a next national conference, it was concluded that although the above goal was not accomplished completely, the quality awareness had been considerably increased, not in the least among patients/consumers.

CONCEPT OF TOTAL QUALITY IN MEDICAL LABORATORIES

At the above conferences the CCKL has been recognized as the umbrella organization for the medical laboratories, and it has decided to formulate its own quality goals. It stated that "a medical laboratory is required to carry out, according to the state of the art, analyses in and/or examination of patient samples as well as interpretation of the results". Total quality management, first noted by Westgard et al. (1), was (re)defined as "to have the right results for the right patient available on time with sufficient analytical performance".

What does this mean in practice and what of this has been accomplished? For decades the laboratory professionals have devoted much time and effort to enhance the quality of analytical results by professional training and education, introduction of internal quality control and external quality assessment schemes.

In contrast, with respect to the matter of linking the right results to the right patient, Boone (2) in a recent review paper concludes that the major percentage of laboratory errors are made in the administrative phases before and after the actual analysis. Moreover, in the above definition it is important to note the term "sufficient" analytical performance which is not necessarily always the "best possible" analytical performance. In some circumstances the demand for a result may be so urgent that concessions have to be done towards the analytical reliability. It should therefore be considered that some of the traditional attention, time and effort devoted to analytical quality be shifted to the pre- and post-analytical administrative phases.

CCKL CODE OF PRACTICE

To discover the weak and inefficient spots of the laboratory organization, it is necessary to describe the various processes regarding the laboratory as a modern, infallible medical sorcerer’s shop but as a modern
manufacturing plant instead. This is not an easy task and many laboratories do not know where and how to start. The CCKL decided to develop a Code of Practice (3) to assist in descriptions that focus not only on events between the receipt of the sample and the reporting of results and interpretation to the requester, but also apply to the items that are indispensable to achieve this, i.e. personnel, equipment, chemicals and disposables, and housing facilities. First, existing documents as EN 45001, the ISO 9000 series, and others were collected. Irrelevant parts concerning study plan, study director, property rights of analysis results were deleted and specific medical items as service round the clock, patient's privacy aspects and the links to other health care facilities were added. For each subject explanatory notes and minimum requirements were formulated. The resulting document, updated in 1995, was also translated in English and French. It is available at a small handling charge at the author's address.

TRAINING COURSES FOR QUALITY MANAGERS

Next, training courses were developed for laboratory managers to make them aware of the advantages of a quality system and to encourage them to appoint a quality manager. In separate courses these quality managers were and are trained in developing such systems. Special attention is given to the interrelationships between various kinds of documents, e.g. the quality manual itself in which the quality goals are laid down in general terms as opposed to the very specific and detailed work instructions. It is explained to them that each laboratory must define its own criteria with respect to e.g. sample turnover time, analytical precision, retrieval time of archived patient data, register of complaints, and that these criteria should reflect the current practice rather than desirable but unattainable levels. ("Describe what you do - do what you have described") They are made aware of their own responsibilities with respect to the functioning of the quality system as opposed to the professional responsibility of the laboratory management.

LABORATORY ACCREDITATION

It is a fact that a medical laboratory that has implemented a quality system and continually supports and improves it, has reached a major goal. The reward will be losing less time in reanalyzing samples and rechecking patient's data, and an improved working spirit among the employees. Such a laboratory is very capable to check and spot its weaknesses and correct these by itself. It is a false to think that for that purpose the checking must be done by an independent body as in an accreditation system.

Nevertheless, in many countries in the last 5 years such accreditation systems have been established or are under development under pressure by
the government or the general public. In the Netherlands an accreditation body for medical laboratories was set up in 1994 under the name of CCKLtest. This name symbolises the close link to the earlier mentioned CCKL, although it is a completely separate legal entity.

The CCKLtest accreditation system is based on three pillars, i.e. the presence of a quality system, participation in an intraprofessional visitation system, and the taking part in one or more external quality assessment schemes. When a laboratory considers itself ready for accreditation, it submits its relevant quality documents to CCKLtest for a provisional check. Subsequently, a CCKLtest team consisting of 2-3 persons, at least one of which is a colleague from the same discipline, performs a site visit. Based on the team’s report the CCKLtest Board decides on granting the accreditation. It is estimated that in the next 5 years most medical laboratories will be visited at least once.

REFERENCES