

Methodology of presenting analytical quality assurance courses for medical technologists

Moraba MM, D Tech: Odendaal JSJ, PhD
 Department of Biomedical Sciences, Faculty of Health Sciences, Tshwane University of Technology, Private Bag x 680,
 Pretoria 0001

Address for correspondence:

Dr MM Moraba, Department of Biomedical Sciences, Faculty of Health Sciences, Tshwane University of technology, Private Bag x 680, Pretoria 0001

ABSTRACT

A survey on the quality of service provided by state laboratories in the Limpopo Province was conducted during the period 2000 – 2002. The focus was on accuracy and precision. The service quality evaluation was based on standard deviation index, % deviation and % clinically rejectable results. The scores obtained were evaluated in terms of internationally pre-determined cut-off limits. Education and training were cited by 97% of the interviewees as the major contributory factors to the poor performance.

Subsequent to the discussion, a course in quality assurance was designed, presented and evaluated, as above. Although the post-intervention performance results did not meet the international performance standard at the given time yet; they were much closer to norm and significantly better than the pre-course performance results.

The conclusion is that newly designed course will contribute in reaching the international cut-off standard for clinical laboratories.

INTRODUCTION

Well-managed competent laboratories that meet approved basic standards are mandatory in order to enable doctors to perform their duties with accuracy and preciseness.^{1,2,3,4} However, the current training and developmental approach is often inadequate to confer competence to the laboratory analytical staff, to meet the minimum performance demands⁵. According to two Medical Technology Newsletter reports in 2004, new graduates in biomedical technology from technikons, universities and some of the practicing medical laboratory technologists, struggle to perform to the level of international standards^{6,7}. The deficiency necessitates an intervention to improve knowledge and performance⁸.

A new system and course design for the training and development of laboratory analytical staff was thought to be an answer^{9,10}. Course in quality assurance was thus designed using South African Qualification Authority (SAQA) format on the National Qualification Forum (NQF)^{11,12}. This would be a one-year-certificate course at universities, on an exit Level Six on the NQF and entrance to the NQF Level Seven. The course has been longitudinally designed to address the basic knowledge requirements in the running of medical laboratories and in building analysts towards competence. A specific sequence was followed in the design of the course structure, to ensure incremental knowledge was gaining among learners¹³. The course format is that of outcome-based, competency-based and modular training approaches. The combination of these approaches highlighted the advantages of being learner-centred, acknowledgement of learner diversity, focusing on responsibility and allowing learners to achieve their full potential.^{14,15}

PARTICIPANTS

Learners doing experiential training; medical technologist interns; practicing medical technologists and other analytical staff of all races, genders, from the age of 16 years, from technikons, universities and other training institutions, were the primary role players (n = 80). They represented state medical laboratories in the Limpopo Province (n = 16).

MATERIALS

Lyophilised samples, 3 per participant, (n = 240) were provided by the National Health Laboratory Service (NHLS) and Thistle Quality Assurance divisions. Dried-up materials were preferred for their stability.

A classroom and laboratory were used to present the course and to execute the tests with the standard operating procedures for both automatic and manual procedures.

METHODS

The course was presented in the form of workshops, using selected instructional strategies that included lecturing, demonstrations, practical involvement of participants, group discussions, individual and group exercises and case studies. The quality of the course and its presentation methodology was tested through experiments carried out by the participants. Both pre- and post-course performance evaluation took the following approaches:

A: % Standard Deviation Index (SDI) mean scores for all laboratories

Performance evaluation using standard deviation index (SDI) approach:

$$SDI = \frac{\text{Obtained value} - \text{Mean value}}{\text{Standard deviation (SD)}}$$

This was done for every test. To express performance in a testing event the number of tests with SDI numerically equal or less than two; is divided by the total number of tests in the testing event, expressed as %:

$$\frac{\text{Number of tests with } SDI \leq 2 \times 100}{\text{Total number of tests in the event}}$$

= the individual laboratory's score for that event in %

That was done for all testing events. The scores were added together and the mean calculated by dividing the sum of the scores of all testing events by the number of the scores. This process was done for all participated laboratories and the common mean score for all laboratories was calculated by dividing the sum of their mean scores by the number of their mean scores as follows:

$$\frac{\text{Sum of individual laboratories mean scores in \%}}{\text{Total number of laboratories' mean scores}}$$

= mean SDI score in % for all participated laboratories

B: % Deviation mean scores for all laboratories

Performance evaluation using % deviation approach:

$$\frac{\text{Obtained value (result) - Mean (target) value} \times 100}{\text{Mean (target) value}}$$

= % deviation score

The results are compared with the predetermined cut-off limits and rated either as acceptable or rejectable. Results equal to or less than the cut-off limits are rated acceptable while, those above the cut-off limits are rated unacceptable and rejectable. This procedure was followed for all tests in a testing event and the score for that event was determined as follows:

$$\frac{\text{Total number of acceptable \% deviation values} \times 100}{\text{Total number of tests in the event}}$$

= mean event % score for all testing events for that laboratory.

The mean % deviation score for that laboratory was calculated as follows:

$$\frac{\text{Sum of all mean event \% scores} \times 100}{\text{Total number of mean event \% scores}}$$

= mean % deviation score for that laboratory

The same procedure was repeated for all participated laboratories and the common mean score for all laboratories was calculated by adding all the individual laboratories' mean scores and divided the sum by the total number of all the mean % deviation scores:

$$\frac{\text{Sum of all individual laboratories' mean scores} \times 100}{\text{Total number of individual laboratories' mean scores}}$$

= mean deviation score in % for all laboratories

C: % Clinically Rejectable Results mean scores for all laboratories

The % clinically rejectable results scores were calculated by subtracting the % deviation score from 100:

$$100\% - \text{acceptable \% deviation mean score} = \text{clinically rejectable results score for all laboratories}$$

The average of all participated laboratories' SDI scores constituted the overall mean % SDI score for the entire laboratory population (research sample). Similarly, the average of all participated laboratories' % deviation scores constituted the mean % deviation score for the entire laboratory population.

In the same way, the average of all participated laboratories' rejectable results scores constituted the overall mean rejectable results score.

After consolidation of scores, comparison and rating of performance were done with cut-off references as follows: 95.5% for % SDI, 80% for % deviation and 10% for rejectable results^{16,17,18,19}. Performance scores before and after course intervention were compared. Conclusions were drawn with regard to the contribution to knowledge and performance made by the course programme and its presentation methodology.

Proposed and documented course programme in quality assurance was designed as follows:

- Preparation of reagents and solutions.
- Analytical methods and equipment selection.
- Equipment preventative maintenance.
- Accuracy and precision.
- Quality assurance programmes and techniques.
- The use of quality assurance programmes and techniques in the evaluation and control of laboratory data.
- Programme for error detection, isolation, identification, solving and control.

The course presentation followed subject-specific didactical, outcome-based and modular approaches, with the associated aspects and principles of teaching and learning, to ensure course mastery^{20,21,22,23}. An introduction of

the module was given. This aspect described and provided justification for the module and introduced the learners to the module. Terminology of the module followed the introduction and then, various terms used in the text were explained to ensure common understanding of the text by the readers. Credit level, after terminology, described the number of credits (points) allocated to the module, depending on its complexity. A purpose statement, followed credit level, provided the teaching (presentation) objective(s) of the module in the course.

Outcome level served as an achievement the learner had to demonstrate as a proof of having learned to the satisfaction of the module or of course requirements. Course outcome level is associated with organisational expectations from the learner(s), at the end of the course presentation. Module outcome level is therefore, module exit requirement. Specific outcome served as an instruction to the learner to demonstrate an achievement of a certain learned behaviour. A number of specific outcomes constituted an outcome level. Informative, drill, appreciation, practical and revision lesson types were used. Instructional strategy took the form of lecturing, case studies, group discussions, individual exercises, demonstrations and observation.

Evaluation was formative, diagnostic and summative^{24,25}. Assessment criteria represented demonstration of detailed pieces of knowledge that constituted achievement and mastery of specific outcomes, by the learner. Successful demonstration of the assessment criteria represented the entire module or course mastery and thus, achieved learning.

Table 1: Summary of course structure and presentation methodology

Module	Content	Outcome level	No. of specific outcomes	No. of assessment criteria
1	Preparation of reagents and solutions	Demonstrate the ability to prepare high quality reagents and solutions	6	40
2	Analytical methods and equipment selection	Demonstrate procedures to be followed when deciding on analytical method and equipment selection	7	39
3	Equipment preventative maintenance	Provide guidance to equipment preventive maintenance using maintenance schedule(s)	4	48
4	Accuracy and precision	Apply a systematic approach to express accuracy and precision concepts. Demonstrate their relationship and measurements using their parameters.	5	34
5	Quality assurance programmes and techniques	Provide quality assurance techniques and benefits, with respect to internal and external programmes.	5	73
6	Use of quality assurance programmes and techniques in the evaluation/control of laboratory data	Demonstrate the ability to evaluate the quality of analytical data using integration of internal and external programmes of quality assurance.	20	113
7	Programme for error detection, identification, solving and control	A grossly abnormal patient result is reported. Conduct a systematic investigation into possible contributing factors, applying the three phases in quality assurance.	5	57

RESULTS

The course programme brought about the following improvements in performance:

Table 2: Pre- and post course presentation performances of medical technologists in state clinical laboratories (n=16)

Performance	% Standard deviation index (SDI) mean scores	% Deviation mean scores	% Clinically rejectable results mean scores
Before course intervention	60	56.7	43.3
After course intervention	86.2	71.0	29.0
Differences	26.2%	14.3	14.3%

DISCUSSION

Course in quality assurance for medical laboratories with the above structure and presentation methodology, has improved knowledge and performance by: 26.2%, 14.3% and 14.3% in terms of % SDI, % Deviation and % Clinically Rejectable Results, respectively. Feedback from laboratories is that the course style and the presentation methodology are worthy and have enriched their knowledge and improved their analytical skills and performance.

It is recommended that the course and presentation methodology in medical laboratory technology should be implemented to empower its professionals, adequately. Such a transformation is likely to improve and enable the practitioners to cope with the demands and challenges within the medical fraternity, making them experiencing the sense of professionalism.

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