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TRAINING IN CLINICAL LABORATORY MANAGEMENT (Guidelines 1988)

Prepared for publication by

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Guidelines (1988) for Training in Clinical Laboratory Management

Summary: Trainees in laboratory medicine must develop skills in laboratory management. Guidelines are detailed for laboratory staff in training, directors responsible for staff development and professional bodies wishing to generate material appropriate to their needs. The syllabus delineates the knowledge base required and includes laboratory planning and organisation, control of operations, methodology and instrumentation, data management and statistics, financial management, clinical use of tests, communication, personnel management and training, and research and development. Methods for achievement of the skills required are suggested. A bibliography of IFCC publications and other material is provided to assist in training in laboratory management.

Contents

1. Introduction

The scope of the disciplines that comprise laboratory medicine has expanded significantly in the last three decades. The range of quantities assayed and the variety and complexity of analytical techniques used have substantially increased. The turnaround time from the submission of a specimen to the receipt of a result has decreased and the performance characteristics of analytical procedures have continuously improved.

Simultaneous with these changes, the clinical use of results has also altered. The majority of results from patients in hospitals are used for management rather than as aids to diagnosis. Frequently, laboratory tests are performed prior to the actual clinical examination. In certain countries, the monitoring of apparently healthy individuals makes use of laboratory test results in preventative medicine. Hospital practices also have changed with significant ramifications on laboratory services; for example, more severely ill patients are being treated in specialist units such as intensive care, neonatal, coronary care and oncology units, etc. The changing spectrum of disease, for example, the growing number of patients with acquired immunodeficiency syndrome, also imposes new demands on laboratory services.

Thus, laboratory medicine is not a static discipline and undoubtedly change will continue to occur, probably even more rapidly as time progresses. For this reason and because, with the current worldwide concern about the costs of health care, modifications and improvements in laboratory services will probably need to be introduced without significant new expenditure on staff or equipment, it is therefore beholden upon trainess in laboratory medicine to develop adequate skills in *laboratory management*. This document is intended to serve as guidelines for training in this important area. It is suggested that the guidelines will be of value to laboratory staff learning management skills, directors of laboratories responsible for training staff in management and professional bodies wishing to generate guidelines appropriate to their national needs.

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2. Scope

Although a considerable amount of knowledge about laboratory management is gained by experience, it is vital, particularly for those likely to become directors of laboratories, to learn both theory and application in an ordered and systematic manner. The qualifications regarded as necessary prerequisites for appointment as a laboratory director differ from country to country, but, irrespective of this, the syllabus detailed here is designed to fulfil the needs of both medical and science graduates.

Before commencing in-depth training in laboratory management, an adequate basic training must have been gained ideally, for clinical chemists, the material detailed in the previous recommendations of the Committee/Commission on a scheme for a two year postgraduate course in clinical chemistry should have been assimilated. It is particularly important that the science graduate is familiar with the clinical and interpretative aspects and that medical graduates have sufficient understanding of laboratory techniques before undergoing the training detailed in these guidelines.

3. Syllabus

The subject material to be included in the training programme is organised under the following headings:

3.1 Laboratory planning and organisation
3.2 Control of operations
3.3 Methodology and instrumentation
3.4 Data management and statistics
3.5 Financial management
3.6 Clinical use of tests
3.7 Communication
3.8 Personnel management and training
3.9 Research and development

3.1 Laboratory planning and organisation

It is essential that the individual responsible for laboratory management be able to plan and organise laboratory services and, as a necessary prerequisite to this, training should encompass the following:

3.1.1 Structure of health services in the country of the trainee, current national policy, priorities and resources,

3.1.2 Classification of laboratories (for example, primary, intermediate and specialist), interactions between types of laboratory, functions of the laboratory in diagnosis, management, screening, education and research and development.

3.1.3 Definition of workload and influencing factors, for example, local spectrum of diseases, expertise of clinical staff, availability of laboratory staff and equipment, type of population served – paediatric, adult, aged, chronic sick, acutely diseased, etc., assessment of workload using performance indicators, for example, unit values, number of requests and test per request ratio.

3.1.4 Strategies for organisation of the laboratory; benefits and disadvantages of discretionary and profiling approaches, problems associated with biochemical screening, analytical equipment operated by non-laboratory personnel outside the laboratory (including local regulations, medical requirements, equipment and range of analysis available, training of analysts and quality assurance).

3.1.5 Organisation of workflow including the collection and transportation of specimens; identification of specimens and samples using colour codes, unique numbers, bar codes and other methods, distribution of specimens throughout the laboratory, work simplification techniques, referral of specimens to other laboratories.

3.1.6 Laboratory design; space requirements, optimum utilisation of space, requirements for services such as electricity, gas, water, etc, design requirements for handling radioisotopes, high risk specimens and disposal of waste materials.

3.1.7 Organisation of emergency services; advantages and disadvantages of dedicated laboratories, equipment and methods, turnaround times required for emergency tests, selection of the appropriate repertoire, strategies to monitor use and abuse of the emergency laboratory, setting of a hierarchy of priorities for test requests.

3.2 Control of operations

All aspects of laboratory work should be monitored with the aim of always achieving the highest possible quality of performance. This implies that a *quality assurance* programme must be established, including internal quality control, participation in external quality assessment and a series of monitoring schemes specifically designed for other aspects of laboratory work including the materials used, specimens submitted, staff morale and skills, reporting systems and turnaround times.

Training in laboratory management should therefore include the following:

3.2.1 Establishment of comprehensive internal quality control programmes, participation in quality assessment schemes, the availability of such schemes, analysis of the data generated in the assessment of imprecision, inaccuracy, linearity and other performance characteristics, the use of such data in method and instrument selection.

3.2.2 Quality control of specimens submitted and strategies to deal with inadequate specimens, quality control of materials and reagents, quality control of instrumentation including balances, water baths, incubators, refrigerators, spectrometers, automated analysers, isotope counters, pipettes, diluters, dispensers, etc, quality control of data handling and calculation facilities, monitoring of the performance of individual members of staff, quality control of reporting systems and turnaround times.

3.2.3 Preparation and use of laboratory procedure manuals as both educational material and a means of ensuring that all methodology is maintained at a constant high standard.

3.2.4 Setting of desirable standards of analytical performance, strategies for the improvement of laboratory performance with existing staff, methods, instruments and resources.

3.3 Methodology and instrumentation

Correct selection and use of methodology and instrumentation is of vital importance if the laboratory is to play a full role in the provision of optimal health care; adequate training therefore must be provided in the following:

3.3.1 Preparation of ideal specifications for methods, instrumentation and reagent kit sets in order to facilitate selection, assessment and evaluation of methods, instruments and reagent kit sets, introduction of new methods into regular use in the laboratory.

3.3.2 Purchase of equipment, preparation of documentation required for funding and purchase, negotiation of warranty and service agreements.

3.3.3 Maintenance of equipment, preparation of equipment usage and maintenance logs.

3.4 Data management and statistics

The optimal use of laboratory data is not always achieved; a knowledge of appropriate techniques for data handling and interpretation is essential for the

laboratory manager. Moreover, the ever increasing use of computers requires knowledge of their applications and limitations. A working knowledge of statistical techniques and their correct application is also required.

Training therefore should include the following:

3.4.1 Units, use of numerical data in management, the fundamentals of computers, main-frame, mini- and micro-computers, networks, applications of computers, on-line acquisition of data from instruments, preparation of work lists, patient data-bases and reports, use of computers in quality control and assessment, expert systems, system design, availability of commercial and other laboratory computer systems, data storage, retrieval and confidentiality.

3.4.2 Laboratory calculations, curve fitting routines, data handling for radioimmunoassay and other ligand assays.

3.4.3 Statistics including common parametric and non-parametric techniques; mode, median and mean, range, standard deviation, variance, linear regression, correlation, and probability, *Deming*'s method, *t*-tests, *F*-test, *Wilcoxon* test, simple analysis of variance.

3.5 Financial management

In addition to gaining a basic understanding of budgeting systems, especially those adopted locally, an awareness of the following must be gained:

3.5.1 Costing of laboratory tests, division of expenditure into fixed (staff, instrumentation, etc) and variable (consumables, reagents, etc) costs, patient billing and/or clinical (management) budgeting (if appropriate), virement, methods of obtaining additional resources.

3.5.2 Costs of consumables, advantages and disadvantages of bulk purchase and standing orders, costs of service contracts, amortisation of equipment costs and advantages and disadvantages of hire agreements.

3.5.3 Budgetary planning for future activities, presentation of budgets, projected expenditure on method development, instrument purchase, expansion and/or reorganisation of services.

3.6 Clinical use of tests

It is of vital importance that senior laboratory staff are able to advise the clinician not only on the selection of the most appropriate tests and the interpretation of results, but also on the nosological characteristics of the tests. Moreover, the ability to discuss the introduction of new tests and the phasing out of obsolete tests with clinicians must be gained, as must the knowledge to be able to develop efficient and effective strategies for the use of laboratory. Training should therefore cover the following topics:

3.6.1 The theory of reference values, selection of reference individuals, statistical approaches to generation of reference values, the endogenous, exogenous, ethnic, genetic and laboratory factors that affect reference values and strategies for objective comparison of observed values with reference values, biological variability and the uses of biological variation data.

3.6.2 The uses of knowledge of the nosological sensitivity and specificity and predictive value of tests, receiver-operating characteristic curves and likelihood ratios, objective analysis of clinical literature on laboratory test use.

3.6.3 Strategies to modify the requesting behaviour of clinicians (including rationing, education, budget incentives and development of protocols for investigation), introduction of new tests and elimination of obsolete tests.

3.6.4 Education of medical studies, training of junior clinical staff, establishment of joint clinical/laboratory educational activities, preparation of laboratory case reports.

3.7 Communication

Inter-personal communication is vital and training should not only encompass communication with clinical staff on an individual level concerning the matters dealt with in Section *3.6* but be on a broader basis, to include:

3.7.1 Communication between staff within the laboratory.

3.7.2 Communication with laboratory users through laboratory bulletins, request forms, reports and laboratory handbooks.

3.7.3 The advantages and limitations of the various styles of request forms, styles of single or cumulative reports and laboratory data filing systems.

3.7.4 Communication with administrative and laboratory staff, preparation of reports and memoranda, committee structures and procedures, roles of chairman, secretary and other members, taking of minutes and preparations of agendae.

3.8 Personnel management and training

The individual responsible for laboratory management must be adequately trained in dealing with the most important laboratory resource — the laboratory staff — and, thus, training should encompass the following:

3.8.1 Laboratory staff structures, staff selection procedures, preparation of job descriptions, setting of responsibilities and chains of command, promotional procedures, disciplinary and grievance procedures, legal conditions of service, requirements for licensure and certification.

3.8.2 Evaluation of individual members of staff, assignment of functions and responsibilities.

3.8.3 Training and education of staff according to their level, assessment of capabilities, career needs

and aspirations, development of in-house training programmes and the evaluation of these, liaison with external educational institutions and professional bodies.

3.8.4 Laboratory safety including fire precautions, handling of potentially hazardous specimens and chemicals, disposal of wastes, accident reporting, awareness of local and national requirements of legislation.

3.9 Research and development

Although most individuals who are in the final stages of training for a career in laboratory management will have performed some research and development work, it is essential that adequate skills be gained in the following:

3.9.1 The ability to develop improvements in methods and techniques, to evaluate proposals for both laboratory based and clinical research projects and to critically evaluate published work.

3.9.2 Analysis and documentation of results obtained through research and development, presentation of results in lectures, seminars and workshops, oral and poster presentations at conferences, congresses and meetings and the preparation of scientific papers.

3.9.3 Preparation of requests for grant funding, development of proposals for joint research projects, role of committees on ethics of research.

3.9.4 Supervision of junior staff and students in the day to day performance of research and development projects.

4. Achievement of Skills

As stated earlier, a considerable amount of knowledge on laboratory management will be accumulated through experience; however, it is advisable, if possible, for trainees to attend local or national courses that deal with the more general issues, of management, for example, personnel, finance, etc.

These courses often have participants from a number of disciplines which enhances their value.

Visits to other laboratories should be undertaken and a spectrum of types and sizes should be studied during the training period in order to assess both the common and different management problems and view the different approaches to solving problems. Indeed, attainment of the skills required may necessitate the trainee being formally employed in different laboratories or being seconded for appropriate lengths of time to laboratories of different types.

Ideally, much of the training in laboratory management should be performed in a large tertiary care teaching hospital laboratory where a large repertoire of tests are performed on a wide variety of specimens from patients with a broad range of clinical conditions. This will facilitate review and tutorial sessions with a number of senior members of staff with different qualifications, backgrounds, interests and experience. Moreover, in such laboratories, there is likely to be a cohort of individuals in training which facilitates learning by, for example, the setting up of discussion groups, interactive solution of problem-solving exercises and simple peer pressure. In addition, it is easier in these situations to gradually give the trainee increasing responsibilities and management functions.

It is considered unlikely that a full-time didactic course in laboratory management will be a satisfactory educational vehicle. A part-time course of, for example, one evening or day per week over one year would have advantages; the number of participants should be limited to ensure educational effectiveness.

An important component of the advocated training in laboratory management is the performance of relevant project work. Circumscribed projects, for example, on selection of a new instrument, preparation of a budget for a section of the laboratory, assessment of a new clinical test in collaboration with a clinician, would form useful exercises during training. A summary project, of potential benefit to the laboratory of the trainee, could be a study reviewing the management of the laboratory in which the trainee is employed.

It is most important for the head of the laboratory to ensure the availability of adequate resources for training in laboratory management, to encourage the development of managerial skills and to involve the trainee (even as an observer) in the real decision-making processes of the laboratory.

Laboratory medicine is continually and rapidly evolving, therefore the syllabus detailed in these guidelines should not be regarded as inflexible, but should be modified as changes in practice occur. Moreover, in different countries, there are diverse approaches to laboratory management and these guidelines should be modified locally as deemed necessary; professional bodies are considered to be ideal groups to perform such changes.

5. Suggested Literature

There are no texts which satisfactorily cover all of the material outlined in the syllabus. The list of books, papers and other sources given below is aimed to

(i) facilitate curriculum design, development and implementation by those responsible for training individuals in management and
(ii) aid individuals who are undertaking training in laboratory management.

The bibliography is divided into two sections,

(i) recommendations and other publications emanating from IFCC and
(ii) other material judged to be of value and relevance.

The content is mainly concerned with clinical chemistry.

Much valuable information on many of the topics detailed in this syllabus can be found in the many excellent and widely used textbooks (in the U. S. A. e. g. Tietz, N. W. (ed.), Fundamentals of Clincal Chemistry, 3rd Edition, Philadelphia: Saunders, 1985) these texts should be familiar to those embarking upon in-depth training in laboratory management and are therefore not included in the bibliography.

5.1 IFCC Publications

5.1.1 Quality control

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J. Clin. Chem. Clin. Biochem. *21*, 877–884.

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Logan, J. E.
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J. Clin. Chem. Clin. Biochem. (1983) *21*, 893–898; Clin. Chim. Acta (1984) *137*, 371F–379F; Clin. Chem. Newsletter (1985) *5*, 81–86.

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J. Clin. Chem. Clin. Biochem. *22*, 573–582.

Okuda, K.
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