WHO REGIONAL PUBLICATIONS, EASTERN MEDITERRANEAN SERIES 3

Principles of Management of Health Laboratories

WORLD HEALTH ORGANIZATION
Regional Office for the Eastern Mediterranean

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Foreword

The 1990's will be remembered as the era of evaluation and accountability for health systems and outcomes. This era's health care environment, plagued by spiralling costs, the increasingly complex administration of health systems, and the growing demand for quality health services, has fostered a conscientious effort on the part of health care professionals to formulate approaches for assuring the quality of services and outcomes. This is also true for those administering and managing laboratory systems that support public health programme and the delivery of essential health care services.

This publication represents an effort to develop a laboratory resource manual that discusses basic management tools and principles tailored to the needs of the laboratory manager. The traditional emphasis and approach to improvements in the quality of health laboratory test results have focused primarily on the 'analytical' component of the test system. This manual discusses management functions and systems that are critical to a system of assurance and delivery that will guarantee quality laboratory performance and accurate and reliable test results.

The magnitude and scope of responsibility for laboratory managers has grown proportionately with rapidly advancing technology and the increasing reliance and dependence on laboratory test results for critical patient management decisions. At the same time, however, laboratory resources have rarely kept pace with the level of responsibility and demand. The laboratory manager is faced with the major challenge of maximizing the efficiency and effectiveness of the fiscal, physical and human resources within the laboratory system to assure access and quality, while at the same time containing the cost of service.

This publication is not intended to be a substitute for formal management training or a comprehensive treatment of all management systems critical to the optimal function and operation of the laboratory. Rather, it identifies, highlights and offers management tools to improve management performance in areas that are essential to optimal laboratory performance, but are often inadequately addressed and presented for use and application by the laboratory manager.

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Preface

In many developing countries a major obstacle facing the development of health laboratory services is the lack or insufficient managerial skills among health laboratory managers. The World Health Organization's Eastern Mediterranean Regional Office (WHO/EMRO) is aware of this problem and continues to encourage countries of the Region to apply modern management techniques. Senior health laboratory services staff participate in workshops and attend training courses on health laboratory management organized by WHO in collaboration with non-governmental organizations.

EMRO is also promoting the inclusion of laboratory management in the curricula of health laboratory technology training institutes. Tutors from some countries have been sent for training on this subject to the Centers for Disease Control (CDC), Atlanta, Georgia, USA.

This publication is intended to serve as a guide for laboratory managers at all levels and to be used in the preparation of material to train in laboratory management all those who can contribute to the development of health laboratory services.

The authors would like to express their deepest gratitude and appreciation to Dr Hussein A. Gezairy, Regional Director of the Eastern Mediterranean Region, for his valuable continuous support. Our special thanks are due to Dr M.H. Khayat, Director, Programme Management, for his sustained support, encouragement and help. The provision of both information resources on laboratory management together with material used by the CDC for laboratory management training, and reviewing of the draft and ensuing constructive suggestions by Dr Joyce Essien and her colleagues have been invaluable to us.

Introduction

The mission of health laboratory services is to provide a high quality service to meet the needs of patients, the community and health staff. The successful achievement of the aforementioned mission and the provision of such an array of services are key elements of an effective and efficient health laboratory service which relies on highly complex management activities.

In many developing countries one of the major weaknesses of laboratories is that many professionals and technicians hold managerial positions without being trained in the specific skills needed for related responsibilities. This may partly explain the numerous difficulties hindering the smooth operation of the laboratory services in many countries of the Region, as well as in many other countries.

In this document we try to provide all managers working in the area of health laboratory services, i.e. from the frontline technician supervisor to the top managers (including the director of the national service as well as the directors of the provincial or governorate health laboratories), with a basic managerial background through some concrete case studies or examples. Major issues encountered in the development and operation of national health laboratory services, or an individual health laboratory, in many countries of this Region are given in the seven chapters of this publication. At this stage we prefer not to deal with some aspects such as interviewing and appraisal of staff, computer applications in health laboratories, laboratory accreditation and licensing, which could be dealt with at a later time.

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CHAPTER 1

Management - general points

Mission of health laboratory services

In the field of laboratory services, there are several subjects of concern for both providers and consumers. These include: the quality of test results, financial resources, motivation of staff, as well as overall efficiency and effectiveness. Before scrutinizing how management methods may help resolve many of the difficulties faced either by individual health laboratories or by the National Health Laboratory Service (NHLS) (sometimes referred to as the national service in this document), particularly in the countries of the EMR, it may be worthwhile briefly reviewing the role or mission of health laboratory services in order to define better the nature of such concern.

The mission of health laboratory services is to provide high quality services, in the right place and at the right time, in respect of the needs of patients, the community and/or health staff, including not only clinicians but also epidemiologists and environmental sanitarians.

Laboratory contributions to patient's care and community health

With regard to the needs of physicians/clinicians the laboratory should contribute to:

- making prompt and correct diagnosis and hence initiating appropriate therapy;
- establishing prognosis through the provision of indicators of levels of severity; and
- follow-up, through the establishment of baseline data.

Laboratory contributions to public health services in the community

The contribution to community health services and particularly to disease prevention and control, is a responsibility of paramount importance for the national services in the EMR where infectious diseases account for 40% of deaths compared to 8% in industrialized countries*. Accordingly, the laboratory should:

- Ensure case detection and early identification of epidemics, which form an essential part of any control programme.
- Identify important reservoirs and their relative role in disease transmission.
- Identify important modes of transmission through examination of common vehicles, such as water and food, to verify absence of pathogens.
- Identify vectors related to vector-borne diseases.

* Figures for 1980.

Many of these health laboratory contributions are essential for an evaluation of national disease problems, which in turn is essential for decision on priorities and strategies to be adopted for the control of disease and for monitoring operation control and certification of their success.

Management - definition

The term management is used in several ways depending on the situation and background of the person using the term. There are many definitions of management; a frequently used one is the art of getting things done through people. It appears that the most suitable definition for health laboratory services may be formulated as follows:

> Management is the guiding of human and physical resources (money, equipment, reagents, material and space) through the complex, changing and difficult environment towards determined goals and objectives, achieving beneficial results for those served.

From the above definition, it clearly appears that management is the process by which an organization seeks to identify what should be done, who will do it and how to use people and other available resources at the organization's disposal to achieve the desired results.

In certain cases the term *managers* refers to top officials of an organization, (e.g. director-general, under-secretary of health) who are usually in a position to set general policies and determine the manner in which the organization will operate. In the present document, the term *top managers* will be used to refer to the director of the national health laboratory services and the directors of provincial or governorate central laboratories. It is to be remembered that there are several managerial approaches which include a connotation of participative management. In conclusion and according to the definition given above, it may be stated that a manager *guides*, or in other words, gets work done though others.

Who are the managers in health laboratories?

In health laboratory services, as is the case in other organizations, there is a hierarchy of managers, starting from the frontline supervisor technician at the district hospital laboratory responsible for supervising the work of: the laboratory assistant operating at the health centre peripheral laboratory, the chief technician heading a laboratory section, and the chief supervisor-technologist or operations manager assisting the director of the laboratory. These personnel, as well as those handling the top management of the NHLS, are managers. The difference between them depends on the level of expertise required for each level.

What does a manager have to manage?

Four key functions are required of managers at all levels. These are:

- planning
- organizing
- directing
- controlling

These four functions may not be equally used by managers at different levels. While top managers may be more involved in planning, particularly long-term planning and broad policy-making, the mid-level managers will be more involved in the establishment of further detailed operational policies, development of more detailed programmes of activities or plans of action, and any readjustment of the organization as appropriate. Finally, the frontline supervisor will be more involved in directing and controlling the implementation process, i.e. checking that the activities proceed according to pre-established standards.

At what should the manager aim?

A director of the NHLS or an individual health laboratory, being *accountable* to governmental organization, is responsible for converting *social resources* (budget) into certain *social returns*. Keeping this basic principle in mind, the aim of health laboratory managers should, above all, be consistent with the mission of the health laboratories and the definition given for management. Efforts should be directed towards achieving the greatest *efficiency* and *effectiveness* in the following three areas:

- laboratory quality assurance and/or total quality
- services delivery
- resources management

Efficiency is an expression of the relationship between the results obtained from the planned activities and the effort spent in terms of human time (work-hour) and financial and other resources. In the field of health laboratories, efficiency is measured using indicators such as work-unit cost, cost of tests and productivity. These will be discussed in more detail at the end of this document. Efficiency can be expressed by the following general formula:

$$\text{Efficiency} = \frac{\text{output}}{\text{input}}$$

Effectiveness is defined as *producing the intended result*. In the case of health laboratory services, it measures the degree of achievement of the mission and attainment of the predetermined plan objectives and targets as set by the managers of a laboratory or the NHLS. According to the basic principle stated above, the effectiveness of the NHLS will depend upon the *social gain* of the services delivered. The NHLS will be effective only if

the resulting *social benefits* (B) exceed the *social costs* (C) incurred in conducting the NHLS, as shown in the following formula:

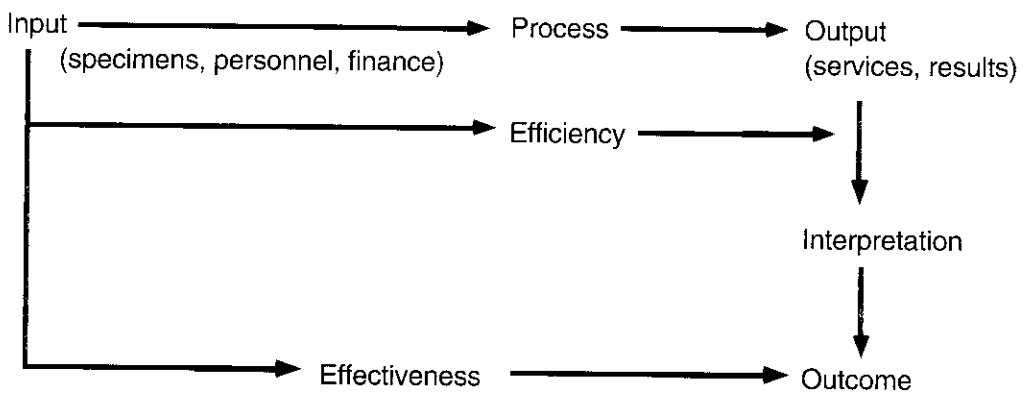
$$\frac{B}{C} > 1$$

In practice, the effectiveness of the NHLS and the laboratories involved depends on the relevance of their objectives and targets to the national health policy and priorities which have social gains as a basic constituent. Objectives should be based on the needs of physicians and, ultimately, patients. When deciding on objectives, needs should not be confused with *what is wanted.*

The following general formula may be used to express effectiveness:

$$\text{Effectiveness} = \frac{\text{achieved results}}{\text{goals and objectives}}$$

In summary, while efficiency is concerned only with the output produced, effectiveness carries the process one step further by measuring the effects of the output, i.e. *outcome.* Efficiency is judged by what is done; effectiveness is judged by what is done but in the light of what was needed and the goals and objectives of the health services and the NHLS. This can be illustrated by the following flowchart:



It is clear that an organization's effectiveness is best demonstrated when it can be measured. This requires the establishment of precise and quantified goals and objectives, thus leading to the achievement of the mission of the NHLS.

The following section represents discussions on the key functions that laboratory managers are expected to perform.

The planning function

Planning has been defined as the conscious process of selecting and developing the best course of action to accomplish objectives and goals. This definition implies that planning starts with the determination of what is to be accomplished or what end is to be reached, i.e. what is the goal. In general, the purpose of planning is to bring about changes, improving the organization's structure and the services delivered, in the light of either (a) the existing goal(s) and objectives of the organization or (b) new ones developed in response to new needs. The planning process can be summarized as follows:

Planning process = determination of goals and objectives +
determination of best course of action required accordingly

As there may be more than one way to attain a goal or an objective, it is necessary to determine the means by which the predetermined goals and objectives are to be achieved. This process is referred to as *strategic planning*.

Strategic planning

In the present document strategic planning is defined as a way of thinking about problems or difficulties, current strengths and weaknesses, the future needs of the organization concerned (i.e. the NHLS) and devising ways of meeting them, identifying priorities and, ultimately, determining goals and operating objectives leading to operating plans and detailed programmes of activities.

The following flowchart shows the strategic planning sequence:

Policy

As the whole process should be based on the mission (policy) statement of the NHLS or health laboratory, it is of utmost importance that it should be clearly understood and constantly remembered by managers at all levels, particularly during the planning process. *Policy* in the present document is defined as a set of decisions to pursue courses of action aimed at achieving defined goals. It is a general statement of intention, based on human aspiration, and presupposes a political will to commit national resources to achieving the goals. To be effective, a policy should be put into writing. In this connection the following statement is of the essence:

> **A policy is not a policy until it is written down and made known to all concerned.**
>
> The statement regarding the mission of health laboratory services has already been mentioned at the beginning of this chapter.
>
> The higher the formulation level, the more the policy will appear as principle and, conversely, the lower the level, the more it becomes a rule.

Situation analysis

Situation analysis is geared towards the identification of current points of strength and weakness, and subsequently the assessment of how well the laboratory mission has been achieved.

The laboratory mission is influenced by two types of factor: external factors expressed by the needs of patients, the community and health staff (including not only clinicians but also epidemiologists and environmental sanitarians), and internal factors reflected in the mission statement by *the effective and efficient provision of high quality services in the right place and at the right time*. The thinking process applied for the analysis should thus concentrate on these two groups of factor. The following two series of questions are suggested to help in the thinking process, the first one oriented toward the utilizers:

- How well does the health laboratory service fulfil its mission? What are the points of weakness?
- How far are the provided laboratory services relevant to national health policy and priorities?
- Who are the laboratory utilizers? What are their specific needs?
- What do the utilizers think of the currently-provided laboratory services and what are their wishes?
- How well do the health laboratory services cover needs, geographically and technically?

The second series of questions covers internal factors, e.g. those that affect the smooth operation and the standards of performance of the laboratory or the national services.

- Have top managers of health laboratory services or provincial laboratory managers gained leadership recognition? If so, are they able to fulfil their role? If not, why?

- How efficient and effective is the national laboratory network?
- What is the quality of the services provided? What is the level of health laboratory services as compared to international standards? What steps could be undertaken for further improvement?
- What is the available new technology that is appropriate to local conditions and resources and that could fulfil needs not yet provided for?
- How do the laboratory technicians judge their working environment? What improvements are needed?
- Where do the financial resources stand with regard to the need for laboratory services support as related to the health policy and priorities?

Determining priorities

Once the problems have been identified, priorities need to be determined. The criteria recommended to the Directors of the State Public Health Laboratories in the United States in determining the importance of a health problem could be very useful in establishing priorities for laboratory services. The following is an example of their application to the problem of poor reliability of laboratory results which is relevant to quality assurance, one of the three main national service objectives (the other two being service delivery and resources management).

Magnitude. Introduction of a quality assurance scheme should benefit the entire laboratory network and its analytical work.

Seriousness. Erroneous laboratory results can lead to misdiagnosis and subsequent erroneous medical decision with all its consequences. It is an ethical problem.

Urgency. The seriousness of the problem in itself dictates the urgency. Poor reliability of laboratory services leads to the loss of users' confidence, as well as to a low level of financial support from the health administration.

Economic cost. Even without taking into account the cost incurred by erroneous results leading to erroneous medical decision, poor results lead to poor cost-effectiveness of public funds invested in health laboratory services.

Social cost. Apart from the fact that government laboratories can be viewed as converting social resources into certain social returns, under this heading one must also consider disability, lost work, and loss of income or quality of life as a result of delayed reporting or erroneous results.

Practicality. Since the early 1950s, quality control has been introduced as a measure of providing reliable results in clinical chemistry laboratories. Today, experience makes it possible to ensure that only those laboratories doing quality control are reliable. This is valid for all major laboratory disciplines and all laboratories, whatever their size, e.g. hospital laboratory, health centre laboratory.

Efficiency. Considering the magnitude, seriousness, urgency and economic cost, no other programme can be more cost-effective than quality assurance. In view of the current poor reliability of laboratory results, a major benefit can be expected, provided that the programme is enforced by a strong policy and necessary resources.

Feasibility. The programme is within the existing capabilities and resources of most of the countries of the EMR. Some control materials should be produced locally.

Impact on other problems. Improvement of the reliability of laboratory results, and subsequently of the effective support of laboratories to medical decision, should improve the laboratory's image and attract more financial support from the health administration. It should also lead to an improvement in the quality of reagents and maintenance of equipment, as well as in the training and competence of laboratory technicians. Finally, it should contribute to the development of the professional category of supervisor-technicians, an area where there is a great gap in the present general organization scheme.

Coordination potential. Establishment of quality assurance throughout a country contributes to the strengthening of the links between the central laboratory, operating as laboratory organizer, and the rest of the laboratories of the national service network. As the central laboratory should delegate some authority to provincial laboratories for effective supervision (in order to ensure sound application of the scheme in the provinces as well as feedback), so the relationship between laboratories in the provinces is expected to improve.

Political acceptability. Providing solutions to such critical problems as reliability of laboratory information, which encompass both technical and ethical aspects, should receive support from all parties.

Goodwill. By the same token, improvement in the reliability of information, leading to taking the right medical decisions, should contribute to establishing and maintaining good relationships and trust between the laboratory and its users.

Development of goals

Once the national service or the laboratory has identified its points of strength and weakness, efficiency and effectiveness in its service delivery, and priority problems, it is in a position to determine rationally long-term goals and objectives in relation to these priorities. Goals are broad definitions of policy and reflect what it is hoped will be achieved. A goal is the generally desired aim towards which action and resources are directed. It should be remembered that a goal does not necessarily have to be quantifiable or measurable in operational terms.

Let us assume that, following the analysis of priority criteria, it has been decided to upgrade overall quality of laboratory performance. A reasonable goal covering the decision could read as follows:

> Achieve a high degree of excellence, so that all laboratory users obtain reliable information in the shortest time possible and at a reasonable cost. Accordingly, all

laboratory results have to be validated by the implementation of a relevant quality assurance programme.

However, goals tend to be somewhat general, and frequently reflect what it is hoped will be achieved. To reach or come close to realizing a goal, it is necessary to decide on more specific objectives and targets that must be attained while approaching it.

After having decided the policy and developed goals, the policy has to be translated into strategy. Strategy gives effect to national policy and lays down the broad lines for the action required to deal with identified problems. Strategy usually includes specific programmes directed towards the attainment of defined objectives and targets as well as methods of monitoring and evaluation.

Determining general objectives

An objective is the end result which a programme seeks to achieve. Objectives, which are steps towards goals, are essential working tools. They provide not only the course towards which future energies of the national service should be directed but they also contribute to the motivation of staff. To be effective, objectives should be well-thought-out and concisely stated. They should relate specifically to the results desired, not only to the process or activity engaged in. The more quantitative an objective, the greater attention will it attract for its achievement and the less will it be open to misinterpretation and distortion. Objectives should be related to policy and goals of the laboratories and be specific, complete and clearly stated. They should not be subject to continuous changes but, on the other hand, they should have sufficient flexibility to deal with normal variation in different conditions. They should be known and understood by everyone who is involved in working towards them or is affected by them. Therefore, they should be included in procedure manuals.

In practice, the following operating objective for introducing a quality assurance programme could be formulated:

> By ..... (date) all laboratories belonging to the governmental health service should have put into practice a *quality assurance protocol* in compliance with the instructions provided in the quality assurance manual prepared for this purpose. Management will view neglect of the quality assurance programme as just cause for disciplinary action.

Determining targets

An intermediate result towards an objective that a programme seeks to achieve and the period within which it is to be attained is called a *target*. A target is usually expressed in quantitative terms. It is more specific than an objective.

The following are targets for the aforementioned objective for introducing a quality assurance programme.

- By ..... (date) all laboratories should establish an efficient internal quality control as part of routine laboratory work.
- By ..... (date) target values and control limits should be determined by all laboratories for all routinely performed quantitative tests.
- By ..... (date) all laboratories should participate in a quality assessment programme organized by an officially-designated laboratory and comply with the specific instructions provided for this purpose.

Approaches

An approach is a means of attaining an objective or a target. Approaches address the question of how the goals and objectives will be achieved and, as such, they provide a link between planning and organizing what will be done. Of the several possible approaches, the most suitable and realistic one should be adopted.

Plan of action

Once the NHLS's goals or general objectives have been determined, top management will prepare a plan of action defining the broad lines of actions required in all sectors involved to give effect to the objective decided. A plan of action takes into account what to do, how to do it, when to do it, and who has to do what.

As an example, the department of clinical chemistry, among others, may be assigned the responsibility of producing the control material for precision. A programme of action will be determined accordingly, starting with the estimation of the quantity of control material needed per year; then defining the specifications of the control material to be produced; determining the method and procedure of production, identification and procurement of the equipment and material required; determining assigned values and criteria of acceptability; and finally, bottling and organization of distribution to all laboratories.

Standards

Standards are essential for determining whether objectives have been achieved. In other words, they provide the starting point for the controlling process. Lack of standards deprives managers of means of control. Two types of standards are generally considered: performance standards and process standards.

Performance standards, in the field of laboratory services, will cover:

- Quality which includes specificity, sensitivity, precision, accuracy, efficiency, reproducibility, predictive value of tests.
- Quantity which includes productivity, break-even point.

- Time for accomplishment which includes work-unit per run, turnover time.
- Cost of work which includes cost of labour, supplies, instruments, reagents, costs (fixed, variable and total), work-units, tests, cost-effectiveness.

When it is difficult to establish accurate performance standards, process standards are used. This is the case for general objectives; more precise performance standards should be determined by operations managers as they determine specific programme objectives. The following are some examples:

Performance standards	***Example***
Quantity	At least 50% productivity should be achieved by peripheral laboratories after two years of operation. Using two concentrations of an analyte in control material for each run is recommended.
Quality	Targets for intralaboratory analytic coefficient of variations (CVs) range for the following measurements should achieve: - for cholesterol 8% - for triglycerides less than 15% - for albumin 6% - for glucose 6% - for urea maximum 6% External quality assessment error rate should be reduced by 20% each year as relevant.
Time	International performance standards should be reached by ..... (date).
Cost	Cost of locally produced control material should not exceed 15% of that of an equivalent imported product.

Process standards	***Example***
Function	A quality assurance programme should be applied in compliance with the quality assurance procedure manual.
Personnel	Laboratory quality assurance coordinators or supervisors should be selected from among the most experienced and effective technicians.
Physical factor	Reagents will be produced and controlled centrally as far as possible.

Procedures and rules

The following are examples of procedures and rules as applied to quality assurance in the field of clinical chemistry:

Procedures

The purpose of the procedure is to provide all laboratories with a system including (1) the preventive and assessment components allowing the monitoring of the quality of the analytical work performed and the effectiveness of the quality assurance programme implemented (as instructed in the quality assurance procedure manual); (2) the corrective component that furnishes means for determining what causes any quality defect and restores the proper functioning of the analytical system.

At national level a quality assurance committee will be established to assist the director of the NHLS in:

- the planning of a national quality assurance programme;
- formulation of a quality assurance policy;
- preparation of a quality assurance procedure manual; and
- planning and participation in an auditing operation.

The central laboratory will be responsible for producing control material for all health laboratories of the national health service. It will prepare batches of stable and homogeneous control materials each covering the needs for at least a period of six months. The assistance of the WHO Collaborating Centres will be requested for assigning values when relevant.

Quality assessment organizing laboratories will be designated by the director of health laboratory services, assisted by the quality assurance committee.

At individual laboratory level:

- All laboratories will introduce a quality assurance programme on receipt of the quality assurance procedure manual.
- A quality assurance supervisor-coordinator, who is involved in the local planning and is responsible for the good application of the quality assurance programme, will be nominated in all laboratories.
- The laboratory director, assisted by a first-line supervisor/quality assurance coordinator, will be responsible for competently managing the personnel and the resources of the laboratory, and for establishing a working environment adequate for the achievement of top-quality work.

An intralaboratory quality control system will be established in all laboratories to ensure the production of analytical data of a continuing high quality.

All laboratories should participate in an interlaboratory quality assessment programme to calculate the precision and accuracy of results between laboratories, detect poor methodology, and identify training needs.

All laboratories should maintain the following documentation:

- Written laboratory quality control records that comprise a clear and up-to-date compilation of quality control data. Sound record-keeping provides a means by which the laboratory can demonstrate that its tests and methods were operating within normal limits at the time the patient results were produced.
- A written record of the number and types of laboratory examinations and other procedures performed. Any changes in the examinations and other procedures performed should be reported to the director of the NHLS.
- A written record on the qualifications (educational, background, training, and experience) of all the professional and technical personnel working in the laboratory.

All the above procedures should be implemented according to the instructions and standards described in the procedure manual, or meet standards issued by the director of the NHLS as relevant.

Rules

1. The matrix control material should not be derived from the same lot as the calibration reference material used in the analysis.
2. Two concentrations of an analyte in matrix control material must be used.
3. The control of precision must be made in each series of measurements. The shortest series contains a single patient sample. In longer series of measurements control samples should be inserted after each batch of 10 to 20 samples from patients.
4. Quality control samples should be located randomly; however, one control sample has to be placed early in the run to allow analysis of patient specimens to proceed.
5. Target values must be determined in the laboratory using the laboratory's own methods. Stated values of assayed materials used for internal quality control should be used only as a guide. Target values of new lots of control material should be established for each analyte in parallel with the control material in current use. Twenty or more determinations on separate days should be used for establishing target values.
6. Control limits must be established from quality control data obtained from the 20 determinations on the new lots of control material. Alternatively, standard deviations from the expiring pool may be used when the mean values for the analyte concentrations in the two pools apply to the same decision levels.
7. All control results should be documented on a quality control chart as immediately as available and on the worksheet. Excessive random error should be considered if less than 2:3 of the plotted points are within 1 SD of the target values. Corrective action should be undertaken and recorded.

8. Target values should be recalculated at the end of each month and recorded. At the end of each year these should be reported to the quality assessment unit at the laboratory responsible for the national programme of quality assurance.
9. When a control result exceeds the limits, the patient test result should be retained and the same control should be re-analysed immediately. Patient results should be reported only when the control result falls within acceptable limits.
10. Unless a special condition prevails (see below) patient results should be withheld when:

    - a single control result is beyond 3 SD from the mean, perhaps indicative of a random or large systematic error;
    - two concurrent controls on the same run are beyond 2 SD from the mean, in the same direction, showing perhaps a systematic error;
    - results from controls across runs are beyond 2 SD from the mean, in the same direction perhaps indicative of a systematic error; or
    - when the difference between the high and low measurements is greater than four times the SD, showing perhaps a random error.

11. In special circumstances, patient data may be released even if control results fall outside pre-established statistical limits, provided that patient care is not compromised. The decision will be based on considerations such as analytical factors, type and magnitude of deviation, biological variation, medical usefulness limits. When such a decision is taken, control results should be included in the quality control record.
12. Corrective action should be planned, and operational characteristics of the method should be reviewed; the quality assurance supervisor should be informed as soon as an out-of-control result is noted. All corrective actions taken should be recorded in the quality control record.
13. Interlaboratory quality assessment testing should be conducted on a quarterly basis, and should cover all examinations and procedures, except those for which interlaboratory quality assessment cannot be reasonably developed.
14. The analyst has to examine the sample within a specified time and to submit the results to the quality assessment of the organizing laboratory, through the laboratory director. Any result submitted after the specified deadline has to be considered as erroneous.
15. The quality assessment organizing unit collects data, performs statistical analysis and sends a report within two months after the deadline for receipt of results.
16. At the end of each year a qualitative ranking scheme should be prepared by the unit organizing external quality assessment and sent to each participating laboratory.
17. Laboratories showing poor performance should be notified by letter, pointing out unacceptable results, most common causes of erroneous results that need to be reviewed, and requesting a written statement on the corrective action taken. If deficiencies are considered to be of a more serious nature or if poor performance persists, the laboratory staff concerned has to be invited to participate in a training programme, or some technical assistance has to be provided for improving its performance.

18. All participating laboratories should be identified by code numbers, and their performance must remain strictly confidential except to the director of the quality assurance programme.

As shown in the above example related to the establishment and implementation of the quality assurance programme, the procedure indicates how implementation should be carried out, and the rules provide a more specific detailed guide to the action. In the interests of effective achievement, all NHLS's need policies, guidelines, procedures and rules that highlight government willingness and commitment to having the objectives more clearly defined and understandable.

Resources

All activities entail expense; consequently no planning can be realistic until a decision has been taken regarding the resources that will be used and the time needed to attain the objectives. Nevertheless, many directors of the NHLS, or an individual health laboratory, may question to what extent this paragraph is relevant to current practice in the majority of the countries of the Region, where budgetary provisions very often have no relationship to workload. Furthermore, in some cases the head of the laboratory does not even know the sum allocated to the department because there is no specific laboratory budget; the latter is often incorporated into a general budget for drugs and surgical and laboratory material. However, it is believed that these conditions will change as heads of laboratories become skilled managers, knowledgeable not only regarding all laboratory costs, but also regarding the plan, programme and figures relating to hospitals or health activities in general - what is referred to above as *external factors*.

Successful estimation of financial resources is dependent upon the laboratory manager's detailed knowledge of the material and reagents costs of each procedure; an accurate estimate of all equipment-associated costs (e.g. purchase, repair and maintenance); the workload involved in all activities that form part of laboratory operation; and finally, but not the least important, knowledge of the existing capabilities of the technical staff and their need to attend training courses or seminars so as to maintain high standards. All of this explains the reasons for including in this document paragraphs dealing with methods for costing of tests, workload measurement, inventory control and equipment maintenance. In addition, to this, detailed knowledge of the expected in-patient and out-patient census for the budget period (e.g. the demography of the patient population and any anticipated changes in health policy and programmes) represents equally important information for supporting laboratory budget proposals.

Reactive planning

Even when a plan has been properly developed, unforeseen events may occur, often requiring modification or readjustment of the plan. It is the responsibility of managers to attempt to anticipate such developments and to deal effectively with them. To make any necessary readjustments, managers will apply the reactive planning process which is similar for the planning process reviewed above. In fact planning is essential for the solution of all problems and ensures efficiency.

A case study - development of peripheral laboratories

Basis

The Ministry of Health of country X has decided to strengthen the basic health care service in support of primary health care. In response to this new health policy the top managers of the NHLS met to consider the organizational circumstances arising from this new development.

Justification

1. The development of primary health care should enhance the activities of health centres and front-line hospitals acting at referral level.
2. An increasing number of physicians who seek the support of laboratory services will be assigned to these primary health care facilities and will make up a potential for efficient utilization of laboratories at this level.
3. The current rapid development of new technology related to simple rapid methods, intended for the physician office laboratory, opens up great possibilities for peripheral laboratories in the near future.
4. Laboratories at health centres and rural hospitals will assist physicians in direct treatment decisions. Currently, more than 50% of public health service physicians are working at this level without any laboratory support.
5. Establishment of peripheral laboratories will obviate the need to refer patients for simple testing, and will subsequently be more convenient for patients and result in financial savings.
6. The technology used at this laboratory level is usually simple, easy to maintain, and of low cost. High efficiency can thus be expected.
7. Extension of the laboratory network to the peripheral level will not only tend to correct any unbalanced development of the laboratory service, but will also provide

means for better surveillance and control of diseases, as well as a potential for coordination with epidemiology services. The extension of the laboratory network will stretch logistic and technical support and communication lines. Strengthening of the managerial skills of laboratory managers at different levels is essential.

On the basis of this analysis the top managers of the NHLS made decisions on both short-term and long-term objectives and goals.

Situation analysis

The Ministry of Health in country X organized field operational studies, in selected areas, to evaluate the efficiency and effectiveness of peripheral laboratories and determine the organization for supportive services.

Goals and objectives

Goal

- To upgrade the efficiency of health care services at the level of health centres and frontline rural hospitals through establishing peripheral laboratory services .

Objectives

- To design and establish laboratories at health centres and rural hospitals.
- To train technicians on appropriate technology.
- To ensure continuous logistic and technical support to the periphery.

Approaches to setting the goals and objectives

- To identify the essential tests to be performed at health centre and rural hospital levels, and subsequently the laboratory materials required.
- To determine the profile of staff required and to ensure their adequate training.
- To analyse the operational cost of these peripheral laboratories.
- To analyse the actual efficiency and effectiveness of the laboratories under study regarding clinical and public health needs.
- To define the required relationship between the peripheral level and the higher levels of the laboratory service, including the technical supervision of the laboratory staff.
- To identify solutions for the improvement and smooth operation of existing peripheral laboratories.
- To determine an effective organizational pattern or model for the peripheral laboratories.

Plan of action

The top managers prepared a flow chart with the sequential steps leading to the objectives. They started from the end point, and through subsequent identification of each

critical step needed to be accomplished before initiating the following one, they reached the starting point. The identification of all activities and material required through the planning process permits the estimation of the financial resources required for initiating the field studies.

Guidelines

Once the plan of action has been defined, written guidelines and procedures are prepared to guide the implementation of the plan and dictate how the peripheral laboratories should operate.

1. The peripheral laboratory should be set up only on sites with a potential for efficient utilization of laboratory services; this potential comprises a critical mass of population, presence of a physician, and availability of an adequately-trained and technically-supervised technician.

2. The peripheral laboratory will implement all the tests included in the standard list of tests for peripheral level; any changes (due to local disease circumstances) should be discussed with the director of provincial laboratory services and approval obtained.

3. The techniques in the procedure manual should be strictly followed. If any change is considered necessary, the suggestion and the justification must be discussed with the provincial laboratory service. Should any change be decided upon, the director of the NHLS should be informed and the standard list of reagents and material should be changed accordingly.

4. The laboratory assistant working at the peripheral laboratory will be accountable to the direct administrative supervisor, i.e. the medical officer heading the health centre or the rural hospital, according to the workplace location.

5. The laboratory assistant will prepare a monthly activity report for the direct administrative supervisor, according to a defined format. A copy of this, with store stock levels, will be sent to the district laboratory technical supervisor every three months.

6. The laboratory assistant is accountable to the district laboratory technical supervisor regarding the reliability of the test results and the effectiveness of the services delivered. The technician-supervisor will act as technical supportive staff to the medical officer/head of the centre.

CHAPTER 2

Organizing and organization

Definitions

Organizing

For successful management, once the objectives and plans of the NHLS have been developed, an orderly manner of bringing together and coordinating all the required human and physical resources must be designed. This is the managerial function of organizing. It includes two aspects: structural and procedural. The latter has previously been partly touched upon in the discussion of procedures and rule-setting.

Organization

Organization has been defined as two or more people working together *in a coordinated manner to achieve group results*. It is a system with an orderly structure, putting resources together into a working order and establishing a mechanism for undertakings which require cooperation and coordination.

Purpose

Structural organization

Structural organization is a means of focusing attention and energy on goals and objectives, opening the way for their achievement through an orderly and methodical approach. It provides the framework for translating policy and plans into action by indicating how the total labour or operation, related to the purpose of the organization, is divided in a systematic manner into units.

Procedural aspect

The procedural aspect delineates working relationships through the establishment of lines of authority-responsibility, communication and the flow of work for optimal functioning of the interrelated units (coordination). It ensures for the staff a better understanding of their roles and the functions they are expected to perform, and provides them with a mechanism for a clear understanding of their responsibility and to whom they are accountable.

In practice the directors of health laboratories or the NHLS, through the organizing process, seek to achieve an orderly structure, ensuring efficient and effective grouping of: (a) human resources, (b) physical resources, and (c) the functions involved that bring about the successful accomplishment of goals and objectives. The running of health laboratories (including referral laboratories), or the NHLS, can be very complex and without good organization chaos is almost inevitable.

The organizing process

The following are the major steps performed by managers in the organizing process. It is helpful to pinpoint areas where failure might occur, giving possible reasons and indicating ways to achieve improvement so as to increase the efficiency and effectiveness of health laboratories or the NHLS overall.

Stage 1: Developing an orderly structure - framework

- Determining the functions to be performed and types of work to be accomplished.
- Dividing the necessary work into parts small enough to be performed by one person.
- Assessing the human resources required (number and qualifications).
- Assessing the physical resources requirements (equipment, material, and space).
- Grouping and/or coordinating the functions, as well as the human and physical resources, into an organizational structure.

Stage 2: Delineating relationships - interaction

- Assigning the duties necessary for performing certain tasks (responsibility) and the right to make decisions in order to take action to accomplish such tasks (authority).
- Assigning specific work activities.
- Determining whether or not the job has been accomplished (accountability of personnel).

The aim of this stage is to establish relationships and means of coordinating or making arrangements for undertakings which require cooperation. These arrangements should contribute to the elimination of wasted effort and obviate situations in which members of the organization might get in each others' way.

Rationale for developing orderly structure

Generally, laboratories attaining a certain size are subdivided into sections or departments. This subdivision, as indicated in stage one, is based on reasoning aimed at planning appropriate organization. The following are guidelines for developing an efficient and effective organizational structure.

Function and activities should be grouped in units according to a logical system

By *function* is meant a type of work/activity that can be identified and distinguished from another. The process of splitting up functions is known as *functionalization*; its aim is to improve effectiveness and efficiency in the accomplishment of certain work/activities. Within each health laboratory department, the basic grouping unit is the *work station*. This is the smallest personnel unit associated with a specified and relatively constant list of procedures to be performed, generally by an assignable number of people. The size and type of units are determined in such a way that ensures the most efficient operation of health laboratories and the most effective delivery of services.

This division of labour permits technicians to achieve a high level of quality and output through the expertise and skill acquired by concentrating effort on a small and limited number of tasks. However, overqualification may cause increased technician dissatisfaction, due to boredom.

Figures 2.1, 2.2 and 2.3 represent some examples of division of labour into work stations.

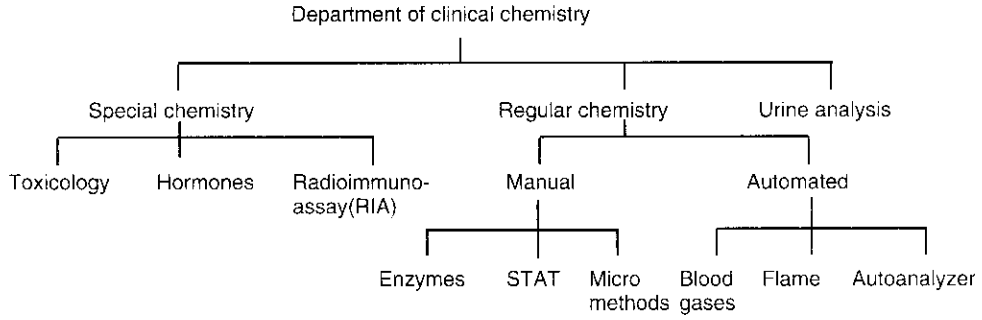


Fig. 2.1 Example of division of labour of clinical chemistry department into work stations

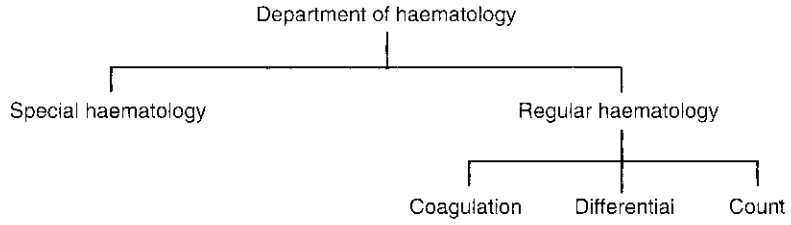


Fig. 2.2 Example of division of labour of haematology department into work stations

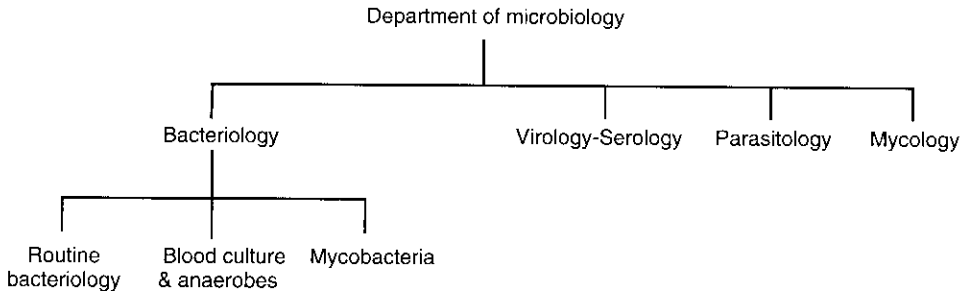


Fig. 2.3 Example of division of labour of microbiology department into work stations

Specialization

A structure should permit similar duties to be grouped together so that benefit could be gained from *specialization*. Experience has shown that grouping according to specialization contributes to the achievement of efficiency and a better consistency of quality. Furthermore, the grouping of specialists into a team also facilitates the achievement of a complex goal. Apart from similarities of duties, other factors are taken into consideration for differentiating work stations, e.g. material, equipment that is common to a group of tests, techniques used, or type of specimens.

In health laboratories the activities involved in a similar discipline are grouped together in a section or a department. Managerially speaking, this process is called *departmentation* or *departmentalization*. It contributes to increased efficiency and effectiveness by streamlining structure and simplifying management, reducing duplication of equipment while solving increasing workload problems and saving space. This is illustrated in Figure 2.4.

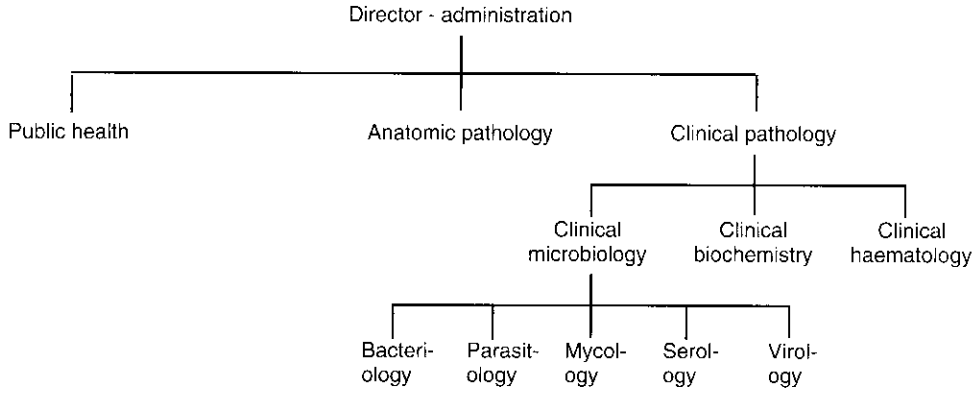


Fig. 2.4 Grouping of activities involved in a similar discipline

Organization of supervision

Plans should not call for the supervisor to supervise too many or too few people. Although supervision is facilitated by the division of labour, it is generally recognized that one person can properly direct the efforts of no more than six other people. This limitation is usually referred to as the *span of control* or *span of management.* In fact, the number varies essentially with the competence and skill of both the supervisor and the technicians supervised, the complexity of the work, the degree of standardization established, and the diversity and volume of work, as well as the stability of the organization concerned. Figures 2.5, 2.6 and 2.7 are illustrations of the development of different levels of responsibilities within the health laboratory.

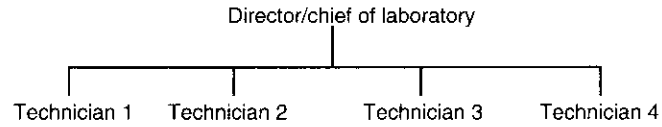


Fig. 2.5 One-level management organization in a small laboratory

Figure 2.5 represents a small laboratory. Unlike a peripheral health centre laboratory, which is often staffed by only one laboratory assistant as the activity is limited, its workload is beyond the capacity of one person and therefore additional persons are employed. The related organizational chart shows one supervisor and four technicians. This is the starting point at which the process of organization begins, where two levels of organization appear: i.e. the management (the director) and the operative levels (Figure 2.5). This type of development is called *downward differentiation.*

As the volume of tests continues to grow, or as the variety of tests and testing processes increases, more operative functions may be differentiated and work stations developed, resulting ultimately in the need for additional technicians. However, as one manager cannot supervise an unlimited number of personnel, a two-level management organization is developed (Figure 2.6).

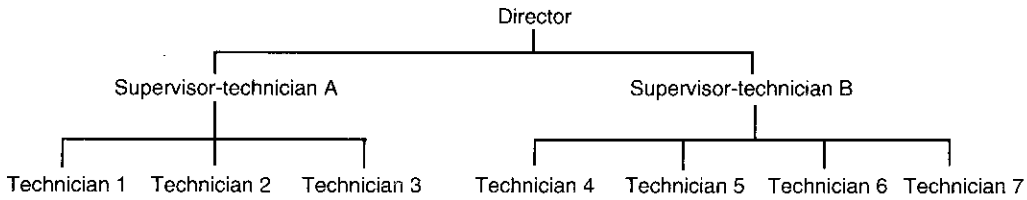


Fig. 2.6 Two-level management organization

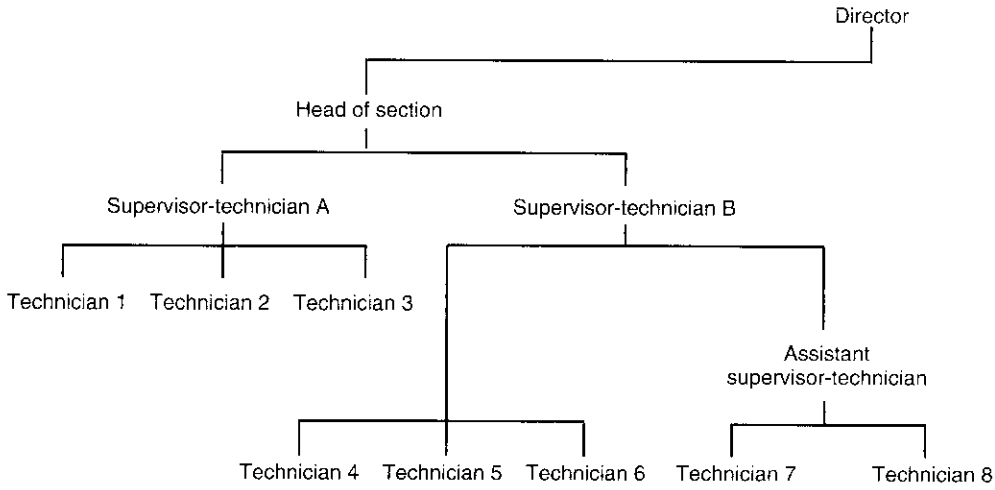


Fig. 2.7 Multi-level management organization

In the case illustrated above in Figure 2.7 the control span of supervisor-technician B is overloaded. To secure and maintain high quality services and efficient utilization of personnel, one of the technicians has been designated as assistant supervisor to technicians 7 and 8. The newly-appointed assistant supervisor, who may continue to perform some operative work in addition to the new directing job, remains accountable to supervisor-technician B.

From the figures it will be seen that two types of structure can be differentiated, mainly the *tall* and the *flat* structure. The tall structure is generally used when there is an increased specialization. It permits greater unity of direction, provided that the authority, or coordinating responsibility, of the direct supervisor is strictly respected. It is a fact that an increased number of levels may prompt uncoordinated decisions and bypassing. In general, the recommendation is therefore to minimize the number of levels, in order to maintain the quality of the administration. This is usually dependent upon the adequacy of the upward and downward flows of communication; difficulties of communication increase with the number of levels.

The flat structure, conversely, is characterized by a broad span of control. While too broad a span of control may lead to poor quality and delay in getting decisions made (by the supervisor), when the span of control is too short, the supervisor may interfere with supervised technicians' responsibilities through over-supervision.

Unity of command

No person should have more than one immediate supervisor thus ensuring unity of command. The strict application of this principle is very important to management as it

clarifies relationships, obviates confusion, and tends to improve decision-making, thus leading to more effective performance. For example, in Figure 2.6 it is clear that technician 1 is operating under the supervision and authority of supervisor-technician A, who in turn works under the supervision of the director.

On the other hand, in Figure 2.7, if the supervisor-technician B were to insist on having a say in the assistant supervisor technician's decisions regarding the work of technicians 7 and 8, this would render the unity of command ineffective.

Basis for relationships between levels

Obviously, the larger the laboratory the more authority the manager is forced to delegate to the lower managerial level(s) to maintain optimal functioning of the operative level. Similarly, in a multilaboratory system such as the NHLS, the director of the national service will rely on directors of provincial/governorate health laboratories for the implementation of the national health laboratory policies and programmes of action, e.g. quality assurance programme, development of peripheral laboratories, disease control, and accordingly relevant authority needs to be delegated for this purpose.

In order to ensure effective delegation, a formal relationship between tasks, individual and workplace, must be clearly defined, reflecting *what*, *who* and *where*. This can be achieved provided appropriate delegation, with a system of relationship based on authority, responsibility and accountability, is strongly established. Figure 2.8 illustrates these relationships. Failure to achieve this relationship will generally end in major organizational problems, including lack of coordination.

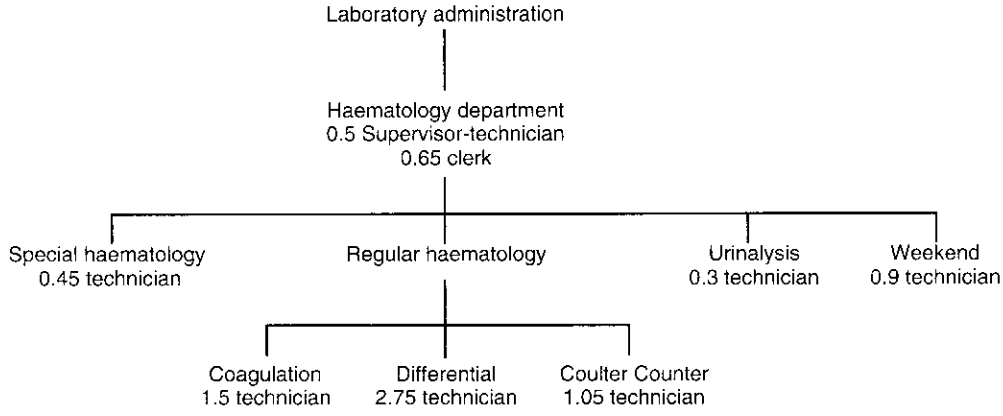


Fig. 2.8 Relationship between task, individual, and workplace

Delegation

The assignment of specific work to the supervisor-technician and the technicians, and providing them with the right to perform these functions, is referred to as *delegation*. It contributes to the efficiency and effectiveness of the organization by:

- allowing more rapid action to be taken (handling of routine matters at a higher-than-necessary level leads to waste of time and poor output);
- leading to a higher level of motivation (feeling of being trusted);
- resulting in more appropriate decisions (better adjustment to local conditions);
- improving attitudes and morale of staff (increased confidence of personnel); and
- creating opportunities for training and development of personnel (learning by doing).

However, delegation will be effective only if proper feedback for control is provided, and also if the work delegated matches the capabilities and skills of the technicians.

Authority

Authority means the right to decide and direct others to perform certain duties in achieving organizational goals.

Delegation of authority and responsibility cannot be separated. In all organizations there should be a clearly-defined chain of authority, also referred to as the *chain of command*. Specific terms of the delegated authority must be set. A proper selection of staff to which the authority can be delegated is essential. Although delegation of authority involves an element of risk, delegating some responsibilities to others increases the manager's available time for other, greater responsibilities. It may also bring up new ideas about how the job can be done better. Although delegation of authority and responsibility cannot be separated, the manager must be prepared to share the responsibility for actions taken by others to whom authority has been delegated.

For example, the laboratory assistant assigned at the peripheral laboratory must have the right to prepare orders for supplies if responsible for continuity in the delivery of services. Similarly, the director of a health laboratory, responsible for the quality of the services provided, should have a say in the recruitment of technicians who will work under his/her authority. In the same way, the director of the NHLS must have the appropriate authority to support responsibility for the effectiveness and efficiency of the national service.

Responsibility

Responsibility is an obligation to perform the work assigned.

When technicians in the laboratory are delegated responsibilities or work assignments by their supervisors, a relationship based on an obligation exists between the two. However, it must be borne in mind that no delegation can relieve the delegator of any

portion of the original responsibility; delegation allows only for someone else to do the work.

The laboratory assistant responsible for carrying out the testing at peripheral laboratories has the obligation to plan, organize, and implement the work; to communicate with the health centre or polyclinic physician(s); and to maintain laboratory facilities in operating condition, e.g. maintenance of equipment and supplies. Responsibilities or obligations must be clearly defined and understood by the laboratory assistant in order to secure their fulfilment: this is the entire reason for having a job description.

Accountability

Accountability refers to the obligation to a higher authority for the successful fulfilment of the assigned task. However, in order to be held accountable, the following three conditions have to be met:

- responsibilities must be thoroughly and clearly understood (need for job description);
- the person accountable must be qualified and capable of fulfilling the obligation (need for competence-oriented training); and
- sufficient authority to accomplish the task concerned must be delegated (need for appropriate job description).

The laboratory assistants working at the peripheral laboratory are, for example, accountable for the delivery of high quality services for which they have been trained. The supervisors are accountable not only for their own actions and decisions but also for the actions of the technicians working under their authority. Likewise, the director of the NHLS, if formally given the required authority, is accountable to his/her supervisor, e.g. the under-secretary for health at the ministry, for the efficient operation of the national service and the effective delivery of the services required, both by the mission statement and by the goals and objectives of the national service as related to the health policy.

Centralization versus decentralization

A centralized organization is usually characterized by a limitation in the amount of authority delegated. An example of centralized organization was given in the case of a small laboratory staffed by a director and four technicians (see Figure 2.5). The director of that laboratory is supposed to be able to supervise all staff members effectively, time being available for making decisions without a delay that could diminish the efficiency of the laboratory.

Conversely, if a significant amount of authority is delegated to lower management levels, as shown in the other two examples, the organization is considered as being decentralized. Nevertheless, in this system the director continues to assume the key roles of

recognising general problems and finding solutions for them; setting goals and objectives; developing programmes and policies; obtaining funds and other resources; and forecasting and planning. This implies that, even in a decentralized system such as the national service or big laboratories, the director must continue to know what is to be done, how it should be, and how to get it done. To fulfil all these conditions the director will have to rely on two essential components in a decentralized system, as described hereunder:

1. **A managerial** team, made up of leaders who may or may not have been selected by the director but who are capable of exercising authority, and who share many of the director's ideals and objectives, and are thus prepared to take the lead in their area and strive for the achievement of such goals and objectives. Such cooperation will require the director to put a considerable amount of time and effort into developing and advising the managerial team, acquainting them with relevant philosophies and concepts, stimulating their imagination, teaching them the techniques of management, assisting them when difficulties arise, and helping to chart their course (as seen in the "Plan of action for the development of peripheral laboratories").

2. **Good lines of communication**, ensuring information feedback, are essential to the director if both the authority and the responsibility inherent in the role are to be assumed effectively.

In some instances, centralization may better apply to certain operations such as procurement whereby the rate of discount is generally related to the volume of purchase. Likewise, the basic policy for standardization, quality assurance, and the related standards and control material should be issued from the central level to ensure interlaboratory comparability. On the other hand, intralaboratory quality assurance monitoring must be decentralized so that any correction can be made immediately.

Organizational charts

Organizational charts constitute one of the most commonly used organizational tools. They provide a means of visualizing the organizational structure, permitting the identification of the major operational units (where), with their attendant job positions (who and what).

Organizational charts are an aid to: evaluating and fixing responsibility and authority; improving communication channels; clarifying accountability and reporting relationships; improving management appraisal and training; and eliminating overlaps and conflicts.

If an organizational chart is to be interpreted correctly, a correct identification of both line and staff positions is needed.

Line position

A line position (or line authority) is one in which there is a supervisor who exercises direct supervision over a subordinate. In a laboratory organizational chart, beginning from the top, the line positions are filled by directors, supervisors, and technicians who are directly responsible for the delivery of laboratory services and are in a direct line from the directors of laboratories. These vertical lines of authority or position impose the working order upon the system; they allow each employee to know to whom he/she is accountable.

Staff position

The staff position (or staff authority) is filled by people who provide a supportive or administrative service for the organization. To obviate the occurrence of line/staff conflict it is essential to define clearly the operational difference between the two. This is shown by Table 2.1 and Figure 2.9.

Table 2.1 Role and relationship of key individuals in a quality assurance programme

Position	*Responsibility/Authority*
Technician	Implement quality assurance procedures as recommended in protocol manual. Assure that the work achieved meets standards. Report to the supervisor any situation in which the quality of work falls below the expected level. Report to the supervisor any situation beyond his/her experience or skill.
Supervisor-technician	Provide first-line support to the proper application of the quality assurance programme. Review the completed work and monitor results of standards and control materials.
Quality assurance technician	Coordinate all quality assurance activities. Monitor proficiency of sample analysis. Evaluate facilities and procedures. Interact with supervisor-technicians to stress reliability and accuracy of the work.
Laboratory director	Assure that all activities comply with national quality assurance policies. Provide an adequate environment to permit high quality performance.

Table 2.1 Role and relationship of key individuals in a quality assurance programme (cont.)

Position	*Responsibility/Authority*
Quality assurance coordinator (national/provincial)	Ensure the application of national quality assurance policies at national/provincial level. Manage the quality assurance programme at national provincial level. Ensure that quality assurance technicians located at different levels are able to carry out their responsibilities. Make recommendations on quality assurance policy and assist in its formulation. Make recommendations on staff training.
National coordinator	In addition to the responsibilities of the quality assurance coordinator indicated above: Ensure the availability of standards and control material in sufficient quantity. Manage the quality assessment programme. Coordinate with the quality assurance audit team.
Quality assurance audit team	Evaluate the laboratory procedures currently applied. Visit work stations and assist local staff to make necessary corrections and changes. Detect potential system problems that may be overlooked locally.
Director of the NHLS	Plan the national quality assurance programme and formulate related policies with the support of the national quality assurance committee (includes quality assurance coordinators and consultants as required). Obtain all necessary support for the development of the quality assurance programme. Take decisions on reports prepared by the audit team. Review qualification requirements for positions in health laboratories and make necessary proposals for training curricula adjustment.

Peripheral laboratory supervisor - line or staff position

Take as an example the organization of a peripheral laboratory located in a health centre or polyclinic and staffed by one laboratory assistant. If the head of the centre is a physician without the necessary expertise for the effective technical supervision (accuracy of the

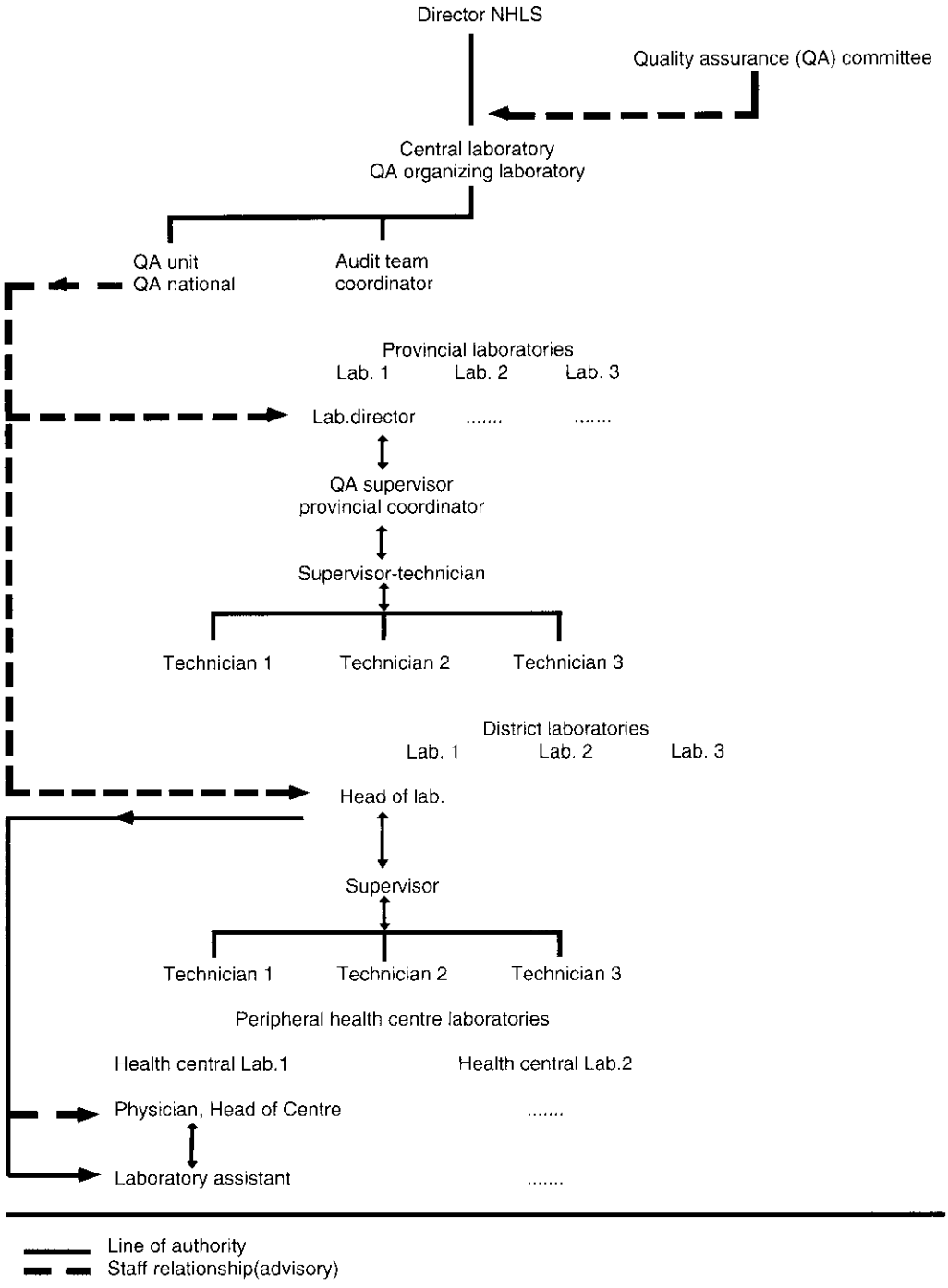


Fig. 2.9 Organization chart of a quality assurance programme

analytical work) of the laboratory assistant, alternative solutions need to be found, as shown below.

Alternative A - The supervisor-technician is given command or line authority

The physician of the health centre, on the basis of the established policy, will seek the support of the supervisor-technician working at the district hospital laboratory. The supervisor-technician will be assigned the responsibility of supervising the laboratory through periodic visits and on special request of the physician. He/she will keep the physician informed of all the instructions given to the laboratory assistant to correct inadequate performance.

In this situation the supervisor has been given line authority over the laboratory assistant; he/she has authority to issue orders in well-defined areas of the work, thus allowing fulfilment of role of superrvisor. In this particular case, a direct line relationship (referred to as *functional authority*) has been created. The chain of command of line authority and the principle of single accountability is broken as a multiple accountability system takes place. The related organizational chart would be as in Figure 2.10.

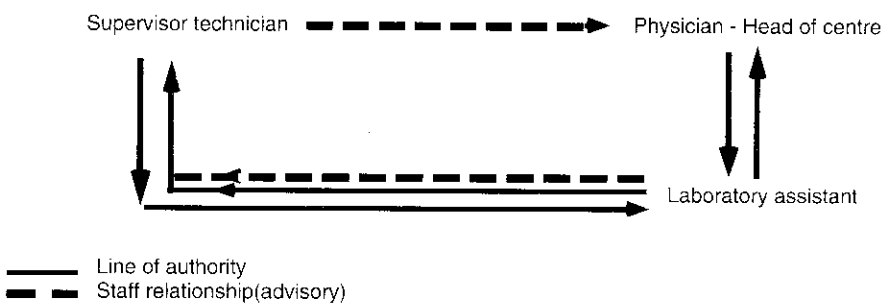


Fig. 2.10 Organizational chart of functional authority

Alternative B - The supervisor has only advisory authority

Another alternative, which may not be the most appropriate for the function of supervision, is to use the specialized expertise of the supervisor-technician without disregarding the principle of single accountability, thus maintaining the full authority of the line manager-physician. The supervisor-technician will be in staff/line position and provide advisory services in a well-defined specific technical area. Successful implementation will very much depend on the ability of the supervisor-technician to adjust to the role of being an adviser and the willingness of the subordinate to cooperate. Even in these conditions, the physician may feel that he/she has lost authority over the laboratory. As already mentioned, much misunderstanding and confusion can be avoided if any operational

differences between the physician and the supervisor with regard to the laboratory assistant are clearly defined. In the case under discussion the organizational chart would be as in Figure 2.11.

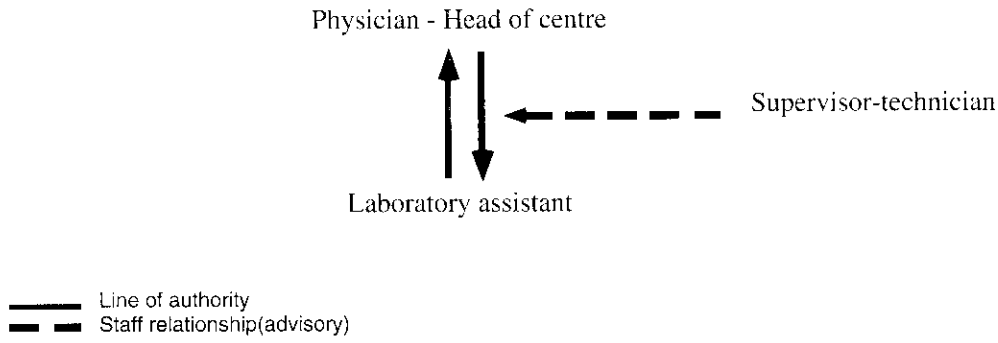


Fig. 2.11 Organizational chart of advisory authority

When interpreting the charts, the horizontal lines represent the *span of control of authority* of which coordinating authority is an important aspect. As a consequence, the more delegation has been made, the more coordinating responsibility will have to be borne by middle level management for achievement of global effectiveness of the area under its authority.

Project organization

Project organization is a type of temporary organization which is developed within the existing one for the time necessary to achieve specific results. Its purpose is to provide a highly effective means by which all the necessary human talent and physical resources can be focused for a time on a specific project or goal. The project teams or task forces resulting from this development are formed mainly of specialists from different functional areas within the organization.

This type of structure is most suitable when the work to be achieved is:

- definable in terms of a specific goal and target date for completion;
- unfamiliar to the existing organization;
- complex with respect to interdependence of activities and specialized skills necessary for accomplishment;
- critical in terms of possible gain or loss; or
- temporary with respect to duration of need.

Project organization as 'start-up' programme

Let us assume that for years a country has attempted in vain to introduce a quality assurance programme for the entire national health laboratory network. In view of increasing dissatisfaction among physicians, the director of the NHLS has decided to solve the problem once and for all regarding the unreliability of the laboratory results. A national quality assurance coordinator is nominated and assigned the authority and responsibility to take up the programme. The national coordinator establishes a national quality assurance unit at the national institute of public health, acting as the national central laboratory, and convenes several preparatory meetings with a group of specialists (mainly from the institute) to make a clear analysis of the situation, identify causes of failure, develop a broad plan of action, and determine the expertise and financial resources required for its implementation.

To ensure prompt and efficient accomplishment of the task assigned, the group of specialists suggests to the director of the institute that a project organizational structure be established to achieve an intensive 12-month 'start-up' programme. The objectives of such a 'start-up' programme would include: the preparation of a procedure manual; the local production of the first batch of control material; the organization of quality assurance seminars for the directors of the provincial health laboratory service; and the organization of training courses (for quality assurance coordinators in the first stage and subsequently for all laboratory supervisors).

To draw up the team of specialists or *task forces* essential for the successful completion of the above objectives, the director and national coordinator meet managers of the different departments concerned to decide on the specialists who temporarily (on a loan basis) would be committed to spending a portion of their time on the project assignment.

The specialists assigned to the project from the existing permanent organization are placed under the direction and control of the national coordinator for the well-defined tasks specific to the project. In practice, the national coordinator specifies what effort is needed and when the work needs to be performed, while the department managers concerned, who have suggested who in their unit is to do the work, may also decide on how the work should be accomplished. The chart for the project structure is shown in Figure 2.12.

Obviously, the division of authority between the project manager and heads of department is one of the crucial issues. A sound understanding of the importance of the programme objectives, the establishment of informal relationships allowing for full and free communication, and constant discussion in a search for consensus, should override formal levels of authority. The national coordinator (or project managers in general) and the department managers should be able to achieve successful cooperation by focusing all their attention on the relevant competence and roles in relation to the project's objectives rather than to the formal authority.

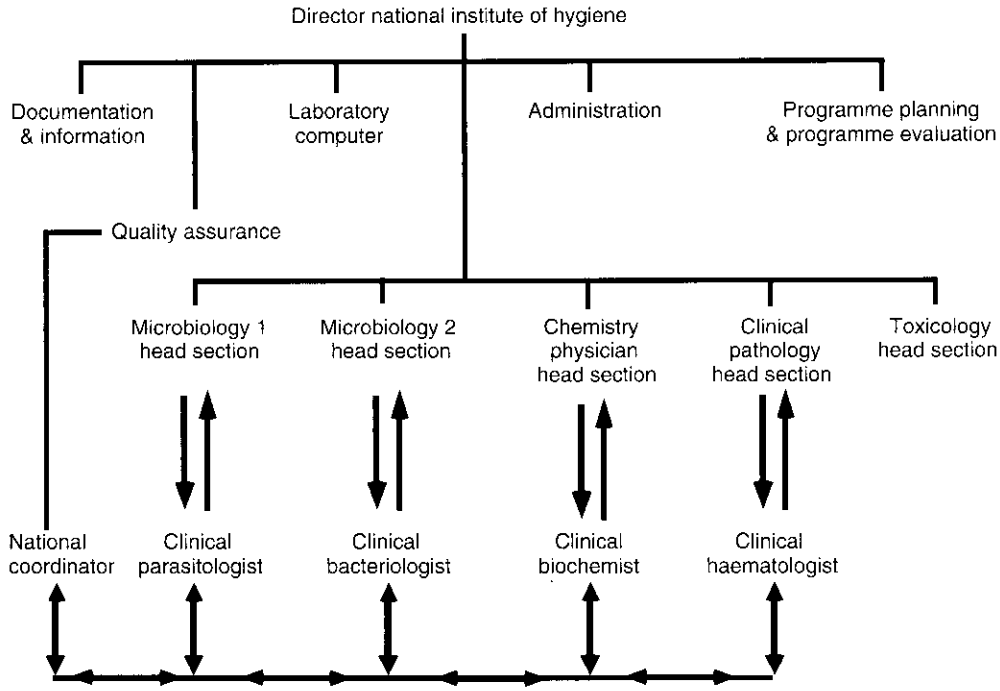


Fig. 2.12 Project structure chart: introduction of quality assurance programme

How efficient is the health laboratory structure?

Following the review of the organizing function of the manager, the health laboratory structure may be more efficiently assessed. This may be done through a series of questions, as done for planning, it being understood that if deficiencies are detected, structural changes may be undertaken (as shown in the previous chapter regarding the establishment of the quality assurance unit in the institute). As an example, these questions could be:

- How do the laboratory services provided by the NHLS fit in with the health policy and its priorities?
- What are the views of the users? (Direct users: clinicians, epidemiologists sanitary engineers; indirect users: health policy makers at the ministry of health). Does the laboratory have all the reagents necessary for performing all the essential tests for the users, at the same time keeping the stock at a level to ensure continuity? If not, what are the reasons for the lack or unavailability of reagents for essential tests?
- How accurate are the laboratory results delivered? Is the quality assurance programme operational in all governmental health laboratories in the country? If not, why?

- Is there a national health laboratory policy? Is there the means (or authority) to develop one and the structure to put it into operation?
- Is there an authority accountable for the effectiveness and efficiency of the NHLS?

Not surprisingly, many of these questions may remain unanswered or they may reveal a confusing situation. This may call for improving the organization of the health laboratories in the Eastern Mediterranean Region. The importance of providing the NHLS with a structural organization is illustrated in Figure 2.13:

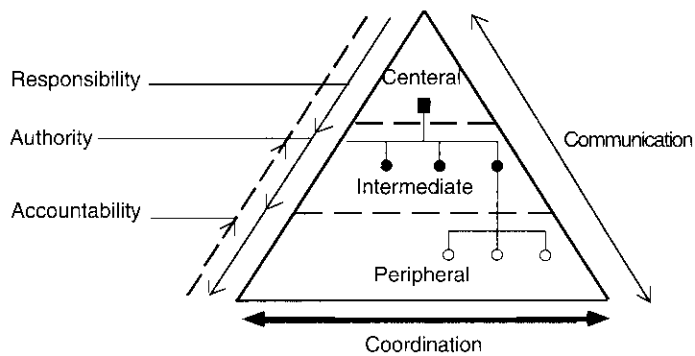


Fig. 2.13 Structural organization

Figure 2.13 illustrates the essential role played by the structural organization as a vehicle through which the instructions related to policy and procedures are communicated to those concerned. It also shows clearly the need for a commanding authority, if the whole laboratory system is expected to achieve its mission in an orderly manner and to progress towards some objectives in a coordinated way.

The absence of an organized NHLS in many countries, and the lack of clearly delineated authority, responsibility, and accountability for all job positions are major causes of the poor performance of individual laboratories, and the lack of effective support from the NHLS in the implementation of a national health policy.

Position of director of the NHLS within the ministry of health

In the following section the responsibilities and the corresponding authority of the director of the NHLS will be reviewed, as well as the position to be held within the ministry, for proper execution of the mission. The director should:

- Establish, in close coordination with other departments, the NHLS's goals and objectives in harmony with national health policies and objectives, as well as with needs of laboratory users.

- Establish and maintain the NHLS's plan and policies designed to ensure the good performance of all laboratories, and the achievement of the goals and objectives of the national service in accordance with accepted policies, procedures and defined budgetary resources.
- Obtain the necessary resources (including financial) and ensure the appropriate environment for the efficient and effective implementation of plans.
- Monitor by measuring results, in order to improve both present execution and future planning.
- Ensure that all activities are conducted in an environment that provides all possible security for the staff and the means necessary to assure the reliability of the services delivered.
- Forecast, identify, and analyse general problems encountered and find solutions for them.

In spite of these important responsibilities borne by the top management of the NHLS, and the essential role its services play in the diagnosis and treatment process of many diseases incurring substantial expense, it very often occupies a secondary position in the ministry of health. In most cases the laboratory service appears as a division of a directorate within the global health care system. These are inadequate conditions for good decision-making, and in many cases represent the root cause of many of the inconveniences encountered that lead to poor performance of the laboratories.

Figure 2.14 shows the different positions within the ministry of health currently held by the directors of the national service, i.e. positions 1 and 2, and the ideal position 3, where more effective decision-making is made possible.

As indicated by position 1 or 2, the director of the NHLS is often placed under an authority who in most cases lacks the technical knowledge and understanding of the needs of the laboratory as well as of the highly complex management and processes involved in an efficient and effective delivery of services.

In position 1 or 2 the NHLS director has no access to budget discussion nor the possibility to compete effectively for a better share of scarce resources. If the head of the department is a clinician or surgeon, when allocating resources within the department higher priority may be given to divisions with which he/she has a professional affinity. Obviously, in such a case the director of the NHLS does not have authority appropriate to the responsibility given or that would allow efficient and effective direction of the national service.

The director of the NHLS under the pressure, either conscious or unconscious, of the director of a certain department, may give emphasis to a specific area activity, e.g. hospital or clinical medicine in position 1, and neglect the development of laboratory services within a national perspective.

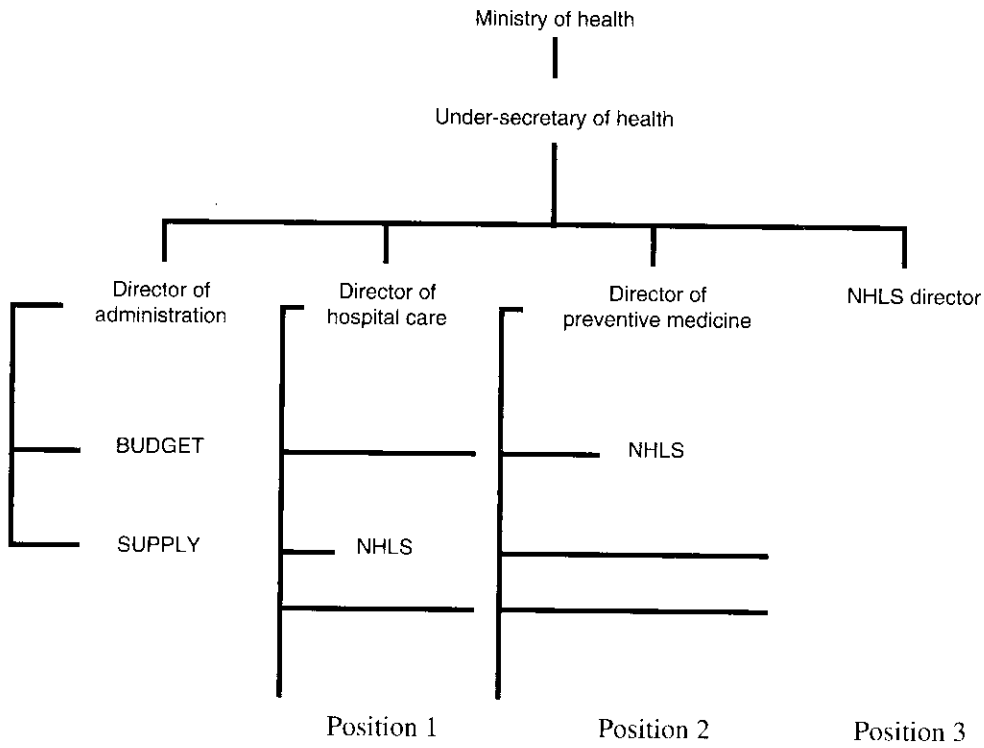


Fig. 2.14 Different positions of directors of the NHLS within ministries of health

In position 1 or 2 the director of the NHLS has no access to the ministry's top management discussions when health policies are developed and goals and objectives are defined. Again, there is a lack of authority regarding the responsibilities assigned to the director of the NHLS.

As the director of a national service is, moreover, supportive to many national programmes (e.g. disease control, water and food analysis, malaria/schistosomiasis/tuberculosis control programmes), it is logical for the director to be accountable to the top management of the ministry of health which bears the responsibility for the efficiency and effectiveness of the total health care system. It thus appears more appropriate to assign the director of the NHLS to position 3 of this chart.

In this position the director will have the possibility for better coordination with other departments or directorates and will be able to initiate joint planning and programming (see tables at the end of section on communication, Chapter 3) so as to achieve better harmony of the services of the laboratories within the national health policies, and will also be able

to compete more effectively for limited budgetary resources. Furthermore, at this level the director will also be in a better position for open exchange of ideas on needs and concerns with regard to major problems that chronically hamper the smooth operation of a laboratory, e.g. procurement and supply, and will subsequently find solutions in collaboration with others concerned.

CHAPTER 3

Directing, motivation, communication and leadership

Definition

Planning and organizing will lead nowhere if plans are not implemented. The managerial function of directing deals with implementation. It is a display of methods and means, not only for getting the work done through the efforts of other people, but also for getting the best out of these people. Along these lines it involves the establishment of the proper climate, or work environment, providing employees with the opportunity to fulfil their expectations (or aspirations). Such a proper climate, favourable for the achievement of efficiency and effectiveness, depends very much on the leadership style adopted by those at the managerial levels, and subsequently the human relationships established, as well as the possibilities of communication between staff members at different organizational levels.

Directing and people

As the definition of management is surveyed, human resources clearly appears as managers' most important and most powerful resource, but it is also the most difficult to manage. The major responsibility of managers holding a directing function is to make optimal use of the enormous potential of energy that lies within every person.

The mobilization of a human being's energy requires, above all, a good understanding of human nature, which is essential for creating the proper climate that will arouse the motivation lying within each individual and which is essential for fuelling good performance.

What is motivation?

In health laboratories, motivation may be defined as the process that directors and other level managers apply to create the work environment that will influence or stimulate technicians and other staff to take action, whereby both the health authorities and/or health laboratories' main goals and objectives, e.g. effective implementation of quality assurance, timely delivery of essential services needed, efficient management of resources, the aspirations of staff, are achieved.

The Webster's dictionary definition of motive states: "Motive is some inner drive, impulse that causes a person to do something or to act in a certain way". It also defines motive as: "the sense of need, desire, fear etc., that prompts an individual to act."

Preliminaries of motivation

It is the responsibility of the manager to ensure that staff are well motivated. When the directors of health laboratories and the NHLS seek to motivate their staff to improve job performance, some preliminary conditions must be established beforehand. These conditions are: the technicians must have the skill and ability to do the work requested (this underlines the emphasis to be placed upon a proper level of education and training of laboratory staff); the appropriate technology must be available; the equipment, reagents and material necessary for the application of the recommended methods must also be available as needed; and a rewards system, matching laboratory staff needs, must be made available. Overlooking any of these preliminaries could not only lead to failure in motivating, but could also be very frustrating and harmful for the staff concerned.

Further to these considerations it must be borne in mind that sources of motivation vary from one person to another, with various factors influencing motivation, for example the local economic situation, religion, or culture. Consequently the present chapter will aim only to provide the basic principles of human motivation that will permit managers to develop a thought process which, ultimately, will lead them to their own concept of motivation, adapted to their own environment. Ways of motivating will probably change with time as motivating factors may change.

The motivation process

Numerous theories regarding human motivation, reflecting human complexity, have been proposed. However, in the present manual only the essentials will be given.

Basic theories on human motivation emphasize the needs approach, which assumes that every person has certain needs. When the need to satisfy him/herself arises within a person, goals intended to fulfil this need are established, and the behaviour believed necessary for the accomplishment of these goals is developed by the person. In summary, in many instances there is a cause-and-effect relationship between human needs and behaviour.

Some behaviour can either be constructive such as working hard, efforts in the application of good laboratory practice, proper keeping of all quality control records, keeping the turn-around time as short as possible, or some behaviours may be negative, e.g. absenteeism, aggressiveness, passivity, and reflect in some way unsatisfied needs. Figure 3.1, illustrates the role of behaviour in satisfying needs.

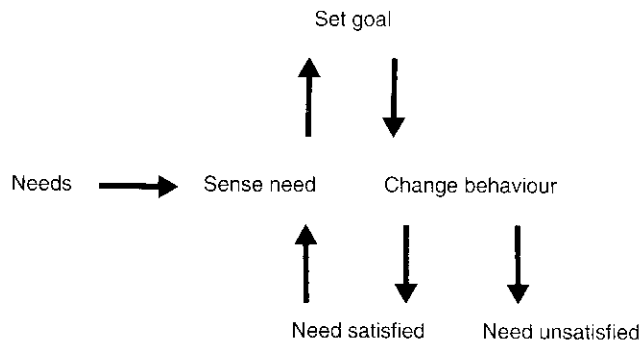


Fig. 3.1 Role of behaviour in satisfying needs

Obviously it is essential for all laboratory managers to be aware of what the people they supervise want from their work, as well as to have a good understanding of the behaviour they observe.

What do people want from their work?

According to Figure 3.1, it may be necessary to review briefly the different theories on human needs and identify these before discussing methods of creating a motivational climate or work environment and those job factors or motivators that allow an employee to have his/her needs and aspirations responded to and fulfilled.

Human needs

Maslow developed a theory on the hierarchy of needs, according to which the human species has an in-built set of needs that it will always be attempting to satisfy in a certain way. Starting from the lowest step, these needs in an employment situation are:

Physiological needs. The desire/need for survival of the employee for himself and his/her family e.g. the fulfilment of basic minimum needs, such as housing, enough foodand clothing, a reasonable and fair salary. These are the most basic needs to be satisfied before other needs can be considered.

Security needs. The desire for total security. This includes not only a good understanding of job objectives, what is supposed to be done, how it is supposed to be done, and safe working conditions, but also security of employment in order to ensure the employee's children's education and growth.

Belonging (social acceptance) needs. This includes the desire to be accepted as a member of a group, e.g. a health team and/or professional society.

Esteem needs. This includes the desire to be appreciated, especially by the group, which involves recognition of achievement, title and responsibility involved in a job. Most employees need to believe that they are productive and that their work is meaningful. Therefore, apart from knowing the what and the how, laboratory staff must also know the why.

Self-actualization (growth) needs. This includes the desire for autonomy, to have some say in the running of the organization and to take decisions as a natural outcome of being conscious of personal worth.

According to Maslow's theory, the higher-level needs which are related to self-fulfilment and social needs will not, in general, motivate until those at lower levels (connected with basic physiological needs) have been reasonably satisfied. On the other hand, needs already satisfied will not prompt a person to work harder.

Along similar lines, Alderfer has proposed a theory referred to as the ERG theory where:

E = existence (equivalent to basic physiological needs)

R = relatedness of affiliation (equivalent to social needs)

G = growth (equivalent to needs for self-fulfilment).

On the basis of the needs approach reviewed above, it can be concluded that today people view their work not only as an economic activity but also as a social one, which helps in determining one's status and class as well as one's self perception. Also people are motivated by what they need, not by what they already have, although they will spend energy on any already-fulfilled need which is threatened or is felt to be threatened, at any particular moment.

What are the types of motivators for staff?

According to Hertzberg's theory, human needs fall into two categories:

- The hygiene category (or job dissatisfiers) which corresponds to Maslow's lower-level needs.
- The motivator category (or job satisfiers) that correspond to Maslow's upper-level needs.

This theory is based on the premise that, in a work environment, satisfaction and dissatisfaction are not opponents but are two separate entities.

According to studies made, satisfying hygiene needs does not introduce satisfaction nor does it motivate employees; it solely eliminates dissatisfaction. Thus, acting on dissatisfaction factors in general will not result, at least in the long term, in an increase in job satisfaction and performance, as would occur if motivators or job satisfiers were introduced. It is therefore necessary to distinguish dissatisfiers from motivators.

Dissatisfiers (hygiene factors)

- ineffective organization and policy;
- supervision attitude worsened by technical incompetence;
- lack of interpersonal communication;
- low salaries, and lack of benefits; and
- unsatisfactory working conditions, etc.

Satisfiers (motivators or motivation factors)

- opportunity for achievement;
- recognition;
- doing interesting and meaningful work;
- responsibility; and
- growth and advancement.

Major components for establishing a motivational climate

From the above-mentioned studies, it appears that the major components for establishing a motivational climate, or work environment, should include:

Achievement. Job characteristics such as standards and provision of feedback on performance are essential for this purpose. Technicians need to measure their progress.

Recognition for specific achievement in different forms, e.g. letters of recognition, time off, increased status. Private recognition should be given for achievement within expectations and public recognition when achievement is exceptional or beyond expectation. A golden rule to be borne in mind by all managers is: Admonish promptly, always in private, and praise promptly, in public, when relevant.

Esteem. This calls for the establishment of proper human relationships between staff of different levels. The respect of the supervisor for the laboratory staff is fundamental for self-confidence. The supervisor has a tremendous impact on the way a person feels about his or her job.

Responsibility. Giving the technicians and other laboratory staff opportunities for extended freedom to do the job as their experience and skills increase, and to make decisions and exercise more self control over the work, not only provides the staff with a participative role, but also contributes to the development of future managerial staff.

Growth and advancement. This implies the creation of a new learning experience, thus encouraging personal growth of the individual.

Directors of the NHLS or health laboratories are responsible for ensuring that all opportunities which may raise motivation are present, as well as for making the technicians and staff realise that it is their responsibility to take the opportunities offered.

In summary, the process for motivation viewed from the manager's side can be formulated as in Figure 3.2.

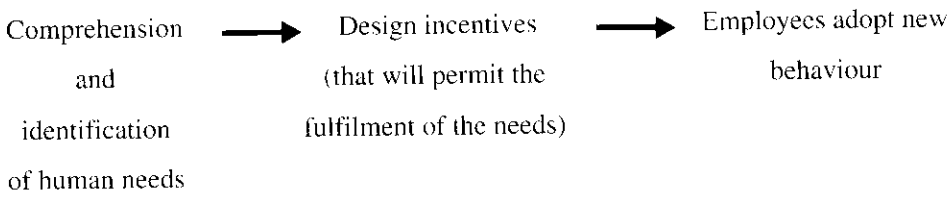


Fig. 3.2 Process of motivation as viewed by the manager

Difficulties in recognition of human needs

The major difficulty is the recognition of employees' needs, which may be quite different from what managers expect, as illustrated below. Furthermore, there is no formula to determine each individual's complex mix of motives; one good way to discover the job factors or motivators that will motivate your laboratory personnel is to ask them what do you want from your job? What are your desires? How would you rank these desires in order of importance?

Along these lines, a survey was done in the USA on employees and managers. The results are shown in Table 3.1. These are ranked in order of importance as expressed by the employees and the top managers. It appears clearly from the table that the priorities of the employees were different from what the top management had expected. Good pay ranks only in the fifth position for the employees, while for managers it ranks in the first position.

Provided physiological and security needs are reasonably satisfied according to local standards, employees' needs will shift towards higher-level desires and ambitions. Directors of the NHLS or health laboratories in countries having reached a good economic situation should recognize technicians and other staff wanting more from work than money, which in this case becomes no more than a dissatisfier.

In countries where financial resources are still scarce it is important to remember that money is not the only motivator. Much motivation can be generated and work energy mobilized through improved relationships between managerial and operational levels. No motivation can be expected, unless the laboratory personnel develop the self-confidence to do their work, and unless a system of incentives has been provided by the directors of the NHLS and/or health laboratories. Unless all these requirements are provided from the managerial level, most laboratory staff's work potential will go to waste. This was stressed at the Arab Congress of Clinical Chemistry in Cairo in 1988.

Table 3.1 Priorities of the employees

Employees	*Managers*
1. Full appreciation of work performed	Good pay
2. Feeling of being informed about things	Tactful discipline
3. Job security	Sympathetic help on personal problems
4. Sympathetic help on personal problems	Promotion
5. Good pay	Job security
6. Interesting work	Good working conditions
7. Promotion	Interesting work
8. Organization's loyalty to workers	Organization's loyalty to workers
9. Good working conditions	Full appreciation of work performed
10. Tactful discipline	Feeling of being informed about things

Appraisal or performance evaluation

Appraisal or performance evaluation can be a good means of acquiring understanding of the needs of the staff and raising motivation when this is considered not merely as an attempt to think clearly about each person's performance and prospects for advancement, but also as an opportunity for providing feedback on how they are doing or assisting supervisors in decisions concerning needs for further training and development. If appraisal is constructive, staff will view it as something worthwhile career-wise, resulting in a healthier, more positive attitude about the job and chances for advancement. Following appraisal, the supervisor may have a better appreciation of the staff and a better understanding of their thoughts. Appraisal should be part of standard operations.

Orientation of behaviour through a rewards system

Whereas in the previous paragraphs the subjects of human universal needs and the job factors or elements that may assist staff in fulfilling their expectations have been dealt with, in the present paragraph it will be seen how people behave differently to satisfy similar needs. According to Vroom's expectancy theory for satisfying similar needs, different people will react differently on the basis of the values and expectancy attached by the individual to specific outcomes. Vroom believed that the degree of motivation is a product of both the values and the expectancy.

Motivation = value x expectancy where:

Motivation = the degree to which the laboratory staff want the job to be done.

Value = importance of the laboratory staff's (not the manager's) place in a specific outcome, e.g. pay increase, promotion. Managers may assess this factor through a questionnaire.

Expectancy (or expectation) = perception (or estimates) by the laboratory staff of the chances of reaching the outcome as a result of certain behaviour. Managers are thus responsible not only for creating opportunities but also for identifying those who have a potential for success and who should subsequently be rewarded.

It may be assumed that (a) people behave in ways they find personally most rewarding, and (b) people's behaviour can be controlled and shaped by rewarding desired behaviour and ignoring the undesirable, as suggested by Skinne's reinforcement theory. On the basis of these assumptions, directors of the NHLS and health laboratories may attempt to orientate and shape staff's behaviour through the establishment of an incentive system appropriate to the staff's abilities.

Motivation is related to performance by the following formula:

Performance = expectation x motivation x ability

The expectation and ability factors will be discussed later in relation to leadership style.

Practical approaches to enhance motivation in health laboratories in the Eastern Mediterranean Region

There are several approaches that may serve to enhance motivation of staff of the NHLS and health laboratories in this Region. The following are three examples of such approaches:

Managing for results. The working conditions, and subsequently the performance of the laboratory service, could be improved and this would lead to greater satisfaction and recognition from users of laboratory services, which in turn would enhance further motivation. This requires, from the very first stage, utilization of more appropriate technology, i.e. technology which is more adapted to the available resources. These resources include financial resources, staff's qualifications, and maintenance capabilities. Managers focusing on results rather than activities should encourage reviews of job design and take advantage of any new technology developed for physician offices as well as for countries with limited industrialization. Among the most interesting technologies are the latex agglutination reagents and other simple rapid methods used for disease detection, and the robust and simple-to-use photometers for chemical measurement.

Staff training and development. Organizing training programmes and developing laboratory technicians' new working experience, while achieving the NHLS's goals and objectives, is of paramount importance. This would include strengthening laboratory support services to disease control. The implementation of such a programme (or a disease elimination programme if relevant) would require the reinforcement of the application of specific laboratory test(s) and reporting the results to people responsible for epidemiology.

More appropriate, new, highly sensitive and/or specific tests may need to be introduced and training organized for their proper implementation.

Introduction of a quality assurance programme. Introduction of a quality assurance programme provides each member of the laboratory technician team with better defined criteria of what is expected to be achieved and with the means to monitor performance. It creates challenges within the job, while keeping in line with the goals and objectives of the NHLS. The staff's perception that the results delivered are reliable and that their work is effective, leads to higher morale and self-confidence, which in turn contributes to improved performance and efficiency.

Leadership

Definition

While motivation deals mainly with the attitudes of subordinates, conversely, leadership deals essentially with the attitudes of those working at the managerial levels. The latter have a great influence on the attitude and morale of those working under their supervision, and thus have an impact on the overall performance of the organization.

The terms 'leader' and 'leadership' may have different meanings for different people. For the purpose of this publication we use, and understand, management leadership in the context of the definition given by Alloni: "the work of planning, organizing, leading and controlling, performed by a person in a leadership position to enable people to work more effectively together to attain identifiable ends". Adopting this definition, we are, therefore, including only effective leaders. A person who just has followers or who has gained authority alone and does not fit in with the aforementioned definition is not a leader.

Not everyone in a leading position is a leader

Leadership is the ability to inspire and influence others to contribute to the attainment of objectives and the achievement of goals. This is obviously necessary for getting work done through others, which is the manager's task. Successful leaders should be interested in getting work done, not by imposing their own way, but by using the best way. The leaders should have faith in people and should remember that their followers are working with them, not for them.

Managers of the HLS, directors of laboratories and first line supervisors are usually appointed. An appointed person in a leading post is one of three types of people occupying leading posts; the other two types are elected and emergent.

Directors of the NHLS or of an individual health laboratory, as well as chief technologists and first line supervisor-technicians, i.e. all those who have people working

under their authority, hold leading positions. However, as mentioned above, being in a leading position and being a leader are not synonymous. Effective leadership is really reflected through the ability to influence subordinates not only in doing the work that is needed, but also in doing it with confidence, enthusiasm, and the professional conscience required. Authority alone is not enough to command respect.

Effective managers are not born, they grow. To be a good leader it is not necessary to copy someone else, but rather to develop insight and build up one's own skill. Technical ability is essential for laboratory service managers, but it is not the sole quality required. The style of leadership in performance determines whether a leader is a success or a failure.

Leadership styles

In communicating or providing directives, leaders will behave in accordance with or adopt a style more or less related to their personalities, backgrounds and, consciously or unconsciously, will be guided by some human behaviour theory such as Theory X and Theory Y of McGregor. These theories incorporate the following propositions:

Theory X

- The average person does not like and will avoid work whenever possible.
- People lack ambition and dislike responsibility.
- People are inherently self-centered and indifferent to organizational needs.
- People are resistant to change.
- Most people have little creativity, except when it comes to getting around rules.

Theory Y

- People are not by nature passive or resistant to organizational needs.
- Motivation, potential for development, capacity for assuming responsibility, and readiness to direct behaviour towards goals and objectives are present in all people.

Depending on his/her concept towards people, the manager will adopt one of the following leadership styles.

Autocratic

This style of leadership is focused on the concept of centralized authority; there is no participation in the decision-making. Only one way of communication is generated. As one progresses towards lower organizational levels, staff are increasingly passive. The lack of upward communication deprives the higher management level of crucial information and advice.

Persuasive

This style differs from the autocratic style as shown by the following formulae:

Autocratic: Decision → instruction

Persuasive: Decision → reasons provided → instruction

Democratic

In this concept achievement is needed through full but structured participation. Delegation of responsibility is given major importance. The leader defines objectives, initiates the movement and provides motivation. Communication is generated in both ways through a well-defined chain of command that encourages exchange and integration of ideas; however, input is channelled in an orderly and uniform manner.

Participative

Whilst democratic management is characterized by complete confidence and democratic decision-making, in participative management there is substantial trust and participation but with control and decision-making retained by the leader.

Laissez-faire

The laissez-faire style is an abdicated leadership. All authority is delegated to the staff who are led by an informal leader.

Concern-based

Some behavioural scientists have differentiated two types of leadership based on the concern of the leaders:

The task-oriented leader. Efforts are concentrated on establishing well-defined patterns of organization, channels of communication and methods of procedure. The workers are provided with guidelines defining exactly what is expected of them.

The worker-oriented leader. More warmth is sought in the relationship between the leader and members of his/her staff; the leader has greater willingness to listen, resulting in greater receptiveness to change.

These two types of behaviour are not mutually exclusive. The production and people concerns are complementary and must be integrated to achieve effective leadership. Similarly, the democratic style of leadership does not imply poor discipline; on the contrary, good discipline is a prerequisite for an effective democratic style of leadership.

Useful characteristics for effective leadership

The primary challenge for leadership is to lead an organization towards the accomplishment of its goals and objectives. This is achieved not only by guiding and/or issuing directives but, just as importantly, by creating the proper climate, or working environment, that would drive the employees' motivation to attain the highest level of performance within the limitations of available resources, skills and technology. The attitude of the leader, or leadership style, has a tremendous influence on the working climate and leadership effectiveness.

Many studies have been carried out, and as many theories proposed, in an attempt to identify the pattern of qualities or behaviours that are consistently related to effective leadership. As there is a necessity for a variety of approaches to motivate each individual (in view of the great diversity of human beings' personalities and their needs) similarly there is no single attitude or leadership style that is appropriate to all circumstances. Nevertheless, six emotional and/or behavioural traits are outlined below resulting from the research of Ghiselli, which are considered basic to effective leadership.

Supervisory ability. This includes the basic function of management.

Need for achievement. This implies seeking responsibility and making things happen; the willingness to work hard for success.

Intelligence. This includes good thinking capacity; ability to acquire new knowledge, to understand and to create; ability to perform good communication, judgement and reasoning.

Decisiveness. Ability to make decisions and solve problems with competence.

Self-confidence. Perception of own ability to cope with problems.

Initiative: ability to develop innovative programmes of action not readily obvious to other people.

How effective is a leader?

To ensure effective leadership it is necessary to determine parameters that will permit its continuous assessment. Parameters proposed for measuring leadership effectiveness are:

Production. Two of the three major objectives of laboratory managers are effective service delivery and quality assurance (the third is resources management). These are basic for assessing productiveness. Production represents the ability to perform all the testing required, taking into account reliability of results as well as turn-around time.

Efficiency. As has been defined above, efficiency represents the ratio of output to input. It emphasizes the third main objective, i.e. the efficient use of laboratory resources or efficient operation of the NHLS and/or individual health laboratories.

Satisfaction. Satisfaction reflects to what extent the laboratory director and/or the leader are able to establish an adequate human relationship between leaders and staff members, resulting in the creation of a proper climate and meeting the needs of the staff. It is reflected by the morale of the staff, and their behaviour; absenteeism, turnover, grievances, etc. are good indicators.

Adaptations - development. This is the ability of laboratory directors and/or leaders to respond to internal and external change or new needs, such as the introduction of new and appropriate technologies, extension of the laboratory facilities network in response to a new health care policy, introduction of continuing education programmes for staff, etc.

Basic behaviour-shaping leadership style

Relationship behaviour

Relationship behaviour, which defines the leader-staff relationship, is often referred to as concern for people. It is the extent to which leaders have relationships with subordinates, including the level of emotional support, trust and confidence in staff and consideration of their ideas and feelings. The greater the relationship between the leader and the staff, the more staff-oriented the leader will be. The greater the leader's willingness to listen, the more can receptiveness to change be expected.

Nevertheless, it must be borne in mind that the staff-oriented or democratic style of leadership does not imply poor discipline. Good discipline is basic and cannot be bypassed if efficiency and effectiveness are to be achieved. A balanced amount of guidelines, procedures and rules is essential for this purpose.

Task behaviour

Task behaviour is related to the extent to which goals, roles, decisions, and solutions to problems are established and/or made by the leaders. It includes the degree of freedom to discuss openly with management work-related matters or the level of structured conditions of work allowing for human elements to intervene.

In contrast with the aforementioned concern for people attitude, this type of leader is mainly concerned with production (or is task-oriented), and will concentrate efforts on establishing well-defined patterns of organization, channels of communication, and methods or procedures. The workers are provided with guidelines defining exactly what is expected of them without freedom to discuss work-related matters with management.

It should be remembered that these two types of behaviour are not mutually exclusive; production and people concerns are complementary and must be integrated to achieve effective leadership. The leader must at first be able to create in the staff the desire to work so as to attain the goals and objectives. This requires that the leader should make continuous and active efforts to establish proper human relationships between him/herself and staff members; to do and to

say things that will make the staff like, trust, believe him/her and ultimately respond to his/her expectations. Once this habit is established, in most circumstances, no more effort will be necessary. The thoughts of the leader will naturally be directed towards others while remaining in keeping with the objectives. It is on this basic human relationship foundation that leadership style should be built.

In practice

The leader has to practise building up leadership style on the foundation of basic human relationships described above. The style has to be adjusted to the maturity of the staff in relation to a specific task to be performed, as well as to specific circumstances.

Maturity

Maturity is made up of the following elements:

- Desire for achievement.
- Willingness and ability to accept responsibility.
- Education, experience and skill relevant to the tasks to be performed.

The lower the level of staff maturity, the greater the amount of task behaviour that must be included in the leadership style. Conversely, the higher the level of maturity, the greater the amount of relationship behaviour that must be included, and a more staff-oriented style adopted. Table 3.2 shows an attempt, which is not claimed to be considered optimal, to illustrate a balance between relationship and task behaviours in connection with maturity of staff.

Table 3.2 A balance between relationship and task behaviours

Level of maturity	*Leadership style*
New inexperienced staff lacking task-relevant maturity	Leader defines goals and roles, tells staff what, how, when and where to do the work.
Lack of experience or skills required for accepting more responsibility.	Leader provides a higher level of emotional support and encouragement. Exhibits greater trust and confidence in employees.
More experience and skill. More achievement-motivated. More willingness to assume responsibility.	Leader provides a high level of emotional support and consideration, reinforcing staff's performance
Skilled and experienced with a high achievement motivation. Capable of exercising self-control.	Employee no longer needs or expects a high level of supportive or task-behaviour from leader.

It should be borne in mind, however, that whatever the level of maturity is, the leader should always be worker-oriented to some extent, because in the long term it is the participative aspect of this style of leadership that will contribute to future personnel growth and development. In other words, this leadership style will pave the way for developing new categories of lower- and middle-level laboratory managers.

Circumstantial factors

There are some circumstances or situations in which, whatever the level of maturity may be, a specific style should be adopted. In an epidemic situation for example, particularly at the early stage when the aetiology has not yet been defined, the task-behaviour-oriented leadership style, providing immediate problem resolution, should be adopted; in fact, this should be the case whenever an emergency situation arises. Similarly, when introducing a new activity, such as a quality assurance programme, development of peripheral laboratories, or developing a new test procedure, there may be a need to exercise higher task and lower relationship behaviour. Once the new activity is well-established, relationship behaviour may again prevail.

In summary, effective leaders must be flexible enough to adopt the leadership style that fits needs, e.g. their own needs and those of their subordinates, as well as those of the moment and the situation. In the EMR, leaders must be aware of the rapid changes in social and cultural values that may be taking place within the development of the country in general. They must also be aware of the educational level of the people entering the work force.

A director with an effective leadership style will have opportunities for better coordination with other departments or directorates. He/she will have better development of joint planning and programming and achieving better integration of the laboratory services within the national health policies and will also be better equipped to compete more effectively for limited budgetary resources. At this level, the director would also enjoy the possibility of open exchange about needs and concerns with regard to major problems that chronically hamper smooth laboratory operation (for example, procurement and supplies) and subsequently find solutions in collaboration with other staff concerned.

Communication - how important is it?

Definition

In the case studies given in the present publication, various methods of communication have been used. In some cases, the purpose was to seek the opinion of the users of laboratory services on areas where laboratory diagnostic support is most needed, or to exchange views between the director of the NHLS and the directors of provincial laboratories, or to provide working directives through written policies and procedures related to the implementation of a quality assurance programme.

Communication can take various forms and can be either verbal or written. Only some forms of communication, that in the immediate term appear to be the most important with regard to the needs of the laboratories in this Region, will be tackled here.

Whenever possible, contact should be direct and paper work should be kept to the necessary minimum. However, written communication has the advantage of providing the recipient with more time and possibility for a thorough study. Some messages such as policies, rules, regulations and instructions must be written. The golden rule for all functional writing is: accuracy, clarity, and brevity.

The effectiveness of a director, either of the NHLS or of an individual laboratory, depends much on the number of people with whom he/she communicates. However, due to limited possibilities for daily or frequent contacts, he/she has to give priority to having satisfactory communication with key personnel to whom authority has been delegated or a special task assigned. In a large teaching hospital or research institute laboratories this group of people may comprise clinical pathologists. At regional laboratory level the group may be restricted to a secretary and a chief technologist; the latter may also have the responsibility of being a head of a section. The key collaborators with the director of the NHLS outside the central laboratory are the directors of the regional or provincial laboratories. Similarly, at the regional/provincial level the director of regional health laboratory services will work closely with the heads of district hospital laboratories.

In spite of time constraints, the director of a health laboratory should endeavour to know and understand every member of his/her staff, and in turn should give every worker an opportunity to know and to understand him/her. Periodic staff meetings, as well as annual meetings, for information exchange and eventually public recognition of staff who have shown outstanding performance, can provide an opportunity for the director to have direct contact with staff.

The importance of communication in management is obvious, as by definition management is getting work done through others. Indeed, the effective transfer of information on what needs to be done, how it should be done and why, from the supervisors to the subordinates (which is of utmost importance for ensuring the correct achievement of the tasks requested) depends on good communication. Similarly, the feedback from the subordinates to the supervisor is critical for the monitoring and control of good understanding of the assigned tasks and the progression of the tasks' implementation according to a time-frame.

The director of the NHLS needs to know from the departments of clinical medicine and epidemiology, their needs and objectives and, more specifically, the laboratory support expected for the achievement of the objectives and satisfaction of needs. It is only after providing this information that the director of the NHLS will, in turn, be able to plan and programme the activities of the national laboratory network to offer the optimal support required. This justifies Duerr's statement that management is communication. This could be expanded as follows to say that no management is possible without communication.

According to J.A.C. Brown, communication is defined as "the capacity of an individual (or a group) to pass on his/her feelings and ideas to other individuals or groups". In other words, it is the achievement of understanding between people, through verbal or non-verbal means, in order to achieve the desired end result.

In summary, the major problem for effective communication lies in how the receivers perceive the message, and the effort made by the communicator for successful transmission of the message.

Effective communication

Effective communication means that the receiver correctly interprets the perceived message. It is the ability of executors to achieve the goals through correct understanding of information transmitted through messages. Effective communication thus implies overcoming the barriers of the complex communication process, and making use of all the means that facilitate the receiver to understand the message.

Complexity of the communication process

It may be important first to recall the definition of J.A.C. Brown of communication: "It is the capacity of an individual or group to pass on his/her or their feelings and ideas to other individuals and groups."

Drucker has identified four fundamentals of communication that pinpoint barriers which may occur in communication and prevent accurate understanding. These four fundamentals are:

- Communication is perception.
- Communication is expectation.
- Communication is involvement.
- Communication is **not** information.

Perception

A good communicator should bear in mind that the recipient will not perceive what he/she cannot understand. Consequently the first attempt for the communicator is to find out what the recipient can perceive and to use the appropriate wording and terms to communicate.

Expectation

The recipient will generally perceive what he/she expects to perceive, on the basis of his/her own experience and background. To make communication possible it is necessary to ascertain what the recipient expects to hear and subsequently use this knowledge in

communication and show the differences between what he/she is expecting to hear and what he/she is told.

Involvement

The recipient has a tendency to ignore all information that conflicts with what he/she believes. The divergence of opinion created must lead to a dialogue to identify the exact differences. Once this has been achieved, the recipient should be provided with all the information that allows him/her to understand the rationale of the decision taken. Although consensus may not be achieved, the benefit of such an approach is a better understanding by each party of the other's point of view.

From the above it may be concluded that communication is more than speaking and writing; it is an effort to make others understand the message and it involves the understanding of others and their thought processes.

Facilitators to communication

Recognizing the occurrence of breakdown in communication, it becomes necessary to seek means to facilitate overcoming barriers and to improve the communication ability. According to the authors' experience the following important facilitators will be discussed briefly:

Empathy. Empathy is the ability to identify feelings and thoughts of another person about a certain subject. This deeper understanding does not imply agreement with the viewpoint of the receiver. The information gathered in the understanding of the people with whom we work every day is essential in order to perceive why people act as they do; it also greatly facilitates communication, and subsequently problems might be resolved more easily. In many countries of the EMR, where laboratory staff face hard working conditions (with regard to salaries, equipment, reagents, and material), empathy may be one of the most important factors that laboratory managers need to consider when they want to communicate and mobilize those with whom they work.

Listening. The ability to listen is one of the most effective tools. To be able to communicate we have first to be able to listen. A person constantly talking is not listening, and he/she deprives himself of opportunities of learning from others. Full understanding requires giving full attention to the speaker. When the speaker has finished and after full understanding of the message, evaluation and judgement can be made and remarks may be spelled out.

Trust. Mutual trust between managers and staff must exist for effective communication. In general, when trust is absent, barriers to listening and communication arise. Promises for changes and improvement that never materialize contribute to erosion of trust and growing difficulties in communication. This highlights the need for realistic plans and programmes of work within available resources.

Good performance of the health laboratories and reliability of results are essential for effective communication between laboratory staff and clinicians and other users of laboratory services, e.g. epidemiologists.

Communication line within extended laboratory system

Communication channels illustrated by vertical and horizontal lines in the organization charts of the ministry of health, the NHLS, hospitals or laboratories, indicate which departments or laboratories (or groups or individuals) should communicate with which. The communication channel is an important guide for effective communication. Its use is critical, not only for the good operation of the organization but also, in some cases, for its survival. This is the case for the communication line linking a health laboratory to the administration department (provider of the operating financial resources) as well as to the procurement agency. Formal communication channels appear on the organization flow chart as vertical and horizontal lines. Within the laboratory they represent channels for internal communication. External communication links the laboratory with the extended laboratory services and health services systems which include all the health departments, such as the supportive health administration as well as the health departments using laboratory services. External communication plays a keyrole in the quality of services provided by the NHLS and is vital to its effectiveness. Without neglecting informal personal contact, effective external communication can be achieved through effective coordination at the top management level in the ministry of health.

Through such coordination:

- Policies of health departments and institutions needing health laboratory support (users) can be known and their needs better understood by the HLS (providers of services).
- Realistic plans and adequate decisions can be made in the light of the conveyed messages and information.
- Details of situation analysis can be provided and may be very useful, particularly when new plans and objectives are prepared. This leads to initiating better cooperation and coordination.
- Everyone concerned is made aware of problems and thus is able to give suggestions and share in finding solutions.
- More efficient approaches can be adopted.

To sum up, the top management is the one which creates the forum, allowing interdependent health departments (including the health laboratory services, medical departments, disease surveillance and epidemiology, and the departments responsible for financing and procurement of equipment, reagents and material) to convey messages and useful information which will help departments to make reasonable decisions jointly, leading to the achievement of common objectives of the national health plan. This ultimately leads to health

protection of the population and a better quality care of patients. One has to emphasize that laboratory and other health departments' interdependency means that laboratory service effectiveness and testing quality are not problems of the laboratory alone, but of all the departments involved in the pre-analytical, analytical and post-analytical cycle.

Vertically, the line of authority and accountability channels the orders flowing down and feedback information flowing up. If the downward channel is essential to get the work done, the upward channel (the reporting channel) is as important for the evaluation of the work achieved. The use of the upward channel is encouraged if the staff perceive that the managers are open minded and receptive to their ideas.

Within a laboratory (intralaboratory), horizontal communication lines linking different laboratory sections are pathways through which coordination and cooperation are developed and information is shared for the sake of effectiveness of the sections within the laboratory. This also applies to laboratories within the NHLS (interlaboratory).

What should be communicated?

Communicated information should be appropriately selected. It should be motivational and should not have a negative impact on laboratory operations. Among basic information to be communicated is that related to:

- The mission of the health laboratory services, its role in clinical medicine and community health, including protection of the environment; the role and importance of the profession; what has been achieved and how far progress towards goals has been achieved.
- Information about policies and rules related to laboratory personnel and their jobs, including job descriptions and accountability.
- Information about specific programmes initiated by a laboratory or the NHLS, including the purpose of the programme and the role of every level of laboratory and every category of staff in the implementation of these programmes.

Suggestions for effective communication

In order to acquire a better grasp of what communication is all about within the laboratory, it is interesting to examine the job description which delineates the relationships of a supervisor-technologist who plays a key role in getting tests done by technicians in the laboratory. It intends also to illustrate the importance of communication within the laboratory between the supervisor and the front-line technician on the one hand and the laboratory supervisor and the director of the laboratory on the other.

Job description

Functions of the supervisor-technologist in a clinical chemistry laboratory

- Under the supervision of the pathologist (or director in the case of a small laboratory), the supervisor is responsible for all technical and administrative duties assigned to the chemistry laboratory.

Duties

- The supervisor-technologist is responsible for ensuring the laboratory's cleanliness and neatness and for organized and efficient work.
- In agreement with the pathologist, the supervisor-technologist recommends and assists in selecting and developing all tests needed for the clinical chemistry laboratory and keeps the procedure manual up-to-date. This manual must be available at all times to technicians for use and review.
- The supervisor-technologist supervises and assists in the implementation of all procedures assigned to the clinical chemistry laboratory. He/she is responsible for the accuracy of results and clarity of reports.
- In agreement with the pathologist, the supervisor-technologist is responsible for implementation of an efficient, effective and documented quality control programme in the chemistry laboratory.
- The supervisor-technologist ensures that all duties of the laboratory personnel are well defined and understood. He/she is responsible for their development, training, performance and motivation.
- The supervisor-technologist provides guidance and advice to all technicians in the clinical chemistry laboratory, and others as relevant, in order to improve total performance. He/she also conducts the yearly job appraisal.
- In agreement with the clinical pathologist, the supervisor-technologist interviews all applicants for positions in the chemistry laboratory.
- The supervisor-technologist reviews and analyses, with the pathologist, all quarterly activity reports (for both work volume and budget) for the chemistry laboratory.
- In accordance with the approved policy, the supervisor-technologist is responsible for:
  - maintaining up-to-date catalogues of material and reagents used by the chemistry laboratory, as well as all inventory control cards;
  - preparing purchase orders for the chemistry laboratory; and
  - maintaining a constant watch on efficient and economic utilization of supplies in the chemistry laboratory.
- In accordance with approved policy, the supervisor-technologist is responsible for an efficient and effective application of all preventive maintenance protocols for the instruments of the chemistry laboratory.
- In accordance with approved policy, he/she is responsible for the safety of all chemistry laboratory personnel, by assuring continuing compliance with the safety programme.

- In agreement with the clinical pathologist and/or director, the supervisor-technologist is responsible for organizing refresher courses and bench training for personnel of peripheral laboratories.
- The supervisor-technologist performs other assignments, as indicated or approved by the director of the laboratory.

Job relationship

- Workers supervised: laboratory technicians, laboratory assistant.
- Accountability: supervised by the clinical pathologist (or director of laboratory in smaller laboratory).

Laboratory communication with the administration

In countries of the EMR, few laboratories have been successful in attracting health administrators' interest. However, it has to be admitted that few health laboratory directors have made enough effort to prepare activity reports that can assist the administration in perceiving the way the laboratory operates as well as its problems and needs. A well-prepared activity report would serve as a useful tool in decision-making when the budget is discussed and

FIRST QUARTERLY REPORT: HAEMATOLOGY SECTION

Date: _____

Total available technician hours: _____ Total worked technician hours: _____

Potential workload units available: _____

		IN-PATIENTS		OUT-PATIENTS		TOTAL	
PROCEDURE	UNIT VALUE	RAW	UNITS COUNT	RAW	UNITS COUNT	RAW	UNITS COUNT
Blood cell profile							
Coulter S	3	1818	5454	981	2943	2799	8397
Platelets	9	473	425	174	1566	6475	823
Prothrombin time	5	87	485	19	95	106	580
Bleeding time	11	7	77	8	88	15	165
Activated partial thromboplastin time	5	86	430	22	110	108	540
Reticulocyte count	9	109	981	53	477	162	1458
Differential	1	1703	18733	965	10615	2668	29348
Sedimentation rate	4	127	508	167	668	294	1176
TOTAL		4410	30925	2389	16562	6799	47487

Total actual worked hours _____ Workload unit per total actual worked hours _____

Chief of the laboratory _____

Fig. 3.3 An example of a quarterly report

prepared. An example of a laboratory quarterly activity report is given in Figure 3.3. It provides information on the workload and technician hours worked rather than a list of types and numbers of tests performed. Nevertheless, there is no doubt that the latter type of report is irreplaceable and is essential for preparing the above-proposed reporting form intended for administrators. According to needs, these laboratory reports could be half-yearly or yearly. The terminology used in this example is explained in the chapter of this publication dealing with workload measurement. Meaningful information that is understandable by the administrator is reflected in the given example of an activity report, which thus becomes an effective communication document. Effective communication between the NHLS and the financing administration within the ministry of health is crucial to ensure necessary funds for good performance of the laboratory service. A report similar to the example given complemented by the costing system, is given in the chapter dealing with accounting and provides useful information for budget preparation and monitoring.

Communication with disease surveillance programme

Effective communication with the disease surveillance and control department, leading to joint activities, is one of the most cost-effective operations a NHLS could achieve, particularly in countries of the EMR where infectious diseases remain a scourge and resources are scarce. Despite the great importance of, and necessity for, cooperation between these two services, this is often not well established. The major initial step for such joint programming should be taken by the epidemiologists, who should determine: the priority diseases to be included in the national surveillance programme; the objectives of the surveillance; and the information needed to assess achievement of surveillance objectives and epidemiological decisions. The laboratory specialists will respond positively, particularly when information about epidemiological needs is discussed in the light of their knowledge of existing technology and/or testing procedures already operating at different laboratory levels in the country. The sensitivity and specificity of the testing procedure, as well as the predictive value in connection with the prevalence of the specific disease under study are also important. Joint discussion may then take place on the value of a specific test, either for diagnosis and treatment or for surveillance purposes. Tables 3.3 and 3.4 were developed during a joint planning and programming meeting between senior representatives of the Department of Disease Surveillance and control and the NHLS in country X. However, effective and successful cooperation between the two departments depends also on periodic follow-up evaluation meetings after the initial joint-planning or programming.

Tables 3.3 and 3.4, prepared mainly by the laboratory staff, show not only the testing services that will be offered at different levels in response to the requirements of the department for disease surveillance and control and decided upon in common, but also all the research and development work undertaken at central level in support of the surveillance programme.

Laboratory communication with clinicians

As previously mentioned, clinical laboratory resources are very limited in many countries of the EMR. Despite this fact, clinicians have been relying more and more on laboratory services. For efficient and effective use of health laboratory services, a systematic approach on how to provide the necessary and appropriate laboratory services has to be determined jointly by clinical laboratory services, clinicians and management.

As an example, a system is proposed, illustrated in Table 3.5, which consists of a list of decision criteria that may help in making a decision by a value judgment process as to whether or not a test should be done. This approach may be useful for establishing service levels for new laboratory facilities as well as for periodic review and changes in the testing programme as a new development takes place. To achieve optimal quality laboratory services, it is essential to have periodic meetings between clinicians and laboratory staff. Establishing a quality assurance programme leads to enhancement of the technical quality of laboratory performance. However, the clinical usefulness of laboratory tests has also to be considered. As laboratory tests are requested by clinicians and laboratory results are also used by them, it is evident that the proper utilization of laboratory services depends to a great extent on knowledge about the value of the test with regard to the intended use. The usefulness of a test would depend on to what extent its result will establish or validate a diagnosis. The usefulness of a test would depend also on its sensitivity, specificity and the prevalence (or probability) of the disease to be diagnosed or confirmed by that test, and the value of the result for treatment and/or monitoring. A better sustainable communication between laboratory specialists and clinicians, as well as organization of joint studies on the clinical usefulness of certain laboratory investigations in specific medical conditions, may contribute to the improvement of laboratory utilization and its cost-effectiveness.

Table 3.3 Proposals for integrated surveillance

DISEASE	SURVEILLANCE OBJECTIVES	INDICATORS	TYPE OF REPORTING	PERIODICITY	DATA SUPPORT
Poliomyelitis	1.Evaluate N.P.I. 2.Evaluate progress in disease elimination 3.Early detection/control of epidemics	1.Morbidity: Laboratory confirmed cases. 2.Paralysis sequelae prevalence	Punctual reporting Investigation	—	Formula for case investigation
Diphtheria	1.Evaluate N.P.I. 2.Disease Control	Morbidity: laboratory confirmed cases	Punctual reporting only	—	Formula for individual case investigation
Tuberculosis	1.Disease Control 2.Evaluate BCG immunization	1.Morbidity: (active case finding included	Data	Monthly/ quarterly	Register
		2.Morbidity: TB meningitidis & other miliary TB in children <15yrs.	Punctual reporting	—	Hospital registers - Paediatric department
Meningitis/ meningitidis	Early detection & control of epidemics	1.Morbidity: Laboratory confirmed cases	Punctual reporting	—	Register
		2.Pyogenic meningitidis confirmed through macro examination			Register
Urethritis (male)	Evaluate STD programme	a)urethritis morbidity	Data	Monthly	Register
		b)gonococcal urethritis morbidity	Data	Monthly	Register

and control of priority disease in country X

LEVEL OF DATA COLLECTING	LABORATORY CONFIRMATION	CASE STUDY OR INVESTI-GATION	LEVEL FOR OPERATIONAL AND/OR DATA COLLATION & ANALYSIS	REMARKS
Hospital	(+) National laboratory for virology	(+)	Province	Home visit
Hospital	(+)	(+)	Province	
All health care insti-tutions including health centres	(+)	(+)	Province	
Hospital	(+)	(+)	Province	
Hospital	(+)	Limited to meningococcal meningitidis confirmed cases	Province	CSF collection essential
Hospital	(±)			
District	(-)	(-)	& analysis District	
Laborato-ries	(+)	(-)	Province	

Table 3.3 Proposals for integrated surveillance

DISEASE	SURVEILLANCE OBJECTIVES	INDICATORS	TYPE OF REPORTING	PERIODICITY	DATA SUPPORT
AIDS	- Evaluation disease progression	1.Morbidity - confirmed case of AIDS/ reporting very early stages of disease	Punctual reporting	—	Register
		- antibody seropositive cases in blood donors	Data	Annual	Blood Trans-fusion centres registers
Shisto-somiasis	- Disease control - Evaluate control programme	1. Morbidity of confirmed cases	Data	Quarterly	Register
Typhoid/ enteric fever	- Disease control	1. Morbidity: - confirmed cases	Data	Weekly	Register
	- Detect and control epidemics - Evaluate programme of environ-tal health	- hospital confirmed cases in patient	Punctual reporting	—	Hospital register

* BCG: Bacillus Calmette-Guerin
CSF: cerebrospinal fluid
N.P.I.: National Programme of Immunization.
TB : Tuberculosis.
STD: sexually transmitted diseases.
NOTE : This table represents the first stage the epidemiologists decide on disease priorities, type of information needed and for which purpose. At this stage laboratory scientists provide support on the type of contribution they can provide for the purpose intended.

and control of priority disease in country X *(Cont.)*

LEVEL OF DATA COLLECTING	LABORATORY CONFIRMATION	CASE STUDY OR INVESTIGATION	LEVEL FOR OPERATIONAL AND/OR DATA COLLATION & ANALYSIS	REMARKS
Hospital	(+)	(+)	Province	Coordinate with national AIDS programme
Blood transfusion laboratories	(+)	(-)	Province	
Laboratories	(+)	(+)	District	
District	(+)	Limited to confirmed cases	District	Sanitary network Specific investigations
Hospital	(+)		Province	

Table 3.4 Readjustment of laboratory services level

DISEASE	USEFULNESS OF LABORATORY TESTING		
	DIAGNOSTIC OR TREATMENT	DISEASE CONTROL PROGRAMME	
		INVESTIGA-TION/ EVALUATION	EARLY DETECTION OF EPIDEMIC
1.Poliomyelitis	-	+	+
2. Diphtheria	+	+	+
3. Tuberculosis	+	+	-
4.Meningitis Meningitidis	+	-	+
5. Urethritis (male) gonococcal	+	+	-
6. AIDS	+	+	-

in connection with disease control programme

METHODS AVAILABLE	LEVELS OF EXECUTION			REMARKS
	PERIPHERAL (1)	INTERMEDIATE (2)	CENTRAL (3)	ACTIONS TO BE TAKEN
Serology	-	-	+*	Central laboratory of Virology: Laboratory diagnosis of all cases.
Culture	-	+(1)	+(2)	1) Diagnostic, through direct examination of smear from culture. 2) Diagnostic confirmation on material provided by intermediate level. 3) Evaluation of the diagnostic scheme proposed. Development of rapid test
Direct examin.; Culture; Susceptibility testing	+ - -	+ + +	 (3)	1) Decentralization & integration of cases detected by direct examination. 2) Culture of samples positive at direct examination. Culture of TB patient specimen for confirmation of "negativity." 3) Research & Development of rapid test for detection of specific antigen.
Direct examin.; culture, serotyping. Susceptibility testing	+ - -	+ + +	 (3)	1) Rural Hospital 2) Boosting of CSF cytochemistry laboratory method. 3) R & D development of grouping reagents, e.g. sensitized particles - local preparation of immuno/sera grouping.
Direct examination. Culture Susceptibility testing	+	+ + +	 +	1) Application of direct examination or growth from urethral discharge. 2) Isolation & identification of gonococcus and rapid test for detectionfor ß-lactamase. 3) Epidemiological surveillance of susceptibility of gonococcus.
Immunnodiagnostic techniques.	-	+	+	Blood transfusion Centres.

Table 3.4 Readjustment of laboratory services level

DISEASE	USEFULNESS OF LABORATORY TESTING		
	DIAGNOSTIC OR TREATMENT	DISEASE CONTROL PROGRAMME	
		INVESTIGA-TION/ EVALUATION	EARLY DETECTION OF EPIDEMIC
7.Shistosomiasis	+	+	+
8. Typhoid fever	+	+	+

NOTE: This table represents the second stage of joint planning between policy makers and scientists of the laboratory and epidemiological departments.

At this stage the discussions are mainly conducted by the laboratory scientists on the basis of the decisions taken during stage I which as far as it concerns laboratory activities, are summarized in the first four columns.

Laboratory scientists have reviewed the technology available, and decided on the tests that would be conducted at different level, and the activities that should be undertaken by the Central Laboratory (3).

As the programme activity approaches finalization, the third stage with the participation of the health administrators dealing with joint budgeting will be initiated, completing the joint planning programming and budgeting exercise.

in connection with disease control programme *(Cont.)*

METHODS AVAILABLE	LEVELS OF EXECUTION			REMARKS
	PERIPHERAL (1)	INTERMEDIATE (2)	CENTRAL (3)	ACTIONS TO BE TAKEN
Direct examination Urine sedimentation	-	+		1) Decentralization & integration of passive case detection 2) Regional Bilharzia Central Laboratory provides support to peripheral level for active case detection and conduct quality control programme.
Serology	-	+	+	- Standardization of O and H antigen suspension production. - Evaluation of optimal dilution for decision-making sensitivity & specificity. - Epidemiological surveillance of susceptibility - Research & development rapid test, eg., latex VI reagent
Culture	-	-	+	

PROCEDURES	A		B		C		D	
CRITERIA	YES	NO	YES	NO	YES	NO	YES	NO
Medical needs								
Clinical service	+		+		+		+	
Disease prevalent		+	+			+		+
Immediate diagnosis and treatment	+			+	+			+
Diagnostic confirmation	+		+		+		+	
Epidemiological considerations		+		+		+		+
Legal or professional requirements								
Local regulations	+			+		+		+
Professional certification		+		+		+		+
Technical resources								
dentical test		+	+			+	+	
Equipment, methods and reagents	+		+			+		+
Qualified and competent personnel	+			+		+	+	
High workload	+			+		+	+	
Safety	+		+		+		+	
Stability and transport of specimens		+		+	+			+
Transport of patient		+		+		+		+
Managerial consideration								
Possibility of referral		+		+	+			+
Improve efficiency	+			+	+			+
Decision								
eliminate					+			
test locally	+							
refer			+				+	
other								

CHAPTER 4

Workload measurement

Definition of workload

Workload is the sum of the work achieved or to be achieved, obtained by multiplying the raw count of each individual procedure by its unit value expressed in units (minutes). Individual workloads for procedures are accumulated to obtain the total workload for laboratories, laboratory sections, shifts, etc.

When discussing workload one has to consider a number of points. For example,how much work the laboratory does; whether the staffing level is adequate; whether the laboratory needs expensive equipment; whether the laboratory is working efficiently.

Why using the number of tests is not accurate

Traditionally, the activity of the laboratory has been expressed by total number of tests achieved for a given period of time (raw count). This method does not take into account complexity, which varies greatly from test to test, and subsequently the specific time required to perform any test. The following case study shows the deficiency of this method.

Total work performed in laboratory X

PROCEDURE	NO. OF TESTS
Rapid plasma reagin (RPR) qualitative	1 000
All micro-manual	1 000
Red cell count	6 000
White cell count	750
Cholesterol	750
Cretinize	300
Platelet count	200
Total tests	**10 000**

$$\text{Cost per test} = \frac{\text{total operational cost*}}{\text{total tests}}$$

$$= \frac{\text{US\$ 85 000}}{10\,000} = \text{US\$ 8.50/test}$$

Performing a red cell count is much more time consuming than performing a RPR qualitative test,
Cost of 1 red cell count = 1 RPR qualitative test = US$ 8.50
US$ 8.50 is the average cost per test.

* Total cost for running the laboratory for the period during which 10 000 tests were performed, representing the total activity for that given period.

Workload unit method

This is a standardized counting method for measuring technical workload in a consistent manner. It had been under development since early 1950 and was eventually consolidated through an international cooperative venture between the College of American Pathologists (CAP) and Canada Stat[illegible].

1 work unit = one minute of productive technical, clerical and aide time.

Unit value per procedure

Unit value per procedure, more often referred to as unit value (UV), is the mean number of units involved in performing all activities required to complete the defined procedure once. It includes the time required for:

- Initial handling of the specimen: includes all activities related to the specimen once it reaches the laboratory.
- All steps involved in specimen testing. Does not include incubation or centrifugation time.
- Recording and reporting: includes calculating, entering results in the computer, checking and filing the final report. Telephone calls for reporting results are also included.
- Daily and routine preparation of reagents, preparing standards, diluting quality control vials, instrument cleaning, warm-up and calibration.
- Maintenance and repair: includes regular weekly or monthly preventive maintenance, emergency repairs, time spent in identifying defective reagents. Does not include major breakdowns.
- Solution preparation.
- Glassware wash up: includes washing, drying and sterilization.
- Technical supervision.

Unit value per procedure does not include specimen collection. Standards, quality control, and repeats are counted as tests and are included in the raw count.

Workload value (WLV) is expressed in minutes:
raw count for each procedure x its unit value (UV)

It will now be seen how the workload system changes the cost of the test.

Case study from laboratory X

PROCEDURE	NO. OF TESTS	UNIT VALUE (UV)	TOTAL UV*
RPR qualitative	1 000	1	1 000
ASO micro-manual	1 000	10	10 000
Red cell count	6 000	10	60 000
White cell count	750	7	5 250
Cholesterol	750	3	2 250
Creatinine	300	5	1 500
Platelet count	200	25	5 000
Total	**10 000**		**85 000**
			(Total WLUs)

* Total UV = no. of tests x unit value

$$\text{Cost per WLU} = \frac{\text{total laboratory operating cost}}{\text{total WLUs}}$$

$$= \frac{\text{US\$ 85000}}{\text{US\$ 85000 WLUs}}$$

$$= \text{US\$ 1/ WLU}$$

Cost of red cell count = US$ 1 x 10 = US$ 10

Cost of RPR qualitative test = US$ 1 x 1 = US$ 1

How is UV determined? - time study

A surveyor actually uses a stopwatch and times the procedure being done in the laboratory. The stopwatch is a decimal-minute stopwatch using the snap-back method. The watch is started at the beginning of the first step of the procedure and continues throughout its entire cycle. Step endings and delays are noted as they occur.

The procedure is broken down into steps. Each step must be outlined in detail, and must have identifiable beginning and ending points. The sum of the steps must be equal to the total cycle of the process. To this end, flow charts are prepared in detail in steps. The procedure is performed in the same way as it is dealt with under routine conditions, for example, individually or in batches, with different technologists. These surveys are sent to coordinators by whom surveys are evaluated, using 10 different laboratories, before a permanent unit is acquired. As a start, it is suggested that the UVs given in Table 4.1 should be used. These units have proved to be applicable in some countries of the Eastern Mediterranean Region.

Management application of WLU system

When the system has been in operation for a few months and monthly reports are converted into WLUs as shown in the paragraph on Communication', the following information (essential to good management) can be obtained.

Table 4.1 Some unit values tested in country X

TYPE OF TEST	UNIT VALUE
Stool parasites	10
Gram stain	3
Ziehl Nielsen stain	12
Vaginal discharge	9
Microscopic examination of hair	10
Haemoglobin	5
Red cell count	6
White cell count	6
Differential count	11
Sedimentation rate	5
Packed cell volume	3
Blood grouping (ABO)	7
Blood grouping (ABO+D)	9
Basic urine chemistry	3
Proteinuria (quantitative)	8
Blood glucose	8
Urea	8
Albumin	12
Alkaline phosphatase	7
Amylase	10
Aspartate aminotransferase (AST)	7
Total bilirubin and direct bilirubin	16
Total bilirubin or direct bilirubin	11
Calcium	6
Total carbon dioxide	14
Chlorides	6
Cholesterol (without extraction)	7
Creatinine	10
Lactate dehydrogenase (LDH)	7
Na+ and K+ (single chanel)	7
(dual chanel)	4/specimen
Total protein	8
Triglyceride	12
Urate	8

Productivity

Productivity measures how well the laboratory does the work. Usually it is expressed in the ratio of output to input.

$$\text{Productivity} = \frac{\text{output}}{\text{input}}$$

Total output = sum of products and services produced
Total input = total resources expended including labour, material, equipment, facilities

In the case of laboratory productivity the above data are difficult to assess. Laboratory productivity is calculated as a partial index. As the laboratory is a labour-intensive centre, labour productivity is measured, and labour hours are used as an input. Productivity is expressed in terms of output per man-hour. One man-hour is the expenditure of one hour of time on the job by one person regardless of the output.

$$\text{Labour (productivity)} = \frac{\text{output}}{\text{man-hours}}$$

$$= \frac{\text{total WLUs}}{\text{total available man-hours}}$$

= laboratory average number of WLUs produced per available man-hour.

Determination of the 'input' man-hours to the productivity equation

When considering man-hours, all personnel on the laboratory payroll must be included. Man-hours are of three types: paid man-hour, worked paid hour and actual worked hour.

Paid man-hours leading to paid productivity

This is represented by the ratio of output expressed in workload units to total technical, clerical and aide time in hours, for which laboratory employees are being paid, *whether or not the employees are on site*. It determines cost-effective use of personnel. It identifies the overall productivity of all employee resources dealing with the laboratory workload.

$$\text{Paid productivity (units/hour)} = \frac{\text{total WLUs/year}}{\text{total paid hours/year}}$$

Total paid man-hours = 52 weeks x Z working hours per week.

The total for each employee's hours for each category for the year is thus calculated.

If one health centre laboratory employs one laboratory assistant or full time equivalent (FTE) and produces a total of 37 319 WLUs annually:

Total paid time = (7 hours per day) x (5.5 days/week)x (52weeks/year)
= 2002 hours

$$\text{Paid productivity} = \frac{\text{WLUs/year}}{\text{total paid hours/year}}$$

$$= \frac{37\,319 \text{ WLUs}}{2002 \text{ hours}} = 18.6 \text{ (or 19) WLUs/hour}$$

Worked productivity

Worked productivity is represented by the ratio of output expressed in workload units to total technical, clerical and aide time in hours *on site*.

$$\text{Worked productivity (units/hour)} = \frac{\text{total WLUs}}{\text{worked man/hours}}$$

(Worked man-hours = total paid man/hours – total paid man-hours not worked).

Worked hours reflect the time actually available for performing laboratory activities, timed (having assigned UVs) or not timed.

Paid man-hours not worked are:

- vacation;
- official holidays;
- sick leave;
- other professional (congress, continuing education, leave) and personal leave.

Worked productivity at the health centre laboratory is calculated as follows:

- Paid time off: vacation 22 days x 7 hours = 154 hours
  official holidays 15 days x 7 hours = 90 hours
  sick leave 5 days x 7 hours
  other paid time off 10 days
- Total paid ...
- Worked hours for the year = ...
- Worked productivity $= \frac{37\,319 \text{ WLUs}}{1653 \text{ total worked hours/year}}$

  $= 22.5$ (or 23) WLUs/hour

Actual productivity (specified or workload productivity)

Actual productivity is based on actual worked hours or specified hours. It is useful to assess the impact of non-workload activity on the laboratory's productivity.

$$\text{Actual productivity (units/hour)} = \frac{\text{total WLUs}}{\text{total actual worked hours}}$$

Total actual worked hours = total worked hours – paid hours devoted to unticked activities.

Untimed activities include:

- breaks (coffee breaks, prayers, etc.)
- laboratory administrative duties
- prayers (Islamic countries)
- training others
- ordering and inventory of supply
- preparing monthly activity reports
- staff meetings
- other laboratory activities not included in the WLU

The health centre laboratory is staffed by one laboratory assistant who is in charge of all administrative work and various laboratory activities apart from analytical work.

- Non-timed activities : breaks = 118 hours
  administration = 120 hours
  meetings = 26 hours
  = 264 hours
- Total worked hours per year = 1653 hours
- Actual worked hours for timed activities = 1389 hours

$$\text{Actual productivity} = \frac{37\,319 \text{ WLUs/year}}{1389 \text{ actual worked hours/year}}$$

= 26.8 (or 27) WLUs/hour

Moving from paid productivity to worked productivity and on to actual productivity, the calculated indicator increases. It should be borne in mind that differences are due to utilization of different bases (or inputs) for calculation.

Efficiency of productivity expressed as a percentage

$$\text{Productivity as percentage} = \frac{\text{units per hour}}{60} \times 100$$

$$\text{Paid productivity} = \frac{19 \text{ WLUs}}{60} \times 100 = 32\% \text{ efficiency}$$

$$\text{Worked productivity} = \frac{22 \text{ WLUs}}{60} \times 100 = 37\% \text{ efficiency}$$

$$\text{Actual productivity} = \frac{27 \text{ WLUs}}{60} \times 100 = 45\% \text{ efficiency}$$

Personnel forecasting via workload recording

Following a visit to the health centre laboratory, the director of provincial health laboratory services informed the chief medical officer of the health centre that the efficiency of the laboratory rated at 45% i.e. only 27 minutes out of 60 were occupied (or worked). It was thus decided to improve productivity through decentralization and integration of Ziehl Nielsen (ZN) stain and microscopic examinations of malaria smears (actually done at the regional laboratory) in the health centre laboratory. It was also decided to establish a local standard of productivity for this laboratory, based on experience and knowledge of local conditions.

However, figures given above are cited only as an example. The median productivity will vary according to the local working facilities of the environment of the laboratory. Some believe that the actual average of normal productivity ranges between 35 and 45 minutes of every paid hour.

Work-out estimation

Tuberculosis case finding. It is estimated that there are an average of 15 outpatients per month requiring sputum examination by Ziehl Nielsen (ZN) smear microscopic examinations, to enable a decision as to whether the patient must be referred to a tuberculosis centre for further investigation.

Total number of specimen for ZN smear microscopic examinations/year:

15 x 3 specimen/patient x 12 months = 540

Follow up of patients under treatment: there are 13 patients followed up by the health centre requiring an average of 25 smears per month.

Total number of ZN smear microscopic examinations /year related to follow up:

25 smear/month x 12 = 300

Total WLUs/year:

1 ZN smear examination = 12 WLUs

Therefore (540 + 300) x 12 = 840 smears x 12 WLUs = 10 018 WLUs/year

Malaria case finding. It has been estimated that, of the total population of the subdistrict, 15 000 will be screened as part of the malaria control programme.

1 malaria smear thick and thin microscopic examination = 12 WLUs

Total WLUs/year:

15000 x 12 WLUs = 180 000

New laboratory's workload:

Existing current WL (rounded up from figure 37 319)	37 500
Tuberculosis case finding and follow up	10 018
Malaria active screening	180 000
	227 518 WLUs/year

Manpower required:

- Actual man-hours available/year = 1389 hours
  = 1 full-time laboratory assistant or full-time equivalent (FTE)
- Convert to minutes: 1389 x 60 = 83 340 minutes
- Number of FTEs needed = $\frac{257\ 518\ \text{WLUs}}{83\ 340}$ = 2.73 FTEs

If two additional laboratory assistants are recruited to deal with the new workload the efficiency will be:

$$\frac{227\ 518\ \text{WLUs}}{83\ 340 \times 3} = 0.90 \text{ or } 90\%$$

What would the efficiency be if only tuberculosis is integrated due to space facilities (1 technician/6 m^2) with other laboratory activities?

The total workload would be 37 500 WLUs + 10 018 WLUs = 47 518 WLUs

$$\frac{47\ 518\ \text{WLUs}}{83\ 340} = 0.57 \text{ or } 57\%$$

The efficiency will be raised to 57%. However, about 6 minutes (60 minutes x .43) will remain unoccupied.

What is needed to achieve a productivity target?

From the productivity formula = $\frac{\text{total WLUs}}{\text{total man hours}}$

It appears clearly that productivity can be increased either through raising the total WLUs or diminishing the total man-hours.

Based on observations made in other laboratories the director of provincial laboratory services considered that a reasonable productivity target for the health centre laboratory might be an actual man-hour productivity of 50 units/hour.

How much malaria laboratory work could be undertaken by the health centre laboratory with one laboratory assistant?

Total WLUs to be produced	=	FTE(s)x hours per FTE x target productivity
Total WLUs	=	1 x (83 340 : 60) x 50 units/hour
	=	69 450 WLUs
WLUs available for malaria	=	69 450 WLUs -- 47 518 WLUs
	=	21 932 WLUs

Equivalent to $\frac{\text{21 932 WLUs}}{\text{12 (UV for malaria smear)}}$ = 1827 malaria smears

It has been decided that 1800 specimens would be received and smears read at the health centre laboratory.

In the present chapter the laboratory as a whole has been dealt with. However, when dealing with a large laboratory, the department or the work-post may be used as a basis. The more specific the post the more accurate the results. Nevertheless, when measuring productivity of a specific post within the laboratory, overhead hours i.e. hours worked in the laboratory by support services that are shared by various posts, must be allocated on some consistent basis. Allocation is discussed in detail in Chapter Five (Cost accounting for laboratories).

When dealing with productivity it must be remembered that overload may cause poor quality. Good quality result is one of the high priorities in the mission statement.

CHAPTER 5

Cost accounting for laboratories

Now that it has been seen how to measure activity and productivity, cost accounting can be approached; we can be show how this can be used in the management of the laboratory.

Purposes of cost accounting

There are four major purposes of cost accounting:

- **Identifying cost of activities.** All activities entail cost. To ensure that you will be able to accomplish a task on a continuous basis, first be sure that you have the resources required.
- **Planning and controlling activities.** In no case should limited resources be given as justification for poor quality. Proper planning makes it possible to achieve good quality. *Remember that poor laboratory results can threaten life.*
- **Controlling and possibly lowering costs.** As resources are scarce in most developing countries, more than ever it is the duty of those concerned to optimize use of the available resources.
- **Negotiation of budget.** If a manager wants to communicate with the finance officer, he/she has first to learn the latter's language so that the finance officer can perceive accurately what the manager communicates.

How to perform a cost accounting study

There are three major phases in processing a cost accounting study:

- Determine the cost centres.
- Collect the costs: direct costs and indirect costs (or overheads).
- Reapportion indirect costs.

We shall define the terms used as we go through the process. Once the terms are well understood, estimating costs should not be difficult.

It must be noted that the word *estimating* will be used throughout this chapter instead of the word *identifying*. Although the manner in which accounting data are presented gives the impression that they are 100% accurate, in reality they are a mixture of facts (e.g. direct costs of material and labour), estimates, and opinions (e.g. allocation of indirect costs).

Finally, the present cost system is intended for *laboratory managers* for the purposes listed at the beginning of this chapter, and not for *accountants*.

Phase I - Determination of cost centres

Cost centres

A cost centre is the smallest unit or area of an organization from which it is desirable to identify and collect costs or evaluate its unique expenses. Most laboratories have at least the following cost centres: director's office (administrative);microbiology; haematology; and clinical chemistry.

There is really no best answer as to how many cost centres should be identified. Usually, the larger the laboratory, the more practical it is to identify a greater number of unique work areas as cost centres. The more specifically a laboratory identifies each cost centre, the closer its cost estimate will be to the actual cost of any given test. However, a logical approach when starting from zero, is not to have too many cost centres, particularly if at the first stage we are interested in estimating *laboratory total operational cost*. The organizational chart is a good tool to start with and ensures that all cost functions clearly appear. Figures 5.1 and 5.2 show two possible organizational charts for a laboratory.

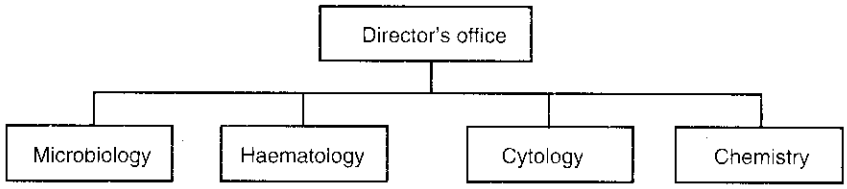


Fig. 5.1 Organizational chart of laboratory X

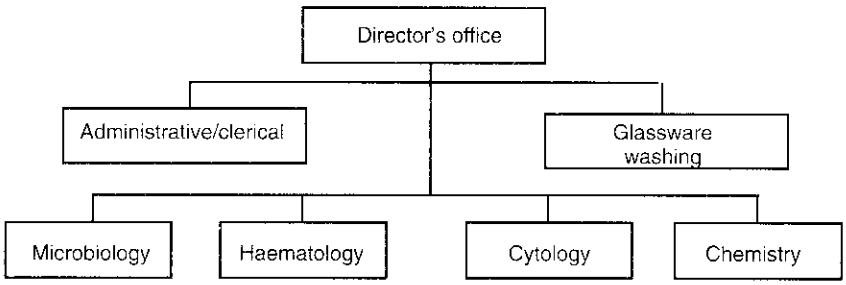


Fig. 5.2 Organizational chart of laboratory Y

The identification of cost centres requires knowledge of the way the laboratory works. This may best be achieved by asking the following questions about each staff member or group of staff involved in similar activities:

What is he/she doing?

What is the end product?

For whom is the end product intended?

This approach permits identifying one more function that meets the criteria of cost centres: *providing services on a continuing basis with a person in charge*.

Non-revenue or supportive cost centres and revenue or productive cost centres

For reasons that will appear clear when the stage of allocation is dealt with, it is necessary to differentiate cost centres into two types:

Non-revenue or supportive cost centres. These are centres with support functions directed toward cost centres inside the laboratory. Among these are administrative/clerical and glassware-washing cost centres.

Revenue or productive cost centres. These are centres that provide services for users outside the laboratory. As the name implies, these cost centres incur costs but could also bring in revenue if fees were charged to outside users for the analytical work provided.

Phase II - Cost collection

After cost centres have been determined and those that are supportive or productive have been identified, the cost collection phase can be embarked upon.

Prerequisites for cost collection

The first prerequisite is a supply system which identifies the cost of material consumed by each cost centre, both supportive and productive.

The second prerequisite is an equipment record system which records or identifies: each item of equipment by cost centre; date of purchase; cost; estimated life span; and estimated salvage value when relevant.

The third prerequisite: the manpower serving the cost centre and the labour cost incurred.

When collecting costs, two types of costs will be encountered:

Direct costs. These are costs that can be conveniently traced to a specific physical unit or unique cost centre; direct labour and material are then included.

Indirect costs. These include those costs that cannot be specified or conveniently traced to a particular cost centre or test.

For these reasons cost collection is divided into two steps:

Step 1. Accumulation. Accumulation means the collection of direct costs and includes: salaries and benefits, supplies, equipment depreciation, and services and others. In general the first three items will cover 90% or more of the total laboratory operational costs.They are the easiest to collect, particularly when good supply and equipment recording systems exist.

Determination of instrument costs as depreciation

Depreciation is the process by which the cost of an instrument is spread over its useful life which is five to ten years for most laboratory equipment. It is a means of charging part of the remaining, unexpired cost each year as an expense until the remaining cost is equal to zero, or some predetermined salvage value.

Straight-line depreciation basis

$$\text{Instrument depreciation cost/year} = \frac{\text{price at purchase}}{\text{expected years of service}}$$

For example, price at purchase = US$ 10 000

Expected years of service = 10 years

$$\text{Instrument depreciation cost/year} = \frac{\text{US\$ 10 000}}{\text{10 years}} = \text{US\$ 1000}$$

As the duration of 'expected years of service' of equipment in countries of the EMR is relatively short the following scheme may be relevant:

Depreciation

Accelerated cost recovery system (ACRS)

CLASS	YEAR				
	1	2	3	4	5
3 year property	25	38	37		
5 year property	15	22	21	21	21
10 year property	8	14	12	10	10
15 year property	12	10	9	8	7

The following model is provided to illustrate the principle of cost finding:

What is the total laboratory operational cost? - Part I

Laboratory X

Step 1. Identification and differentiation of cost centre.

4 cost centres have been identified:

- *supportive cost centres:*
  - administrative/clerical cost centre
  - glassware - media cost centre
- *productive cost centres:*
  - microbiology
  - haematology/chemistry

Step 2. Cost collection.

For simplification 4 costs have been identified:

- salaries 60 000
- material 7 000
- electricity 4 000
- housekeeping 1 000

The following costing format has been prepared and direct labour and material costs have been identified by cost centre:

	ADMINIS-TRATION	GLASSWARE MEDIA	MICROBIO-LOGY	HAEMATOLOGY/ CHEMISTRY	TOTAL
Direct costs					
• salaries	20 000	7 500	22 500	10 000	60 000
• material	500	1 500	3 000	2 000	7 000
Indirect costs					
• electricity					4 000
• housekeeping					1 000
Total					72 000

Step 2. Allocation. In the above model, costs for electricity and housekeeping have not been allocated because these are indirect costs. The purpose of allocation is to identify an appropriate basis, called the allocation basis, to estimate the appropriate share to be allocated to the various cost centres. These allocation basics are:

For electricity: electrical equipment and devices, taking their energy consumption specification into consideration in each cost centre.

For housekeeping: the floor space for each cost centre. It is important that the allocation basis is a quantifiable element and is related to the cost to be allocated. Having defined the principle of allocation we can proceed to the second part of Part II of the case study.

What is the total laboratory operational cost? Part II

Laboratory X

Step 3. Allocation.

	Floor space	Housekeeping	Potential of electricity consumption	Electricity
	%	US$	%	US$
Cost centres:				
• administration	10	100	10	400
• glassware/media	20	200	40	1 600
• microbiology	30	300	30	1 200
• haematology/ chemistry	40	400	20	300

Step 4. Complete the table.

	ADMIN./ CLERICAL	GLASSWARE MEDIA	MICROBIOLOGY	HAEMATOLOGY/ CHEMISTRY	TOTAL
Salaries	20 000	7 500	22 500	10 000	60 000
Material	500	1 500	3 000	2 000	7 000
Electricity	400	1 600	1 200	800	4 000
Housekeeping	100	200	300	400	1 000
Total	US$ 21 000	10 800	27 000	13 200	72 000

Total operational cost of:

Laboratory	= US$ 72 000
Admin./clerical	= US$ 21 000
Glassware/media	= US$ 10 800
Microbiology	= US$ 27 000
Haematology/ chemistry	= US$ 13 200

Phase III - Reapportionment

The cost of a test can be estimated only after the total operational costs of the productive cost centres (e.g. microbiology and haematology/chemistry) have been made. This requires the allocation of the total cost of supportive cost centres to the productive cost centres on a fair basis, using a causal relationship. This process is called *reapportionment*.

Services provided by supportive cost centres can be utilized by both supportive and productive cost centres. It is necessary to use the step-down reapportionment method that allocates costs to the supportive cost centres according to a ranking of services provided to the other cost centres. The most common basis used for this purpose is the quantity of services provided, expressed as other costs in the local currency unit.

In practice, when processing reapportionment, one factor is essential: this is the number of cost centres serviced by the supportive cost centres, as reapportionment will start with the supportive cost centres that serve the largest number of other cost centres.

To illustrate the process we will return to our model with a new objective:

What is the total cost of the productive cost centres?

Laboratory X

Step 1. Looking at the organizational chart of the laboratory, the director/laboratory manager has identified the administrative clerical cost centre as the one providing services to the target number of cost centres.

Step 2. Through a survey in the two supportive cost centres, he/she has made an estimate of the services provided to other cost centres and has produced the following table.

	Services % provided	
Provided to:	*Administration/clerical*	*Glassware/media*
• Admin./clerical	0	0
• Glassware media	20	0
• Microbiology	50	60
• Haematology/ chemistry	30	40

Step 3. The reapportionment of supportive cost centres to productive centres was calculated as follows:

Cost centres:	Administration/clerical	Glassware/media	Total
	US$ 21 000	10 800	31 800
		4 200	
		15 000	
Glassware-media	4 200	-	
Microbiology	10 500	9 000	19 500
Haematology/chemistry	6 300	6 000	12 300
Total	US$ 21 000	15 000	31 800

Step 4. The total operating cost of the productive cost centres are:

	Accumulated cost		Reapportionment		Total
• Microbiology	US$ 27 000	+	19 500	=	46 500
• Haematology/ chemistry	US$ 13 200	+	12 300	=	25 500
Total					US$ 72 000

A costing of total laboratory operational cost or total cost of productive cost centres is an extensive and time consuming procedure. It is a useful and necessary tool for laboratory management, but it does not need to be performed too frequently. It will be done only if it has been found that information has significantly changed. Direct and indirect (or overhead cost) items will mostly be changing with time. These frequent changes may or may not be significant to the cost-finding conclusions and may warrant a totally new cost-finding study or simply minor refinements in accordance with the principles of cost-finding.

Estimation of cost of tests

Once the total cost of productive cost centres and the workload for the costed period have been obtained, the cost of a test can be estimated with accuracy. Two different approaches have been designed for the estimation of cost of a test. These are:

- The macro-approach, which is a rough estimate.
- The micro-approach, which provides a more refined estimate.

Macro-approach

This is the most simple method once the total laboratory operational cost has been obtained. It is based on the average cost of WLUs.

$$\text{Cost of WLU (global average)} = \frac{\text{total laboratory operating cost}}{\text{total WLUs (for the costed period)*}}$$

The cost of the test is obtained through the following formula:

Cost of WLU (global average) x test UV = cost of test

* This calculation should not be based on a period of less than 6 months.

What is the cost of test in our model?

Laboratory X

- The total laboratory operational cost is US$ 72 000
- Assuming that the total workload for the costed period = 87 666 WLU

Step 1. Cost of WLU: (global average) = $\frac{\text{US\$ 72 000}}{\text{US\$ 87 666}}$

= US$ 0,82

Step 2. The cost of antistreptolysin (ASO): 0.82 x 10 = US$ 8.2

The cost of total white cell count: 0.82 x 7 = US$ 5.7

(one ASO examination = 10 WLUs;

one total white cell count = 7 WLUs).

Since efficiency and effectiveness as well as personnel equipment and testing differ from one area to the other, the laboratory manager decided to distinguish the direct labour costs of microbiology and haematology and chemistry, and make a new estimate and also a new estimate of test cost.

Assume that the total WLUs for microbiology is 31 000 WLUs total operating cost of microbiology section US$ 46 500.

$$\text{Specified cost of WLU} = \frac{\text{US\$ 46 500}}{\text{31 000 WLUs}} = \text{US\$ 1.50}$$

Cost of ASO micro: US$ 1.5 x 10 = US$ 15 (instead of US$ 8.20)

Total WLUs of haematology and chemistry is assumed to be 56 666 WLUs.

The total operating of this section being US$ 25 500

$$\text{Specified cost of WLU} = \frac{\text{US\$ 25 500}}{\text{56 666 WLUs}}$$

$$= \text{US\$ 0.45}$$

The cost of total WLU: O.45 X 7 = US$ 3.15 (instead of US$ 5.7)

The difference of costs obtained in the two distinct macro-approaches shows how each laboratory procedure is unique.

Micro-approach

This method, as opposed to the macro-approach, takes into account the relationship of a procedure's workload time to its individual reagent, instrument, or non-patient (standards and controls) requirements. This will be illustrated in the following case studies where more refined costing is needed (e.g. rate setting, justifying equipment purchases).

Laboratory X

Test cost - alkaline phosphatase

Step 1. Direct labour cost : per patient results

- Determine patient WLUs per total WLUs

Total patient workload	757 365
Quality control and standards	82 635
Total workload	840 000

$$\text{Patient WLUs/total WLUs (or units per patient results)} = \frac{840\,000}{757\,365} = 1.10$$

- Direct labour per patient result: = 20 units x 1.10 = 22 units

- Cost unit:

$$= \frac{\text{salaries + benefits}}{\text{total WLUs (for the section)}}$$

$$= \frac{\text{US\$ 225 500}}{840\,000}$$

$$= \text{US\$ 0.268}$$

- Direct labour cost per patient result = 22 units x US$ 0.268 = US$ 5.90

Step 2. Direct supply - reagent material cost: (per result)
It is assumed to be US$ 2.50

Step 3. Indirect cost per patient results:
assume that overhead or indirect cost for the total section is US $ 271 343

$$\text{Indirect cost per WLU} = \frac{\text{US\$ 271 343}}{\text{US\$ 840 000}}$$

$$= \text{US\$ 0.323}$$

Indirect cost per patient result = 22 units x 0.323 = US$ 7.10

Step 4. Total chargeable cost per alkaline phosphatase result:

Direct labour	US$ 5.90
Direct material supply	US$ 2.25
Indirect cost	US$ 7.10
Total	US$ 15.50

Explanation

The **direct cost** in the above example includes:

- equipment depreciation and maintenance cost calculated on the following basis:

$$\frac{\text{equipment + maintenance depreciation costs/year}}{\text{number of tests processed by the equipment/year}}$$

- reagents supplies costs are determined by collecting all reagents material and disposable costs incurred for doing the test:

$$\frac{\text{total reagents supplies costs/year}}{\text{number of tests processed during the year}}$$

We are interested in knowing the cost of a patient result that obligatorily is validated by the use of blanks, standards and control materials, thus making the number of tests more important than the number of results. It is necessary first to calculate the number of tests per patient results so as, in turn, to calculate the direct material for patient results.

$$\text{Number of tests per patient result} = \frac{\text{total number of tests/year}}{\text{total number of patient results}}$$

$$\text{Direct cost of material per patient result} = (\text{tests per patient results}) \times (\text{direct cost of material / test})$$

The **indirect cost** may include the indirect cost of the laboratory which is calculated, as seen previously when dealing with *allocation* and *reapportionment*. If the laboratory is included in a hospital it may have in addition *hospital overheads*.

CHAPTER 6

Laboratory equipment preventive maintenance programme

Introduction

Precise information on effectiveness of laboratory equipment purchased in countries of the EMR is conspicuously lacking. All health care top managers, however, are conscious that it is a major problem. The lack of information prevents action being taken. A survey made some years ago showed that US$ 70 million out of every US$ 100 million worth of equipment remains idle due to lack of maintenance and major or minor breakdowns.

Purpose

The purpose of a preventive maintenance (PM) programme is to minimize instrument breakdown and reduce the number of costly (and often inefficient) services for instrument repair, through appropriate *planning* for maintenance and repair.

PM = scheduled inspection results in minor adjustment or repair delays and/or obviates major repair or emergency replacement of equipment.

The cost of inspections, lubrications, and adjustments of equipment would appear to be insignificant when compared with the cost of emergency repair or withdrawal of the equipment before it has completed its *expected utilization time*.

The ultimate objective of the PM programme is to provide an optimally operating instrument, the performance of which meets established criteria/standards.

Advantages

The advantages offered by a PM programme are:

- Greater safety by preventing hazards resulting from some breakdowns.
- Less unexpected shut down time during operating mission.
- Improved performance with regard to standard requirements.
- Lower repair costs.

- Elimination of premature replacement, improved effectiveness of laboratory equipment, and diminishing cost of test.
- Identification of equipment with high maintenance costs and creation of a basis for improved equipment selection and purchase policy. High maintenance costs in relation to expected costs may result from faulty manipulation of the equipment, abuse by operators, poor maintenance procedures, or equipment obsolescence. In these cases early correction can be applied.

In summary a preventive maintenance programme achieves maximum efficiency of instruments through:

- maintaining a high level of performance;
- lengthening instrument life;
- diminishing interruption of services due to breakdown;
- improving satisfaction of laboratory users;
- improving laboratory technicians' morale, confidence and their knowledge of how the equipment works and how to maintain it.

Programme design

Step 1. The organization of a PM programme begins with the creation of an *equipment history record or inventory card.* All instruments should be recorded, including centrifuges, waterbaths and refrigerators.

The following is a model with the items of information required to be included in the record.

(Front)

INSTRUMENT HISTORY INVENTORY RECORD

Instrument .....

Model No. ..... Serial No. ..... Location .....
Inventory No. ..... Specification .....
Date purchased ..... Cost .....
Depreciation cost ..... Maintenance cost year .....
Manufacturer .....
Telephone ..... Contact person .....
Vendor .....
Telephone ..... Contact person .....
Warranty ..... Expiration date .....
Technical service representative .....
Telephone .....

On the back of the card should be an outline of function checks and routine maintenance as well as the required frequency (daily/monthly/yearly). To this may be added a list of spare parts recommended by the manufacturer, with prices.

(Back)

Maintenance outline

Function verification	*Periodicity*
1. Control of linearity with national standards	weekly
2. Control of wavelength calibration	monthly
3. Control for stray light	monthly
Routine maintenance	
1. Control cuvette	weekly
2. Dust optical surface	weekly
3. Check exciter lamp	monthly

Spare parts recommended

	Name	Factory number	Number recommended
1.	.....	.....	.....
2.	.....	.....	.....
3.	.....	.....	.....
4.	.....	.....	.....

Step 2. When each item has been recorded on an inventory card the next question to be answered is *what to inspect* or what maintenance services need to be provided. This information can be obtained from the service manual or instrument operation manual. These manuals should contain the list of necessary function controls, a maintenance protocol and a troubleshooting guide. The required frequency of different controls should also be indicated. The outline of the controls recommended should be recorded on the back of the history-inventory card for control/monitoring purposes.

Step 3. Once the outline of the maintenance required has been made a written protocol should be developed. This should be in the form of concise step-by-step instructions applying defined performance criteria. The latter are generally included in the operational manual or can be obtained from specialized journals or documents.

This written protocol should also include a brief troubleshooting guide. The document should be kept in a protective slip on the bench next to the instrument.

Step 4. Establish a maintenance record card and a performance control chart to keep track of the maintenance services provided and the workload entailed. The maintenance tasks to be performed are listed on the left; the technicians will fill in their initials in the appropriate box indicating the control done, with the date.

Example of maintenance protocol:

Maintenance protocol

Instrument: Freezing point osmometer

Daily:

1. Check bath temperature.
   - Lift probe assembly and insert controlled thermometer into bath. Temperature should be - 7°C (± 5° C)
   - To adjust:
     . Remove the 2 screws at the back of the refrigerator grill.
     . Slide the grill towards the back of the instrument.
     . Turn the black knob at the left of the thermostat to the desired temperature and replace grill.
     . After allowing time for equilibration, check bath temperature with thermometer to verify correct temperature.
2. .....

Example of maintenance record card:

MAINTENANCE RECORD CARD

MONTH

DAY	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
ACTIVITY																															
Check linearity monthly																															
Check flow cell daily																															

Instructions:

1. Put initials.
2. When a problem is detected circle space and complete the instrument problem logbook.

It is also recommended that a performance chart be developed; it would include a title giving information on the purpose, date of result of performance control, and space for the initials and comments of the technician who has performed the checking. In the comments it should be highlighted when the results are outside, or show a tendency to be outside, the

accepted limit of performance. This chart should be posted near the instrument as a reminder of the required care and for easy and rapid review of equipment function. These charts are not only helpful to technicians, but are also good indicators for the quality assurance programme as a whole.

Step 5. Establishment of an instrument problem logbook. In the instrument problem logbook should be recorded all breakdowns and failures (problems), whether being taken care of by in-house or by outside services. It should include the following information, presented in a concise manner: problem; nature of problem; action taken; time taken for the repairs; cost of labour and material; and comments, with particular emphasis on corrective measures needed to be taken, e.g. improvement in the operation of the instrument, in its daily maintenance, or increased frequency of certain maintenance measures as the equipment gets older.

The instrument problem logbook should not only be a tool to evaluate the performance of the instrument and the cost of its maintenance, but should also be the register where all the action taken and experience in troubleshooting are recorded. It is thus a valuable document when compiling the experience that needs to be included in the training on preventive maintenance and basic repair. The following is a model for the format of a page of the instrument problem logbook.

Date: .....
Person(s) performing the repair: .....
Time spent: From .....to.....
Cost of labour .....material/spare parts .....
Problems: (how breakdown or failure occurred) .....
Nature of breakdown: .....
(reasons) .....
Action taken .....
.....
Comments and recommendations: (emphasis on improvement of PM programme)
.....
.....

Step 6. It is important to set up a stock of spare parts that are most frequently needed. These should be identified with the manufacturers if not indicated in the instrument operation manual. An inventory of spare parts should be established and maintained according to the same policy and scheme established for the reagents and material. However, due to the high cost of some spares, a central storage and inventory maintained by an *instrument technologist* could be more appropriate. The inventory card should indicate the equipment for which the spares are to be used, the average consumption per

year and the minimal items to be stored, the cost and date of ordering, date of entrance of new items and date of issue, with the balance.

A special card for recording the summary of interventions included in the instrument problem logbook would be very useful for setting a policy with regard to the selection and purchase of laboratory instruments. This card would be attached to the instrument history inventory card. Summaries should include the problems identified and costs incurred in maintenance and repair, as well as employee/technician lost time, if any, due to breakdown.

Step 7. From step 1 to 6 it will have been seen that PM is not complex but requires organization. Many forms have to be developed for the efficient operation of the instrumentation management system, on which ultimately relies the effective and efficient functioning of laboratory equipment.

Creation of the position of instrument technologist

For the initiation and implementation of the programme it is essential to assign an instrument technologist as preventive maintenance programme manager. This person should have a medical technology background. Apart from being technically proficient, he/she should also have a special interest in instrumentation and electronics, whenever possible.

The instrument technologist would be responsible for planning, organization and administration of the programme. He/she would supervise and coordinate preventive maintenance at the laboratory level and handle instrument breakdowns on a priority basis. However, his/her first task, after having developed all the recording forms and logs and bringing up to date all the maintenance protocols, would be to provide in-service education and training for the technologists and technicians.

Preventive maintenance is everybody's responsibility. Before attempting to use an instrument, the technician should be acquainted with its operation, its performance capabilities, and its preventive maintenance protocol. He/she will perform daily function verification, keeping the performance chart updated, as well as routine maintenance for the instrument. When instrument reading exceeds established performance criteria he/she should be able to adjust (restore) instrument function and record accordingly the action taken in the instrument problem logbook. Should he/she be unsuccessful, the supervisor technologist should be notified and the instrument technologist called if needed. The supervisor technologist, besides being responsible for assisting the technician in adequately implementing preventive maintenance responsibilities, is responsible for designation of specific maintenance assignments, provision of a schedule with effective reminders for the technician and performing of minor repairs.

The instrument technologist should provide all the training necessary to the technicians and technologists, according to the tasks involved and the knowledge and skills required. He/she should provide emergency repairs and call on the technical service representative when necessary. In supervising the preventive maintenance programme, the instrument technologist has to ensure good performance of all the instruments, in line with established criteria. He/she has also to identify recurring or prevailing problems through a survey of the instrument problem logbook. The results of such a survey should lead to an improvement of maintenance protocol, with related training sessions, or to establishment of a new policy on the selection and purchase of equipment.

The instrument technologist has also to be responsible for collecting all documentation on instruments and new developments and, within this framework, organize (preferably with the cooperation of the manufacturers) seminars on new technology. It is understood that these seminars should be carefully planned with health laboratory top management to ensure that the technology is appropriate within the local context.

In a large country, one instrument technologist may not be sufficient: every region or province may need to have at least one instrument technologist.

Development of expertise in maintenance and repair

Availability of in-house preventive maintenance competence is the factor that determines the importance (or extent) of the preventive maintenance contracts that need to be negotiated with technical service representatives.

The less skill and experience one has in preventive maintenance and repair, the more one will have to rely on outside services. However, it must be accepted that, for quality and safety purposes, responsibility for the maintenance of certain highly complex and delicate items should remain with the manufacturing company, through scheduled visits, bearing in mind the ethical responsibility to patients. Nevertheless, as experience is gained, and well-targeted training has been provided, an effective and efficient maintenance programme can result in minimizing equipment breakdowns, leading in turn to less calls on outside technical services, and services being performed more economically on a non-contract basis.

Taking into account that expertise can be gained only through hands-on experience, the following scheme of training may be valuable in initiating the instrument technologist in maintenance and repair technology.

Step 1. Prepare inventory-history card for all equipment not operating in the country.

Step 2. Concentrate all this equipment in one place with good facilities that could be used for maintenance and repair work.

Step 3. Group all the equipment by category and by order, according to inventory number given on the inventory-history card.

Step 4. Recruit a laboratory equipment maintenance repair specialist who has been informed beforehand on the type of equipment and the work expected of it.

Step 5. Make available an instrument problem logbook for each category of instrument. The problems arising in each item of instrument are to be identified and, when possible, the action to be taken. All these are to be recorded in the corresponding instrument problem logbook, including the spare parts needed. This work should be done by the instrument technologist under the instruction and close monitoring of the maintenance repair specialist.

Step 6. Pending the receipt of the spare parts ordered for the instruments that can be repaired, on the basis of all information gathered in the instrument problem logbook, the following may be done:

- Prepare the plan for the maintenance repair workshop, taking into account the programme of activities and the equipment/tools that are considered necessary.
- On the basis of the specific knowledge and skills identified as needed for the implementation of the PM programme, prepare curricula for the training of the technologists and technicians. Define the policy and procedures for their implementation.

The advantages of this scheme for the development of a national laboratory instrument preventive maintenance programme are fourfold:

- Recovery of much of the equipment (and corresponding capital investment) that is remaining idle.
- Development of local operational expertise, based on specific concrete practical experience linked to national needs.
- Establishment of maintenance and repair facilities based on specific immediate local needs.
- Development of candidates showing increased readiness to profit from a specialized training centre in maintenance and repair.

Replacement of equipment*

It is important to replace equipment on a timely basis when average annual maintenance costs exceed the book or scope value of the equipment. The following replacement analysis technique, suggested by C E Stewart Jr, can be applied:

1. Compute an annual allowance for depreciation using the following formula:

$$D = \frac{C - S}{N}$$

* Excerpt from "Preventive Maintenance of Laboratory Equipment" by G. Richey Elwell. Management Analyst, Laboratory Management Consultation Office, Bureau of Laboratories Center for Disease Control, Atlanta, Georgia, USA.

where

D = annual depreciation allowance
C = initial cost of equipment including installation
S = estimate salvage value at the end of the equipment service life
N = number of years of estimated equipment service or useful life (considering obsolescence)

2. Compute the depreciated value (D.V.) of the equipment for any particular year: after one year ($D.V._1$), after two years ($D.V._2$) and after three years ($D.V._3$) and so on.

$$D.V._1 = C - D$$
$$D.V._2 = D.V._1 - D$$
$$D.V._3 = D.V._2 - D$$

3. Total the annual functional costs which consist of scheduled preventive maintenance, breakdown and emergency maintenance, equipment modification, overhaul and rebuilding.
4. Plot the relationship of functional costs to depreciated value on equipment replacement graph (Figure 6.1). The Y-axis shows the depreciated value of the equipment for every year of estimated equipment service life, and the X-axis shows time in years.
5. Consider replacement when the functional costs approach or exceed the depreciated value of the equipment. Also consider the cost of new equipment and its installation costs as well as possible gain in operating effectiveness and decrease in maintenance costs.

Example:

The equipment replacement graph (Figure 6.1) shows an item of equipment that has an initial cost of US$ 3000, an estimated service life of ten years and no salvage value.

Annual depreciation allowance is:

$$D = \frac{C - S}{N} = \frac{3000 - 0}{10} = 300$$

$D.V._1 = 3000 - 300 = 2700$

$D.V._1 = 2700 - 300 = 2400$

$D.V._3 = 2400 - 300 = 2100$ and so on

The graph shows that after six years of service life, the functional costs approach the depreciated value of the equipment. At this stage replacement of this equipment should be considered.

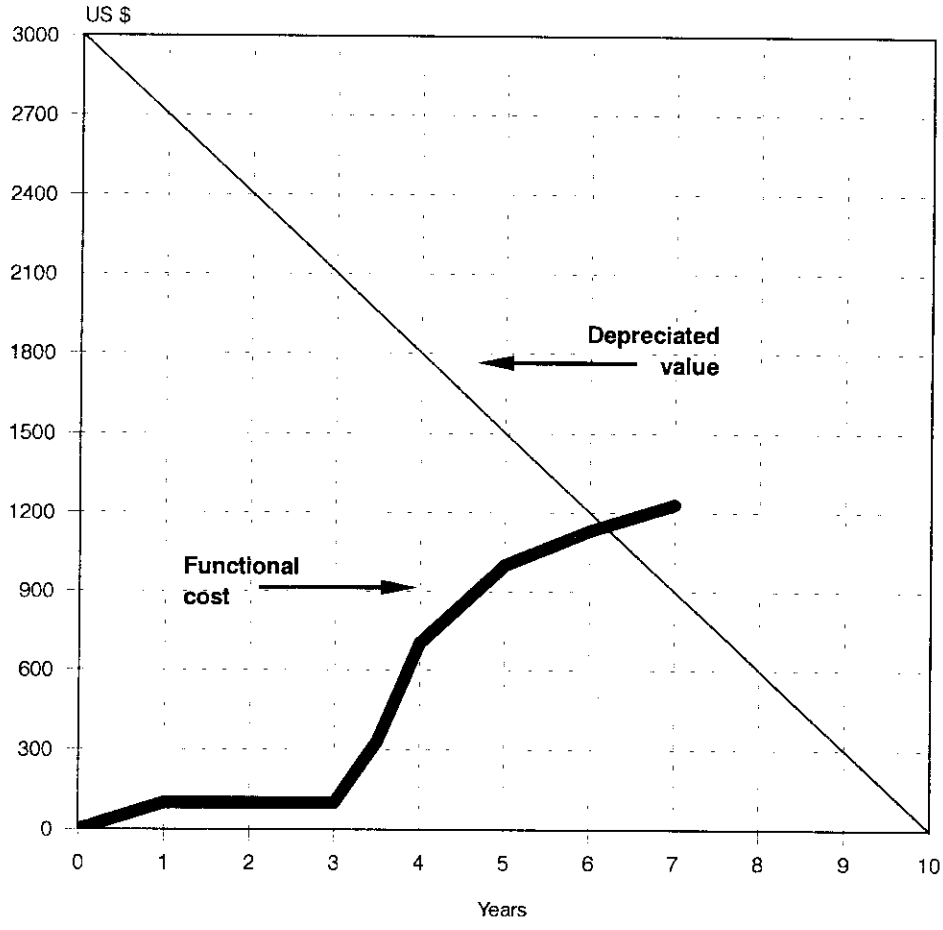


Fig. 6.1 Example of equipment replacement graph

CHAPTER 7

Inventory control system for laboratory supplies

Why do we need an inventory system?

In health laboratory services, purchasing a sufficient quantity of quality supplies at a minimal possible price and their immediate availability are critical factors. The ethical importance of this cannot be ignored, as lack of supplies may potentially have serious effects on patients and the community due to failure to perform needed laboratory services.

Administrators, responsible for the purchase of equipment and supplies for the governmental health laboratories, may not be sufficiently aware of their responsibility for the timely and adequate provision of supplies to the health laboratories providing clinical laboratory services.

The objectives of inventory control are to:

- Prevent running out of reagents
- Minimize the cost of wastage
- Avoid reagent outdating

By ensuring proper quality of the reagents, inventory control is an essential component of quality assurance.

The importance of having the reagents, material and equipment needed for the effective and efficient functioning of health laboratories, implies a control mechanism for supply-related activities such as ordering, receiving, storing and issuing. Inventory control procedure is the control mechanism. It includes records control and storage control of inventory.

What control procedure to use?

There are two kinds of control procedure, the perpetual inventory control procedure and the periodic inventory control procedure.

The perpetual inventory control procedure

This procedure is used for those items for which closer control is needed for the following reasons:

- they are relatively expensive;
- they require a long and/or varying lead time for procurement; or

– they are critical for the operation of the laboratory.

It is mandatory that an entry be made for each and every transaction, i.e.:

– receipt
– issue
– items on order
– items on inventory

The periodic inventory control procedure

This procedure is used for items:

– with high issue rate;
– that are easy to procure;
– that are less critical for a laboratory operation;
– that are of general use in all laboratory functions;
– that require no special handling or storage problems; or
– for which cost can easily be identified to a cost centre, or pro rata to all cost centres for accounting purpose.

In this procedure an entry is made only when:

– stock is replenished;
– inventory is concealed; or
– items are on order.

Usually, periodic inventory control takes place annually but it could be done at other regular intervals. Technically speaking, inventory control procedures (both perpetual and periodic) should be used in a health laboratory supply system dealing with products that have variable expiry dates. A yearly ordering system, as scheduled for health laboratory services in many countries, certainly leads to obsolescence and wastage.

Development and implementation of an inventory control procedure

The following flowchart, which spells out the different stages to be achieved in establishing an inventory control system, is useful.

Inventory control - work analysis chart

Day 0 **Step 1.** Item identification (each laboratory section uses 'supply analysis form' distributed by the laboratory manager).

Day 30 **Step 2.** Classification of items by category and alphabetical order within the category; (use standard grouping system distributed by the laboratory manager).

Day 37 **Step 3.** Evaluation of frequency of use; (use activity report as information basis).

Day 52 **Step 4.** Compare lists of different laboratory sections (compiled by laboratory manager and section supervisors):

- Eliminate duplication.
- Apply programme of simplification on consensus basis.

Day 60 **Step 5.** List all items in a stock catalogue by category (to be done by the laboratory manager).

Day 67 **Step 6.** Assign numerical code (stock number) (to be done by the laboratory manager).

Day 80 **Step 7.** Set up stock record forms (to be done by the supervisor-technician responsible for inventory control).

Day 110 **Step 8.** File stock record forms by category in appropriate filing device.

Day 115 **Step 9.** Establish a policy and procedures for laboratory requisitioning (to be done by the laboratory manager and supervisor-technician).

Day 118 **Step 10.** Relocate all items in store rooms, following classification (to be done by supervisor-technician responsible for inventory control).

Day 140 **Step 11.** Indicate location on stock record forms (as above).

Day 150 Date line for achievement.

Before initiating an inventory control system it is necessary to nominate a supervisor-technician who will be responsible for initiating and, afterwards, for maintaining the control of the inventory and to this end will coordinate with the laboratory sections' supervisor-technicians. He/she should be a well-organized person. Only the supervisor-technician responsible for the control of the inventory should have access to the laboratory store room. Likewise, only the section supervisor should have access to the section storage areas, when these exist. In this section storage areas, items purchased in small quantities and used specifically by one section, may be kept. This may be the case for radioimmunoassay kits or blood bank reagents having particularly short shelf-lives; these will probably be best controlled within the section involved. Nevertheless, as will be seen below, all sections will apply the same basic principle of inventory control, as applied to the general laboratory inventory. The latter will in turn be compatible with the system adopted by the central purchase agency when this exists.

Details of subsequent steps

Step 1. Item identification per laboratory section

For this purpose, each laboratory section should be provided with basic analysis forms, prepared on ordinary white paper. The form should be designed to record the following information:

- Stock item description and specification.
- Unit of count or unit of issue.
- Priority level.
- Comments including procedures for which the product is used.

Most of this information can be obtained from the laboratory procedure manual and catalogues of commercial companies. At this stage the basic analysis form will be completed as follows:

BASIC ANALYSIS FORM

Date : 14/12/89 Page 3/5

Section/cost centre: CHEMISTRY Supervisor:

ITEMS	UNIT OF COUNT	PRIORITY LEVEL	COMMENTS
Pipette 0.5 mL graduated in mL 0.01, tolerance 0.005 draining time 2-8s	Pack of 12		
Sodium dodecyl sulfate	10, 25 g		
(sodium laurylsulfate) 99%	100, 250 mL		
Gloves, disposable, unsterile powder-free size 6 - 7	Box 50 pieces		
Wooden applicator approximately 15 cm	Box 1000 pieces		

Step 2. Classification by category

Similar supplies, materials and other items should be grouped by category and by alphabetical order within each category. The categories that can be used in the laboratory are as follows:

Glassware. This category includes all glassware, glassware apparatus, disposables, plasticware, caps, corks, and related items used in conjunction with glassware. In some cases this category is subdivided into graduated and non-graduated glassware.

Media - chemicals and reagents. This category also includes test kits, dyes, stains, and other related items.

Specimen kits and components. This category includes corrugated boxes, containers of all types, and other items specifically used for packing and shipping specimen containers and kits.

General medical, surgical, and scientific items. This category includes items such as rubber (or other material) , clamps, cotton, gauze, needles, syringes, gloves.

General laboratory equipment. Included in this category are items used in support of operating equipment such as wire and metal baskets, racks, trays, bottle brushes, burner lighters, glass cutters, and microscope lamps. Equipment such as microscopes, pH meters, spectrophotometers is not included.

General supplies. This category includes all office supplies as well as supplies for housekeeping.

Step 3. Determination of which item should be controlled under each procedure (perpetual/periodic)

Besides those factors indicated above, the total amount in dollars expended annually and the demand for the particular item are considered. Each item may be assigned the letter A or B depending on the frequency of control needed.

Step 4. Comparison of lists

With a view to preparing a stock catalogue where all items in use by the whole laboratory can be identified easily, all the basic analysis lists prepared by the laboratory sections should be compared in order to identify duplicates or similar items used by several sections.

Simplification and standardization of supplies

At this stage simplification and standardization of supplies may be considered. The laboratory manager, through discussion with the supervisors of each section, may wish to set standards for fixed size, type, quality, measure, flow speed and other measurable variables to reduce the varieties and types of items in the inventory. It will also reduce handling of items, maintenance of stock records, space requirements, labour costs, procurement costs and overall costs if an inventory is to hand. This is the most appropriate stage at which to implement such a process for simplification and standardization of supplies as the stock records will not yet have been established and numerical codes not yet assigned to each item.

The need for simplification can easily be verified by determining whether different materials (e.g. glassware, plasticware, tubing) are used for the same or similar purposes in the various laboratory sections.

Example:

Laboratory X

When reviewing the draft catalogue, the laboratory manager identified that 11 sizes of beaker were listed. He/she grouped the size by incremental graduation where interchangeability of use could be expected:

Group	*Size (mL)*	*Incremental graduation (mL)*
	10	10
	30	10
1	**50**	10
	100	10
	150	20
	250	25
2	**400**	25
	600	50
		100
3	**2000**	500
4	**4000**	500

Following analysis of the table and considering the analytical requirements and the possible combination of notes with the section supervisors, it was found that it was possible to reduce the list to four sizes (figures in bold).

A similar method of simplification can be applied for glass cylinders and other items. This simplification may lead to substantial savings since the cost of the larger-sized graduated items may often be triple that of the next lower-sized item. These savings may not only be used for the purchase of greatly-needed items, but may also contribute to reducing the overall supply costs, which in turn reduces overall unit costs of laboratory output.

A standardization procedure, though not always obligatory, should be considered simultaneously for necessary items. For example, plastic cylinders can be used in place of glass cylinders to eliminate the high cost of breakage. Basic sizes and related considerations such as quality of materials could be established for all items (e.g. vials, prescription bottles, pipettes, aluminum foil, plastic tubing) used in the laboratory.

Step 5. Establishment of a stock catalogue

Having all the items used in the laboratory listed in an orderly manner, with all the specifications required and the unit of issue considered as the most convenient or economical determined for each item, we can proceed to the establishment of a stock catalogue which will facilitate the identification of items by the laboratory personnel. The location of the items should also appear on the document, to facilitate search.

Step 6. Numerical coding

To each orderly listed item a 2-digit numerical code will be assigned according to the category to which it belongs. This number will serve as group designator.

Example:

CATEGORY	NUMERICAL CODE
Glassware	10
Media	20
Chemicals and reagents	30
Specimen kits and components	40
General medical, surgical and scientific equipment	50
General laboratory equipment	60
General supplies	70
Other and miscellaneous	80

To the group designator number will then be added a 2- or 3- digit numerical code (according to the number of items within each group) to be assigned to every stock item in the system.

Example:

STOCK CATALOGUE		LAST DATE OF REVIEW: 15/12/89		
CODE	ITEMS	UNIT OF COUNT	COST PER UNIT	LOCATIONS
10050	Pipette 0.5 mL graduated	Pack of 12		
30123	Sodium dodecyl	250 g		
50009	Gloves, disposable	Box 50 pieces		
50085	Wooden applicator			

A separate stock number should not be set for each vendor supplying identical or nearly identical items, unless the item is of some special or limited use.

The code (or stock) number serves not only to identify a particular stock item, thus keeping requisitioning paper work to a minimum, but also when a computer system is used to control the inventory, the code number can serve as a key for retrieval and identification of all stock transactions.

Finally, when all procurements are made through a governmental agency, which may have a numerical code system, it is essential for the laboratory to adopt the same system or develop a system which is compatible with that of the central purchasing agency.

Step 7. Designing of stock recording form

During this stage of development we will use all the information collected and structured to design stock recording forms. The following two types of information should be provided by the forms:

- Inventory control information
- Ordering information

Effective inventory control should ultimately increase efficiency by providing an uninterrupted flow of reagents and materials needed to operate the laboratory while keeping both quantity of inventory and space for storage at a minimum.

Major parameters for controlling inventory are:

Maximum inventory levels. In the countries of our Region, inventory is generally measured by the amount of a particular item used in a budgetary year period.

Maximum inventory levels = minimum inventory level + safety stock

As shown by the above formula, the inventory level should be maintained at a minimum to maintain cost effectiveness and efficiency and save space.

Minimum inventory levels. Minimum inventory levels are the amount necessary to support normal operation until additional material is supplied: this fixes the ordering point (OP).

Monthly usage rate (MUR). This is the basic indicator that will allow determination of the amount necessary to support normal operations. It is computed as follows:

$$\text{MUR} = \frac{\text{yearly wage}}{\text{inventory level}}$$

In some instances projected usage data also need to be considered.

Lead time (LT). This is the total time between placing an order and receipt of the product in the laboratory. It is a prime consideration in setting inventory levels.

Safety stock (SS). This is the amount of inventory that allows for unusual demand (culture, media and epidemics) or variation in the LT.

Case study:

The chief supervisor-technician of laboratory X has received through the director instructions from the hospital administration to prepare the purchase requisition for the laboratory reagents and material covering the needs of the coming budgetary/financial year. As in many countries of the EMR, local rules and procedures allow for only one purchase requisition during the year. Taking into consideration the great activity of the chemistry section and the high demand for glucose measurement, the chief supervisor with the section supervisor has decided to start with blood glucose kit.

After consulting the stock inventory record it appears that:

MUR (monthly usage rate) = 100 units.

Maximum inventory level is thus:

100 units x 12 (months) + SS (safety stock)
Assuming that SS = 2 months or 100 units x 2 (months) = 200 units.
Thus maximum inventory level = 1200 units + 200 units = 1400 units.

However, from the stock inventory record it also appears that only 600 units were left in stock, while the minimum inventory level necessary to cover the need during the lead time (LT) is

MUR x LT = 100 units x 9 (months) = 900 units

The total amount to be ordered will be:

1400 units + (900 units + 600 units) = 1700 units.

For the time being, the chief supervisor will have to obtain on loan from the safety stock of other laboratories the 300 units lacking, to complete the minimum inventory level and allowing normal operation of the laboratory until delivery.

Inventory records

The stock records are the basis for effective and efficient storage and inventory control; they are decision-making tools. The records consist of simple heavy-weight cards. Each item should have a record card. The card should be designed to provide the items of information that are essential to fulfil the purpose adequately.

Three types of recording sheets are suggested:

- a stock ledger card;
- a perpetual stock inventory record card; or
- a periodic stock inventory record card.

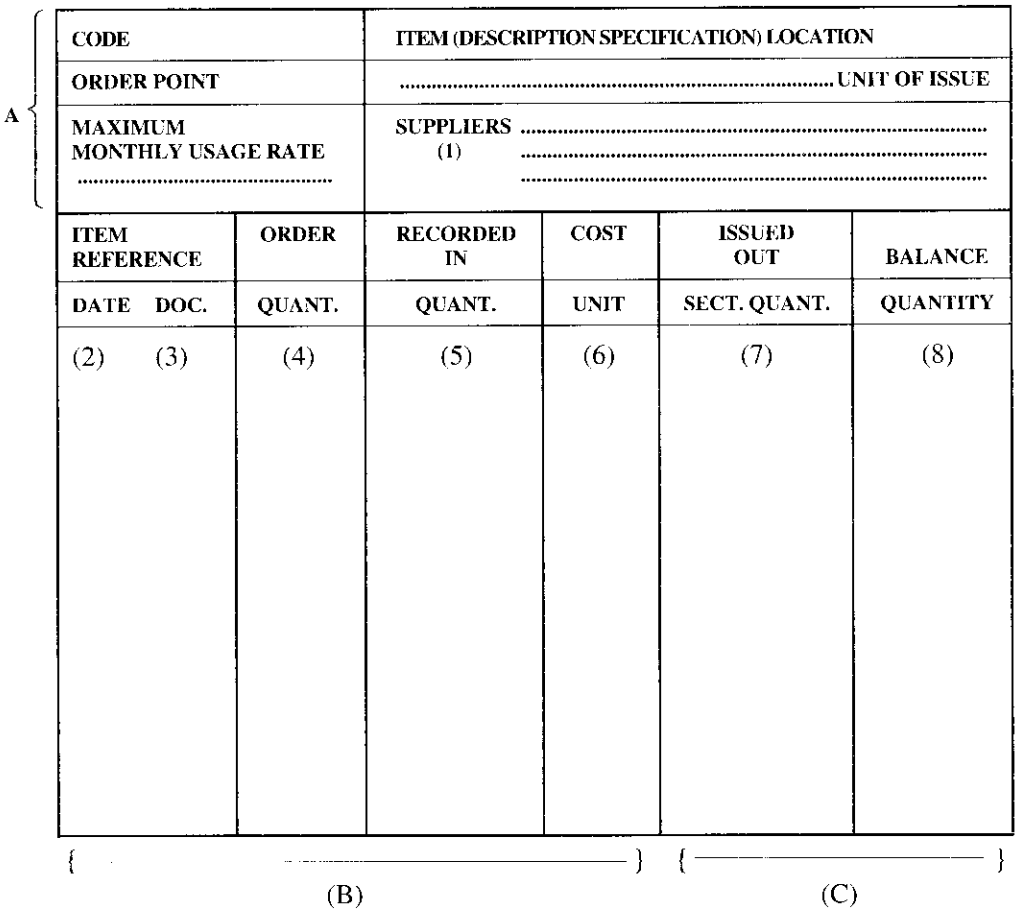
Stock ledger card

This card serves mainly as a record of lead time, cost and material usage. Unlike the other cards, it provides information not only on the inventory level but also on all those items related to the ordering. They should be filed by category and alphabetical order, as determined by the catalogue, in one of the three designated boxes: 'On hand', 'Order point', and 'Safety stock'. Each card is moved to the appropriate box according to the level of inventory. Such a box system should be applied to all items included in the perpetual inventory control system, including all items that are critical to the minimal effective and efficient operation of a laboratory or a laboratory section. A model for an inventory record is given in Figure 7.1.

This stock ledger card will serve both the perpetual as well as the periodic inventory control procedures. The only difference will be in its utilization.

For the perpetual inventory control procedure, each withdrawal from the inventory and the date will be recorded (in all three columns of area C). The card should provide, at any time, an accurate physical count. Unlike those items coming under the periodic inventory control procedure, entries are made only when items are placed on order and when stock is replenished - each of which event occurs annually in an annual procurement cycle. Entries will also be made (in all three columns of area C with the date) when periodic counts of stock in inventory are made. This should take place regularly, at least every four months during the first three or four years of implementation of the inventory control system. It could help in determining all items and the optimal quantities to be ordered, keeping the inventory at the most economical level. In an ideal situation, by the end of the year when orders are placed, all the cards should be in the order point (OP) box, indicating that the inventory level of the items lies within the lower limit and the safety stock. It should nevertheless be kept in mind that shortage of material, resulting in stoppage of work, is also a waste of resources.

An additional advantage of the three boxes system is that it should facilitate the identification of obsolete items or dead stock whose c ards do not move.



(1) This item provides for alternative suppliers, and may be deleted if not applicable.
(2) Date of each transaction.
(3) Number of purchase order.
(4) Ordered quantity.
(5) Recorded quantity.
(6) Cost per unit of issue (this information may be obtained from purchasing agency).
(7) Laboratory section to which the item was issued.
(8) Balance.
(A) Demographic information
(B) Ordering information
(C) Inventory level and usage information

Fig. 7.1 A model for an inventory record

Stock issued to laboratory section (or cost centre) record

The purpose of the record is to cross check with the periodic count of stock in the inventory, and to complete the stock ledger card with regard to the items coming under the periodic inventory control. It will also serve in the computation of the costs incurred for reagents and material by each individual laboratory section or cost centre.

Whilst the stock ledger cards remain with the supervisor-technologist responsible for the overall laboratory inventory control, the stock-issued card will be maintained by the laboratory section supervisor. Entries will be made by the supervisor whenever an item is withdrawn from the laboratory storeroom or any other storage area, e.g. cold storage area (refrigerator, cold room), flammable and hazardous chemicals (e.g. strong acid and bases) storage area.

To operate the system with maximum efficiency, only the supervisor responsible for the overall laboratory inventory control and the designated assistant should have access to the inventory storage room. The following is a model for the stock issued record:

STOCK ISSUED TO LABORATORY SECTION RECORD SECTION

STORES LOCATION (1)	CODE (2)	ITEM (NAME ONLY) (3)	UNIT OF ISSUE (4)	DATE OF ISSUE QUANTITY ISSUED (5)	UNIT COST (6)	TOTAL UNIT ISS/D (7)	TOTAL COSTS (8)
24 columns could be made available. 36 items could be entered on one card printed recto verso							

COMMENTS	GRAND TOTAL

Step 8. Control of inventory and storage document

Use the overall laboratory (or general) stock catalogue which includes most of the information necessary, classified in an orderly sequence, to fill the inventory and storage control document developed in the previous step.

The stock ledger record should be completed and maintained by the laboratory supervisor technologist/technician responsible for the control of the overall laboratory inventory. The stock issued records should be completed by the laboratory section

supervisor, using as a reference the section stock catalogue. As the numerical code numbers will figure in column 2, the items in column 3 should not be fully described with their specification. The name, with a major characteristic, should suffice. Column 6 will provide the number of items withdrawn from the store room, with the date, thus providing the document with the function of 'Requisition' (for within the laboratory). Should an item not be available, the related box should be completed as follows:

17/12
0

Columns 6, 7 and 8 on the extreme right hand side of the form will serve to compute the total amount of reagents and material used by the section as well as the total cost incurred. There should be a space for any comments that may serve in the interpretation of the data, or when preparing the laboratory global requisition for the coming annual cycle.

Step 9. Establishment of laboratory requisitioning procedure

As the present document deals mainly with governmental health laboratories, the ordering forms used by the laboratories will be printed and provided by the procuring or purchasing agency. This agency often operates as an independent administrative entity, responsible also for the procurement of all supplies and material including scientific equipment needed by the entire health care service.

Good communication needs to be established between the procurement department and the health laboratory service. To achieve effectiveness and efficiency in supplies procurement, a standard catalogue of all reagents and material used by all laboratories of the health services should be set up and copies provided to the procurement department.

When low-bid procedures are applied by the procurement department, samples should be submitted, whenever applicable, to the national central laboratory for control of conformity with performance requirements before procurement contracts are drawn up. Part of the samples should be retained by the central laboratory to check the product delivered in case any problem should arise after procurement.

Step 10. Location of stock

With the aid of the classification determined when preparing the laboratory stock catalogue, the display of the stock item may need to be reviewed. As far as possible, the stock items should be located by alphabetical order as in the catalogue. This alphabetical and numerical designation should allow for rapid location of stock item storage points for

both stock loading and issuing of supplies. Following the above example the particular stock item would have A5D22 as location code, or C5D22 if stored in the cold room.

AREA	DESIGNATION	EXAMPLE
Room	Alphabetical	A
Cold room	Alphabetical	C
Section	Numerical	5
Row	Alphabetical	D
	Numerical	22

To avoid expiration, deterioration or spoilage of supplies use a first in, first out system for moving supplies in and out of the stock room.

As all the stock items have deficit storage points and these have been designated with alphabetical-numerical codes, the stock ledger record as well as the stock issued record and the catalogues can be completed using the catalogue or code number.

Wastage is a natural outcome of lack of a good inventory control system. Establishment of an inventory control system is a must for effective and efficient operation of a health laboratory service.

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