

LECTURE NOTES

For Medical Laboratory Technology Students

Health Laboratory Management and Quality Assurance



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In collaboration with the Ethiopia Public Health Training Initiative, The Carter Center,
the Ethiopia Ministry of Health, and the Ethiopia Ministry of Education

2004



Funded under USAID Cooperative Agreement No. 663-A-00-00-0358-00.

Produced in collaboration with the Ethiopia Public Health Training Initiative, The Carter Center, the Ethiopia Ministry of Health, and the Ethiopia Ministry of Education.

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Preface

It is apparent that a well-managed health laboratory with an appropriate quality assurance program has a major role in enhancing the standard of health service delivery to the community. Textbooks on laboratory management and quality control for students of medical laboratory technology are rare in most teaching institutions of the country. This lecture note has been produced to help alleviate the severe shortage of textbooks and reference materials on this topic. It is also hoped that the material will be used by those responsible for the management and organization of health laboratories besides the contribution it provides in the training of laboratory students. This is not meant; however, to replace textbooks or other teaching materials, it is rather an aid with the existing textbooks and references. The lecture note includes a total of eight chapters on the management and organization of laboratories, laboratory safety, and quality assurance programs.

The author is very happy with any constructive comments, suggestions from users of this material.

Acknowledgments

I would like to acknowledge The Carter Center, USAID for the financial and material support, which was very important for the preparation of this lecture note. My appreciation also goes to all teaching staff of the Departments of Medical Laboratory Technology and Microbiology and Parasitology, Gondar University College (GUC).

Special thanks are due to:

Ato Getachew Hailemariam (Department of Medical Laboratory, GUC)

Ato Biniyam Mathewos (Department of Medical Laboratory, GUC)

Ato Aregawi Yalew (Department of Medical Laboratory, GUC)

Ato Feleke Moges (Department of Microbiology and Parasitology, GUC)

Ato Tesfaye Bekele (School of Med Laboratory Technology, Jimma University)

Ato Misganaw B/Selassie (School of Med Laboratory Technology, Debub University)

W/o Selamawit Debebe (School of Medical Laboratory Technology, Alemaya University); for their invaluable comments and suggestions during review of this lecture note.

I am also very much pleased to extend my thanks to Dr. Seyoum Taticheff and Dr. Abera Geyid to critically review, comment and enrich the material with their high expertise in the field of medical laboratory sciences.

Acknowledgement is expressed to all those who lend their hands in one-way or another for the betterment of this material.

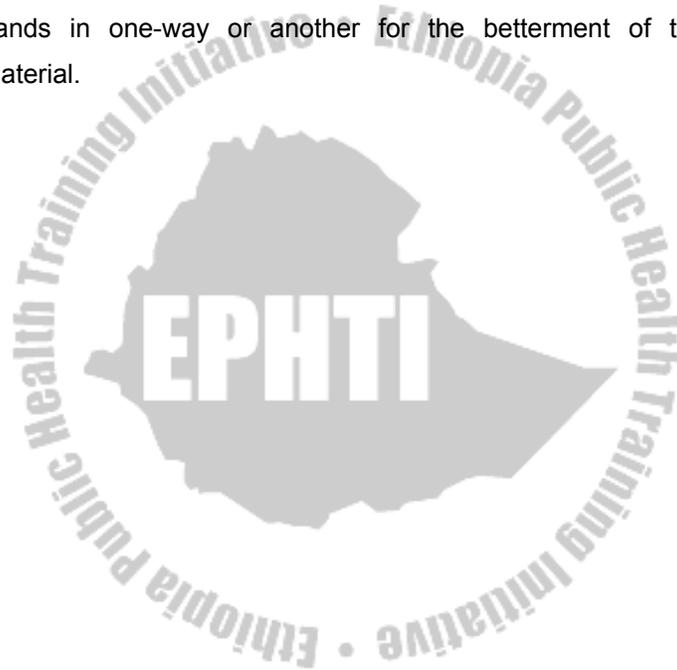


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Abbreviations

1. EQA - External quality assessment
2. EQC - External quality control
3. IQC - Internal quality control
4. Lab - Laboratory
5. MBE - Management by exception
6. MBO - Management by objective
7. NPV - Negative predictive value
8. PER - Planning, Executing, Reviewing
9. PHC - Primary health care
10. PIE - Planning, Implementing, Evaluation
11. PV - Predictive value
12. PPV - Positive predictive value
13. QA - Quality assurance
14. QC - Quality control
15. SOP - Standard operating procedures
16. TQM - Total quality management
17. VDRL - Venereal Disease Research Laboratory

CHAPTER ONE

INTRODUCTION TO MANAGEMENT

Learning Objectives

At the end of this chapter, students are expected to:

- Define management
- Describe the basic principles of management
- State the function of management

1.1. Definition and General Principles of Management

Many definitions exist to indicate what management is. Henri Fayol, in the early twentieth century, defined it as the process of 'forecasting, planning, organizing, commanding, coordinating and controlling'. E.F.L Brech called it 'the social process of planning, coordination, control and motivation'. Writing in the 1980s Tom Peters defined it as 'organizational direction based on sound common sense, pride in the organization and enthusiasm for its works'. It is clear that management is partly the process of getting things done through people; and partly the creative and energetic

combination of scarce resources into effective and profitable activities and the combination of the skill and talents of the individuals concerned with doing this.

Management is conducted in organizations. A context must be established. Organizations are variously described as: 'systems of inter-dependent human beings' (D.S. Pugh); 'a joint function of human characteristics, the task to be accomplished and its environment' (H. Simon). Organizations may be seen as combinations of resources brought together for a purpose; they have a life and a permanent identity of their own; and are energized by people.

Principles of Management

What are the commonest management principles?

There are a number of principles of management and the following 11 are the commonest ones.

1. Principle of management by objective (MBO)

Every activity of a given organization must have an objective. This objective, which could be qualitative or quantitative, should state:

- What is to be accomplished
- How much of it
- How it is to be done
- When it is to be completed

Clear statement of the objective speaks it possible to evaluate how effective one is in approaching and reaching the objective. There are five important characteristics of objective and are known as SMART.

1. **Simple:** Objective should be clear and understandable to the health team. A familiar maxim, "If you do not know where you are going, even you do not know where your destination is" works here.
2. **Measurable:** in terms of quality and quantity for two important reasons:
 - i. To monitor the day to day activity (assessment of performance)
 - ii. To help evaluate the activities (for the future course of action)
3. **Achievable:** Feasibility is an important criterion for good planning. Objective should be something that can be reached at; it should be realistic.
4. **Relevant:** All action plans should be directed to the major problems of that community. The objective should address the real problems of the community.

There are two kinds of approaches when talking of relevance:

- i) Felt problem: What the community has sensed as major problem.
- ii) Real problem: what the planners (health workers, professionals) identified as a problem in that community.

It is, therefore, important that health professionals identify the felt needs of the community.

5. **Time bound:** Time should be a common denominator for all objectives. It should have a time frame like this: EPI coverage of X district should go up from 35% - 60% within 5 yrs.

Effectiveness is the degree to which a stated objective is being achieved; it is something that management tries to improve. At the end of all the activities achievement is compared with the objective, i.e. evaluation is done. This helps us to judge how effective our management was and to plan for the future course of action.

Under achievement (negative) ← Objective → Over achievement
Over planning Under planning

2. Learning from Experience

This is a management principle that underlines the comparison of objective with achievement to judge effectiveness. It is directly or indirectly dependent on MBO. When a gap occurs between objective and achievement or result, management makes analysis of how the observed results are achieved and discovers what causes the gap. In this process learning can take place. This process is

sometimes called feed back of information from experience to decision for action.

3. Division of Labor

This is the principle of specialization that maintains that work should be distributed among members of a group. Where there is specialization and division of labor, each kind of manpower exercises its own knowledge and skill towards achieving the set objective.

4. Efficient utilization of Resources

Management is the efficient use of resources. Resources are the inputs that will be needed or consumed to achieve an objective. Efficiency is the degree to which our resources are utilized in a balanced way. This balance must be maintained between the different resources, through economic utilization of resources, substitution of resource, etc.

5. Unity of Command

This principle of management states that every member of the health team should receive orders, instructions, commands, etc only from one supervisor. If more than one command is received at a time, the individual will go into conflict, dilemma, and confusion, and so will not carry out the desired activity properly.

6. Span of Control

The average number of people who are under the direct control of a given supervisor is determined by the nature of the work, i.e. complexity, simplicity, contiguity, etc). On average, one supervisor can effectively supervise not more than six subordinates (a maximum of ten subordinates).

7. Principle of Management by Exception (MBE)

Health Managers at district and regional level should concentrate only on strategic and highly important tasks and leave the routine and standardized tasks to operating personnel.

8. Principle of Delegation

Delegation is the process whereby somebody's authority is lent to another person, conditionally or not so that to enable that person to take responsibility when the occasion arises. It is the most forward thinking principle whereby as many operating tasks as possible are granted to the subordinate. The principle "Never do your self what another can do for you as well as you would" applies for delegation of authority and responsibility.

9. The principle of Convergence of Work

Work activities should be designed and directed so as to support each other towards achievement of objectives. It also

implies that working relations should continue to the success of each activity and so to general effectiveness.

10. Scalar Chain Hierarchy

This refers to an interconnected chain of relationships extending from top of an organization to the bottom. This shows graded chain of authority from top to bottom through which all decisions flow.

11. Structures determine function

A major concern in working relation is to enable decisions to be made where and when necessary by the most suitable person. In a health team any person might be called to make decisions at one time or another. Decisions should be made by the right person and be channeled down or in any other appropriate direction and the flow of decision is alongside the organizational structure.

There are also other principles of management such as the principle of centralization, decentralization, coordination, equity, etc.

1.2. Concepts of Management

Management is variously defined as a science, profession and an art. The truth of its status lies somewhere between the three and it has strong elements of each.

There are precise elements, scientific and exact aspects that have to be learned and assimilated. Any manager must have a good grasp of certain quantitative methods and financial and statistical data, as well as certain, less scientific but well tried and tested elements such as human motivations, and the effect of different payment systems on the performance of different occupations.

It is a profession as far as there is a general recognition that there are certain knowledge, skills and aptitudes that must be assimilated and understood by anyone who aspires to be a truly effective manager. Management is not a true or traditional profession in the sense that it is not a fully self-regulating occupation, and nor is there yet a named qualification that must be achieved before one is allowed to practice. However, pressure to be both educated and qualified is growing universally. There is recognition also of the correlation between this and expert and effective practice.

Management is an art in the sense that within these confines and strictures there is great scope for the use of creativity, imagination, initiative and invention within the overall sphere of the occupation. The scientific methods and body of knowledge referred to must be applied in their own way to each and any given situation, issue or problem. This is the creative aspect of the manager's role and function; and

anyone in a managerial position who seeks for prescriptive solutions to organizational problems is likely to fail.

The subject of management is thus concerned with both the precise and the vague; the ordered and the creative. Within these broad concepts it is possible to pin down certain elements that are present in all effective management and successful managers.

The most critical of these elements are communication and decision-making. Anyone who aspires to management must understand the processes involved and be able to carry them out effectively in their own situation.

The overall managerial task is concerned with getting things done through people; the combination and ordering of a variety of resources for given productive purposes; the actions and processes involved in the combination of those resources; and the balancing of resource utilization with the commercial, environmental and operation variables of quantity, quality and time; and coping with change and uncertainty. This task is, in turn, broad and strategic at the top of organizations where the manager is concerned with broad direction and the future; and narrower, concerned with short term and operational matters at the lower levels of organizations. In all cases, it is the ability to communicate

effectively, and to take effective decisions, that are fundamental to any successful managerial activity.

1.3. Function of Management

What is Function? It is a broad area of responsibility composed of many activities aimed at achieving a predetermined objective. It explains managerial performance or the activity of manager.

There are basically two approaches to look into performance of any manager:

- i) The function approach (what one is supposed to do or must do)
- ii) The role approach (what one is actually doing).

The function approach

Functions may be classified in different ways. For example:

- a) PIE approach- Planning, implementing, evaluation.
- b) Planning, organizing, leading, controlling.
- c) POSDCORB- Planning, organizing, staffing, directing, coordinating, reporting, budgeting.
- d) PER- Planning, executing, reviewing.

The role approach

Managerial roles refer to behavioral attributes towards job or job position.

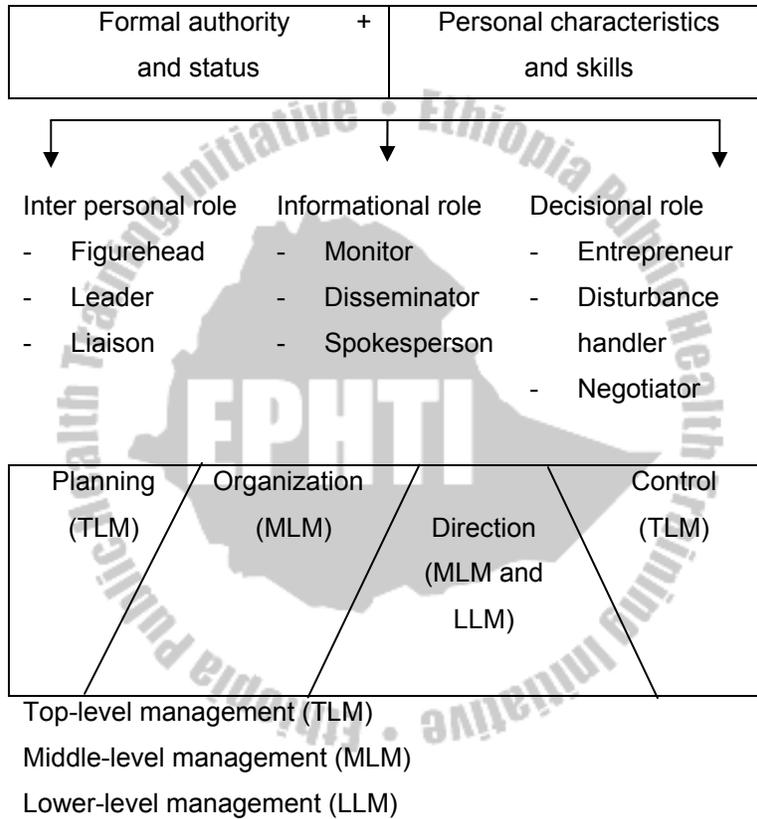


Figure 1.1. Management functions versus management level



Figure 1.2. Relations among the functions of management

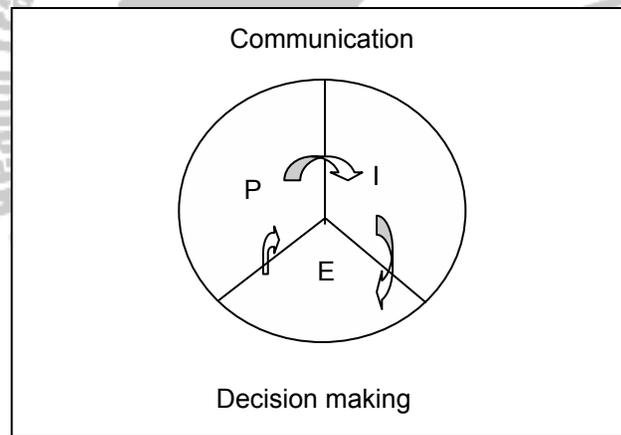


Figure 1.3. PIE model of management function.

Review Questions

1. Define management.
2. Mention the basic principles of Management
3. What is a Function
4. Explain the two approaches of a function.



CHAPTER TWO

HEALTH LABORATORY MANAGEMENT

Learning Objectives

At the completion of this chapter, students will be able to:

- Describe the role of laboratory in the health care activities
- Elaborate the essential steps followed in the management of health laboratories
- Explain the code of conduct referring the laboratory personnel

2.1. Definition and Principles

The first step in a systematic approach to the management and organization of a health laboratory begins with the establishment of general goals and specific objectives by the laboratory staff. The use of such objectives for purposes of management is known as management by objectives (MBO). In order to achieve these objectives, the laboratory must have adequate facilities, equipment & supplies, and an adequate number of qualified personnel. As used here, goals are those

general and qualitative statements of overall philosophy of the organization. An example of a goal is “ a commitment by the hospital laboratories to be a vital component of a hospital whose goal is to provide a patient care environment of excellence, to serve the community, and to serve as a setting for clinical teaching.

The goal should be consistent with the organizational structure, the management style of the laboratory director, and the available resources. In turn, such goals should influence the future programs of the laboratory and the activities of the director and lab staff.

The types of goals set for a laboratory will vary greatly. For instance, the goals for operation of an office laboratory with two physicians are different from those of a reference laboratory serving thousands of patients over a large geographic area. A useful exercise for a new laboratory is to write the overall goals of the lab after discussions with appropriate persons in the organization. As part of this process, laboratory directors should encourage written input from each organization level toward the development of the goals and objectives. Such written goals may be organized as follows:

1. A statement of the primary external goals of the laboratory

2. A statement of the secondary and tertiary goals of the lab in reference to service, research, or education.
3. A statement in reference to the management philosophy of and need for cost effectiveness.
4. A statement as to what kind of environment is desired in the laboratory with respect to interpersonal relationships, working conditions, and attitudes toward teaching and scholarly activities.

Such overall goals, once established, should be reviewed every year and appropriate modifications should be made. In contrast to the general goals mentioned above, objectives should be in quantifiable statements which are achievable over a designated period of time. An example of an objective might be “to evaluate available approaches to automation of antibiotic susceptibility testing and also to implement the optimal approach by the end of the fiscal year”. Allowing concerned personnel to have input into formulating such objectives generally enhances the success of this approach of management by objectives.

Management by objectives is a process of formulation, performance and assessment, and as such it provides means of focus on pertinent factors and issues that affect the practice of lab medicine. As a tool of management, MBO encourages

discussion, interaction, and consensus decision making among all organizational levels of the laboratory.

Good management means getting work done. A well-organized laboratory service is efficient, and produces work of high standard in a safe and pleasant working environment.

The main steps to good management are:

- Setting up the main working room
- Arranging stocks of laboratory items
- Establishing routine procedures for disinfection and disposal.
- Establishing good communication with clinicians
- Organizing patient flow
- Keeping laboratory records
- Ordering laboratory supplies
- Organizing staff activities
- Establishing a reliable quality control system
- Setting planned programme for lab personnel trainings to the highest possible qualification
- Setting plans for enhancing the lab activities to the highest possible technical level

2.2. Role of Laboratory in Health Care and Training of Laboratory Personnel

The laboratory is an integral part of a nation's health service. It gives the service a scientific foundation by providing accurate information to clinicians and to other responsible bodies for:

- Treating patients
- Deciding health priorities and allocating resources.
- Monitoring the development and spread of infectious pathogens as well as status of non-infectious acute or chronic diseases or their markers; tumor markers, hormones, cancer cells, etc.
- Investigating preventable premature loss of life.
- Deciding effective control measures against major prevalent diseases.

With out reliable laboratory support:

- Patients are less likely to receive the best possible care.
- Resistance to essential drugs will continue to spread.
- The sources of disease may not be identified correctly.
- Epidemics and the spread of major communicable diseases will not be checked reliably.
- Valuable financial and human resources may be diverted to ineffective `control measures.

Training of Laboratory Workers

Basic training should be undertaken nationally in accordance with a country's health needs, available resources, and laboratory working environments. A trainee should be taught the technical skills, knowledge, and attitudes required to perform reliably and confidently the functions of the type of laboratory in which he or she will serve. Performance needs to be assessed during training and supervised adequately after training.

A job related approach to the training and continuing education of laboratory personnel is essential if laboratories are to provide a service that is reliable, cost effective, efficient, and relevant. Inappropriate or inadequate training is not only wasteful but also dangerous.

The following are some of the indicators of poor training of laboratory personnel:

- a. Increase in the number of wrong test results
- b. Delay in the issuing of reports
- c. Frequent and serious complaints from those requesting lab tests and an increase in requests for repeat tests as confidence decreases.
- d. Increase in the damage to equipment
- e. Increase in the contamination of reagents and materials
- f. Greater incidence of lab acquired infections

- g. Poorly motivated staff and job dissatisfaction
- h. Lack of laboratory ethics such as not respecting confidentiality of lab results and informing a patient results directly which should have been dealt by the concerned physician, etc

A good training programme will help students to learn the right facts, skills, and attitudes in an efficient and integrated way. It will assess whether students have learned the right things and help students to put into practice what they have learned. A job related training program is usually referred to as competency-based or task-oriented and is recommended for the basic training of lab personnel. It is ideally suited to the training since it fits a person to do a job that is needed, where it is needed, and to take on the responsibilities that go with the job. The better a person can do a job, the greater will be the effectiveness and satisfaction. Competency and job satisfaction are major factors in achieving and retaining quality of service.

Upgrading and Career Development

For all laboratory personnel there should be opportunities for upgrading and career development. This may be effected, to name a few, through advanced formal training, continuous education,, seminars and assignments to a higher post on merit basis.

2.3. Code of Conduct

A code of professional conduct for medical laboratory personnel should include those practices and attitudes which characterize a laboratory professional. Such code are necessary to ensure that technicians' works are of recognized standards which patients and those requesting the tests are confident of the results they receive. Above all a code of professional conduct can keep alive motivation and remind us that the medical laboratory profession is primarily dedicated to the service of the sick and promotion of good health care respecting ethical and psychological issues of patients.

Code of professional conduct for medical laboratory personnel

- Be dedicated to the use of clinical laboratory science to benefit mankind
- Place the well-being and service of patients above your own interests.
- Be accountable for the quality and integrity of clinical laboratory services.
- Exercise professional judgement, skill, and care while meeting established standards.
- Do not misuse your professional skills or knowledge for personal gain, and never take anything from your place of work that does not belong to you.

- Be at all times courteous, and considerate to patients and their relatives. Safeguard the dignity and privacy of patients.
- Do not disclose to a patient or any unauthorized person the results of your investigations and treat with strict confidentiality any personal information that you may learn about a patient.
- Respect and work in harmony with other members of your hospital staff or health center team.
- Promote health care and the prevention and control of disease
- Follow safe working practices and ensure patients and others are not put at risk. Know what to do should an accident or fire occur and how to apply emergency First Aid
- Do not consume alcohol or take unprescribed drugs that could interfere with your work performance during laboratory working hours or when on emergency stand-by.
- Use equipment and laboratory ware correctly and do not waste reagents or other laboratory supplies
- Strive to improve professional skills and knowledge and adopt scientific advances that benefit the patient and improve the delivery of test results.
- Fulfill reliably and completely the terms and conditions of your employment

Taken from the Code of Ethics of the International Association of Medical Laboratory Technologists.

Review Questions

1. State the role of laboratories in public health activities
2. What are the main steps to be followed in the management of health laboratories?
3. List the code of conduct for medical laboratory personnel.



CHAPTER THREE

LABORATORY ORGANIZATION

Learning Objectives

At the end of this chapter, students will be able to:

- Elaborate how to organize and administer the laboratory for delivery of quality laboratory service
- Explain the structure, staffing and function of various health laboratories
- Describe the facilities and safe design of laboratories

3.1. Introduction

Organization by definition means a system, an orderly structure, putting things together into a working order, and making arrangements for undertakings which involve cooperation. Actually, the emphasis is on arrangements which enable people to work together and to accomplish common objectives in an efficient, planned, and economic manner.

Efficient organization is the product of good ideas and good planning. In turn, these are dependent upon certain qualities of the director and his/her associates, which comprise

leadership, experience, industry, enthusiasm, and a desire to do things well. In the clinical laboratory there are two interlocking components of organization. These are:

1. The overall management provided by the director,
2. The organization of units provided by section heads

The director and his/her associates must define goals, set down policies, analyze general problems and find solutions for them, provide funds for the laboratories, outline programs, coordinate the work of sections, set down personnel policies, and interpret policies of the hospital board.

In a section, the head must work within the policies, rules, and regulations of the director. To be productive, he/she must utilize the skills of the staff members in the section; supervise and systematize the use of space, equipment, and supplies; streamline work flow; develop systems to handle specimens and paper; and design detailed responsibility to designated individuals. Someone in every successful organization is looking after details. Everyone in the organization has certain details for which that person is responsible. To analyze problems, to define details of their solution, and to assign responsible persons to tackle the identified problems are essential components of organization.

3.2. Organization of Health Laboratory Service in Ethiopia

The Italians established the first health laboratory in Ethiopia during the Second World War. Immediately after independence, health laboratory activities in Addis Ababa were taken over by British scientist and organized under the name of the Imperial Medical Research Institute. But, the British did not stay long and the organization was handed over on a contractual base to a French team that developed the first well-organized laboratory in the country under the name of Institute Pasteur d' Ethiopie. Between 1951 and 1964, they established facilities for the production of vaccines, and some diagnostic service. Rabies was the main research area for French team in Ethiopia.

The name of the Institute was changed to Central Laboratory and Research Institute (CLRI), and the Ethiopian Scientific and Medical Officers who took over the responsibility somehow managed to keep its activities. They attracted some able Ethiopian candidates and introduced more activities. Meanwhile, laboratory technicians training programmes were launched at the Gondar Public Health College, the Menelik II Hospital and the Jimma Hospital among others.

Today there are many laboratories throughout the country ranging from a huge central laboratory of Ethiopian Health and Nutrition Research Institute (EHNRI) to the smallest zonal and health center laboratories.

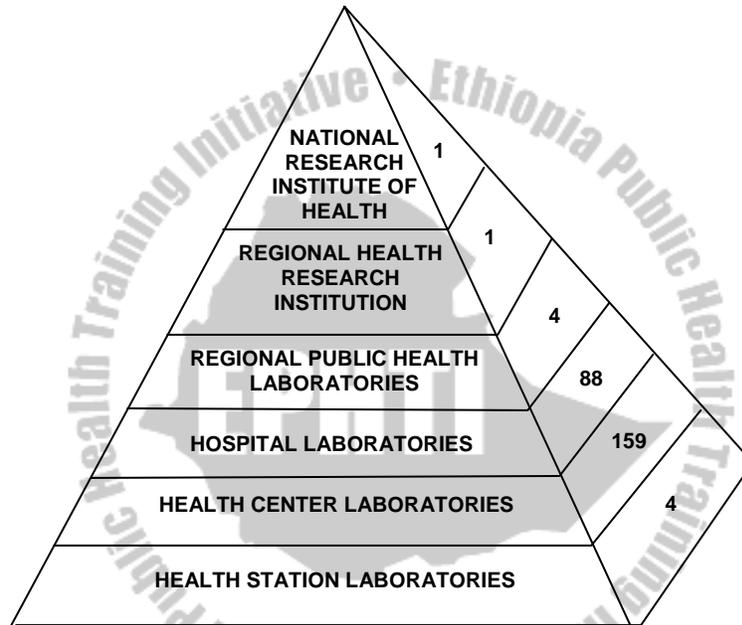


Figure 3.1. Organization of Health Laboratories in Ethiopia in the 1980s

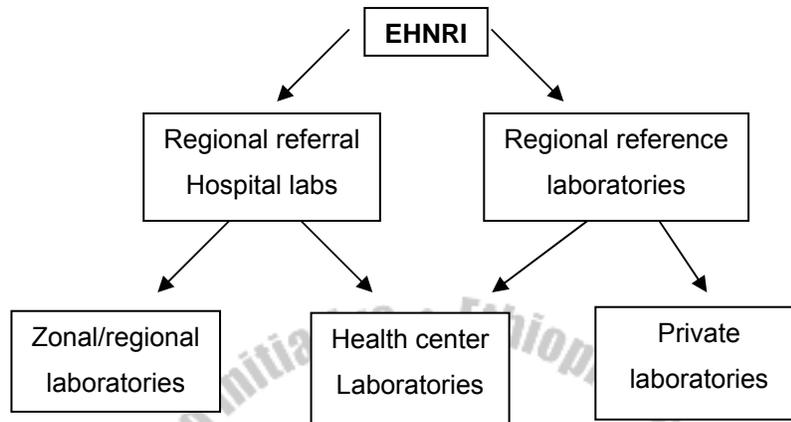


Figure 3.2. Flow Chart for implementation of lab networking

Source: Laboratory networking in Ethiopia proposal for support (Ministry of Health, Nov. 2002)

3.3. Structure and Function of Laboratory Service in Developing Countries

In 1981, an attempt was made to standardize the functions of health laboratories at all levels. The tests, their methods, and equipment needed at all levels of health laboratories in the country were listed in a publication, standard list of tests and basic laboratory materials for health services in Ethiopia. According to this publication, the functions of the laboratories are as follows:

3.3.1. Community Based PHC Laboratory

In the Ethiopian context these laboratories are called zonal/district and health center laboratories. Many of them are situated at the periphery of the country.

Community based primary health care laboratories are becoming increasingly important with the reorganization of health services. Essential health care facilities which at one time were only available to a minority of the population are now becoming community based and accessible to all.

The work of the community based primary health lab is to support primary health care in investigating, controlling, and preventing major diseases in the community, and in promoting health care by integrated health education.

Staffing

A laboratory in a primary health care center will usually be staffed by a junior laboratory technician with certificate or a local community health worker trained to examine specimens microscopically, perform appropriate diagnostic and screening tests, collect and refer specimens for specialized tests, and participate in community health education. Depending on the workload of the health center, one or two laboratory aids may also be required.

Functions

To investigate by referral or testing on site, important diseases and health problems affecting the local community. Such investigations usually include:

- Bacterial diseases like tuberculosis, leprosy, meningitis, STDs, ARI, etc
- Parasitic diseases like malaria, schistosomiasis, intestinal parasitic infections, and locally important parasitic diseases.
- Other causes of ill health like anemia, diabetes, etc.
- To collect and refer all kinds of specimens for testing to the district laboratory
- To screen pregnant women for anemia, proteinuria and malaria, etc

To promote health care and assist in community health education by e.g. demonstrating microscopically the parasites of important local diseases

To keep records and send a simple informative monthly report to the district laboratory.

The main equipment is a microscope, others include manual centrifuge, materials for complete blood count tests, ESR racks and tubes, etc.

3.3.2. District Hospital Laboratory

In Ethiopia these laboratories are called sub-regional public health laboratories.

These labs have an important role in supervising the work of the peripheral community based laboratories, testing referred specimens, and performing a range of tests compatible with the work of the district hospital.

Staffing

A district lab is usually staffed by at least one diploma holder senior laboratory technician and depending on work load, by two to four lab assistants and several lab aids. The staff of the district laboratory should also include a laboratory tutor to train and supervise the work of primary health laboratory workers.

Functions

The main functions of the district hospital laboratory are as follows:

To perform a range of tests relevant to the medical, surgical and public health activities of the district hospital.

- All investigations listed above for primary health laboratories.
- Basic hematology, serology, and urinalysis diagnostic services

To support the work of the community based laboratories by:

- a. Testing referred specimens
- b. Providing reagents, controls, standards, and other essential lab supplies
- c. Training community health laboratory workers

To refer specimens to the regional laboratory

To participate in the external quality assurance program organized by the regional lab.

3.3.3. Regional Hospital Laboratory (Referral)

The main role of the regional laboratory is to assist and supervise the district laboratories, to test referred specimens and to perform a range of specialized and other tests required by the work of the regional hospital.

Staffing

A regional lab is usually staffed by one coordinating chief laboratory officer a medical lab technologist having a B.Sc. degree or an M.Sc, an experienced specialist lab technician and two or three technicians in each department, laboratory tutors, a safety officer, a stores officer, clerical staff, and several lab aids according to the work load.

Function

The main functions of the regional laboratory are as follows:

To perform a range of tests as required by the medical and health needs of the region.

- To operate a regional blood transfusion center.
- To prepare reagents, culture media, controls, clinical chemistry standards, and specimen containers.
- To investigate epidemics and perform tests of public health importance in the region.
- To perform bacteriological and chemical analysis of foods, water, beverages and other industrial products
- To support the work of the district hospital labs in the region.
- To send specimens that require specialized investigation to the central and public health labs.
- To participate in external quality assessment program organized by the central laboratory, etc.

3.3.4. Central Public Health Laboratory

This laboratory is responsible for the planning, expenditure, and co-ordination of the national laboratory service. It has equally important roles in ensuring the reliability of the service, the appropriateness of its technology, training and motivation of its workforce, and ensuring that the service extends into

areas of health needs and its facilities are made available to as many people as possible.

In Ethiopia the only well-known central and public health laboratory is the Ethiopia Health and Nutrition Research Institute (EHNRI).

Staffing

A central laboratory is staffed by a director (ideally pathologist, at the moment a microbiologist, but no specification is of a limit)), a senior coordinating officer, several research scientists of various discipline with qualifications of B.Sc., M.Sc., M.D., MPH, DVM, PhD and several senior technologists and technicians, a senior safety officer, clerical staff, and several lab aids according to the size and workload of the laboratory.

Functions

This is the highest responsible body to provide technical support and advice for all regional laboratories or regional referral hospital laboratories.

The main functions of a central and public health laboratory are as follows:

- To formulate a professional Code of Conduct for medical laboratory personnel.

- To perform with high tech methods and facilities a range of specialized tests not normally undertaken in the regional laboratories, such as bacteriological, mycological, viral, histopathological, cytological, immunological, nutritional, hormonal, metabolic, forensic, molecular and genetic investigations,
- To carry out appropriate research on important national health problems.
- To organize a national blood transfusion service. This is presently done by the Ethiopian Red Cross.
- To evaluate new technologies, standardize techniques, and test the appropriateness of new equipment.
- To purchase supplies and equipment for the national laboratory service and to organize an efficient system of requisition, distribution, and maintenance of equipment.
- To prepare control sera, blood grouping antiserum, antihuman globulin, complex biochemical reagents and culture media that require standardization and are more economically prepared in the central laboratory.
- To communicate and collaborate with International Organizations in promoting laboratory standards and a Code of Safety for indigenous medical laboratories.
- To train specialist technicians and to organize laboratory teaching seminars.

- To prepare, and where required, translate appropriate training manuals for the different laboratory training programs.
- To prepare laboratory request forms, record sheets, order forms, and other essential stationery, which require standardization.
- To prepare and distribute an annual report on the activities of the country's laboratory service, to co-ordinate the work of the laboratory service within the national health programme, and to prepare a budget for presentation to health authorities.
- To support the work of the regional hospital laboratory by:
 - Providing control sera, certain standardized reagents, chemicals, bacteriological media constituents and ready-prepared complex media, blood collecting packs, standardized stationery, specimen containers, and other essential laboratory supplies.
 - Visiting each regional laboratory every six months to discuss with the medical and technical staff the work and needs of all the laboratories in the region, to check records and quality control measures, service major equipment, install and demonstrate any new complex equipment, and ensure that safety measures in each department are being followed.

- Co-ordinate an external quality assessment programme in parasitology, bacteriology, haematology, blood transfusion and clinical chemistry.

Note: The above functions of the Central Public Health Laboratory are ideals and not necessarily practiced in Ethiopia at present.

3.4. Safe Laboratory Design

3.4.1. The Laboratory Environment- Facilities

All laboratories need at least a building, power supply, and water supply that suits their activities. Most often, laboratories are hampered in their operation because of limited space or inefficient use of the space available. This is because insufficient attention has been given to the design and planning of the laboratory.

The first and most essential part in planning a health laboratory is for those involved, i.e. the laboratory personnel, health officials and administrators, and the architect, to have a clear idea of laboratory requirements.

The laboratory technician plays a leading role in the planning and design of laboratory facilities. Therefore, he/she must

have full knowledge of the needs of a clinical laboratory, particularly:

- The geographical area where it will serve best
- The space and equipment required

The lab technician should work out this in collaboration with the health administrator and the architect, to prepare a functional program giving details on the size and the general characteristics of the laboratory to be designed, taking budgetary considerations into account. This functional program will consist of a detailed description (qualitative and quantitative) of the activities of each unit and thus determine the space and equipment required. It should also give full information about the operation of the laboratory so that the architect may design the layout more efficiently.

3.4.2. Standard Design for Laboratories

In Ethiopia like in other developing countries, laboratories do not have standard designs. If laboratories do not have standard designs, it is impossible to expect effective and efficient laboratory services. Therefore, laboratories have to be designed following standard procedures. The procedures for establishing basic requirement for laboratory facilities are determined after considering the following points.

1. The amount work to be performed

2. The type and number of technical units (e.g. parasitology, hematology, etc), i.e. the level of the laboratory
3. The number of personnel that will be working in each unit
4. The equipment and furniture required in each unit
5. The auxiliary areas needed:
 - a. Administration, reception
 - b. Technical washing, sterilization, reagent and media preparation, storage.
6. Utility Services and Distribution

The basic utility services such as water supply, sanitary drains, electricity etc, should always be provided in a laboratory. Proper and adequate supplies of these utilities have to be well thought and provided for a continued operation. In high laboratories, power failures or voltage drops may cause a lot of damage on expensive equipment. Therefore, adequate provision of power and emergency power supply like generator, have to be provided. The main objectives of an emergency power system are:

 - To ensure continued operation of safety equipment
 - To prevent loss of specimens and reagents due to insufficient refrigeration or incubation.
7. The preferable locations for different units of the laboratory.

In this exercise of designing laboratory facilities the modular concept of J. H. Barker and L. Honague was strictly followed and adapted.

The following considerations are worth noting in the making of a laboratory building.

a. Walls

External and corridor walls are permanent. They can be made from a wide variety of materials depending on the cost and performance. Internal walls or inter-laboratory partitions especially for regional/referral hospitals and regional public health laboratories are to be considered as temporary; relatively inexpensive wall materials should be used so that they can be replaced easily at minimal cost.

b. Ceilings

Ceilings in laboratories must be of material that can be easily cleaned and disinfected. The entire ceiling area must provide a continuous seal to prevent contaminants from seeping through. Ceiling heights should be 2.55-2.88m.

c. Floors

Floors should be preferably of materials that are resistant to acids, alkali and salts. It should also be easily cleanable and disinfected.

d. Doors

Doors should provide an easy exit and be located in places where they will not interfere with equipment and laboratory benches. Laboratory doors should not be less than 1 meter wide so that equipment can pass through with ease. The doors in laboratories should always open towards the corridor. Splitting the main door in half, and keeping the upper half open when the laboratory is in use can increase ventilation of the main laboratory room. This design is also convenient for receiving specimens from patients.

e. Windows

Natural light should be made available through windows. Therefore, windows should be fixed at least 90 cm above floor level. The window should be proportional to the floor area in the ratio of at least 1:5. The main laboratory working room should be built with large windows to provide a bright working environment. This is also essential since laboratory workers frequently handle and use volatile toxic chemicals, hazardous biological materials, etc. The windows should not face the directions of the prevailing wind. This helps to avoid disturbance of weighing scales, blowing away of fine powders, excessive movement of fine particles in wet preparations. The windows should be protected and placed so that direct sun light does not enter the laboratory.

f. Air handling

Complete control of air circulation can be best achieved by taking advantage of natural ventilation, shading and thermal barriers.

The use of natural ventilation includes the following measures:

- Provide windows with screens for maximum flow of air and protection from insects,
- Provide vents in the upper portion of the roof to allow hotter air to escape from the building through the ceiling vents;
- Orienting the building to take full advantage of prevailing winds.

The use of shading includes the following:

- Providing wide roof coverage to protect windows from direct sunlight;
- Planting trees or building screens to provide shade to buildings during the hottest period of the day;
- Orienting or designing the building to decrease the amount of afternoon sun exposure.

The use of thermal barriers include the following:

- Providing insulation in the roof and exterior walls to decrease the transmission of heat into building.
- Providing reflective materials on windows that cannot be shaded, in order to redirect the rays of the sun.

Good laboratory planning and design requires some knowledge of laboratory activities or consultation with a person with laboratory experience. The ideal health center laboratory, for instance, should include the following rooms:

- Main working room (minimum 4x5 meters): for specimen collection, processing and examination.
- Washing room (minimum 2x2 meters): for cleaning all laboratory ware and disposal of excreta.
- Store room (minimum 2x2 meters): for safe storage of stocks of reagents and consumables, and equipment that is not in use.

In addition the following things are required:

Water supply: Ideally, the health center laboratory should be supplied with continuous running water. Distilled water or de-ionized water (water with a low concentration of salts) is essential for the preparation of lab reagents from basic chemicals. In rural areas the water supply is often salty and the resins in the deionizers require frequent recharging or exchanging, sometimes as often as every day. The quality of water produced by deionizers must be constantly monitored using a gauge or an indicator system.

Electrical power: This is essential to operate the microscope and other lab equipment and to provide lighting for emergency

work at night. Fluorescent tube lights provide bright light with low energy consumption. Light in the lab is enhanced by white paint on the walls, shelves, benches and cupboards. In areas without mains electricity, power may be supplied by:

- 12 volt batteries charged intermittently from a fuel generator,
- 12 volt batteries charged by solar (photovoltaic) power.

Benches, Lockable cupboards, Shelves: Laboratory benches must be high enough to enable the lab staff to work while standing (0.9 meter high and 0.5 meter wide). Cupboards underneath the benches may extend through out the main working room except near the power socket, where space should be left to allow the staff to sit comfortable while working. Benches should have a white Formica top, or be painted white oil-based paint, for easy cleaning.

Sinks and basins: The health center lab should be provided with two sinks in the main working room and one sink in the washing room. In the main working room one is used for staining and the other for hand washing. Ideally, the hand-washing sink should be placed near the exit door. Sinks must be made of chemical resistant material, e.g. ceramic (porcelain), or PCV (plastic).

Laboratory Furniture: An official table and two chairs may be used as a reception desk and for collection of blood samples from patients. Stools for sitting while performing bench work should be approximately 0.6 meter high. A long bench should be placed in a covered, patient waiting area outside the lab.

Refrigeration: The following items in the health center laboratory require refrigeration:

- Control blood samples
- Serological kits
- Transport medium
- Specimens awaiting transportation to a reference labs, etc

The lab may share a refrigerator with other sections of the health center if not adequately available.

Toilets and latrines: Patients attending the health center lab should have access to toilets or latrines for specimen collection. These should be separated from those used by the health center staff. Where flush toilets are in use, latrines should also be available, in case of water shortage.

Toilets should be constructed according to recommended plans, to ensure adequate depth and ventilation. Toilets and latrines should be kept clean at all times. Disposable laboratory items should never be discarded into latrines.

Review Questions

1. What does organization of the laboratory means?
2. Describe the structure, staffing and functions of health laboratories at different levels.
3. What are the basic facilities of a well-designed health center laboratory?



CHAPTER FOUR

EFFECTIVE COMMUNICATION IN THE LABORATORY

Learning Objectives

At the end of this chapter, students will be able to:

- Describe how to make effective communication
- Elaborate the various communication skills needed in the laboratory
- State the guidelines for effective communication

4.1. Communication

If a laboratory service is to function smoothly, reliably, and effectively, laboratory workers must be able to communicate well.

By definition, communication is the accurate passing on or sharing of information.

In communication, it is important to consider the following points

- Nature of the information being communicated.

- Person or persons to whom the information is being communicated.
- Most effective way of communicating the information.

In laboratory work, there are three main ways of communicating information, by:

- Writing
- Speaking
- Actions

4.1.1. Written Communication

To be effective, written communication needs to be:

- Presented legibly and neatly
- Expressed clearly and simply
- No or little orthographic error

Writing Legibly and Neatly

In laboratory work, serious consequences may result when hand-written figures or words are read incorrectly because of poor handwriting or untidy corrections. An illegibly written report may result in a patient receiving incorrect treatment.

The presentation of well-written and neat reports not only avoids errors, misunderstandings, and frustrations, but also inspires confidence in the person issuing and receiving the

reports. The most senior member of the lab should check all reports.

To promote standardization and neatness of reporting and also from the legal point of view the use of rubber stamps is recommended but care must be taken to ensure the stamp is positioned well and sufficient ink is used.

Writing Clearly and Simply

Opportunities for laboratory personnel to develop written skills should be provided during training. A trained laboratory technologist needs to know how to write clear reports and instructions with regard to test methods, use of equipment, preparation of reagents, safety measures, collection of specimens, laboratory policies, notices, agendas for meetings, budgets, work reports, and requisitions for laboratory supplies. Laboratory personnel should be encouraged to contribute to newsletters and journals.

4.1.2. Spoken Communication

Important aspects of spoken (verbal) communication include:

- Clarity of speech
- Tone of voice
- Ability to speak informatively.

Clarity of Speech

The main requirement of spoken communication is that the words spoken can be heard distinctly by the person to whom they are addressed. A barrier to effective spoken communication is background noise. Noise should, therefore, be kept to a minimum when speaking e.g. reduce the speed of a centrifuge.

It is particularly important to speak clearly when addressing patients. Hesitant and mumbled instructions are causes of misunderstandings and lack of confidence by patients.

Tone of voice

A kind and understanding tone of voice may greatly help a patient, especially a child, to feel less frightened, whereas a loud and impatient tone of voice may cause fear and add to the suffering of a patient. A laboratory worker should always try to reassure patients by explaining simply the procedure of a test and, without disclosing professional information, seek to answer patients queries.

It is particularly important to communicate well in difficult situations, for example when called to cross match blood during a night emergency. Under these circumstances it is essential for the laboratory worker not only to function rapidly and reliably but also to reply calmly and patiently to anxious

relatives and blood donors. Spoken communication is influenced by temperament and fatigue, but a courteous response based on respect for all persons should always be possible.

Ability to speak informatively

This is particularly important when giving the results of tests by telephone or directly to a medical officer or nurse. An understanding of the clinical significance of investigations is required.

If a laboratory worker does not have sufficient information to answer a question about a report, the questioner should be referred to a more experienced member of staff. If unable to reply and no other person is available, the laboratory personnel must advise that he or she is unable to assist. Inaccurate information must never be communicated.

The ability to speak informatively is also required when attending hospital interdepartmental meetings to discuss laboratory policies.

4.1.3. Action Communication

Communication through bodily manner and actions (body language) is particularly important when relating to patients. A pleasant friendly manner and a neat clean appearance

inspire confidence whereas an impatient aggressive manner or an untidy appearance can make patients nervous and afraid. When unable to speak the language of a patient, facial expressions and actions become extremely important in reassuring a patient. A smile and a caring look and action can inspire trust.

Action communication is also important among staff members if a pleasant working environment is to be maintained.

Establishing good communication with clinicians

The clinician plays a vital role in assisting the laboratory to provide a useful service to patients. The logical sequence of patient diagnosis is history taking, physical examination and then laboratory & other diagnostic investigations. In general the clinician should not prescribe treatment before sending the patient for lab investigations. It is a misuse of the laboratory service if results of tests are not considered when prescribing treatment for patients. The clinician must include the following essential information with all laboratory requests: name of patient, outpatient/inpatient number, age, sex, brief outline of clinical problem including relevant drug use, investigations required and whether urgent, name and signature of requesting technician, and other relevant information about the patient.

Communications with laboratory staff: If the clinician is not sure what test to order, what specimen to send, or whether the laboratory is able to help at all, he or she should discuss the problem with the lab staff. If the laboratory staff feel that an alternative investigation may clarify the patient's problem, the lab staff should discuss this with the clinical staff.

The clinician should visit the laboratory regularly to review interesting test results and microscopical findings and to become more familiar with the lab service.

4.2. Guidelines for Effective Communication

The following are among the guidelines for effective communication which Shirley Pohl presented at a Congress of the International Association of Medical Laboratory Technologists.

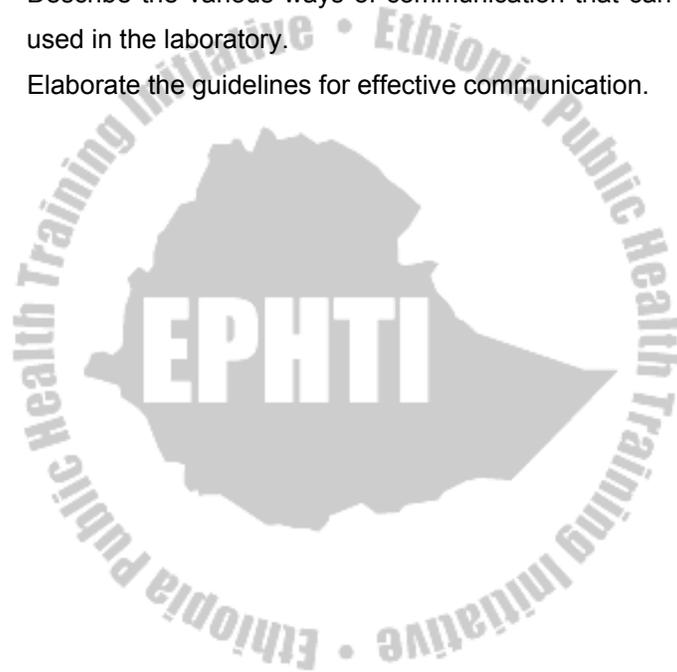
- Seek to clarify your ideas before communicating.
- Consider the total physical and human setting whenever you communicate.
- Meaning and intent are conveyed by more than words alone.
- When you communicate, be mindful of the overtones as well as the basic
- content of your message

- Take the opportunity when it arises, to convey something of help and value to the receiver.
- Follow up your communication.
- Be sure your actions support your communications.
- Seek not only to be understood but also to understand and be a good listener.
- Communicate for tomorrow as well as for today.



Review Questions

1. Define communication.
2. State the things to be considered for effective passing on of information.
3. Describe the various ways of communication that can be used in the laboratory.
4. Elaborate the guidelines for effective communication.



CHAPTER FIVE

LABORATORY POLICIES

Learning objectives

Upon completion of this chapter, it is expected that students are able to:

1. Describe how, and what kind of specimens are referred
2. Explain how to collect specimens, make records and reports of lab results

5.1. Definition and Purpose

By laboratory policies are meant those decisions which are taken in consultation with medical and nursing staff to enable a laboratory to operate reliably, effectively, and in harmony with other departments of the hospital or health center. Such policies usually cover:

- Laboratory hours and emergency work
- Range of tests to be performed and referral of specimens
- Collection of specimens
- Work load capacity of the lab
- Delivery of reports

- Reporting of results and record keeping
- Safety measures

5.2. Laboratory Hours and Emergency Work

As far as possible there should be definite laboratory working hours. In peripheral laboratories it is often more difficult to maintain working hours because of large out patient clinics and the emergency nature of much of the work. Outside of normal working hours, each laboratory should organize a system for testing urgent specimens. Only those investigations that are essential for the immediate care and assessment of patient should be requested urgently. Written details of the emergency laboratory service (on call service) should be circulated to all those concerned. Lab staff that participates in the emergency service must be able to work efficiently and reliably without supervision.

5.3. Range of Tests to be Performed and Referral of Specimens

In deciding which tests should be undertaken in a district hospital or primary health center laboratory the following are important considerations.

- What is the clinical value of each investigation and which tests should have priority because they are needed to:
 - a. Establish a diagnosis,
 - b. Assess patient's condition and prognosis,
 - c. Judge whether to refer a patient to a center with more facilities,
 - d. Select a suitable treatment and follow a patient's response to it,
 - e. Prevent and control serious disease in a community,
 - f. Assist health authorities to plan cost effectively.
- What is the level of experience and training of lab staff? If required, can further training be obtained?
- How well is the laboratory equipped and can equipment be operated reliably and safely?
- Can the tests be controlled adequately, i.e. can tests be performed with adequate precision and accuracy?
- What are the costs involved, especially the cost of reagents, standards, controls, and of running and maintaining essential equipment?
- Is it possible to refer specimens for testing, especially those that are non-urgent and can be more economically and reliably tested in batches in a larger laboratory? If able to refer, can specimens be preserved and transported safely? How quickly can the results of referred tests be known?

5.4. Work Load Capacity of the Laboratory

The workload capacity of a lab must be matched to the number of staff and to their level of training, and to the size of the laboratory and its facilities. If the amount of work requested is beyond the capabilities of a laboratory, this must be brought to the attention of the medical officer with overall responsibility for the laboratory. When workload is excessive, the testing of specimens becomes unreliable and safety measures tend to be ignored.

Too little work can also lead to unreliable test results due to a lack of concentration.

5.5. Collection of Specimens

The correct collection of specimens is essential for reliable test results. The laboratory must issue written instructions regarding the collection of routine and urgent specimens to all those responsible for the collection of specimens from inpatients and outpatients

There should be an organized system for the collection of routine specimens from wards. Specimens for urgent analysis should be delivered to the laboratory as soon as possible.

A request form must accompany every specimen. This should provide essential patient information, and a clinical note regarding diagnosis and treatment. Those responsible for collecting samples must check that every specimen is clearly labeled with the patient's name and hospital number, date and time of collection, and that the name and number agree with what is written on the request form. Clerical mistakes can have serious consequences.

Any specimen found to be unsuitable must not be accepted by the laboratory for testing. When an error of collection has been made, a note indicating how to correct the fault should accompany the returned form. If the investigation is required urgently, every effort must be made by both the laboratory and ward staff to obtain a repeat specimen as soon as possible. Lab staff should encourage medical and nursing staff to seek advice if they are uncertain about the collection of specimens for particular investigations.

5.6. Delivery of Reports

The most experienced member of the laboratory's technical staff must check all results before they leave the laboratory. Any unexpected result should be investigated and repeated if necessary. It is important for laboratory workers to understand

the clinical significance and accepted reference values (normal range) of the tests they perform.

A clinically serious abnormal result should be brought to the attention of the medical officer concerned as soon as possible. When a result is phoned, it is advisable to request the person receiving the report to repeat back the name of the patient and test result, to make sure that the report has been heard correctly. A written report should follow as soon as possible.

There should be an organized system for the delivery of reports to wards and clinics and from referral laboratories to the peripheral hospitals and community health centers. To avoid any loss of reports and to keep results tests confidential, all forms should be placed in marked envelopes or in closed folders which can be returned to the lab for re-use.

5.7. Reporting of Results and Record Keeping

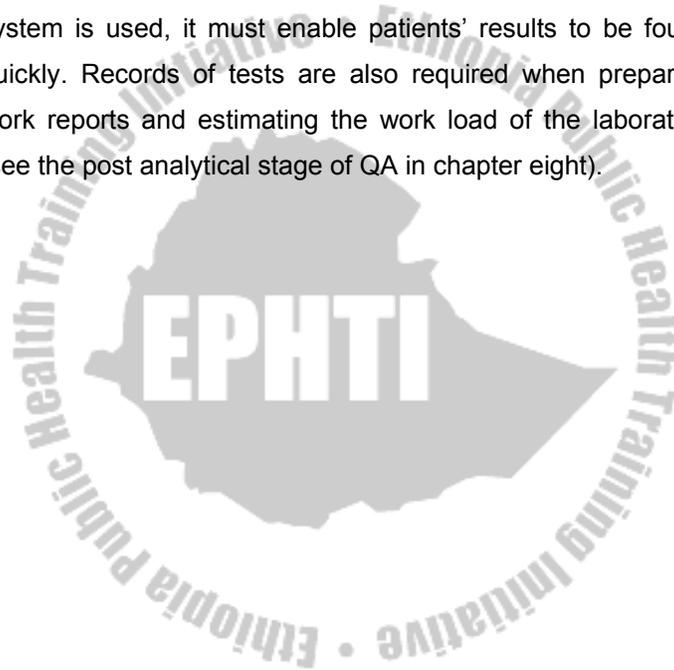
Reporting

Standardization in the reporting of laboratory tests contributes to the efficiency of a laboratory service and is of great value when patients are referred from one hospital to another. Whenever possible, request forms and other laboratory

printed stationary should be prepared and issued by a central stationary office.

Keeping records in the laboratory

The laboratory must keep a record of all tests as carbon copies, work sheets, or in simple exercise books. Whichever system is used, it must enable patients' results to be found quickly. Records of tests are also required when preparing work reports and estimating the work load of the laboratory (see the post analytical stage of QA in chapter eight).



Review Questions

1. What does a laboratory policy mean?
2. How are specimens referred to a laboratory?
3. Explain the important steps to be considered in the collection of specimens.



CHAPTER SIX

MANAGEMENT OF LABORATORY RESOURCES

Learning Objectives

Upon completion of this chapter, students are expected to:

- Know how to manage time and space
- Prepare a laboratory time table, schedule, and duty rosters
- Know how to arrange work space and work flow
- Manage equipment and laboratory supplies
- Explain how to order, issue, store and control laboratory chemicals and equipment

6.1. Management of Time and Space

Many health care units (health centers and health stations/posts) in Ethiopia have been built without a laboratory room. In some health centers, laboratory rooms have been built but they are too small to enable the laboratory staff to work safely and efficiently. Moreover, it is not uncommon to

observe in many laboratories problems in using the available time and space which are believed to be among the many factors that affect the quality of laboratory service.

6.1.1. Management of Time

Time is different from all other resources in that it is too precious, non recurrent and it cannot be stored, purchased and maintained. It is something invisible which can be highly wasted and corrupted resource. Especially in a country like Ethiopia this resource is highly corrupted and not wisely managed and much has to be done in this regard. Time can be managed through planning for future utilization. Time can be managed by forming a schedule, timetable, rosters, programs, etc.

Schedules

Schedule is an easy way of dividing and managing time and is used for routine, repetitive activities which takes place daily, weekly, monthly, etc. For the laboratory of an average general hospital, an amazing number of schedules are planned to provide personnel and service for regular workdays, weekends, evenings, and holidays. Additional plans are required to make provisions for annual leaves, for special procedures, and for a disaster plan. The approach varies with

individual hospitals, each having a plan designed to meet its requirements.

Timetable

This is different from schedule for the following reasons:

- It is used for non-repetitive activities,
- Irregular activities at different times and place.

Programme

This includes a variety of wide range of activities done over a long period of time at different place by different people. A program gives answer for the questions what, who, when, and where.

Roster

In this, activities are repetitive and take place at the same time, by different people at different times. An example is a duty roster.

Various plans for nights and weekends

Callback System

Labor laws and union agreements may define the rates of standby pay, minimum pay per call back, rate of pay per hour for each call, port-to-port and return time, transportation, or allowance for it. A breakeven point may be reached for which regular shift work may be more economical.

Regular Shifts

These shifts require a definite number of personnel who work stated hours and by some system of five days on with two days off.

Teams for Shift Work and Weekends

D.F. Moore of Saskatoon used the following system: Six technicians made up a team to cover evening and night shifts. The technicians on duty covered a short evening shift and then assumed stand-by duty callbacks. The team consisted of registered technicians who had recently joined the laboratory staff. As each technician joined the staff, this person was assigned to the evening/night team and replaced the technician with the greatest seniority on it who, having served in the team, was never required to do night duty again.

Permanent Non Rotating Staff

Occasionally, a laboratory technician may request evening and night duty as a permanent arrangement. Superficially, the arrangement is attractive, but there are problems. For example, it is difficult to control the situation where there is little or no contact with the technician. The technician has no contact with the day staff and eventually becomes out of touch. New methods are difficult to introduce. Short cuts and modifications are often introduced without prior consultation. Technicians who are involved in evening and weekend work

are often rotated through certain sections of the laboratory in order to provide them with necessary experience.

6.1.2. Arranging Work Space and Work Flow

Intra-laboratory Relationships

The relationship of various laboratories to each other and to supporting areas such as phlebotomy, specimen receipt, data processing, glass washing, media and/or reagent preparation & sterilization, storage should be taken into account. A workable arrangement is to have a specimen receiving, data processing, and reporting center serve as the hub of the laboratory. Radiating from this could be the various laboratories. The critical care laboratories and large volume laboratories (such as hematology and chemistry) might be most closely related to these central areas. Those laboratories with greater turn around time and/or less volume, as well as those requiring special safety features might be more removed from the central area.

Traffic flow: It is very important to plan the traffic flow so that intra-laboratory traffic is separate from outside traffic. Provisions should be made for ambulatory patients and blood bank donors coming into the laboratory.

Specimen and data flow: A diagram of specimen and data flow through the proposed laboratory will be helpful in arranging a schematic layout. Questions, which should be considered, include: (1) Do all specimens come to a central processing area or to the individual laboratory section? (2) Are pre-analytical processing and storage of specimens to be done centrally or by each laboratory? (3) Are routine and stat (emergency) specimens to be treated in the same manner?

Organizing patient flow

Outpatients: These are usually sent to the lab with their own requisition form. In health centers that do not use lab requisition forms, lab requests should be written on a separate piece of paper to avoid the clinical notes becoming contaminated in the lab. Specimens are collected in the laboratory or patients are given instructions to bring specimens directly to the laboratory. Patients either wait for the results or are told when to return to collect them. Patients take their own results back to the clinician.

Inpatients: In health centers that do not use lab requisition forms, lab requests should be written on a separate piece of paper. The patient's notes should not leave the ward as they may be needed in an emergency.

Stool and urine samples are collected by the nursing staff and taken to the lab. Blood samples are collected on the ward unless the patient is well enough to walk to the laboratory. Clinical staff must assist the laboratory staff to collect venous blood from infants and small children, and also samples like CSF or other invasive fluids and send them immediately to the laboratory..

Emergencies: In emergency all health staff must be prepared to attend to patients. If the patient is unable to come to the lab, the lab staff must go and attend to the patient.

6.2. Management of Equipment and Supplies

In any laboratory there are two main types of items. These are:

Expendable (also called consumable)

Materials that are used until exhausted are expendable items and may include matches, cotton, wool, laboratory stains, disposable syringes, glass wares, etc.

Non-Expendable (also called capital)

These are instruments/equipment that are used for several years and need care and maintenance and include

microscopes, autoclaves, centrifuges, water baths, incubators, spectrophotometers, balances, etc.

Procedures in the Management of Laboratory Items

- I. **Ordering:** obtaining lab items from stores or procuring items from suppliers or manufacturers.
- II. **Storing:** Recording, labeling and holding items in a stock or storeroom.
- III. **Issuing:** Dispensing items to users.
- IV. **Controlling and Maintaining:** This includes controlling expendable items and maintaining and repairing equipment/instruments.

6.2.1. Ordering Lab Items

Ordering lab items only senior staffs are authorized to order lab items. Laboratory supplies are ordered regularly before stocks are depleted. Check the prices of items before ordering to ensure that laboratory expenditures do not exceed the budget. One has to follow government guidelines carefully when ordering supplies.

The following skills are needed to order equipment:

- To list requirements with relevant and clear specifications.
- To balance requirements with available resources and make cost estimates.

- To use a catalogue to make correct lists of items
- To complete an order form or requisition form.

Note: It is important that in procurement of items there should be certificate of origin of each required item and expiry date clearly labeled to have more than 80% laps of time before this date.

Making Lists

Make a list of laboratory items with appropriate place of purchase, for example, paper is bought from the government stationary, spectrophotometer is brought from EPHARMICOR etc.

For each item write down the exact type required (specification of items is very essential). For example, microscope, binocular 220v.

Estimate the quantity of each item. For example, 5 packs of applicator stick for a year.

The Quantity of an item used depends on the number of people using it and can be estimated from experience or by asking experienced persons. Since resources are always limited it is important that consumable items be used immediately.

1. Balancing Requirements and Resources:

Health services all over the world are short of resources. Therefore, requirements must always be balanced against resources. Sometimes one can obtain more resources, e.g. if a donation is made, equipment/instruments may be ordered without affecting the regular budget. In any event, a cost estimate must be made before completing the order form.

2. Making a Cost Estimate

Draw a columned sheet of paper and list the items, quantity, and price per unit and total price.

Items	Quantity	Price per unit	Total price birr
Sterilizer	1	2,000.00	2,000.00
Centrifuge	2	5,000.00	10,000.00
Total			12,000.00

Suppose that only 8000.00 birr is available then revise the list, reducing or omitting items until the total matches the budget allocated for that purpose.

3. Using a Catalogue

A catalogue is a book that contains a list of article available for purchase from a certain place. A catalogue is used wherever things are purchased at a distance. A catalogue may be

published by a government store or by a private firm, manufacturer or shop.

The disadvantage of catalogue purchasing is that the purchaser does not see the articles (equipment) he/she is buying often there are several types of the same item e.g., there may be six different kinds of centrifuges. Therefore, the catalogue must be read with greater care and the exact item number, description and price carefully identified. There must also be a need to request suppliers to submit certificate of origin which is required by our government policy.

4. Completing an Order-form or Requisition Form

An order form or requisition form is usually supplied together with the catalogue. If not supplied the person responsible should prepare his/her own order form. An order-form for example should have a column for each of the following:

- Item number
- Name of article (material)
- Specifications in detail/ Type
- Quantity required
- Unit and total price

Item No	Name of Article	Specifications/ Type	Qty	Unit price	Total Price
1	Hematocrit centrifuge	Brand: ALC INTERNATIONAL SRL Mod: 4203 CAT NUMBER: 11172010 VOLTAGE: 220v FREQUENCY (Hz): 50/60	2	15,000	30,000

Ordering Supplies

A well-organized laboratory should submit its supply need to the central supply store (PHARMICOR) every 3 months. To draw up order, check the stock cards one by one. An ideal stock card should provide information as depicted in the following table.

Laboratory supplies consumption indicator

Item, e.g. WBC diluting fluid in ml.

Quantity used per Month	Jan	Feb.	March	April	May	June	July	Aug.	Sept.	Oct	Nov	Dec	Total
2002	50	60	45	75	20	10	15	30	20	25	35	35	420
2003	10	20	50	70	15	30	20	50	25	30	40	30	390

In the case of chemicals, stains and reagents, order the quantity used in a 3 months period, taking into account any recent increases or decreases in amount used.

For example: 8 bottles of Giemsa stain each of 50ml have been used in a year

- This gives an average of 2 bottles every 3 months (i.e. 100ml)
- Order 2 bottles every 3 months (or 4 bottles every 6 months, if orders are submitted twice a year).

Expiration Dates

Some reagents, for example, blood grouping anti-sera, VDRL and other serology and chemistry reagents etc have to be used before a certain date. Make a note of the expiration date on the stock card. NEVER USE AN EXPIRED REAGENT.

6.2.2. Storing Equipment

Equipment is stored in a main Store or reserve store where stocks are kept but not used

- It is important that a record-book (stock-book) is kept during reception and issuing of new articles

N.B. Separate ledger should be used for expendable & non-expendable equipment.

A ledger balance should be kept, for example:

Date	Item	Received from	Invoice	No Received	No Issued	Balance in Stock
	X			120	29	91
	Y			40	7	33
	Z			21	16	5

6.2.3. Issuing Equipment

After equipment has been ordered, and then received and recorded in the stock-book or ledger it is issued for use when it is needed.

There are three paper procedures used in issuing equipment.

1. A larger record: i.e. writing the issue in the stock ledger.
2. Issuing a voucher: to be signed
3. An inventory: record of the section or lab receiving the equipment and using it.

1. A ledger Record

When an issue is written in the stock ledger, the balance remaining in stock can be found by subtracting the amount issued from the total in stock. When the balance is getting low, it is time to order new equipment.

N.B. It is important to record issues in the stock ledger and to calculate the balance of stock remaining. This is how to find out when to order more stock.

2. Issue Voucher

There is an official form on which are recorded:

- Date of issue
- What is issued, and how much
- Where it is to be used
- Who is responsible (usually head of the lab section)
- Signature of person responsible for its use.

N.B. The person who signs the issue voucher takes responsibility for the care of the apparatus or equipment. Issue files must be filed and kept in the store.

Duplicate copies are given to the department (section) that receives the equipment.

3. Inventory

- An inventory is a list of items that are kept at a certain place. (Each section of a laboratory keeps an inventory of its non-expendable equipment).
- New equipment issued must be added to the inventory.
- This inventory is used to check stocks of equipment in use, at intervals.

6.3.4. Controlling and Maintaining Equipment

- Expendable equipment needs to be controlled to avoid wastage.
- Non- expendable equipment needs to be maintained, i.e. kept in good working condition.

To control and maintain equipment the following skills are needed.

- To convince staff of the importance of cleaning, keeping equipment in order, inspecting, reporting defects immediately, and returning equipment to its correct place after use.
- To use an inspection checklist and inspection schedule
- To detect discrepancies and explain them

A. Convince staff:

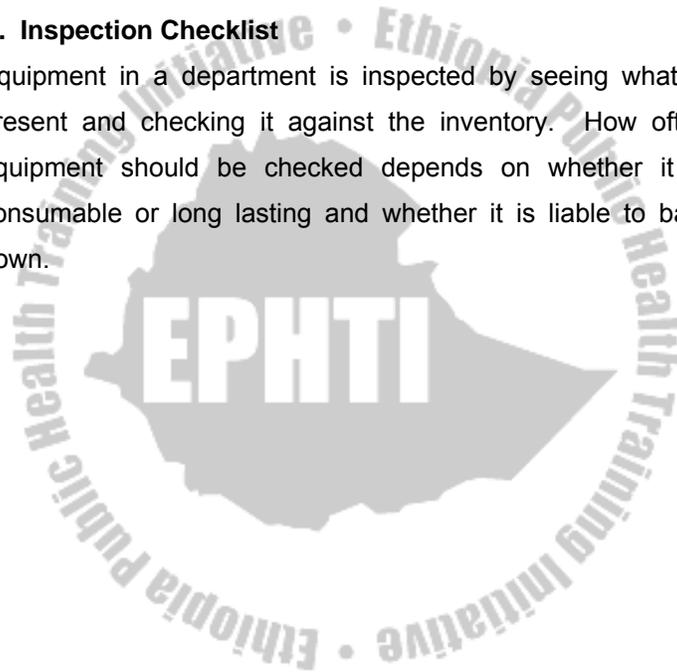
There is no easy way to convince staff of the need to clean equipment and keep it in good condition. The best way is for the supervisor (manager) to set a good example and to emphasize that equipment must be cared for:

- To prevent transmission of infection, e.g. by a dirty or untidy instrument
- To keep it in good condition (dirty or damp equipment deteriorates more rapidly than equipment that is kept clean and dry), and

- To economize:
- One works economically by making the best use of equipment and supplies;
- Well- cared equipment lasts longer;
- Materials used correctly are not wasted.

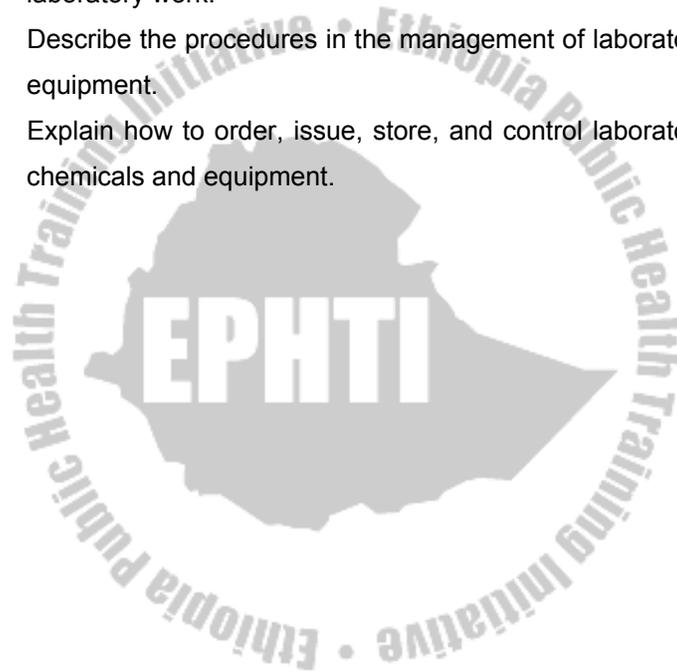
B. Inspection Checklist

Equipment in a department is inspected by seeing what is present and checking it against the inventory. How often equipment should be checked depends on whether it is consumable or long lasting and whether it is liable to bark down.



Review Questions

1. State the difference between a timetable, schedule, programme and roster.
2. Describe how workspace and workflow affect the laboratory work.
3. Describe the procedures in the management of laboratory equipment.
4. Explain how to order, issue, store, and control laboratory chemicals and equipment.



CHAPTER SEVEN

SAFETY IN THE LABORATORY

Learning Objectives

At the end of this chapter, students will be able to:

- Identify the main sources of laboratory hazards and accidents
- Elaborate the elements of lab safety programme
- Describe possible factors that contribute to lab accidents

7.1. Importance of Safety

Quite common hazards and accidents occur in the laboratory. The need and importance of laboratory safety should be the real concern of the laboratory. Laboratory accidents and hazards are controlled by the use of:

- Simple precautions
- Foresight (prudence)
- Safety devices

Above all a 'real concern' or a 'built in concern' or 'safety mindedness' for oneself and the other fellow working at the next bench is very essential.

Laboratory accidents range from minor injury, illness or loss of body parts to death. There are many factors that contribute to laboratory accidents. These include:

- Poorly designed laboratory
- Over crowding of materials
- Poor training
- Lack of concentration
- Noisy and untidy working environment
- Carelessness and neglect
- Overwork and fatigue
- Hot and humid climatic conditions
- Hurrying to finish work on time
- Emergency condition (especially during night hours)

7.2. Source of Laboratory Hazards

1. Physical
2. Chemical
3. Biological

7.2.1. Physical

A. Poorly Designed Laboratory Buildings

Due attention should be given in the design of laboratories. The management, the laboratory personnel and the architecture should be involved in the standard design of the

lab, (for more information, see chapter 3 under safe lab design).

B. Burns

Burns may be caused by:

- Flammable chemicals and stains, or by reagents catching alight.
- Fires from spirit lamps, Bunsen burners, lighted tapers (e.g. when heating Ziehl-Neelsen stain), or from faulty electrical equipment or overloaded circuits. Spirit burners should not be used in direct sunlight because in bright light the flame can be difficult to see.
- Corrosive chemicals being spilt on the skin or ingested when mouth –pipetting.

C. Electric shock

Electric shock can be caused by:

- Faulty electrical circuits.
- Incorrect installation of equipment.
- Touching exposed live wires.

D. Cuts

Cuts may be caused by:

- Breakages.
- Using glassware that is cracked or has damaged edges.
- Walking on glass chippings.

7.2.2. Chemical

A. Toxic harmful chemicals

- Inhaling fumes from toxic chemicals
- Ingesting toxic chemicals by mouth pipetting
- Skin contact

B. Explosive chemicals

Injury from explosions can be caused by:

- Incompatible chemical exploding
- Leaking gas

C. Flammable chemicals causing fire

- Burns

D. Kinds of chemicals

a. Corrosive (strong acids & alkalis)

- Concentrated sulphuric acid
- Nitric acid
- Sodium hydroxide
- Potassium Hydroxide

b. Toxic irritating chemicals-cause death or serious ill health if swallowed, inhaled, and by skin contact.

- Potassium cyanide - Chloroform
- Barium chloride - Sodium azide

c. Flammable chemicals

- Ether - Acetone
- Romanowsky stains - Methanol

d. Explosive chemicals

- Picric acid

e. Carcinogens

- Chemicals that cause cancer through ingestion, inhalation, skin contact
- Proven carcinogen chemicals include benzidin, o-toulidine, and Nitrophenol.
- The risk is proportional to the length of exposure, frequency of exposure, and concentration of the chemical.

7.2.3. Biological

A. Laboratory acquired infections

Infection can be caused by:

- Pathogens being inhaled in aerosols (airborne droplets) when snap-closing specimen containers, dispensing or pipetting infectious fluids, or centrifuging infectious material in open buckets. Aerosols may also be formed and inhaled following breakages or after spilling infectious fluids. Breakages in centrifuges can be particularly hazardous if the centrifuge is opened before the aerosols have settled.
- Pathogen being ingested from contaminated fingers, or in food that has been contaminated, e.g. by being stored in a laboratory refrigerator. Care should be taken to avoid

the fingers or other parts of the body touching infected material. Mouth-pipetting specimens and cultures is one of the commonest ways of ingesting pathogens.

- Pathogens entering the skin through needle punctures, cuts, scratches, insect bites, sores or other open skin lesions. Laboratory workers must always handle infected needles with great care.
- Pathogens can also be acquired from unclean or non-disinfected room floors and walls, water taps and laboratory benches.
- Pathogens are acquired directly through careless contacts with patients or carrier staff through breathing, hand contact, etc.

B. Laboratory animals - are source of a biohazard and they might present physical injury like scratches or infection through inhalation of organisms or by skin contact.

7.3. Safety Measures

7.3.1. Safely Designed and Organized Laboratory

It is clear that a poorly designed laboratory and over crowding can increase the risk of laboratory accidents. It is, therefore, important to know how the laboratory should be designed with regard to safety considerations. The following are some of the

features, for further detail refer safe lab design in chapter three.

- A. Adequate floor, bench and storage space
- B. A floor that is well constructed with a surface that is non-slip, impermeable to liquids, and resistant to those chemicals used in the laboratory.
- C. Walls that are smooth, free from cracks, impermeable to liquids and easily washable.
- D. A door at each end of the lab so that lab staff will not be trapped should a firebreak out.
- E. Adequate ventilation with windows that can be opened.
- F. Sectioning of the laboratory into separate rooms with places for patients, visitors, and reception of specimens.
- G. Bench surface that are without cracks, impervious, washable, and resistant to disinfectants and chemicals.
- H. Suitable storage facilities that include a well ventilated, fire proof, locked store, for the storage of flammable chemicals.
- I. A good supply of gas, water, electric power & wall electric points
- J. Provision of protective safety cabinets, fire extinguishers at accessible points, and adequate waste disposal area, etc.

7.3.2. Safe use of Laboratory Equipment

A. Positioning

- Suitable and ideal place for operation
- Avoid over crowding of a bench with equipment
- Position equipment correctly that requires special facilities like ventilation, shield from sunlight, and great care.

B. Installation

- Should be carried out by the supplier or by the health unit electrician or trained lab equipment technician.
- Important points to consider for safe installation:
 - Ensure that the voltage of the new equipment is the same as that of the electricity supply.
 - Check that the power required by the instrument does not exceed the power supply circuit of the lab.
 - Make sure that the equipment is wired correctly, and the wiring system have grounded conductor.

7.3.3. Safe use of Electrical Equipment

The supplier should demonstrate the use of an apparatus. If this is not possible, the operation and service manual should be carefully studied before the equipment is operated.

Points to consider with regard to the safe use of electrical equipment:

1. Hands should be dry completely, and also the floor on which the operator is standing.
2. The electric supply must be disconnected when performing any maintenance and at the end of the day's work.
3. If a fuse should blow, do not automatically put in a new one until the circuit is checked.

7.3.4. Safe use and Storage of Chemicals and Reagents

Even in the smallest lab, dangerous chemicals are used directly or incorporated into stains and reagents. These include highly flammable chemicals such as ether or methanol, highly corrosive chemicals such as phenol or sulphuric acid, or toxic and harmful chemicals such as formaldehyde solution.

The correct handling and storage of hazardous chemicals is essential to prevent injury and damage. It is particularly important to keep chemicals out of direct sunlight and avoid overheating in chemical stores and the laboratory. Overheating can decompose many chemicals, cause explosions, or the formation of toxic fumes.

Labeling of dangerous chemicals and reagents

To reduce accidents caused by chemicals, many countries have introduced legislation, requiring manufacturers to label dangerous chemicals with hazard symbols and to provide simple safety instructions.

The six accepted danger symbols currently in use are toxic, corrosive, explosive, oxidizing, highly flammable, and harmful or irritant. The safe use and storage of these hazardous chemicals is presented in detail in the lecture note introduction to med lab.

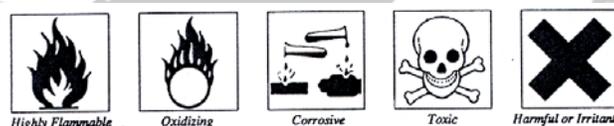


Figure 7.1. Common symbols of hazards

7.4. Preventing Laboratory Infection

All specimens received in the lab should be regarded as potentially pathogenic. For example, a blood specimen sent for measuring hemoglobin may contain highly infectious organisms.

Laboratory acquired infections can be prevented by:

- Practicing personal hygiene

- Wearing of laboratory coat and protective gloves
- Safe handling of specimens and infectious materials.
- Avoiding mouth-pipetting
- Disposing safely of specimens and contaminated material.
- Being immunized against highly infectious pathogens

7.4.1. Practice of Personal Hygiene

This includes:

- Washing of hands and arms with soap and water before and after work
- Wearing protective clothing and gloves whenever possible.
- Covering any cuts, insect bites open sores, or wounds with a water proof adhesive dressing.
- Wearing closed shoes and not walking barefoot.
- Not eating, drinking, chewing gum, smoking or applying cosmetics in any part of the lab.

7.4.2. Safe Handling and Disposal of Specimens

Special precautions should be taken when collecting specimens, especially blood specimens, and when testing specimens and handling infected material.

Safety measures involved are:

- Careful handling and disposal of materials used for collecting specimens.
- Making contaminated materials non-infectious by using appropriate decontamination methods.
- Wearing gloves and a plastic apron when collecting blood suspected of having a highly infectious disease like AIDS.
- Avoid contamination of fingers, other body parts, and working surface.
- Specimens suspected of having hepatitis, viral hemorrhagic fever, and AIDS must be labeled 'HIGH RISK'.

7.4.3. Strict Prohibition of Mouth Pipetting

Pathogens may be ingested during mouth pipetting, either by direct aspiration or from the mouth ends of pipettes which have been contaminated from fingers or benches. Accidents caused by mouth pipetting include infection, poisoning, chemical burns, and other injuries from chemicals. There are many inexpensive and simple ways to measure and dispense safely without mouth pipetting.

7.4.4. Miscellaneous

- Immunization- protective inoculations against certain pathogenic organisms are necessary.

- The use of signs- display suitable safety signs both prohibitive (don't) and commands (do).
- First aid- basic practical training in first aid helps to reduce suffering and consequences of serious accidents.

7.5. Elements of a Laboratory Safety Programme

- A successful laboratory safety programme requires the participation of persons at every level of the laboratory staff.
- Safety does not occur only with the appointment of safety officer or safety committee.
- Safety does not occur by having employees solely perform their assigned duties in manner which they feel is most efficient.
- Laboratory safety requires the full participation of every member of the staff.

7.5.1. Management Responsibility

- Establish a policy relative to the design and implementation of the safety programme.
- Delegate authority for implementing the program
- Provide a safe and healthful work place
- Provide fund for the implementation of the program

- Assess the program- establish a mechanism to ensure safety
- Establish safety committee- regular report, recommendations regarding need for modification of the program.

7.5.2. Safety Officer Responsibility

- Technical advisor to the program
- Assist in the development of safe work method
- Advise management on safety issues
- Assist safety committee
- Provide a variety of communication, e.g. hazard notice, safety data
- Review a variety of plans which include facility designs, special equipment purchase in relation to safety.

7.5.3. Supervisor Responsibility

- Train the staff in lab practices required for safe conduct of work.
- Evaluate regularity of the laboratory facilities, equipment, personnel and work place.
- Correct unsafe condition as fire hazards, physical hazards, and defective equipment.

7.5.4. Employees' Responsibility

- Use of safe equipment
- Report of malfunctioning of equipment
- Report injuries or exposure
- Report hazard or unsafe condition to supervisors



Review Questions

1. What are the possible causes of laboratory accidents?
2. Mention the types and sources of laboratory hazards.
3. Discuss the importance of first aid for laboratory accidents.
4. Describe the elements of laboratory safety programme.
5. What are the merits of planning for safety in minimizing laboratory accidents?



CHAPTER EIGHT

QUALITY ASSURANCE

Learning Objectives

At the end of this chapter, students will be able to:

- Define quality assurance
- State the purpose of QA
- Identify the components of QA

8.1. Introduction

The importance of quality assurance procedures in all phases of health laboratory activities has received increasing emphasis in recent years. Quality assurance program is an indispensable part of modern laboratory. This is certainly true in the laboratory where a multiplicity of tests and constantly expanding volume of work make occasional errors inevitable.

Quality assurance is more than a set of routine procedures. It is also a state of mind and intellectual commitment to meet, and a determined desire to exceed a specified set of performance criteria.

Laboratories practicing quality assurance program improperly, incompletely or erratically, and with out a strong commitment, cannot expect to maintain a satisfactory laboratory result. It is only with a complete QA system you can know where you are and have the right to say so.

8.2. Definition and Purpose of Quality Assurance

Quality assurance has been defined by WHO as the total process whereby the quality of laboratory reports can be guaranteed. It is a set of activities followed starting from specimen collection up to issuing of test results to ensure test results are as accurate and precise as possible.

It is the sum of all the activities in which the laboratory is involved to ensure that test results are of good quality.

It has been summarized as the:

- right result, at the
- right time, on the
- right specimen, from the
- right patient, with result interpretation based on
- correct reference data, and at the
- right price

The purpose of quality assurance (QA) in laboratory practice is to provide test results that are relevant, reliable, timely, interpreted correctly.

A quality assurance program has four separate aspects, namely, internal quality control, external quality assessment, proficiency surveillance, and standardization.

i) Internal Quality Control: also called internal QA, is based on monitoring the test procedures that are performed in the laboratory. It includes measurements on specially prepared materials, and repeated measurements on routine specimens, as well as statistical analysis of, day by day, of data obtained from the tests which have been routinely carried out. Internal quality control is intended to ensure that there is continual evaluation of the reliability of the work of the laboratory and that control is exercised over the release of test results. However, it is primarily a check of precision (i.e. reproducibility) but not necessarily accuracy.

ii) External Quality Assessment: is the objective evaluation by an outside agency of the performance by a number of laboratories on material which is supplied specially for this purpose. This is usually organized on national or regional basis. Analysis of performance is retrospective. The objective is to achieve comparability, but again not necessarily

accuracy unless the specimens have been assayed by a reference laboratory, using methods of known precision, alongside a reference preparation of known value.

iii) Proficiency Surveillance: This implies critical supervision of all aspects of laboratory tests, where as internal quality control and external quality assessment relate only to the actual analysis. Thus, account must be taken of collection, labeling, delivery and storage of specimens before the tests are performed and of reading and reporting of results. Proficiency includes maintenance and control of equipment and apparatus. It is also necessary, for correct interpretation of results, for the laboratory to establish normal reference values that are valid for their test methods and for their local population.

iv) Standardization: This refers to both materials and methods. A material standard or reference preparation is used to calibrate analytic instruments and to assign a quantitative value to calibrators. A reference method is an exactly defined technique which provides sufficiently accurate and precise data for it to be used to assess the validity of other methods.

QA in general includes all those activities both in and outside the laboratory, performance standards, good laboratory practice, and management skills that are required to achieve

and maintain a quality service and provide for continuing improvement.

QA is an essential requirement of health laboratory practice.

Implementing QA requires:

- Preparation and use of Standard Operating Procedures (SOPs) with details of QC for all laboratory tests and activities.
- System for monitoring whether test results are reaching those treating patients at an early enough stage to influence clinical and public health decision making.
- Policies of work, i.e. decisions that are taken in consultation with medical and nursing staff to enable a laboratory to operate reliably, effectively, and in harmony with the other department of a hospital or units of a health center. Such policies should cover:
 - Laboratory hours and arrangements for emergency testing of specimens outside of normal working hours.
 - Range and cost of tests to be performed.
 - Tests which can be referred to a specialist laboratory.
 - Arrangements for the collection and transport of routine and urgent specimens, and their delivery, to the laboratory.
 - Labeling of specimens.
 - Laboratory request form and patient information required.

- Time it takes to perform tests, i.e. target turn around times.
- Reporting of routine and urgent test and delivery of reports.
- Recording and storing of laboratory data.
- Health and safety regulations.

QA has three activities:

1. **Preventive activities:** this helps to prevent error before it occurs by:
 - Method selection- accurate and precise methods
 - Good laboratory design and organization
 - Hiring competent personnel
 - Use of SOPs
 - Effective maintenance program for equipment
2. **Assessment activities:** This is used to maintain the process. Items included are:
 - Testing a QC system
 - Perform instrument function check
 - Participation in external quality assessment schemes
3. **Corrective actions:** This includes all activities performed to correct errors after they occur. It includes:
 - Review of work
 - Trouble shooting of instruments
 - Timely communication with users, etc

8.3. Components of Quality Assurance

Effective quality assurance detects errors at an early stage before they lead to incorrect test results. Laboratory personnel need to be aware of the errors that can occur when collecting specimens (pre-analytical stage), testing specimens (analytical stage), reporting and interpreting test results (post analytical stage).

8.3.1. Pre-analytical QA

This includes all the activities performed before the actual work (examination, analysis) is started. Reagent preparation and dilution is an example of pre-analytical QC. This stage considers different variables that might affect laboratory test results.

Variables:

- Biological
- Technical
- Professional skill
- Environmental factors

Biological: source of variation are wide.

Genetic variation: sickle cell anemia is common among some people in West Africa.

Age related variation: The number of blood cells is higher in infants and small children than adults.

Sex related variation: The Hgb level is higher in males than females under normal physiological condition.

Biorhythm: (periodic change)

Short periodic change- variation within hours or days. Serum iron, for example, increases at noon and decreases in the afternoon.

Long periodic change- variation for long period of time. Cholesterol level, for instance, decreases at a time of ovulation.

Geographic and climatic effects: Hgb is higher at high altitudes.

Nutrition:

- Serum triglyceride concentration increases after heavy fat meal.
- Phosphate and calcium concentration increases after ingestion of milk.
- Urea increases after meat ingestion.

Drinking: Excessive drinking dilutes the substance in blood and lowers its value.

Activity: excessive physical exercise may cause dehydration of body, i.e. low plasma volume.

Technical Influences: These are usually associated with instruments, reagents, and controls.

Professional skill: This is experience or skill of either a performer of lab tests, or user of the laboratory results.

Environmental effects: These are associated with laboratory organization, workload, and working environment.

Essential Components of Analytical Stage

Details of patient and specimen identification
Request specification
Patient preparation
Specimen collection, storage, transportation, and processing
Reagent & control preparation, stability, storage
Instrument testing and calibration
Knowledge of reference values

Sources of error in pre analytical stage

- Incorrect specimen: mistakes in collection, handling, labeling etc.
- Use of wrong preservatives or anticoagulants
- Wrong storage

- Repeated thawing of specimen
- Delay in delivery of specimen
- Incomplete or incorrect patient preparation
- Contamination of specimen by microorganisms or chemicals
- Incorrect preparation of reagents, controls, etc

Patients' misidentification

In health laboratory practice, the misidentification of a patient is mainly the result of:

- Clerical errors or incomplete identification data, e.g. when names are only used with no check of an outpatient or inpatient identification number at the time a specimen is collected.
- Language difficulties when staff do not speak or understand sufficiently the language or dialect spoken by the patient.
- Specimen containers that are incorrectly labeled or when a specimen is misidentified on a ward because it is first collected in an unlabelled container such as a bedpan or sputum pot. Mistakes can also occur when the writing on a label is illegible or part erased
- No reliable check-in system when specimens reach the laboratory to ensure that the patient data on the request form is the same as that written on the label of the specimen container.

8.3.2. Analytical QA

This stage includes those activities employed during performance of test. It is mainly concerned with the control of errors during the actual analysis of materials and also verification of test results. This is mainly effected by the use of laboratory bench manuals which are also called standard operating procedures (SOPs).

Standard Operating Procedures (SOPs)

SOPs sometimes referred to as the local laboratory bench manuals, are required for the following reasons:

- To improve and maintain the quality of lab service to patients and identify problems associated with poor work performance.
- To provide lab staff with written instructions on how to perform tests consistently to an acceptable standard in their laboratory.
- To prevent changes in the performance of tests which may occur when new members of staff are appointed.
- To make clinical and epidemiological interpretation of test results easier by standardizing the procedure
- To provide written standardized techniques for use in the training of laboratory personnel.
- To facilitate the preparation of a list and inventory of essential reagents, chemicals and equipment.
- To promote safe laboratory practice.

SOPs must be:

- Applicable and achievable in the laboratory in which they will be used.
- Clearly written and easy to understand and follow
- Keep up to date using appropriate technique

Preparing SOPs

SOPs must be written and implemented by a qualified experienced lab officer, and followed exactly by all members of the staff. For each SOP it is best to follow a similar format with the information presented under separate headings. The following is a suggested layout for district laboratory SOPs and appendices to be included in the SOP manual.

What to write under headings

Value of test

State the main reason(s) for performing the test, i.e. clinical and/or public health reasons (consult with medical officer(s)).

Example: To detect, identify, and quantify malaria parasites in a person with suspected malaria? (malaria test).

Indicate any relevant limitations of the test.

Principle of test

State briefly the technology used.

Examples: ‘ Microscopical examination of Fields stained thick blood film for malaria parasites (malaria test) or chemical

reagent strip test to detect glucose in urine based on glucose oxidase reaction (urine glucose test).

Specimen

State the specimen required and how to collect it, including:

- Volume required,
- Container and its preparation,
- Use of any anticoagulant or stabilizer/preservative,
- Collection procedure with health and safety notes,
- How container should be labeled,
- Stability of specimen and requirements for storage and transport,
- Time within which the specimen should reach the laboratory.

Describe the checks to be made when specimen and request form reach the laboratory and criteria which may make it necessary to reject the specimen.

State if the specimen requires priority attention (e.g. C.S.F.)

Equipment

List the items of equipment needed to perform the test. Main items of equipment such as a microscope, centrifuge, colorimeter, incubator, water bath/heat block, colony counter, autoclave, shaker, deep freezer, refrigerator, etc should be listed in a separate appendix.

Reagents/stains

List reagents, stains, reagent strips, etc needed to perform the test. Include the reagents and stains in a separate appendix at the back of the SOP manual.

Controls

List controls and source(s) to be used in the test, e.g. positive and negative controls in serological tests, control sera in clinical chemistry assays, positive and negative controls in urine chemical tests, etc.

Method of test

Describe in a numbered sequence how to perform the test. For quantitative tests include details of calibration, use of graph or factor, and calculations. Describe how to control the procedure and also the health and safety measures which apply. Full details of safety procedures should be included in a separate Health and Safety appendix.

Reporting results/interpretation

State how the test should be reported, including:

- Units to be used and format of reported, including:
- Accepted reference range for a quantitative test
- Action to take if a result is seriously abnormal or unexpected, e.g. need for verification, additional testing, and, or immediate notification of the result.

- Give target turn-around time for issuing the report.
- Interpretation comments that should accompany the test result.

Sources of error

Summarize the important and commonest causes of an incorrect test result.

Examples: Sample not well mixed, smear too thick for staining, inaccurate measurement (pipetting) of a blood or serum sample, clots in anticoagulated blood sample, air bubbles in the solution when using a colorimeter or the sides of the cuvette not being clean and dry, etc.

References

List the main source(s) of the information contained in the SOP, e.g. book, journal, published paper, manufacture's leaflet, WHO guidelines or document, etc.

Additional notes

Examples of other procedures and information which are commonly included in a laboratory SOP manual include laboratory work policies covering laboratory operating times, emergency out-of-hours testing arrangements, specimen collection times, arrangements for the delivery of reports, and also procedures relating to the packing and transport of

specimens to the packing and transport of specimens to the public health laboratory or other specialist laboratory.

SOPs must be kept up to date and reviewed at least annually. Any amendments must be authorized, referenced, dated, signed, and brought to the attention of all members of the staff. Users of the laboratory must also receive written amendments to SOPs when these involve changes in the ordering of tests, the collection of specimens and the reporting of tests. No new test should be introduced without an SOP.

Accuracy and Precision

The terms accuracy and precision are used to define the quality of an analysis. Accuracy of a test result is its closeness to the true value.

Precision of a result is its reproducibility. Precision is possible without accuracy, but accuracy is not possible without a certain degree of precision.

A method is said to be repeatable if in a one day run it is capable of giving one specific value again and again for a test sample when the analysis is repeated by the same technician using the same lots of reagents and the same instruments.

A method is said to be reproducible if it is capable of producing the same result when the test on one sample is

repeated on different days by different technicians using different sets of reagents. It is possible that a method is repeatable but not reproducible. Reproducible methods, on the other hand, are always repeatable. The requirement for precision is reproducibility and not repeatability alone.

When the same test result is obtained on two or three repeated analysis of a sample, one might think that the value is accurate. However, one can only say that the repeatability of such an analysis is good, and nothing more. The value may or may not be accurate. The test result may be far from the true value. Even the precision may be poor. However, if accurate results are obtained again and again in an analysis, precision is achieved automatically.

A good example of accuracy and precision can be observed during a visit to a shooting gallery as follows. A new member of the club shoots his first 10 bullets, none of which hits the bull's-eye. The bullets hit all over the target, as shown in figure A below. His shots are neither accurate nor precise. The second member shoots 10 bullets. None of them hits the bull's-eye. However, he hits the bottom corner consistently as shown in B. His shots are precise but not accurate. In fact he is trying out a new rifle and probably needs a little more practice in using it. It is also possible that there is something wrong with the rifle; its barrel might be crooked. A third

member of the club also shoots 10 bullets. All of them hit right on the bull's eye, as shown in C. He is an experienced shooter and knows what he is doing. His shots are both precise and accurate.

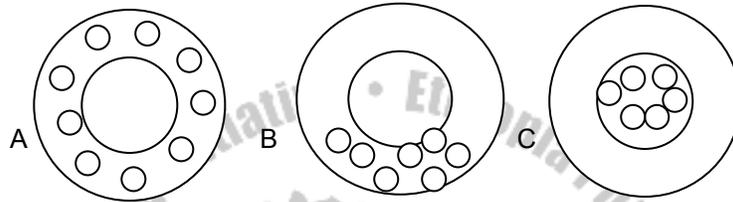


Figure 8.1. Precision and accuracy of target shooting

A= shots are neither accurate nor precise

B= shots are precise but not accurate

C= shots are both precise and accurate

Like the performance of the marksmen, an analysis can be (1) neither accurate nor precise, (2) precise but not accurate, or (3) both accurate and precise.

Calculating precision

Precision in a quantitative analysis is expressed in terms of standard deviation. When multiple samples are involved, all samples are analyzed in duplicates. If $d_1, d_2, d_3, \dots, d_n$ are the differences between the results of duplicate analysis of samples 1, 2, 3, ...n, then:

$$SD = \frac{\sum d^2}{2n}$$

Where: Σd^2 = Summation of the square of the difference between duplicate measurements.
 $= d_1^2 + d_2^2 + d_3^2 + \dots + d_n^2$
n = Number of samples
2n = Number of analysis

Reliable test results depend on lab staff keeping errors of imprecision and inaccuracy to a minimum by good laboratory practice and quality control. Consistently, reliable results depend on the early detection and correction of errors.

Errors of imprecision: Errors of imprecision is often referred to as errors of scatter because they are irregular or random. Results differ from the correct result by varying amounts.

Common causes of imprecision

The following are the commonest causes of inconsistent random errors:

- Incorrect and variable pipetting and dispensing caused when:
- pipetting and dispensing techniques are poor due to inadequate training, no supervision of trainees, or careless working.
- pipettes with chipped ends or unclear markings are used.
- pipette fillers are difficult to use

- Automatic pipettes and dispensers are not used correctly or pipette tips are not adequately cleaned and dried before reuse.
 - Inadequate mixing of sample with reagents.
 - Samples are not incubated consistently where incubation of tests is required.
 - Glassware or plastic ware is not clean or dried completely before reuse.
 - Equipment malfunction caused when:
- Laboratory staffs are not trained in the correct use and maintenance of equipment
- Instrument readings fluctuate due to unstable power supplies and the equipment is not fitted with a voltage stabilizer.
- Dirty or finger-marked cuvettes are used in colorimeters or the sample contains air bubbles.
- In hot humid climates, the glass surfaces of lenses and filters become damaged when not protected from fungal growth.
- Battery operated equipment performs erratically because the battery is not sufficiently charged.
 - Incomplete removal of interfering substances such as red cells when performing serum assays.
 - Laboratory staff prepares a smear that is too thick for direct microscopic examination or subsequent staining.

- Incorrect reporting of microscopic preparations and lack of standardization in reporting.

Errors of inaccuracy: These are often referred to as errors of bias, because they are consistent or regular (systematic). All the test results differ from their correct result by approximately the same amount.

Common causes of inaccuracy

The following are the commonest causes of consistent systematic errors:

- Incorrect or infrequent calibration of a test method or quantitative tests being read at an incorrect wavelength (incorrect filter used)
- Using an automatic pipette set at an incorrect volume or one that has been calibrated wrongly
- Reagent incorrectly prepared and stored, or used beyond its expiry date.
- Consistent calculation error.
- Incubating samples at an incorrect temperature due to the temperature of a water bath or heat block being wrongly set and not checked.
- Use of unsatisfactory reagents caused when:
 - chemical reagents and stains are not prepared correctly according to SOPs

- the quality of water used in the preparation of reagents is unsuitable.
- reagents are not prepared from sufficiently pure chemicals.
- new batches of reagents are not tested prior to being used and no controls are used to check the performance of working reagents.
- temperature sensitive reagents deteriorate because they are not stored at the correct temperature, are frequently removed from the refrigerator into a hot environment, or the refrigerator stops working due to a power failure or running out of gas or kerosene.
- a reagent becomes contaminated when a dirty or wet pipette is used
- light sensitive reagents become unfit for use because they are not stored in opaque containers and protected from light.
- dry moisture-sensitive reagents and strip tests deteriorate due to their frequent use in conditions of high relative humidity, or when the container is not tightly closed after used and no desiccant is used in the cap.
- stains are used without controls, are not filtered when indicated, or absorb moisture and become unfit for use, e.g. alcoholic Romanowsky stock stains.
- Staff negligence and/or technical incompetence

8.3.3. Post Analytical QA

This includes calculation, recording, reporting, and verification of test result, taking appropriate action whenever a result has serious clinical implication; ensuring test results are interpreted correctly.

Calculation may involve plotting of a graph like in clinical chemistry, or arithmetic calculation which is subjected to personal error that might come from wrong conversion factors, standards, control etc.

Records of laboratory results can be kept by:

- Retaining carbon copies of reports
- Recording on registration book
- Inserting data in computer.

Whatever system is used, it must:

- Contain patient identification and some related data,
- Be reliable and enable patient results to be found simply and quickly,
- Contain QC results
- Recording is required for:
 - Preparation of work reports (monthly, quarterly, yearly)
 - Epidemiological studies (retrospective)
 - Estimating budget and workload of the lab
 - Assessing daily QC information

Reporting test result

Laboratory test results should be reported accurately and clearly for the following reasons:

- To provide relevant information as possible to assist those requesting tests are able to interpret results correctly.
- To help information provided from the lab are used in the best possible way to benefit patients and community.

Laboratory result must include the following important items.

1. Type of specimen analyzed
2. Analyte or substance measured
3. Clearly written test results
4. Reference ranges for quantitative tests
5. Authorized signature

Reviewing transcriptional errors

Transcriptional or clerical errors are errors made during transfer of information from read out to work sheet and also from work sheet to the record/report format. These types of errors are probably major errors that occur in the lab.

There are two possible mechanisms to recheck results at this step:

1. Have a second technologist read the results from the instrument, work sheet, or computer to another technologist who will check the final result,

2. Have a supervisor check all results at the end of the day before releasing the results from the lab. Ideally both systems should be instituted.



Review Questions

1. Define quality assurance and elaborate its purpose.
2. What are the steps in quality assurance?
3. State the relationship between QA and QC.



CHAPTER NINE

QUALITY CONTROL

Learning Objectives

Upon the completion of this chapter, students will be able to:

- Define quality control
- Explain the types of quality control
- Know how to calculate and interpret specificity, sensitivity, PPV, NPV

9.1. Definition

The term quality control covers that part of quality assurance, which primarily concerns the control of errors in the performance of tests and verification of test results. QC must be practical, achievable, affordable, and above all continuous. It refers to operational procedures and the activities needed to maintain the quality of results. Quality control involves the use of a variety of methods or techniques to reduce variance in analytical procedures.

Quality control system ensures that results fall within certain limits. Use of either of the limits is dependent on:

- Lab facility- instrument, infrastructure
- Training /experience of lab personnel
- Quality of reagents and other materials

Purpose

1. Monitoring analytical process
2. Monitoring analytical errors, and
3. Correct results of analysis

9.2. Types of QC

Quality control is one of the elements of QA. It is of two types:

1. **Internal quality control** - intra-laboratory QC. This is a quality control program which is carried out in the lab. It encompasses all measures taken and technical performances within an individual laboratory. It is mainly based on the use of control samples like pooled serum prepared for such purpose.

Purpose: To ensure tests are performed reliably and reported correctly.

Effective QC system detects error at an early stage before they lead to incorrect test results. Laboratory personnel need to be aware of the errors that can occur when collecting and

processing specimens, testing specimens, and reporting test results.

Both lab staff and clinicians should realize that QA being their mutual responsibility that can not be achieved by improving and controlling the analytical process without parallel improvement and control of pre and post analytical procedures. For the analytical part of QA program, it should be emphasized that the application of good lab practice is an essential element without which no improvement can be achieved.

2. External QC (inter laboratory QC)

This has very similar application with external quality assessment scheme and is commonly abbreviated EQA. This involves observation of variance in results when the same material is analyzed in different laboratories.

Two principal forms are available:

- I) **Survey program (proficiency survey)**- is very identical with EQA and involves very large number of laboratories (international, continental, national, regional).
- II) **Regional QC**- involves laboratories in a specific locality or specific geographic area.

In the day-to-day activity of clinical laboratories, QC is appraisal of performance within a laboratory by means of

reference preparation, or control material and use of statistical methods.

Controls

Controls are used for different purposes:

1. Expected values are known by the analyst: this helps to know whether analytical system is reliable or not.
2. Expected value is unknown by the analyst: this is important to obtain independent assessment of all the procedures performed in the lab and also to assess the quality of the analyst. Example of this type of control is commercial controls (value is intentionally hidden for quality control purpose), specimens diluted with certain known additives.

External Quality Assessment (EQA)

Although steps are taken in a laboratory to ensure test results are reliable, a system of assessing a laboratory's ability to do this to a satisfactory standard is recommended, i.e. an external quality assessment (EQA) scheme. EQA must never be a substitute for internal QC because it can only assess past performance when test results have already been reported and acted on.

It is a system of evaluating a lab ability to produce reliable results to a satisfactory standard from an outside laboratory.

The aims of EQA is to:

- identify problems
- eliminate (minimize) errors
- identify best practice
- maintain and rise standards of lab practices.

and not to:

- make laboratories compete with each other
- punish poor laboratories

9.3. Assessing Value of Tests

Value of a test method usually depends upon various characteristics. Among these are:

- The need in the specific testing condition
- Characteristics of tests i.e. precision, accuracy, sensitivity, specificity
- The expertise of the lab personnel
- Optimal condition in the lab.

Ability of diagnostic tests to indicate presence or absence of disease

The ability of a diagnostic test to indicate when a disease is present or absent is dependent on its quality and is described in terms of:

- Sensitivity
- Specificity
- Predictive value

Sensitivity (true positive rate)

This is the frequency of positive test results in patients with a particular disease, i.e. a measure of the ability of a test to detect truly infected individuals. It is also called indicator of true positive rate.

It is the proportion of subjects correctly identified as having the disease in question.

$$\begin{aligned}\text{Sensitivity} &= \frac{\text{Total number of positives}}{\text{Total number of infected individuals}} \times 100 \\ &= \frac{TP}{TP + FN} \times 100\end{aligned}$$

The higher the sensitivity of a test, the less likely it is to fail to diagnose a person as having the disease, i.e. the fewer the number of false negative results.

Analytical sensitivity is the ability of the test to detect a small amount of the analyte.

Specificity: is the measure of the ability of a test or assay system to identify all non-infected individuals correctly. This is the frequency of subjects correctly classified as not having the disease in question. It is an indicator of a true negative rate. A 98% specificity implies 2% false positives. The higher the

specificity of a test, the less likely it is to diagnose a person who does not have the disease as having it. i.e. the fewer the number of false positive results

$$\text{Specificity} = \frac{\text{Total number of negative result}}{\text{Total number of uninfected individuals}} \times 100$$

$$= \frac{TN}{TN + FP} \times 100$$

Analytical specificity: is the ability of a test to determine only the substance or analyte under investigation.

Test efficiency (TE or E)

This refers to the overall ability of the test to correctly identify positives from negatives (implies absence of false positives and false negatives).

It is a combination of both sensitivity and specificity, and determines the total effectiveness of a test method.

$$\text{Test efficiency} = \frac{TP + TN}{TP + FN + TN + FP} \times 100$$

Test efficiency, specificity, and sensitivity are not affected by prevalence of disease in a given population. Using a 2X2 table, the sensitivity, specificity and efficiency of a test can be shown as follows.

Disease (gold standard)

		Pos	Neg
Test	Pos	a	b
	Neg	c	d
		a+c	b+d

a = True positives

b = False positives

c = False negatives

d = True negatives

How many "diseased" detected? Sensitivity = $\frac{a}{a+c}$

How many healthy detected? Specificity = $\frac{d}{b+d}$

How many correctly identified? Test efficiency = $\frac{a+d}{a+b+c+d=N}$

Predictive values (PV)

Predictive values are important diagnostically as they give the probability that an abnormal result comes from someone with disease. The higher the predictive value of a test, the higher the possibility in any population that a positive test means disease.

Positive predictive value (PPV)

The proportion infected individuals among all persons with positive result. It is a proportion of positive results that are true positive.

$$\text{PPV} = \frac{\text{True positive}}{\text{TP} + \text{FP}} \times 100$$

The positive predictive value of a test for a disease will increase both with the sensitivity of the test and the prevalence of the disease. To be useful, a test's predictive value must be greater than the prevalence of the disease.

Negative predictive value (NPV)

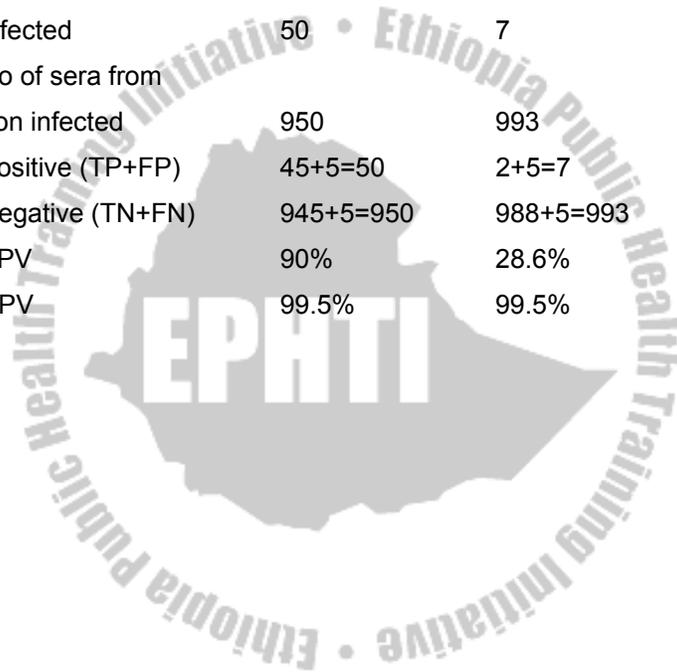
This is the frequency of uninfected individuals among all persons with negative result. It is the proportion of negative results that are true negative.

$$\text{NPV} = \frac{\text{TN}}{\text{TN} + \text{FN}} \times 100$$

Predictive values are affected by prevalence of infection in a tested population unlike sensitivity, specificity, and test efficiency. If a disease has a low prevalence in a population being tested, there will be a higher number of false positive results due to the higher proportion of persons without the disease, and therefore, a positive result has a lower predictive value as shown in the example below.

Example showing that predictive values are affected by prevalence of a disease.

	<u>Population 1</u>	<u>Population 2</u>
Prevalence	5%	0.7%
Sera tested	1000	1000
No of sera from infected	50	7
No of sera from non infected	950	993
Positive (TP+FP)	45+5=50	2+5=7
Negative (TN+FN)	945+5=950	988+5=993
PPV	90%	28.6%
NPV	99.5%	99.5%



Exercise 1.

A female student is interested in determining whether or not she should panic about the positive result she received when performing a home pregnancy test. To answer her question, she finds the following data on the accuracy of the pregnancy test she used when performed on 1,000 college age women.

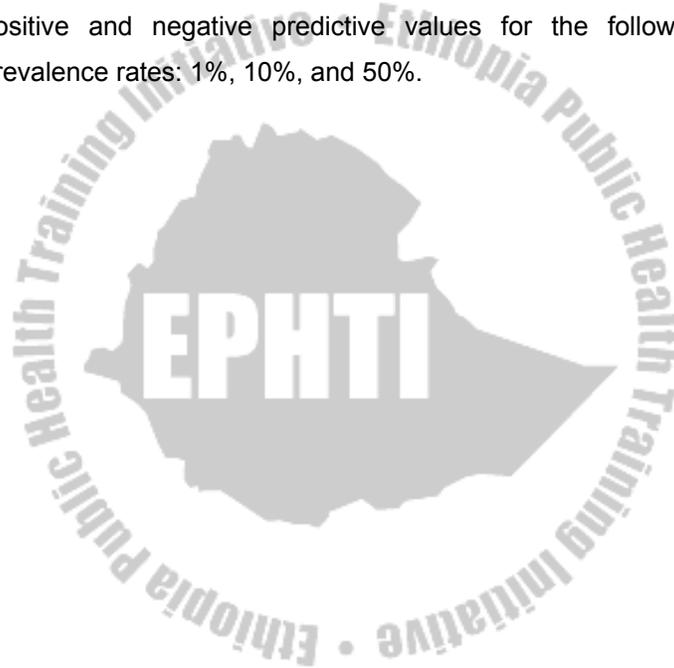
Test result	True status		
	Pregnant	Not pregnant	
Positive	48	38	86
Negative	2	912	914
	50	950	1000

1. What percentage of the women in the sample of 1,000 women were pregnant?
2. What percentage of the women in the sample of 1000 women tested positive?
3. Given a woman s pregnant, what is the probability that she gets a positive pregnancy test?
4. What is the specificity of the test?
5. Given a woman is not pregnant, what is the probability that she is truly pregnant?
6. Given a woman receives a positive pregnancy test, what is the probability that she is truly pregnant?
7. Based on your above answers, argue one way or the other as to whether the student should or should not

panic? Can you recommend the next step she should take?

Exercise 2

You have a test with a sensitivity of 90% and a specificity of 92%. Testing a population of 1000 persons, calculate the positive and negative predictive values for the following prevalence rates: 1%, 10%, and 50%.



Glossary

Definition of Terms

Controlling: The process of ensuring that actual activities conform to planned activities.

Effectiveness: The ability to determine appropriate objectives: “doing the right thing”.

Efficiency: The ability to minimize the use of resources in achieving organizational objectives: “doing things right”.

Figurehead: Ceremonial or symbolic representative.

Goal: The purpose that an organization strives to achieve.

Leading: The process of directing and influencing the task related activities of group members or an entire organization.

Liaison: A connection or link between organizations.

Management: The process of planning, organizing, leading, and controlling the work of organization members and of using all available organizational resources to reach stated organizational goals.

Manager: People responsible for directing the efforts aimed at helping organizations achieve their goals.

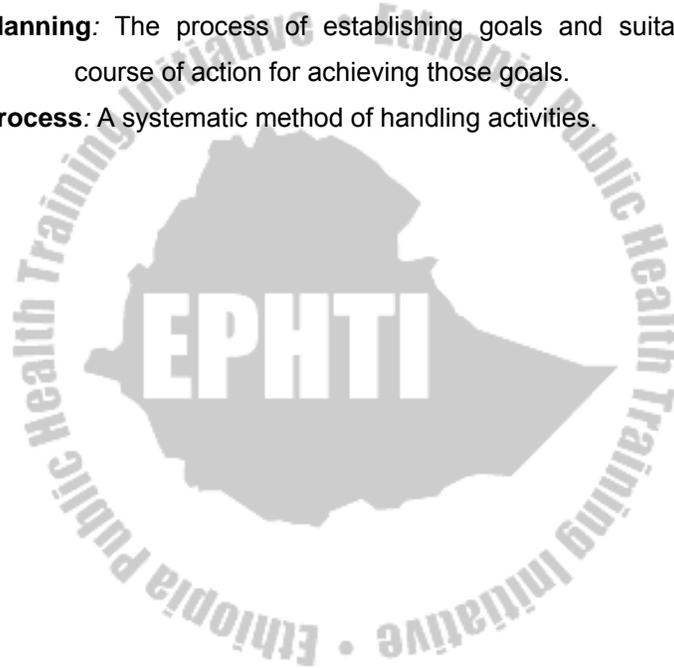
Monitor: To supervise and check systematically that activities are going as expected.

Organization: Two or more people who work together in a structured way to achieve a specific goal or set of goals.

Organizing: The process of engaging two or more people in working together in a structured way to achieve a specific goal or set of goals.

Planning: The process of establishing goals and suitable course of action for achieving those goals.

Process: A systematic method of handling activities.



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