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APPROPRIATE TECHNOLOGY - MANAGEMENT, COMMUNICATION AND EVALUATION

by

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1. Introduction

The past two decades have witnessed many important advances in the clinical laboratory sciences, and there have been corresponding increases in the workloads of health laboratories. New techniques and costly apparatus have been, and continue to be, introduced, often without proper assessment of the relevant cost benefit factors. There is therefore an urgent need to determine the degree of inappropriate use of laboratory investigations and to seek to ensure the optimal use of laboratory technology as it is developed and applied in practice.

At present more than 500 types of test are routinely carried out in approximately 65000 European health care laboratories, a wide variety of assay principles and techniques being used. The total number of analyses performed corresponds to about 10 per inhabitant per year.

2. Appropriate laboratory technology

The world market is constantly being flooded with generations of laboratory equipment of various types for use at all levels of health care. An indiscriminate application of the total range of available technologies to the health care system at all levels is not possible even for the most affluent and industrialized countries. It becomes necessary to identify and select a reasonable range of techniques and appropriate types of instruments adapted to the needs of every community, in order to attain the planned health goals.

It is evident that any necessary containment of sophisticated technology does not imply the hampering of natural technological development, but rather a continuing stimulation of creativity and adaptation in a rational and economic context, associated with a proper assessment before general use.

Appropriate laboratory technology must be planned, implemented, managed, evaluated and readjusted whenever necessary. During the planning stage it is essential to obtain a series of data which include mainly the factual organization of the health care system in the area to be served by the laboratory service together with demographic, geographic, environmental and socioeconomic information. Any technical service incorporated in a comprehensive health service has to balance supply against needs and in an ideal society the two may conceivably be equal. Concepts of health, however, and even more so, concepts of health services are relative and are influenced by traditions, culture, expectations, economy and other factors.

Therefore a constantly shifting and dynamic relationship: NEEDS ⇌ MEANS in the laboratory services is to be expected. Appropriate technology criteria, such as assessment, rationality, acceptance and use, can be used to monitor needs and supplies and thus introduce corrective measures for improvement of the services.

After the necessary type of service, buildings, equipment and personnel (which will not be dealt with in this paper) have been determined, and their availability and logistic support confirmed, implementation could start. At this stage three vitally important aspects must be ensured, an overall managerial skill for effectiveness, rationality and definition of responsibility, an adequate organization of communication lines between the laboratory services and the various consumers and a continuing evaluation of the service as a whole.

3. Assessment of laboratory technologies

Assessment in its widest sense includes evaluation for efficacy but also clinical relevance, acceptance and proper utilization by consumers. There is no shortage of definitions for efficacy. WHO had defined it as "the benefit or utility to the individual of the service advocated or applied". The definition used by the USA Office of Technology assessment may be more pertinent: "The probability of benefit to individuals in a defined population from a medical technology applied for a given medical problem under ideal conditions of use. It is clear that in this definition many factors are highlighted indicating the complexity of the efficacy assessment. We have a population with all its local characteristics which appears to have a health problem, solving of which necessitates a technology under certain conditions of use or misuse where definite costs are involved and where a benefit is to be achieved. The management can decide about the population to be served in the light of its real needs and about the most rational technology, assisted by expert technical advice. It is more difficult to assess the degree of use or misuse and the real benefits obtained. In the latter, it is not simply a question of measurement of mortality or morbidity but one should also consider that the action based on the use of the technology has prevented late effects, rehabilitation, and secondary consequences in the family and community, as well as retained productivity of the affected person or persons.

The performance of a laboratory instrument is governed by the quality of both the hardware and the human operator component, the latter being involved in several activities such as sample taking, preparation, monitoring and interpretation. Thus reliability of results depend on the technical capability and accuracy of the device and similarly in the conscientiousness of the different persons engaged in the handling of the sample. While the human factor is a technico-managerial question, the instrument has to be assessed whether it is appropriate for the task required. The testing of instrument performance is at present rather limited, the main reason being the absence of international recommendations for evaluation. The necessity for coordinating all attempts is universally recognized and would avoid unnecessary duplication of work, use an optimum of expert and financial resources, provide valuable information to potential users and ensure more comparable results. Due to the extensive availability of instruments and the rapid introduction of new ones, certain guiding principles for priority testing should be developed at international and national levels.

With regard to new machines, those which are likely to have a considerable volume impact should be selected for assessment especially if a new technology is involved, an improved performance expected or possessing other advantages such as economy, presentation, reliability, speed or precision. Machines in use have generally already known features, even if they were not evaluated by protocols. These protocols have to be adapted to every type of instrument following a general outline: safety, precision, accuracy, reagent needs, in-built quality control, speed, cost and maintenance. The evaluation must be carried out with financial independance of the testing laboratory from the supplier and the testing may need several types of laboratory such as a physical and a clinical one.

A particular area where urgent evaluation action is needed is the question of kits and rapid methods. While there is no doubt that kits can provide valuable and quick information, it will have to be defined what personnel should use them, under what conditions and how conventional laboratory methods should be used for confirmation.

The neutral nature of the selected testing centres would ensure that objective, non-biased and complete information is made available to prospective consumers. This information can be collated and diffused by international centres which may eventually lead to a more harmonized use of equipment and a better comparability of laboratory results.

A scheme for the purely technical assessment or evaluation of laboratory equipment is given in Figure 1.

4. Management

Management systems in health laboratory services vary in size, structure, scope and function according to the organizational and clinical settings. These systems should be capable of responding speedily and constructively to new developments in science, medicine and technology, and to governmental or social pressures. Technical and managerial criteria very often overlap and are therefore difficult to identify as separate compartments.

As any type of laboratory develops and grows, its internal structure as well as its external relations become more complex, and highly organized so that it is necessary to expend more energy on maintaining its working environment. Managerial skills are therefore of great importance for rational and economic solutions of laboratory problems. While a laboratory scientist may know how to estimate a blood urea by 3 different methods, he may not know the best way of estimating 30 blood ureas a day for 52 weeks a year or 50 on one day and 10 on the next.

Management has to deal with:

- a clear established chain of duties and responsibilities, laboratory technician - senior technician - unit medical officer or scientist-laboratory chief;
- adequate written instructions: methodology, maintenance of equipment, safety;
- proper training and supervision of personnel;
- perfect maintenance and availability of records.

This managerial approach is three dimensional:

- Axis of needs: importance and priorities;
- Axis of means: economics, logistics, manpower;
- Axis of function: frequency of test, implementation.

Apart from mechanization and automation it is often cheaper to introduce work simplification which consists of studying the working scheme, identifying problem areas, assembling the facts and analysing them, trying new solutions and evaluating the results. This may reach as far as reorganizing departments, changing communication lines, reshaping buildings and reassigning duties.

In the complex structure of a health laboratory network, where delicate measurements and highly technical interpretations are constantly performed, it is important to define the hierarchy of responsibility. Therefore a detailed post description and duty assignment must be prepared by the management. This is further strengthened by technical guidelines and instructions.

Laboratory services also need extensive administrative and logistic support. The laboratory scientist should be relieved of administrative procedures by competent administrators, and should have access to economists. It is also important that legal and ethical aspects be kept in mind as the laboratory may be involved for example in prevention and control of hospital acquired infections, alcohol and drug level determination, and disputed parenthood.

5. Communication

A good communications system is vital to efficacy, effectiveness and efficiency of a laboratory service. This would include intra- and extra-laboratory communications. Various systems are currently functioning and every laboratory must choose the one suitable to its needs, means and functions. It must always work in a multidirectional way as the laboratory is a centre of information and it is often forgotten that it should not only give information but also receive it. Figure 2 shows the place of management and communication in a health laboratory setting.

The main lines of communications to be considered include the national laboratory network, the local hospital or primary health care system, the public health and other authorities concerned, supply channels, maintenance centres, referral levels and reference and documentation services.

6. Evaluation

The evaluation of a national laboratory service is a continuous and dynamic process and aims at measuring the degree of realization of the objectives as well as the quality of the results. Evaluation procedures generally pass through several phases which may be consecutive or concurrent. The first phase considers the human and material resources involved, as well as the methodology and the coverage of the population benefiting from the activity. The second phase envisages to determine the costs of the action and the third tries to establish the results obtained on a more or less long-term basis. Laboratory services are providing support to all health care activities and should therefore be evaluated in the context of the entire health care system. As the current working conditions greatly affect the efficiency of any laboratory, certain prerequisites must be considered, the most important being: a realistic planning, an architecture adapted to geographic and climatic conditions, a selection and assessment of equipment, a balanced staffing, a well organized laboratory safety system, the provision of complete work-books and guidelines for all laboratory procedures, adequate and accessible records and filing systems, reasonable storage facilities or in short: an experienced and rational management.

For the specific aspects of laboratory services evaluation it will be necessary to obtain information on the workload, procedures whether manual, mechanized or automated, hierarchy and responsibilities, training facilities, reports, laboratory errors, credibility, clinical relevance of the tests offered and the utilization of the results by the consumers. Evaluation programmes should be planned according to laboratory disciplines and could follow various approaches according to the available means. The simplest procedure would consist in regular examination of reports complemented by periodic supervision visits. Other evaluation procedures include the following:

- Patient data surveys based on the critical examination of a consecutive number of particular tests in relation to clinical conditions.

- On-the-spot control, where a supervising team visits the laboratory, hands out unknown specimens and controls equipments, manipulations and results. This activity is often reinforced by the presence of a maintenance and training team which will remedy any shortcomings.

- Quality assessment; it has two components:

  (a) external quality assessment, which is a system for objective checking of laboratory performance by an external agency, and

  (b) internal quality control, which is a set of procedures used by the staff of a laboratory for continuously assessing results as they are produced, in order to decide whether they are reliable enough to be released.

- Extra-laboratory inquiry based on a questionnaire sent to the laboratory consumers and assessing the credibility of the results and the satisfaction of the users.

FIG. 2. MANAGEMENT, COMMUNICATION AND EVALUATION IN HEALTH LABORATORIES

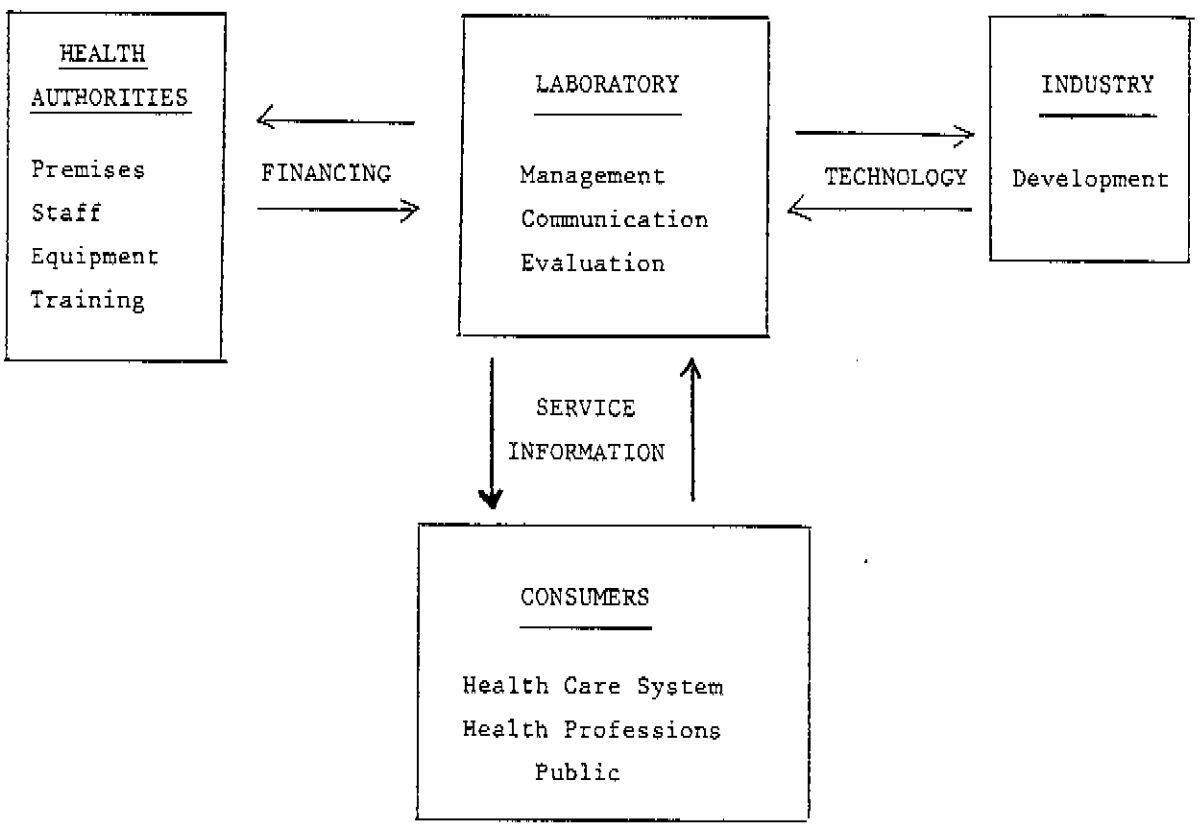


FIG. 1. LABORATORY EQUIPMENT CHOICE,
EVALUATION AND DECISION FLOW CHART

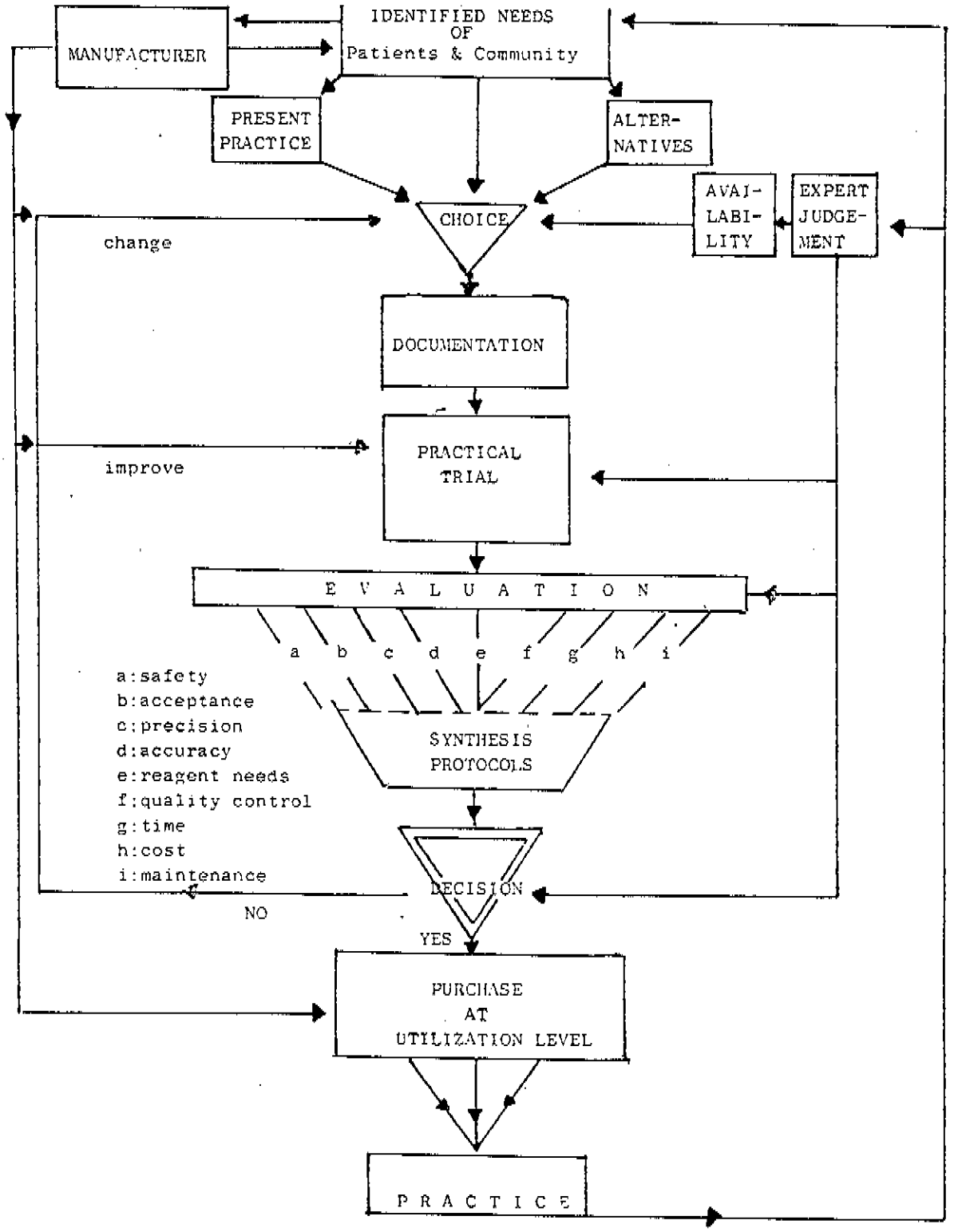
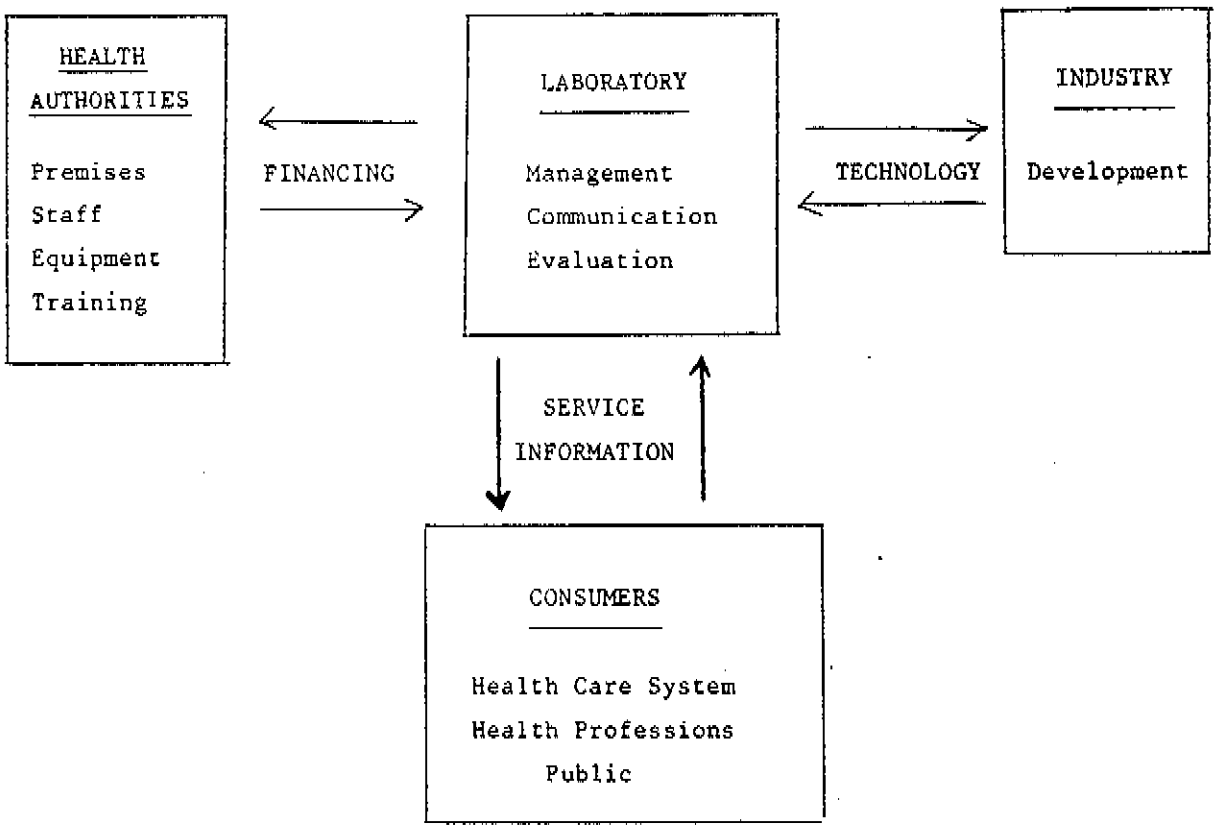


FIG. 2 MANAGEMENT, COMMUNICATION AND EVALUATION IN HEALTH LABORATORIES



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