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INSTRUMENTS FOR DEVELOPING COUNTRIES AND FOR OPERATION IN DIFFICULT CIRCUMSTANCES

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Abstract - Developing countries have, over recent years, achieved considerable success in the training of medical doctors but this progress has not been matched by similar development of laboratory facilities, a lack of which now seriously affects the overall delivery of health care. The special requirements for instruments and systems need careful attention, and maintenance is a serious problem since in some countries sixty per cent of the installed equipment is broken down. Rugged simple-to-operate instruments are required for peripheral laboratories and a special approach is necessary to produce special rugged automatic systems for the central hospitals.

INTRODUCTION - F.L. Mitchell

There are many aspects of laboratory medicine which must inevitably differ with circumstances in different countries but all too frequently it has been assumed that systems and organisations designed to answer the problems of the developed countries are immediately applicable to all developing nations. The fallacy of this is evident on any visit in depth to any such country. There is often a centre of excellence to which foreign visitors are attracted, where medicine, possibly second to none, is carried out in air-conditioned comfort for the fortunate few thousand local inhibitants, but conditions elsewhere can be very different for hundreds of millions of others.

Developing countries have, over recent years, achieved considerable success in the training of medical doctors, but unfortunately similar progress in developing suitable laboratory facilities has been lacking. The consequence is serious limitation of the availability sometimes even of quite basic medicine.

Automatic chemistry as generally understood in developed countries has little place in the health care of the developing world. The workloads in rural areas do not justify the use of large complex analysers and usually there are not the necessary technological support facilities, suitable (if any) power supplies or favourable economic and climatic conditions. Equipment is almost entirely designed for, and made in, developed countries, and its application elsewhere is often at best unsatisfactory and at worst disastrous (1,2,3,4).

The designing of appropriate equipment needs very different criteria to be taken into account from those applied to instruments for use in the circumstances generally accepted for the developed world. For example, it was agreed with The World Health Organisation (WHO) that the specification for a suitable colorimeter should include an ability to operate: in conditions of high and low ambient temperatures, high humidity and desert dust storms, off an integral battery for several years, with reliability of function and minimum maintenance for 5-10 years, in reasonable working conditions after a fall from bench height onto a concrete floor, by persons with limited technical education and above all, the cost should be such as to be acceptable to the poorest countries. The meeting of such criteria requires much ingenuity and skill.

The inclusion, in a congress on laboratory automation, of the type of instruments required, may not at first seem appropriate, but the interpretation of "automation" must inevitably be modified for different situations and in those presently under consideration, any mechanical or electronic aid applied in an endeavour to meet criteria such as above might, for the purposes of this discourse be agreed as coming into the spirit if not the de facto title of the Congress.

Experience in attempting to develop suitable instruments and equipment has indicated two interesting aspects:

first the application of such items is by no means limited to developing countries, but in the developed world there are many occasions where the above criteria fit with remarkable coincidence; for example in geographically isolated communities, when chemical assays are required in special circumstances (haemoglobin assay by teams collecting blood for transfusion, veterinary surgeons treating animals in the field) or in a country such as West Germany where pathological measurements are done on a relatively small scale in over 30,000 general practitioner surgeries;

secondly, industry has little interest in supplying the market, let alone allocating scarce and expensive research facilities to develop the necessary designs. Low cost instruments sold in difficult markets, even in large numbers, do not make good profits. This difficulty may soon be overcome however with the trend in sophisticated societies for laboratory assays and tests to be devolved from central laboratories and carried out nearer the patient by relatively scientifically untrained staff. This change requires a similar approach towards instrumentation to that referred to above except that the market is easier and the profits have a chance of being higher, but sadly, the potential customers can stand high prices and there is little stimulus to bring down the all important cost factor.

Curiously, the organisers of clinical laboratory services in developing countries can be divided clearly into two groups - those who demand western style instruments in their full glory and do not see why they should not be made to function under all conditions; and those who appreciate that the best approach to the WHO slogan "Health for all by the year 2000", is to endeavour initially to provide as far as possible, limited facilities for the whole population of a country, building up as occasion permits. The first group appear to ignore that even if Western instruments could be universally applied, their cost alone would limit their application to a favoured very few.

The correct approach must lie somewhere between the two, with the accent heavily on the latter. Most countries must have a prestige centre forming a pinnacle under and from which the major part of the health service functions. Such a centre or centres need robust, relatively basic automation, and since the circumstances might be expected to provide a reasonably good electricity supply, technological backup and good atmospheric conditions, certain Western systems may be applicable, provided reasonable reliability and availability of spares is assured.

For the peripheral services, the reasoning given previously applies. Some have said that all that are required are re-vamped versions of the robust, simple items of equipment which were familiar in Western laboratories thirty years ago. Such statements are counter productive and play into the hands of the ivory tower protagonists (why should we have Western castoffs?). Special circumstances demand special designs and modern technology can provide all the necessary answers; it has been appreciated for example that the requirements for an instrument to operate fault free for years in the hostile environment of outer space, with no external electrical supply, etc., are not very different from those needed in the central African bush. If modern technology is applied to cover the special requirements of the African bush just as it has already been successfully used in Western laboratories, the dignity of no one is offended. The resulting instruments may look smaller and be simple to operate, but inside (like the electronic calculator) they may be very complex.

Only one reasonably complex instrument could be said to have been developed specifically for usage under the difficult circumstances described - the monochromatic absorptiometer designed at the Clinical Research Centre in London and currently manufactured by Denley Instruments Ltd. (Billingshurst, Sussex, England). This meets most of the desired criteria and in particular the use of rugged light-emitting diodes for light sources, eliminates the need for electric bulb changing, and the requirement for a narrow-band filter; the current consumption is also minimal. Digital readout in concentration units is made possible by modern electronics.

The provision and use of pathology measurements on patient samples are inevitably always a compromise, taking into account such factors as clinical need, cost, speed and ease of assay procedure; in different circumstances it is conceivable that different compromises are appropriate but the criteria for arriving at any decisions for the area being considered are almost always subjective and not easy to obtain. However, despite a vociferous minority who do not agree, there is no doubt that for the millions of people who do not currently have the luxury of any laboratory service, a little slippage in quality is allowable if, by so doing, lives will be saved or the quality of life improved. Work needs to be done in this area. It could be said that since most countries, developed and developing alike, now have serious labour problems, the application of labour-saving automation should be limited. Again, a compromise must be reached, since a modicum of laboratory automation is now considered essential to reduce human errors and blunders to acceptable levels. This argument applies particularly in most developing countries where the level of staff training is inevitably limited, and hence it is appropriate to endeavour to provide relatively simple robust automatic blood chemistry and haematology counting equipment, where workloads indicate. Otherwise human error must be minimised without necessarily providing mechanical automation, by the use of concentration readout colorimeters, etc. Appropriate automation might include basic continuous flow systems, compact discrete systems such as the Abbott ABA and the Coulter Kem-O-Mat, and simple Coulter type haematology counting equipment.

Much thought has been given to the possibility of eliminating problems in the making up of reagents by the user, by providing a system of central supply. The ultimate in this is factory production of complete chemistry systems such as for the Du Pont ACA; this however is so expensive as to be out of the question except where cost is not a major factor. The so-called dry-phase chemistry systems using the Kodak layer chemistry approach or the Ames' dipsticks are another possibility with the considerable advantage that even water is not needed by the end user. The Kodak approach, ideal though it may be in terms of accuracy and precision, is not likely to be appropriate, at least in the near future, because of cost and the need for very sophisticated factory production with a cold supply chain to the user.

The Ames type dipsticks however, tend not to need elaborate factory production and their susceptibility to ambient temperatures tends not to be so limiting. A certain slippage in accuracy and precision has to be accepted but their use with automatic colour development and reading instruments to increase reproducibility is a distinct possibility.

Lastly, problems with maintenance of all types of laboratory equipment have already been mentioned and must not be underestimated as being one of the major reasons for the present parlous state of laboratory services in many countries. WHO recently held in Geneva a consultation designed to formulate proposals to minimise or eliminate the difficulties (5). The main suggestion was that all countries should set up a National Maintenance and Repair Service, which need be neither complex nor expensive but could have a dramatic effect on the cost effectiveness and efficiency of laboratory services.

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THE CHALLENGE OF CHOOSING INSTRUMENTS FOR DEVELOPING COUNTRIES - Jocelyn M. Hicks

The difficulties which need to be taken into account in the choice of instruments for developing countries are remarkably similar to those which obtain for the physician's office, a remote area in a developed country, or at the patient's bedside. Without ascribing priority they are as follows:

the small and erratic workload presents problems in the application of quality control measures;

an absent or fluctuating power supply means that instruments must be independent of mains electrical power;

a dusty and/or temperature fluctuating environment;

operators do not easily comprehend the need for preventative maintenance and the need for training is not appreciated;

the choice of equipment is limited because many companies refuse to make their products available in certain areas;

finance is a major limiting factor and companies are not very interested in making cheap instruments;

any instrument chosen must be flexible in its test repertoire since single instruments doing only one type of test are not necessarily cost effective.

Two instruments, though not ideal in themselves, demonstrate principles which could well meet the rigorous criteria demanded by the situation - The Seralyzer and a small Japanese instrument recently developed for the measurement of blood ammonia.

The Seralyzer uses chemistry systems similar to, but not the same as, those of "dipstick" type. After the serum sample is applied to the stick the process of timing the reaction and the subsequent reading of colour density are done automatically, thus eliminating user error as much as possible. Currently the tests available are glucose, urea, bilirubin, uric acid, lactate dehydrogenase, and triglycerides; they are completed in two minutes. The instrument is small, compact, rugged, relatively insensitive to temperature variation and its reagents are presented in easily usable format.

The small Japanese blood ammonia analyser operates with its chemistry packed in a small slide, the seal of which is only broken for blood to be applied. It is hand-held,battery or power operated, has an easily readable digital display, uses whole blood thus eliminating the need for centrifugation and is ideally suited to bed-side operation or for use in isolated areas by relatively untrained persons.

It would appear that the so-called "solid phase chemistry" (including the Kodak type of layer chemistry) approach to the difficulties might be the most appropriate. It can be applied to a wide range of assays including enzymes, electrolytes, drugs, proteins and hormones. The responsibility for quality of performance is shifted from the user to the manufacturer and it only remains for the costs and site of production of the reagents to be made acceptable.

WHO VIEWS ON THE DESIGN AND SUPPLY OF EQUIPMENT FOR DEVELOPING COUNTRIES - Dolores A.Vazquez R. Olazabal

In accordance with the policy defined by its Member States and the recommendations made by the International Conference on Primary Health Care held in Alma Ata (USSR) in September 1978, the World Health Organisation has formulated a global strategy in which an "overriding priority" is the achievement of health for all by the year 2000.

The key to achieving this goal is primary health care and an important component of it is the development of simple laboratory services for clinical and public health purposes, particularly for rural areas and the first reference level.

To develop these services, a new appropriate technology and methods are necessary. Until now, the developing world has adopted the technology used in developed countries, which, in most cases, did not meet the needs of developing countries and the financial involvements were not in proportion to the available resources. For example, if a cost/effectiveness study including the price of the instruments now in use in many developing countries were carried out, most probably the result would show that the cost per test is higher than the public health expenditure per capita in most of the 31 least developed countries. In fact, a recent report presented by WHO to the UN Conference on the Least Developed Countries, states that the average yearly public health expenditure for health care per capita is about US$1.7. This group of countries covers a population of 280 million. The same type of expenditure in a second group of developing countries covering a population of 3.001 million is US$6.5 per capita which compares with US$244 per capita in a group of 37 developed countries with 1.131 million population.

These figures show clearly how urgent is the development of appropriate technology accessible to developing countries at a cost they can afford, to reduce the gap between health care for people living in developed countries and the less fortunate 280 million people living in the least developed countries.

Affluent countries, international organisations, professions and scientific groups and individuals should match efforts for their own countries with work for the development of appropriate technology which is scientifically sound, accessible and acceptable to developing countries.

Appropriate Technology

There are four key factors: simplicity, reliability, resistance to adverse conditions and low cost:

- In most developing countries in Africa, The Middle East, South America, South East Asia and Western Pacific and even in some countries in Europe, there is an impressive amount of laboratory equipment out of operation. Not infrequently, this is due to the complexity of the instrument - a feature unknown to the customers when they bought it; in other cases, the reason is either that the laboratory staff is not sufficiently trained to operate the equipment or the manual provided by the manufacturer is unclear. This is why WHO is supporting the development of simplified systems, easy to operate but able to produce reliable results.

- Moisture, humidity, dust, and fungus have catastrophic effects on laboratory instruments. The poor quality of water and wide fluctuation in electric voltage and frequency also affect the laboratory equipment. WHO considers that all these factors must be taken into consideration for the development of simplified technology able to resist adverse conditions.

- The socio-economic context of the countries must be carefully considered into any plan for the development of suitable laboratory systems. The cost should be reasonably low so they can be made available in developing countries with limited resources and permit the expansion and coverage of health care. Large items of equipment can be sited in central laboratories (big hospitals, universities, research institutions, etc.). Regional and district laboratories should select smaller instruments capable of performing the number of tests required but not with wasteful spare capacity. In many developing countries the instruments are used at not even 10% of their capacity of operation, increasing tremendously the cost of the performance and subsequently of health care. This is why WHO feels that the concept of adaptation of the laboratory instruments to the real needs of the laboratory services at the different recognised levels, is essential.

The Role of WHO in Production and or/Assembly of Equipment in Developing Countries

Most developing countries express dissatisfaction about the unavailability of small, reliable, low cost equipment for peripheral laboratories. They have to buy expensive equipment, not adapted to the environmental conditions prevailing in these countries and face serious problems because of lack of spare parts. Until now, industry in developed countries has shown little interest to transfer technology to developing countries. One reason, but not the only one, seems to be the uncertainty of the market. Some manufacturers have expressed concern about the quality of the instruments produced in developing countries and the long bureaucratic procedures they have to face in the setting up of the production system.

WHO is determined to cooperate with developing countries, and to continue the dialogue with industrial, professional and scientific groups to mobilize the industrial capacity in developing countries to increase their self-reliance. In addition to the development of appropriate technology, training(particularly in the operation of laboratory equipment, maintenance and repair at national and regional levels) will be intensified and cooperation amongst developing countries themselves will be encouraged.

A good example of the role of WHO in the development of simple and reliable systems for developing countries is its co-operation with the Clinical Research Centre in Harrow, UK, for the organization of an international trial to evaluate a simple photocolorimeter, battery operated, and a package for measurement of haemoglobin in rural areas under difficult climatic conditions. The evaluation was carried out in two laboratories in the Middle East, two in South East Asia and two in the Western Pacific. Several prototypes were prepared following the results of this evaluation, until the instruments met the requirements of reliability and resistance to conditions prevailing in tropical countries. The instruments were proposed to industry for production and although both systems proved scientifically sound and may have an important market in developing countries, it was an extremely hard task for Dr Mitchell and his staff to find a manufacturer. The production of a similar system in a developing country may lower the price significantly.

Although not directly related to health laboratory services, it is important to mention that WHO has also developed the concept of basic radiology systems for use in communities deprived of radiodiagnostic services. This work includes the elaboration of simplified designs so that the equipment can be operated by persons with limited training, can resist adverse climatic conditions, can be battery-operated, need little maintenance and operate with a reasonably low level of radiation exposure to patients and operating personnel. The cost must be reasonably low so that the equipment may be made available in developing countries with limited resources.

Two commercial firms have been involved in the design of this system. The prototypes are under trial in the Democratic Republic of Yemen and in Cyprus. WHO has purchased two pieces of this equipment for operations in Burma and Indonesia.

Within the framework of the Expanded Programme of Immunization, launched by WHO and UNICEF with the goal to control by 1990 the six vaccine preventing diseases - diphtheria, whooping cough, tetanus, tuberculosis, poliomyelitis and measles, a programme was established by the two organizations, to test current equipment and to develop new systems that will work better in tropical conditions. A refrigerator has been designed and manufactured which protects vaccines where electricity is only available for eight hours per day as is the case in many countries in Africa, Asia and South America. Cold boxes have been produced which preserve vaccines cold for up to seven days without any electric power. So far seven developing countries (Brazil, Egypt, India, Indonesia, Philippines, Senegal and Thailand) have started production of this cold chain equipment.

A solar refrigerator is under development in cooperation with WHO, the Center for Disease Control (CDC), USA, and the National Aeronautic and Space Administration (NASA). A method of collecting solar energy will be tested in 13 countries to determine its effectiveness in refrigerators for vaccine storage and to make ice. The electricity is generated by photovoltaic parcels and the refrigerators to be tested are the type which will produce 1 to 2 kg of ice per 24 hours and which are sold in many developing countries. This system will be tested in Colombia, the Dominican Republic, Canada, The Gambia, Guatemala, Guanaco, Haiti, India, Indonesia, Ivory Coast, Maldives, Mali and Peru, over a period of two years.

Laboratory Equipment Suitable for Production in Developing Countries

A group of experts meeting in Geneva in September 1979 considered the following equipment as suitable for local production:

(i) Balance of about 200 g capacity, without external weights
(ii) Centrifuge
(iii) Microscopes for primary health care: (a) for basic work - monocular inclining tube, optical combination eye piece x 10, objectives x 10, x 40, x 100, concave and plane mirror light concentration with 2 axes of movement, blue filter, and mechanical stage with x and y movement; (b) for district hospital work similar to (a) but binocular and with parallel beam lamp source.
(iv) Refrigerators. As mentioned previously, the unavailability of electricity or a stable power source is one of the problems hampering the good functioning of refrigerators; refrigeration is an essential component of any laboratory. We hope that the cold chain developed by the WHO Expanded Immunization Programme will contribute to the solution of this problem.
(v) Plastic laboratory items. These can be produced in developing countries, the dies are very expensive but instruction on their production can be given in training courses such as those provided by the Central Scientific Instruments Organization in Chandigarh (India).
(vi) Voltage stabilizers. For the reasons already mentioned these are essential for the good functioning of electrical laboratory equipment, and their production in developing countries should be encouraged.
(vii) Colorimeters. In addition to what has already been stated, attention needs to be given to the developing of chemistry system packages applicable to developing countries, with instructions for the production of reagents and the maintenance of equipment. Double cell comparator type colorimeters are recommended.
(viii) Water still, water filters, hot-air ovens and incubators can all be produced in developing countries using local resources.

WHO Programme for Production of Equipment in Developing Countries

Depending upon the availability of funds, the following is the WHO programme for cooperation with developing countries in the local production and/or assembly of laboratory equipment which the Health Laboratory Technology Unit intends to implement.

- setting up of specifications for laboratory instruments with high priority on instruments related to primary health care. The major general characteristics being: reliability, simplicity for operation, requiring little maintenance, resistance to adverse climatic conditions, ability to operate without external electricity supply and low cost.
- review of instruments already available and which could be adopted or modified to meet the specifications listed above.
- promotion of the design of appropriate laboratory instruments amongst the industries, scientific and research groups.
- laboratory and field testing of prototypes according to protocols prepared by the designers.

- identification of developing countries with potential capacity for production and provision of technical support and manufacture manuals to set up production.
- cooperation with countries to test the quality of the instruments produced locally.

Some developing countries such as India, Argentina, Brazil, are already producing laboratory equipment at low cost. WHO will promote the exchange of expertise among developing countries.

For the implementation of the overall programme, WHO will work with: governments, national institutes, non-governmental organizations such as IFCC, scientific and research groups, industry, UN agencies dealing with biomedical equipment such as UNIDO and UNICEF, WHO collaborating Centres and Regional Offices.

INSTRUMENT PROBLEMS IN A RAPIDLY DEVELOPING COUNTRY SUCH AS EGYPT - M.S. Mortagy

Although medical education and practice have reached a fairly high standard in many developing countries, laboratory services do not show parallel progress; they are one of the most expensive medical services. The last 20 years have witnessed a revolution in laboratory instrumentation with the introduction of highly sophisticated computerised automatic machines, most of which are not suitable for developing countries, not only because of their high cost but also because the working conditions of our laboratories do not justify having such instruments. They are produced by companies from the Western world to suit Western laboratories. There are many differences between the systems of laboratory services in developed and developing countries, even between different countries in the developing group. In a country such as Egypt, almost 50% of the laboratory services are either given free through university and public health hospitals or a small fee is charged in medical insurance and army hospitals. The workload in these hospital laboratories would justify simple automation, but the finance available in most of them is very small. The other 50% of laboratory services are covered by some 400 small private laboratories, mostly using traditional manual methods since their workload does not justify automation. My concern in this paper is with hospital laboratories.

Compared with developed countries, our laboratories have smaller workloads and a larger but less skilled work force. The accuracy needed is less, the budget and resources are less, and in some places laboratory conditions are poor due to instability of electrical supply, dust and temperature changes since most laboratories are not air conditioned.

After several years of relatively slow progress in Egypt it has been difficult to resist the temptation to acquire new automated systems of laboratory instrumentation. In the late 1970s with the relaxation of currency controls, automatic laboratory machines became available and were purchased and installed without much attention to actual need. Without experience,choice was not based on reliable criteria other than availability and the attractive data provided by salesmen.

Problems became immediately evident, the first being the difficulty of training operators and difficulty of daily running and maintenance. A short time later, and earlier than expected, defects started to show, and the difficulties of repair and the supply of spare parts were encountered. After some time the reagents supplied with the instruments were exhausted, and only when fresh supplies were ordered did it become apparent that running expenses were considerably higher than for the previously used manual methods of operation.

When the overall economic aspects of the running of these instruments was considered, it was found that the costs per test were much larger than in developed countries. This is because of the small work loads, low work-loading of the instruments, loss of reagents due to frequent defects and repetitions, shorter effective life of the instrument, high price of spare parts and the high fees of the agent's service engineer.

An experiment designed partially to solve these problems was very successful. The hospital service engineer was sent to the production factory of one of the automated machines in Europe where he completed a ten day training course. On his return and for almost 4 years, the instrument in question was not idle for a single day. Although it had frequent troubles, they were effectively cured by the engineer. We now consider that the training of service engineers is the most important factor for the effective running of automatic machines in developing countries.

When the evolution of laboratory machines is considered, from the simple basic instruments to those so sophisticated of the present day, it becomes apparent that a stage is missing. While printing and textile machines for example passed for several years through the stage of manual mechanisation, laboratory analysers did not. Even now in developed countries it is possible to see mechanical machines in several branches of industry but why do we not have hand operated mechanical analysers? These would eliminate computers and motor drives, make operation easier, defects less, require relatively unskilled operation and would cost less. The WHO might consider this point through its project for designing instruments for the developing countries.

It can be concluded that hospital laboratories in developing countries need basic automatic machines, mainly discrete single channel batch analysers. The instruments should be as simple as possible, easy to operate and maintain, cheap, with long trouble free life. Training for operators and service engineers is essential. Reagents should be simple and easily prepared by the user. Work simplification equipment such as automatic pipettes, reagent bottle dispensers and diluters is very useful. Robust simple colorimeters, with concentration readout and possibly with automatic, or manual sample changer, can be utilised with other pipetting equipment to provide home-made semiautomatic machines for the ever growing market of developing countries. A way must be found to convince large instrument manufacturers, currently competing in the sale of sophisticated analysers, to produce such systems.

Discussion

Mr. O.P.R.I. Omigie from Benin, Nigeria drew attention to similar problems existing in Nigeria to those described for Egypt.

Dr. H. Sabry Sallam from Cairo presented a more optimistic view of the rapid development of Egypt, indicating that many old universities and new hospitals are now computerised, and the laboratory workloads in these have considerably increased over recent years. Good electricity supplies are spreading to many villages in remote areas. The current problems can be summarised as being administrative, lack of bioengineering facilities and low local stocks of spare parts and reagents held by supply companies.