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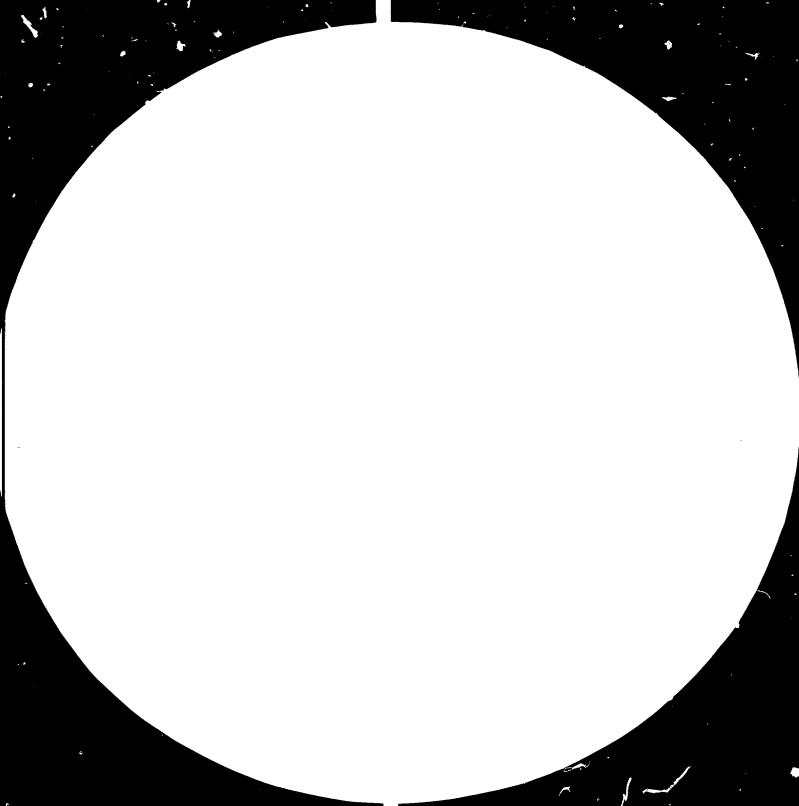
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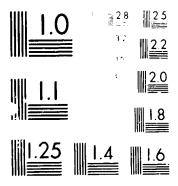
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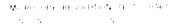
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UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATIO.

Ad Hoc Expert Group Meeting on Biomedical Equipment, 10-14 December 1979

Vienna, Austria

DRAFT REPORT

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INTRODUCTION

Delivery of modern health care depends to an ever-increasing extent upon the proper distribution and utilisation of biomedical equipment. The latter extends from simple mechanical devices to be found in every place where health care is administered to very complicated and expensive mechanical, electromechanical and electronic equipment suitable for installation only in the most sophisticated hospital environments. An understanding of the nature of biomedical equipment and the problems which it presents is therefore as equally applicable to primary health care in rudimentary health centres as to large university teaching hospitals. An acceptance of equipment involving such a broad range of science and engineering in its design and construction brings with it the need to recognise the requirement for adequately trained technologists to ensure equipment is always in a condition fit for its purpose. Unless such technologists are available in adequate numbers and are satisfactorily trained and organised to apply their rare skills in the most efficient manner, the full potential of biomedical equipment will never be realised.

According to available surveys, there are 10,000 hospitals in developing countries with two million beds and 6 to 8 billion US\$'s worth of bio-medical equipment. In some countries, up to 60% . of available biomedical equipment is not being used. The overriding cause of this situation has been identified as the lack of repair and maintenance even where breakdown has arisen from simple, easily rectifiable causes. Against a requirement of about 30,000 maintenance and service personnel, there are only 2 to 3 thousand available. However, other important factors affecting the situation have been the purchase of equipment too sophisticated for its use or of poor design and installation of sophisticated etuipment in places where technical advice on its use has been absent. Such a situation is undoubtedly complicated by the fact that most equipment is imported from suppliers unable to provide an adequate maintenance and repair service. This report concentrates on the major problems facing developing countries in integrating biomedical equipment into their health care system. The advice is unavoidably general since specific advice is impossible without detailed knowledge of the organisation of health care in a particular country, its particular needs and its industrial and educational infrastructure. Recommendations are made as to how this general advice could be particularised for individual countries or areas of the world.

The report recognises an overwhelming need for any developing country to produce a plan for biomedical equipment management. The latter must include availability of information on the range of manufacturers from whom equipment can be obtained and advice on the suitability of such equipment for various clinical purposes and environments. Guidance on the type of equipment best suited to each environment where health care is delivered is essential. An adequate purchasing procedure based on contract conditions which include compliance with technical standards and the provision of training for health technologists will be important. However, by far the most important aspect of equipment management must be the training of an adequate number of technical personnel for the repair and maintenance of biomedical equipment.

Many of the problems of developing countries can be related to the extent to which equipment is imported. This will be pertinent not only to maintenance and repair but also may, of itself, limit the amount of biomedical equipment available if, as is common, foreign currency is scarce. With no substantial manufacturing facilities, developing countries tend to lack the infrastructure for training biomedical engineers and for providing job opportunities; detailed knowledge of the design of the equipment which they use will be limited. This report recognises the need, identified by the 1975 Lima Declaration, for a greater manufacturing rapability in developing countries. If the present circumstances continue, the aim that developing countries should achieve a 25%

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share of industrial output by the year 2000 will not be achieved.

Without detailed knowledge of the industry, capabilities and needs of any individual country, no specific advice on the ecuipment most suitable for manufacture can be given in this report. Such advice, through the offices of UNIDO, must await specific detailed surveys and industrial profiles of countries or areas of the world and adequate feasibility studies. However, this report considers some of the most important general factors and lists only as examples, those simple devices which might be considered for manufacture and some equipment which might be suitable for assembly.

The report finally recognises the need for a continuing dialogue and exchange of information and expertise among the developing countries and the developed countries and welcomes the initiative undertaken by UNIDO. In so saying, it should be recognised that a number of developing countries already have a substantial biomedical manufacturing industry with well organised equipment management programmes and training schemes. Their experience is just as valuable as that of developed countries.

Organisation of the Meeting

The meeting, which took place at UNIDO Headquarters in Vienna, Austria from 10 - 14 December 1979, was opened by Dr.A.Tcheknavorian-Asenbauer, Chief, Fharmaceutical Industries Unit, UNIDO.

Mrs.Tcheknavorian emphasised the importance of biomedical equipment in the general Health Care System and stated that one of the main aims of the meeting was to work out a programme to help developing countries in this field. Amongst the problems faced by the latter are the lack of knowledge of proper maintenance of biomedical equipment and the paucity of information about the different sources of supply of equipment. She stated that UNIDO would like to develop local production of biomedical equipment and in this connection, invited the advice of the participants. She also requested the participants to identify those instruments which were considered essential and prepare a "List of Essential Biomedical Instruments" both from the health care and industrial points of view. Such a list should include the equipment which should be produced as a first priority and which would not be too sophisticated to be produced in developing countries.

Adoption of the Agenda

The agenda was adopted subject to revisior to keep it flexible.

Precis of the Meeting

14 experts from Europe (BRD, Norway, Hungary, Austria,U.K.and Turkey), North America (Canada), from Latin America (Brazil, Mexico, Peru), from Asia (India) and from Africa took part in the meeting. They each gave a description of the actual status of biomedical equipment in their country.

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I. EQUI PMENT MANAGEMENT

Equipment management is the key to the effective use of technology in health care. Many problems have resulted from a failure to recognise all the aspects of management of instrumentation and the commitments that they require.

What is meant by equipment management? In a comprehensive report "Biomedical Equipment Maintenance Service Programmes"* the different aspects of management of equipment are defined. The pages in question are annexed to this report and are summarised below.

In reviewing the different aspects of equipment management the importance of close liaison between the clinical personnel and the technical staff must be considered. This close liaison should start when the problem in question is to be defined.

A. Selection:

- identification and appreciation of the need;
- knowledge of what is available on the market;
- determination of the appropriate equipment for suiting the needs;
- evaluation of equipment;
- compatibility with other equipment;
- environmental requirements.

B. Procurement:

- compliance with the requirements;
- availability of service and maintenance;
- availability of accessories, spare parts and consumables;
- provision of service manual;
- provision of operation manual;
- stability of the supplier;
- price and availability of the equipment;
- varranty.

See Annex I.

- C. Inspection:
- initial inspection;
- acceptance testing;
- provision of specified components, instructions etc.
- D. Implementation:
- preparation for use;
- staff training;
- safety considerations.

E. Follow Up:

- preventive maintenance (periodic inspection);
- evaluation of the use.

F. Repair.

To perform all the above mentioned topics there is an urgent need for an appropriately organised management system. Many modes for implementation of equipment management programmes are described in the above mentioned report, the range from provision of elementary technical staff to professional biomedical engineers or medical physics' personnel. The appropriate system must fit the unique requirements of the local health systems.

The provision of technical and professional staff for management of equipment must be included in the financial commitment for technology in health care.

II. Training of biomedical engineering personnel at various levels in developing countries

For the sustemance and success of any programme in the specialised area of biomedical engineering, be it maintenance, production, development or research, there is a continuous need for adecuate training facilities and trained personnel at various levels. As this is very much lacking in developing countries which is one of the main causes of the existing technological gap, the following training programmes are therefore recommended: Training programmes:

a) <u>Maintenance and Service Technicians</u> - this programme is meant for training basic technicians in taking care of preventive maintenance, detection and repair of faults and in carrying out periodical servicing of biomedical equipment such as X-ray equipment, electromedical equipment, biomechanical and rehabilitation ecuipment and technical aids for the handicapped etc. depending on the particular need of the developing country. The programme may come under the category of vocational or industrial training as in existence in developing countries.

b) <u>Clinical engineers</u> - the clinical engineer would wave the overall responsibility of biomedical engineer ng problems in a hospital/ health care unit such as planning, organising, supervising, guiding all maintenance work and servicing procedures. His training will included the following:

i) technical knowledge of all biomedical equipment used in health care delivery/hospitals;

ii) preparation of maintenance schedules and guidance of technicians working under him;

iii) safety precautions and their implementation;

iv) to recommend appropriate type of equipment towards its purchase, its evaluation and proper installation;

v) to conduct regular continuous training to the staff;

vi) to lead the clinical engineering department and maintain liaison with the medical staff;

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vii) to collaborate and to supply information to the biomedical industry;

viii) to work as a team with medical doctors in operating theatres and others in medical assessment.

The 'evel at thich this programme is to be conducted would depend upon the educational system existing in the concerned country.

c) <u>Biomedical engineers</u> - these will be at a level of training personnel in the area of research, development, design and teaching. Such trained personnel are needed to make the developing countries self-sufficient in technical knew how, to develop and generate their own teaching skills, initiate research and development activities of use to the biomedical industry and medical research.

The priorities to be given to the above programmes depend on the developing countries concerned. It is felt that most of the developing countries would need immediately the first programme of biomedical maintenance and this could be followed by the second programme of clinical engineering. In some countries, all three programmes may be needed simultaneously as they may be involved not only in maintenance of biomedical equipment, but also in the indigenous production of biomedical equipment, research and development activities.

It is also necessary for developing countries to establish rapport amongst themselves through UNIDO for exchange of information on training programmes, technical know how etc.

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III. FRODUCTION

The production of biomedical equipment in developing countries should be encouraged. The size and demand of the market should be taken into consideration together with the existing industrial infrastructure and the industrial and health policy of the country. Cne has to take into consideration that the yearly import of biomedical equipment into the developing countries is about US\$ 500 million which is still growing (taking into consideration the depreciation of the existing equipment and the development of the health care in the countries this figure is not overestimated at all). Feasibility studies should be carried out in individual countries as well as in different areas such as the Andean and Arab regions. Attention should be drawn to the needs of instrument and equipment design for special use in developing countries (e.g. small portable sterilisers and refrigerators for vaccine). The equipment must be designed to meet the local environmental and other conditions.

UNIDO may help in providing the necessary expertise and technology. This would lead to the establishment of the local potential of the design and production of biomedical equipment.

In this matter, the collaboration between the developing and developed countries and between the developing countries (TCDC) can be very useful.

Examples of biomedical equipment which should be considered as appropriate to be manufactured in developing countries are the following: Beds; surgical instruments; injection needles; operating tables; ~ashers; boilers; sterilisers; ~ater baths; thermometers;

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plaster bandages; tissue adhesives; glassware; disposables; gloves; stethoscores; sphygmomanometers; spirometers; balances: laboratory centrifuges; ophtalmoscopes; colorimeters;

technical aids for the handicapped;

For more advanced countries it would be of interest by using premanufactured parts to produce: electrocardiographs; pH meters; X-ray apparatus; X-ray films; photometers; microscopes; dental chairs; operating lamps.

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RECOMMENDATIONS

The 1d Hoc expert group meeting recognised the importance of the role of biomedical equipment in the health care system and specified areas which should be given due consideration by governments and international bodies in order to improve biomedical equipment management, training, maintenance and production. Specific recommendations, based on the above subjects, are as follows:

1. Policy:

a) urge governments of developing countries, especially the
Ministries of Health, to recognise the role of biomedical
engineering in the health care system, especially in hospitals.
This should lead to an allocation of funds within the health
budget for the creation of biomedical engineering departments for
better equipment management, developing research and maintenance
which will lead to a better and safer use of the existing potential,
economise on foreign exchange and raise the standard of health care.
b) recommend the Ministries of Industry, in co-operation with the
Ministries of Health, to consider the development and production
of biomedical equipment for the health care system in the country.
c) urge governments to recognise and accord status to the biomedical

2. Ecuipment Management: a) the group requests governments to take into consideration the guidelines and to act accordingly, in order to ensure proper selection, procurement and utilisation of biomedical equipment. In order to implement the above guidelines, UNIDC or any other capable international organisation, could offer assistance upon request.

b) in this connection, it is recommended that UNIDO, in co-operation with the International Federation for Medical and Biological Engineering, organise workshops on the management of biomedical equipment, in order to assist the governments of developing countries in this area.

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3. <u>Training/Maintenance</u>:a) the group recommends that UNIDO, in co-operation with the International Federation for Medical and Biological Engineering, conduct a survey on existing maintenance facilities and training possibilities at national, sub-regional and regional levels.

b) UNIDO, in co-operation with governments, will establish centre(s) for training, maintenance, repair and research at different levels. These could also be considered at national, sub-regional and regional levels.

4. Production:

a) the group recommends that a survey be carried out by UNIDO on the available production capacities in developing countries and to identify the potential of different developing countries, their infrastructure which is available in this special field.

b) based on the above, UNIDO should develop programmes for improving the ruality of locally produced biomedical equipment by transferring appropriate technology to expand and create new facilities to produce biomedical equipment, as listed under chapter III.

c) in this connection, UNIDO, in co-operation with national and international organisations, institutions and manufacturers, could make available technology, expertise, design and layout for the establishment of such facilities.

d) UNIDO, in co-operation with WHO, should initiate the development of special equipment needed by the developing countries for their health care programmes and to establish facilities for production.

5. General Recommendations:

a) the group recognised that existing expertise in different areas of biomedical engineering, such as equipment management, training, maintenance and production in some developing countries could be transferred to other developing countries on appropriate terms. UNIDO is therefore requested to act as a catalyst for the establishment of such a programme of co-operation between developing countries for the implementation of the above recommendations.

b) in order to promote the idea of technical co-operation amongst developing countries, UNIDO should organise an exchange of information through personal contacts, seminars between policy makers and technical experts in order to establish a dialogue between them and a better understanding.

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Annexe I

Reprinted from the report of the First International Biomedical Engineering Workshop Series: "Biomedical Equipment Maintenance Service Programs" published by the American Institute of Biological Sciences. For further details, write to the Secretariat, Internatural Federation for Medical and Biological Engineering, c/o Wational Research Council of Canada, Ottawa, Canada X14 OR8

A. WHAT EQUIPMENT SHOULD A HOSPITAL ACCEPT?

The choice of the correct equipment to satisfy a specific clinical need affects the speed and efficiency of the desired medical service. Its proper selection is the first step in an effective equipment maintenance program, and should be made with great care. Too often the hospital administration is dependent upon the literature or promotion offered by manufacturers or their agents. Technical guidance almost invariably leads to a more intelligent determination. This function is in fact one of the more important contributions that can be provided by a medical engineering service, whether in-house or external to the institution. The medical engineer can and should evaluate the design quality of the instrumentation, its mode of operation and performance, and, above all, its probable maintenance demands.

Commitment to a maintenance and repair policy begins from the moment of purchase. The initial investment in equipment may be much smaller than the cost of its maintenance. Thus a relatively small saving in the purchase of a less expensive instrument may result in an increased cost of keeping it in operation. This is true in other areas of endeavor, but in the delivery of health care the consequence of failure makes it a mandatory concept.

If quality is the first consideration in purchase of equipment, availability of parts or service must core a close second. The most sophisticated equipment is of little use if it cannot be maintained or repaired without delay. The wise purchaser will examine the service policy of the seller, the advisability of buying reasonable spares, the accessibility of the instrument for servicing, the maintenance data provided by the manufacturer, and the local availability of parts, service facilities, and expertise. Since all these desirable features are seldom available, the buyer should seek to optimize his choice.

Standardization is an important concept in the selection of instrumentation. Mether it be within an institution or a widespread system, the consistent use of proven makes of equipment reduces the volume of spares that must be stocked and the number of maintenance and repair procedures that must be undertaken. It also strengthens the bargaining power of the health care system in dealing with the manufacturer in purchase or repair contracts.

Compatibility of new items with existing equipment is essential. In modern clinical practice, instruments are often integrated into a diagnostic or therapeutic system. The buyer who attempts to purchase without technical guidance may well end up with an 'orphan' that will not fit into the system family.

Compatibility of power sources will become of greater importance in the developing trend toward battery-powered instruments. Not only will it be necessary to standardize on the types of batteries used in order to reduce inventory, but the investment for recharging facilities may be decreased. Standardization of power connectors and other hardware will ______ effect an economy and contribute to safety.

Closely associated with compatibility is *vervatility*. A patient-monitoring instrument with provision for external display or interchangeable functional modules is more useful than a single purpose equipment. Additional channels can be added as the need arises. The module concept also facilitates replacement or repair. The next consideration must be the suitability of equipment for the intended use, for the environment, and for local custom. Thus an equipment which automates many functions that can be done safely and in an acceptable time manually may not be advantageous in an economy where labor is plentiful and inexpensive. Similarly, an instrument designed for laboratory research may not be appropriate for clinical use and equipment designed for a temperate climate may break down when subjected to the high temperature and humidity of tropical regions.

On the other hand, there are occasions when the buyer may seek equipment that reduces the decisionmaking demands by the user in order to obtain the maximum utilization with the minimum expertise. In such instances he must accept the higher technology inherent in the design of such instruments. In a sense, he must trade-off medical for technical expertise and must weigh the cost of this when he makes the purchase.

Operational costs may be a significant factor in selecting equipment. Does the instrument consume excessive power? Does it require expensive chart paper? Does it need conditioning of the environment for its dependable operation? Will it require extensive staff training for operation or maintenance?

The probable period of use before obsolescence of either the equipment or the clinical need should be considered. Solid state electronics (transistors, printed and integrated circuits) revolutionized the lesign of most electromedical instruments in a few short years. In many instances its improved performance, reduced size and power demands, and longer operational life rendered the previous generation of equipment obsolete! Many complex systems have been developed for automated chemical analysis at a great saving of time and effort. However, some of the routine tests are now being replaced as diagnostic needs change. A complete generation of this equipment may be obsolete within the next 5 years. Obsolescence cunnot be predicted with certainty but there are indicators in technology and clinical practice that need to be read in determining instrumentation requirements.

Ne must now add a note of concern about safety in medical instrumentation. Most instruments are intrinsically safe when their interface with the patient is at the body surface. However we are becoming committed to more and more diagnostic or therapeutic procedures which invade the inner tissues of the body. In that milieu, the threshold of electric shock hazard is much more critical. Many safety standards now call for classification of electromedical instrumentation into categories according to the hazard associated with its use. These standards specify safe design features and designate acceptable limits for fault currents. Compliance with such specifications should be an invariable condition of purchase of patient care equipment.

These are the cardinal guidelines for the selection of medical instrumentation. They should be applied, where possible, to the acceptance of donated equipment. Gifts of equipment and instruments pose very special problems in a health care system. They may create operational and maintenance expenditures far in excess of their initial cost and in every case will require some continued outlay by the recipient. The embarrassment involved in specifying requirements for donated instrumentation may be far less than that incurred later in explaining why it is out of service.

The selection of equipment must be followed up by inspection on arrival. Failure to do so may invalidate any claim against the supplier and will invariably increase the maintenance and repair burden. If this appears to be an unlikely occurrence, consider what happens when equipment is ordered at the time of construction of a new facility. It usually remains in a packing case until the facility is completed. Then it is discovered that the patient applicators are missing, there is no maintenance manual or parts list, rodents appear to have eaten the insulation off wires, and the shipment has been dropped in transit. If the warranty is located it probably will have expired. The work and expense of repair then commences before the equipment ever sees service. It is essential that inspection be linked to selection as the first step in an equipment maintenance repair program.

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B. WHAT ARE THE BIOENGINEERING DEMANDS?

Before attempting to determine a policy for the maintenance and repair of instrumentation, the health care authority should look at the demands of the institution or system for bioengineering services. These will be dependent upon many factors and may differ widely between hospitals or regions.

Maintenance requirements are dictated by the amount of instrumentation and equipment, its use (and abuse), complexity, and environmental conditions that may accelerate degradation or failure. The amount and type of instrumentation is determined in turn by the size of the health care establishment, the nature of patient treatment, indigenous health problems, the extent of dependence upon other regional facilities, and economic limitations.

Other bioengineering service demands are conditional upon the sophistication of diagnostic or therapeutic procedures, safety considerations, the extent of clinical research and development or hospital planning, and the need for technological consultation in the procurement or installation of equipment.

The complexity and amount of instrumentation are good indices of service requirements. A small outstation hospital may use basic equipment for radiography, electrocardiography, specimen or tissue analysis, and other relatively uncomplicated procedures. On the other hand, eye disease may be indigenous to the region and even a small health care institution may then provide fairly extensive facilities for its diagnosis and treatmant. In some areas of Southeast Asia, betelnut chewing has produced a high incidence of mouth cancer and therapeutic X-ray equipment is used extensively in its treatment.

Some instruments are relatively insensitive to damage from extended use. X-ray equipment is not. The manufacturer usually gives guidance on the recommended duty cycle. If it is ignored, the life of the X-ray tube and perhaps the high voltage supply will be foreshortened. The X-ray transformer oil cooling system demands rigorous attention in hot climates. Since radiography equipment constitutes a high proportion of hospital instrumentation, its extent and use offers a useful index of the probable service needs of the institution.

Climatic extremes influence service demands. Electrical components are vulnerable to damage from high hamidity. Solid-state circuitry is sensitive to excessive heat. Exposure to cold may destroy components of diagnostic instruments or defibrillators. Sand or other airborne pollution has a most deleterious effect upon equipment.

A large health care center has unique demands for maintenance expertise, depending upon the services it offers. Neurosurgery and cardiac surgery involve complex support equipment and diagnostic instruments. The postoperative monitoring array alone may well equal the total volume of instrumentation of a small institution. Automated analysis and other laboratory equipment have diverse maintenance and servicing needs.

In large hospitals there are many complex diagnostic systems where technical expertise is mandatory to effect compatible and safe application to the patient. If computer data-handling services are provided, they will require maintenance staff in addition to the technically trained personnel who process the data.

At the larger health care centers there is usually a requirement for training of medical, paramedical, and technical personnel and some allocation of biomedical staff must be made. At this level also, there may be a need for professional or technical engineering staff to participate in planning and design, research and development, procurement recommendations, and inspection of new equipment.

The consequence of equiperent failure must be considered in assessment of technical service requirements. Will a delay in restoring it to service endanger life-support systems or even slow up treatment procedures and extend the bed-care period to an overload condition? If so, in-house technical staff or quick access to external help must be itemized as a bioengineering service demand. The quality of public utilities and other services will affect maintenance needs. If the line voltage of the power system varies beyond normal limits, it will degrade the performance of instrumentation and perhaps lead to its failure. Failures or impurities in the water supply will increase the incidence of equipment breakdown.

Type of Institution Services	Mass Screening Unit or Clivic	Rural Hospital	Urban Rospital	Large Medical Center
Purchase evaluation				x
Incoming inspection			x	X
In-house maintenance and repair service	• .		x	1
Safety inspection	•		X	x
Emergency repair		x	X	x
Instrument calibration	x		x	x
Preventive maintenance	x	x	x	x
Equipment user instruction	x	x	x	x

Table 3. Biomedical instrumentation services in health care institutions.

Table 3 provides a schedule of bioengineering services usually associated with various types of health care institutions. In all cases there is a need for some sort of preventive maintenance and basic technical instruction on the use of instrumentation. The mass screening unit or clinic 's primarily a diagnostic center and has an additional demand for instrument collibration service. The consequence of failure generally does not require a staff allocation for emergency repair, unless the unit is large.

On the other hand, to a rural hospital some sort of emergency repair facility is much more vital than instrument calibration. Neither type of institution is likely to need in-house staff specifically for maintenance and repair or safety inspection. This should not suggest that these areas are ustally neglected. In small hospitals the medical, paramedical, and mursing staff traditionally accept some responsibility for the maintenance and safe use of their instrumentation.

Many urban hospitals have some sort of inspection service for new equipment or instruments and the larger university teaching hospitals usually draw upon bioengineering services in the purchase of medical equipment.

Table 3 represents the in-house services in health care institutions. It will be apparent that some essential services are rat shown. In a national or state medical system, these services are provided through a central agency, which in this context is represented by the large medical center category. In the autonomous system, the smaller institutions may have associations with larger centers or may hire technological and technical services on a fee basis when necessary.

C. WHAT IS THE BEST MAINTENANCE SERVICE POLICY?

The dependence of modern health care upon technology in diagnosis of disease, therapeutic procedures, and monitoring of the critically ill makes the maintenance and repair of medical instrumentation a vital necessity. Inevitably, equipment will need maintenance or repair and medical institutions at all levels must consider the establishment of a service structure for this purpose. It may be an "endoskeleton" or an "exoskeleton," but if it is not provided, effective patient care will collapse.

The determination of a maintenance service policy must take into account the restraints imposed by cocioeconomic factors, geographic limitations, the environment, the level of medical practice, the available technic ogy, and even political considerations.

As previously stated, health care authorities often fail to recognize that the economic aspects of hospital equipment maintenance are linked to essential managerial concepts. There is frequently no acceptance of the fact that it may cost more to maintain equipment than to buy it, and that such continuing expenditures must be considered as part of the total investment. The additional costs incurred at breakdown because of disruption of normal procedures and possible damage to other facilities must also be considered. In economic terms, poor maintenance will lead eventually and inevitably to a waste of the health system's assets.

Any effective program for management of medical instrumentation must be based on a realistic appraisal of its cost and available financial resources. It will be limited by its financial support and therefore must eliminate areas of endeavor that are out of economic reach.

If a health care authority chooses to establish its own service agency, it should examine the costs of staff, training, testing, and repair facilities, spare parts inventory, and the maintenance plant itself. It should then compare these costs with those incurred in hiring commercial services plus dispatching defective equipment for repair. It may be practical to utilize the maintenance services of government departments, research laboratories, or universities, but the consequence of inadequate repair or excessive delay must be considered in deciding on such an alternative.

The effectiveness of maintenance and repair may be influenced by accessibility, assessed in terms of time rather than distance. It may be quite feasible to provide effective service at a remote location if transportation is fast and available. In today's world, distance no longer imposes an insurmountable barrier, while speed of execution becomes increasingly more important. This concept goes beyond national boundaries. It may be more satisfactory in some instances to ship equipment abroad than to attempt to provide home facilities for its repair. This is particularly so for developing countries where priorities must be assigned to domestic development. The administration, however, must ensure that provision is made for prompt dispatch to minimize the out-of-service period.

A comprehensive maintenance and repair policy may include both in-house and contracted services. It is realistic to use the latter where available and concentrate the in-house facilities for services that are less accessible in the region. The Western Regional Hospital Board in Glasgow, Scotland, operates a highly competent Department of Clinical Physics and Bio-Engineering with extensive facilities. Its Director strongly supports the contracted services concept on the basis that it often provides better service for less cost.

In developing countries, commercial or other outside facilities are more limited. The greatest likelihood of such help is in X-ray technology. Manufacturers' representatives offer maintenance and repair services and usually will cooperate with a health care system in planning a program to serve its needs. Other major suppliers of biomedical equipment may not have regional agents but generally they are sympathetic to the maintenance and repair problems of the user and can give constructive advice on routine servicing and maintenance manuals and recommendations on the quantity and number of spare parts required in normal remair procedures. The recommendation simply expressed is "do not compete with outside services, collaborate with them".

It is an almost inevitable conclusion that some in-house technical maintenance and repair staff will be required. It should not be associated with the routine plant maintenance services. Such an association has been attempted by many hospitals but is seldom successful. If the institution or system is large,

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a bioengineering service should be organized as an autonomous department. It is best located at a large medical center so that it maintains contact with clinical programs. If it serves a system of other institutions, the autonomous structure is essential to ensure equitable service to all.

The central service agency concept works very well if provision is made for prompt response to the needs of the more remote parts of the system. It may be supplemented by institutional or regional representatives whose function is to provide routine preventive maintenance and minor repairs. A hospital of 100 beds will have a minimum of 30 items of biomedical equipment. The average time required for service of each item is about 10 hours per year. Thus, this activity will occupy about half of one technician's time. The balance can be profitably spent in assistance to or training of equipment operators, maintenance of spares, institution of safety measures, up-dating of his own training, and other activities. By comparison, if each of the equipments was sent to the manufacturer or an agent for service, the cost at current rates would be about \$20,000 (U.S.) per year. Even if available, such services would not cover all the activities essential to the effective operation of a biomedical maintenance and repair program.

A national health care authority should consider establishing a pilot plant prototype at a large center. It could become the nucleus of a broengineering service or be a model for national or regional development. A national institute would demonstrate official recognition of the problem and would serve as a focal point for the development of technical and professional bioengineering expertise.

The development of a maintenance and repair facility should be linked with the planning of new health care centers. When the Malaysian Ministry of Health planned its superb University Hospital in Kuala Lumpur it instituted a program of training for paramedical staff that resulted in a capability that is quite evident now that the hospital is in operation. The role of a central medical engineering agency in technical training should not be overlooked. In an area where there is little or no research or in this trial activity in bioengineering, there is no other base from which to draw expertise.

The health care authority, in planning the facility best suited to its national, regional, or institutional needs, should consider possible adjuncts to a maintenance and repair operation. The bioengineering center might provide an instrument pool to serve transient hospital needs and allocate the disposal of older equipment - for staff training, research use, rebuilding, or dismantling. A pool of laboratory services could answer the needs of many institutions.

Finally, it must be repeated that no biomedical equipment maintenance service program will be effactive if the need for funds, staff, facilities, and transport are not provided, if the program is tied to general maintenance services, and if the organization is not given sufficient autonomy to implement the program.

AD HOC EXPERT GROUP MEETING ON BIOMEDICAL EQUIPMENT

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ACTION TO BE TAKEN BY EXPERTS

(Information to reach UNIDO, Vienna, by January 10, 1980)

1. Individual Contributions $(\frac{1}{2} - 1 \text{ page})$

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- 2. List of Biomedical Equipment for hospitals, clinics, health center etc.
- 3. Source of technology (manufactuers)
- 4. Names of experts for UNIDO roster

Proposal by the International Federation for Medical and Biological Engineering to UNIDO - submitted by Mr.J.A.EOPPS.

The Federation velcomes the action of UNIDO in reviewing the problems and possibilities of implementation of technology in the delivery of health care. Such action complements the programme of the IFMBE committee on Aid for Developing Countries.

The IFMBE has conducted a survey of biomedical engineering in South East Asia (1971) and has participated in the International Biomedical Engineering Workshop Series, for which it organised the first workshop - Biomedical Equipment Maintenance Service Programmes (1972).

As a follow up to these activities the IFMBE has explored various possibilities to contribute to the advancement of medical engineering in developing countries. We now propose to UNIDO that we conduct a workshop in a developing region, to inform health care administrators of the need for and advantage of professional and technical bioengineering services and to give instruction on the benefits of instrumentation management.

To further the documentation needs of UNIDO, we are also prepared to conduct a survey among our member countries and contacts in developing regions, to enquire about present equipment management programmes, estimated costs, industrial commitment, instrumentation priority needs and specific problems in implementing technology in health care. Both enterprises would be undertaken on a contractual basis.

At an appropriate time, the Federation is prepared to submit a detailed proposal for conducting the survey and for the workshop.

