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APPROPRIATE HEALTH TECHNOLOGY

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EXECUTIVE SUMMARY

The introduction of new technology may have economic, social and ethical consequences. Sound evaluation of most new technologies is lacking in most developing countries, which also lack the technical capacity to ensure the safety, quality and compliance with manufacturing practice standards of these technologies. This has allowed introduction of new health care technologies, often before proper evaluation and sometimes based on unjustified preferences or fashions

Appropriate technology is defined as the adaptation to local circumstances and conditions of knowledge and skills which are scientifically sound and acceptable to those who apply them and those for whom they are used. It should be affordable and should include appropriate use and effective interaction between service users and performers, as well as control of the cost and clinical benefits. Appropriate technology does not mean primitive or necessarily simple and/or less expensive. The initial cost should be considered within the context of the overall benefits and the expected outcome in the long run. Priority should be given to technologies improving public health services, with emphasis on equal access to health care for all. Appropriate technology may differ over time as a result of the impact of already available and newly developed technologies on effective service delivery. Countries have different needs, policies, priorities and capabilities in health care. When deciding on appropriate technology, all these factors should be taken into account. Developing countries should avoid wasting precious resources by purchasing sub-standard, obsolete or improperly re-conditioned medical devices with reduced life expectancies.

A number of the future technologies might be appropriate for developing countries. Biomedical and technological progress have provided modern and sophisticated, often expensive, health technologies but development of more affordable and cost-effective high technology is required. There is hope that such development will be stimulated by advances in molecular biology, computerization of analysis instruments and telecommunications.

During the past 10 years there has been a transition in industry focusing on a variety of advanced technologies involving chemical and physical approaches as well as biological approaches and, increasingly, genetic approaches. Owing to the ever-increasing costs of hospitalization it is anticipated that medicine will move out of the hospital. It is also anticipated that health care structures will change more or less dramatically in different parts of the world.

It is recommended that, before embarking on new technologies and looking into the suitability of a technology for a certain level of health service, the cost and cost-effectiveness of these new technologies, compared with existing alternatives are identified. It is also recommended that Member States take necessary measures to formulate sound national policies on health care technology and establish comprehensive plans for policy implementation. Emphasis should be placed on technology selection, evaluation, adaptation, transfer and rational use.

1. INTRODUCTION

During the past forty years, approaches to health care and patient management have changed dramatically, mainly as a result of the remarkable progress made in medical technology. The increasingly important role technology plays in medicine is evident in every day clinical and public health practice; this has had both positive and negative effects. On the positive side are increased life expectancy, greater diagnostic precision, less time needed for investigations and treatment, and consequently less stress to patients. On the other hand, these advances and innovations in medical technology are in part responsible for enormous increases in the cost of health care which, in many countries, has become a serious economic burden. Moreover, in some situations, there are significant time lags before beneficial technologies are made available to potential users. In addition, major investments are often made in expensive medical equipment which is then not used to its full potential or, alternatively, not used at all because appropriate trained personnel are not available or a critical part cannot be obtained.

It is estimated that in 1992 US\$ 80.8 billion were consumed on health care technology again in a very disproportionate manner, with 92% of it spent in the developed industrialized countries where only one-seventh of the world's population live.

Many developing countries face an increase in their population leading to an increased demand for health services. This is accompanied by an ever-growing gap in economic development between them and the wealthy industrialized countries. This gap is a limiting factor for development of services and technology transfer to countries in need. A more effective mechanism is needed for the transfer of appropriate health technology taking into consideration the local forces that may shape the practice environment, among which are: trends in the demographic profile, macroeconomics, government spending, political forces, and changes in structure and financing of health care.

2. DEFINITIONS

2.1 Health technology

“Health technology” as defined by WHO is: the set of techniques, drugs, equipment and procedures used by health care professionals in delivering medical care to individuals and the system within which such care is delivered.

2.2 Appropriate technology

“Appropriate technology” is defined as: The adaptation to local circumstances and conditions of knowledge and skills which are scientifically sound and acceptable to those who apply them and those for whom they are used.

Appropriate technology should be affordable. This does not mean primitive or necessarily simple and/or less expensive. The initial cost should be considered within the context of the overall benefits and the expected outcome in the long run. Appropriate

technology should also include appropriate use and effective interaction between service users and performers, as well as control of the cost and clinical benefits.

When deciding on a new technology it is important to be aware of whether it is in line with promoting equal access to health care for all, or will benefit only a few people. Priority should be given to technologies improving public health services, with emphasis on equal access to health care for all.

Appropriateness of a specific technology may differ with time as a result of the impact of already available and newly developed technologies on effective service delivery. What was considered as appropriate technology yesterday may not be appropriate today, and what is appropriate now may not be appropriate in the future. Moreover, what is appropriate for one country may not be appropriate to another owing to the different needs, policies, priorities and capabilities in health care. Even within the same country appropriate technology may also differ between levels of health service.

As quality is an integral part of appropriateness of a technology, it should be emphasized that developing countries should avoid wasting precious resources by purchasing medical devices that are substandard, obsolete, improperly re-conditioned or have reduced life expectancies. It is also the responsibility of the national health care authorities to protect consumers from unsafe, ineffective technology. Establishment of quality assurance and total quality management programmes for different disciplines of health care services will assist in evaluation and monitoring of the effectiveness of technologies used in health care delivery systems.

The quality of health technology must also be evaluated on the basis of the human and therapeutic needs of the patient rather than, as too often is the case, on the novelty and sophistication of the technology used or the expenditure in the health care settings.

Consideration should be given to whether the use of certain technologies facilitates relationships between physicians and their patients or detracts from them. Medical staff may spend most of their time in coordinating, assessing and manipulating equipment and some physicians are now interacting with their patients through the "technology interface". Unfortunately the medical profession continues to shift further away from a traditional medical ethic and the principles of professional autonomy, doing what is best for patients and justice, and towards a commercial ethic, away from the hands-on therapeutic approach and towards one which is technology-dependent.

Finally, medical technology is not confined to its association with diagnostic or therapeutic devices but is also concerned with procedures. For example, in transfusion medicine technology is not only concerned with the laboratory technology of blood transfusion, but covers broader areas, such as medical and psycho-sociology, communication and public relations.

3. APPROPRIATE TECHNOLOGY AND FUTURE TRENDS

3.1 General

In order to decide on future appropriate technology, it is important to be aware of the present situation and future trends in health care delivery and technologies to be used for this purpose. Today we are witnessing a rapid progress in medical research that has major implications for the diagnosis of diseases and for clinical practice. Technological changes have proceeded at a rapid pace during the past two decades. During the past 10 years there has been a transition in industry, focusing on a variety of advanced technologies involving chemical and physical approaches as well as biological and, increasingly, genetic approaches. It is anticipated that advances will be even more remarkable over the next decade. This will bring about major changes in the therapy for many diseases, including a more rapid expansion of the use of recombinant-DNA technology in the production of therapeutic agents (e.g. biologically active polypeptides such as growth factors, hormones and cytokines) and vaccines. Advances in molecular and cell biology will drive the future. Molecular diagnostics is already available in many areas, such as cancer, infectious diseases, endocrinology, heart disease and hypertension, and neural defects such as Alzheimer disease, and its use will continue to expand.

3.2 Health care

Traditionally, medicine has aimed at the cure of disease. As understanding of the mechanisms of disease advanced, preventive strategies were employed, immunization being among the earliest preventive measures. However, financing has traditionally been directed towards treatment rather than prevention. Physicians are not compensated for preventing diseases from occurring, but they earn a lot of money for treating complications of diseases. Preventive health care technologies are usually not considered to be in the mainstream of technology assessment, but remain tangential to most preventive health care programmes.

In the 19th century and at the beginning of the 20th century health care took place at home and depended on physical examination and clinical diagnosis. Technological development (mostly non-portable hospital-based technologies) changed this situation and clinical care increasingly took place within hospitals. Due to the ever increasing costs of hospitalization it is anticipated that medicine will begin to move back out of the hospital. It is also anticipated that health care structures will change more or less dramatically in different parts of the world. This will include change in the role of the hospital.

Minimally invasive procedures such as laparoscopic, thoracoscopic and arthroscopic surgeries are increasing in use, such that procedures can now be done on an outpatient basis where formerly hospitalization was required. A number of recent technological advances has allowed the safe transition of an increasing number of acutely ill patients from the hospital to the home. For example, cholecystectomy is being done in some centres through a laparoscope without hospital admission. The miniaturization of invasive techniques will minimize side-effects and reduce hospitalization time (for example, coronary bypass operations without open heart surgery have recently been carried out, with the patient

leaving the hospital after two days). In industrialized countries ambulatory surgery centres are now performing laporoscopic surgery.

The advances in telecommunications stimulate decentralization toward the physician's office and the patient's home. For example, patients can be monitored in their homes through telecommunications. This will mean an increase in the demand for telemedicine services that must be based upon relatively cheap technology, although cheap should not be taken to mean ineffective. With all these developments, some people predict that with hospital care declining, and outpatient care increasing, in the long run only the sicker patients will remain in the hospital, changing hospitals into intensive care units.

3.3 Gene technology

Despite the controversy regarding gene technology, developments in this field will have an important impact on the development of future appropriate technologies. Some people question the interests behind it and are concerned about the unforeseeable and potentially negative implications for mankind and the environment together with the questions these raise in terms of medical ethics. Others see that gene technology opens the door to solving problems related to food production, and human and animal health which are not otherwise attainable. The matter, however, is not a matter of yes or no. Gene technology applications must be differentiated according to their purpose and possible implications.

Progress in research into the human genome will have a strong impact on the future diagnosis of diseases. A rapid expansion in the development of techniques for the diagnosis of molecular markers (gene mutations) for the early detection of cancer, hereditary diseases and infectious diseases will shift diagnostic activities more towards disease prevention. There will be a widespread application of DNA probes, including its use for detection of foreign genes such as viruses and bacteria, and to facilitate prediction of the antibiotics or anti-viral agents to which the organisms are sensitive or resistant. The use of nuclear probe techniques will cover the diagnosis of cancer and prediction of probable responses to different treatments, as well as identify individuals with predisposition to diseases having a genetic component.

The revolution in molecular biological techniques is allowing and will increasingly allow the development of systems to screen patients and families at risk. Because of the costs involved, there is the possibility that these services will be denied to certain patients and this raises a serious ethical issue.

3.4 Laboratory medicine technologies

Technological development related to laboratory medicine is advancing at a very rapid rate, as for example in the development of modern tracer-based immunoassays. The emergence of the ultrasensitive methods has transformed immunodiagnostic technology and the development of modern instrumentation and assay kits.

A new generation of technology—the “array-based binding assay”—is now on the horizon. Miniaturized, multianalyte, array-based, ultra-sensitive assays are designed to measure tens, hundreds, or thousands of small substances in a small sample, such as a drop of blood. It is most likely that this will be the technology of the coming decade in the field of diagnostics.

There will also be an expansion of non-invasive diagnostic procedures. For the comfort of the patient non-invasive diagnostic procedures are being intensively promoted. The use of biosensors for example has the advantage: a) that they can be repeatedly used without the consumption of reagents; and b) that they can be applied *in vivo* (e.g. in glucose monitoring and in monitoring of oxygen load in blood). Nuclear magnetic resonance of the whole body or specific organs, and insertion of probes into the mouth or other body cavities to measure specific analytes are other examples. It is hoped that these developments will slow the rise in medical costs, and will certainly represent an important development in the field of appropriate technology.

The development of rapid diagnostic techniques for direct testing outside the laboratory and self-monitoring by the patient will have an effect on the organization and responsibility of clinical laboratories. The technologies involved are transferable to developing countries. The new methodologies using monoclonal antibodies are more sophisticated, but simpler and quicker to perform. Dry chemistry (solid phase chemistry) has become available for a number of diagnostic parameters. This technology covers also infectious diseases (e.g. tuberculosis, HIV, HVB, HVC). However, rapid testing is not as yet cheap although it is thought only a matter of time for prices to go down.

The question of whether the trend will be towards centralized testing or decentralized testing is difficult to answer and will depend on countries' policies concerning the regulation of laboratories and means of reimbursing their services in countries applying a system of reimbursement.

3.5 Transfusion medicine

Transfusion medicine deals with that part of the health care system which undertakes the appropriate provision and use of human blood resources. Technology plays an important role in this, not only in the laboratory but also in the collection and processing, and in the administrative support of the bridging process which links the blood donor with the patient. Technology therefore cannot be limited to laboratory technology of blood transfusion, but includes other sciences such as medical and psycho-sociology, communications and public relations.

The chain of procedures and processes that relate to the appropriate provision and use of human blood resources begins with the public and finishes with the evaluation and recording of the clinical outcome of the transfusion practice at the bedside, a haemovigilance system. Critical points to consider are: public awareness and education, donor recruitment and retention, donor suitability, blood collection, post-donation service, component processing and product quality control, testing of donor samples, labelling and component release, storage and distribution of blood components, pre-transfusion testing,

clinical outcome and adverse effects (haemovigilance), and information/documentation systems.

Of these critical points we will focus on those related to blood donors because in a majority of situations in countries of the Eastern Mediterranean Region, there is little or no professional attention to this area. Currently, blood donor systems are largely based on family replacement of blood and remuneration. Professional donors still exist in some countries, supporting their day-to-day survival by offering their blood to blood banks.

The psycho- and medico-sociological technologies currently available are either not known to the leadership of transfusion services or are not recognized as important basic tools to create and sustain appropriate awareness and education of the public. Demographic information, which changes dynamically in any society and which should be collected and updated on a regular basis through appropriate surveys, is usually limited, underestimated in its value and therefore not used. However, an increasing number of countries are starting to recognize the importance of this fundamental area of the provision of human blood for transfusion practice.

It is of prime importance to create a dynamic and consistent system for motivation, recruitment and retention of voluntary nonremunerated blood donors, based on established public awareness and through continuous education of the public. The technologies available come from the field of environmental psychology and focus largely on public perception of, and identification with, the appropriate use of human blood resources. Panels of voluntary nonremunerated repeat donors are beginning to be set up in a few countries however follow-up and evaluation technologies are virtually nonexistent.

The selection of suitable potential donors has two distinct dimensions: a) selection based on absence of risk factors and behaviour for the transmission of infections, which is part of the continuous public education technology; and b) medical selection providing information on the suitability of both the donor's physical condition and the assumption that the blood to be collected could be used, provided the mandatory safety tests prove negative.

The technology advocated by, amongst others, WHO, the Federation of Red Cross and Red Crescent Societies, the International Society of Blood Transfusion, the European Union and the Council of Europe consists of the appropriate provision of relevant information on risk factors and behaviour, in simple understandable language. Such information should be provided every time the donor comes for donation, either as written material or through interview, and be appropriately controlled with regard to whether the donor really has read and understood the information and the responsibility towards the safety of the potential recipients.

Most lapses in the selection of suitable donors lie in the technology employed for medical selection, particularly that part relating to donors' accounts of their medical history. Despite the many recommendations and requirements for medical selection of donors, most observed situations practise only a rudimentary, non-structured and poorly documented procedure. In many systems donors are left to fill in a simple list of questions on their own, when the responsibility should unequivocally be in the hands of the (para)medical staff. The

importance of an appropriate account of medical history as a fundamental technology in donor suitability selection is grossly underestimated. Aspects of donor privacy are not always observed correctly, violating primary principles of respect for the motivated individual. In many situations observed, the facilities available are not suitable for these functions.

Education on a continuous basis, together with the provision of adequate facilities and technologies will allow the development of a blood supply and transfusion medicine organization based on a system of quality assurance that guarantees true safety, purity, potency and clinical efficacy in blood transfusion practice.

Important trends to be recognized are:

- development of public awareness and positive perception of blood donation and transfusion;
- clear, understandable and continuous information and education of (potential) donors to optimize the awareness of personal responsibility towards (potential) recipients;
- professional and structured medical selection of donors including adequate and comprehensible information and counselling about reasons for and implications of deferral;
- implementation of information technology, automation and bar code technology;
- development and implementation of quality systems, starting with Good Manufacturing Practices (GMP) and quality assurance through education of personnel (introduction of change of attitude and mentality);
- standardization of processing technology including proper in-process controls based on specified product characteristics;
- application of validated and controlled microtitre technology, based on reagents derived from synthetic and monoclonal technology, using computer-controlled robots and automated information technology for data collection and processing;
- application of molecular biology in confirmatory testing, such as standardized and validated blotting and polymerase chain reaction (PCR) technology;
- implementation of cryopreservation technology;
- development and implementation of stem cell mobilization, harvesting and purification technology, the application of cytokines and growth factors in the development of immunotherapy and genetic manipulation/gene therapy;
- development of clinical awareness and the introduction of haemovigilance as important prerequisites for an appropriate, safe and effective clinical transfusion practice.

3.6 Diagnostic imaging

An excellent example of appropriate health technology for developing countries is the Basic Radiology System (BRS), which is the WHO approach to better population coverage with diagnostic radiology. The system is based on carefully developed specifications and standards.

Imaging services should be planned such that they are based on a logical pyramid of services that meet, first and foremost, the common needs of the majority (e.g. a fracture, a

cough, abdominal or urinary pain, trauma, parasites, infections and pregnancy), rather than the demands of the specialists, whether clinicians or radiologists. The minimum technical specifications of WHO, required for all equipment, should be respected. WHO can provide specifications (through its collaborative centres) and advice on equipment and departmental design.

There are five major imaging modalities: 1) diagnostic radiography (X-rays) which uses ionizing radiation; 2) sonography (ultrasound) which is nonionizing and safe in normal use; 3) computerized tomography (CT) which uses ionizing radiation; 4) magnetic resonance imaging (MRI) which is nonionizing and safe as far as is known; and 5) scintigraphy (radionucleic scanning) which includes positron emission tomography and other very special techniques and uses very small doses of ionizing radiation. The choice of modality depends mainly on the clinical needs of the majority of patients at the hospital or clinic, based on the local disease pattern at that hospital, the clinical services available to treat the patients, and the cost and cost-effectiveness.

It is important to mention that the already available Picture Archiving and Communication System (PACS) will enable the replacement of X-ray films with digital images. PACS produces digital images which can be manipulated, transmitted electronically, or stored on disks or other media.

The commonest clinical needs for diagnostic imaging are: trauma, pregnancy, chest diseases and (much less common) abdominal complaints. According to a report from a WHO centre these indications for diagnostic imaging account for 98% of all imaging needs in small (first referral) hospitals and clinics. In district (second level) hospitals, they account for 85% or more. In large regional hospitals and in university hospitals (tertiary level) these are the indications for over 70% of imaging, even in large sophisticated departments. Therefore, in all hospitals and clinics the priority requirement is for high quality radiography of the skeleton, chest and abdomen (without fluoroscopy) and for high quality ultrasound scanning. Even in very small hospitals, mobile X-ray units and small ultrasound units cannot provide acceptable images. So it is cost-effective to ensure that all small hospitals and clinics which are staffed by physicians have good radiographic and ultrasound equipment, because more patients will be treated near their homes and fewer will be transferred to larger hospitals. All X-ray generators should be of the high frequency, multipulse design; single and 3-phase units are NOT acceptable. X-ray tubes should have small focal spots and high heat capacity. Radiation protection should be part of the design.

Two other modalities may be considered in highly specialized tertiary level hospitals: MRI (particularly useful for soft tissues, including the brain, spinal cord, intervertebral discs, joints and cardiovascular systems) and scintigraphy. MRI requires special installation and is expensive. It is only required in large advanced hospitals with a broad range of clinical services. Either CT or MRI are very useful where there is a radiotherapy-oncology service. The "open" pattern of MRI equipment is much preferred.

While scintigraphy is important in a large, tertiary care/teaching hospital, it is the least commonly used of the imaging modalities. It is not a luxury, but is a very specialized, field. The scintigraphy images provided by radioactive isotopes are used to locate disease,

particularly the spread of malignant tumours (metastases to bone, etc.), to assess thyroid, pulmonary, renal, and cardiac function and to locate hidden sources of infection. A constant supply of radioactive isotopes is required. Positron emission tomography (PET) and similar new isotope scanning techniques are mainly used for cerebral scanning and tumour location in research institutes. A radiochemist and an immediate source of short-life isotopes are required. This is a very specialized field of imaging from which more commonly used scanning may eventually develop. It is not yet in every-day use in every large hospital.

The transmission of images over long distances (teleradiology) is advancing rapidly and becoming more widely used. Preliminary reports show that while effective, it is not necessarily cost-efficient. High quality transmission and 2000-line receiving screens are needed. A radiologist or appropriate specialist (e.g. orthopaedic surgeon or obstetrician) must be available to interpret the images. Clinical information on each patient is required. Many tele-networks are functioning in the industrialized countries; few so far have reported on their use in small, remote hospitals to link up with larger centres. Equally important, no tele-service can be satisfactory if the original images are not of the highest quality. This does not alter the basic choices of imaging, but in some circumstances might improve the quality of interpretation. Within a year or two there should be more knowledge and better equipment.

Viewing of images on monitors rather than on films or scans (film-free imaging), and recording them for future reference is being adopted in large hospitals in the industrialized countries. The equipment is expensive and currently needs constant maintenance to obtain the best images consistently. The viewing monitor must be of the highest quality and the finer the detail, the shorter the life of the monitor. It is certainly already a practical proposition in a large hospital with adequate service engineers. It is difficult to guess when, if ever, film will become obsolete. For all its faults, film is reliable, provides good detail and can be stored.

In general, the more expensive the equipment, the fewer the patients who really benefit, the higher will be the running and maintenance costs and the more advanced the training required to accurately interpret the images.

There are six important guiding principles when choosing imaging equipment for any level of hospital and for any method of imaging.

- The images must be of high quality. Poor images cause many errors of interpretation, and thus, of treatment (and often, further expense).
- The equipment must be safe both in terms of radiation and electricity, whoever uses it. There are international standards governing such equipment.
- It must be easy to maintain.
- The supplier must be able to provide qualified service and spare parts promptly and reliably. A five-year comprehensive service contract is recommended as an integral part of the purchase agreement.
- Equipment for small hospitals must be easy and safe to use even if no fully trained staff are available. It must function well with an unreliable power supply.
- Films and other supplies are expensive. Film processing is a major source of poor quality. The best films and accessories are required to obtain good images: not all films

are the same and the cheapest may become the poorest investment (technical advice is available through WHO).

3.7 Automation and computerization

Automation and the use of robotics have found their way into a wide range of applications in health services. The appropriateness of automation and use of robotics has to be considered case by case depending on many factors including the economic situation, policies, effects on employment and infrastructure. Clinical functions are being integrated into in-hospital information systems for administrative and financial functions already available in many hospitals, allowing transmission of diagnostic and therapeutic information from different sources.

Computerized analysis of data will open up a much more sophisticated approach to the diagnosis of diseases and monitoring the effect of treatment by means of expert systems.

Automation and robotics are being introduced in many industrialized countries and are expected to spread rapidly to other countries. In these countries the changes in health care and cost containment are implemented by hospital administrations, which respond poorly to requests for new personnel. The strategy is to reduce to a minimum the need for personnel, and this is being achieved by increasing the use of automation and robotic systems. It is the widespread opinion in these countries that costs are reduced by automation and eliminating human workers. This is not necessarily so in developing countries where personnel are not as expensive and where loss of job opportunities may be deleterious to the efforts being made to raise levels of education.

Automation is not simply a transfer of workload from human beings to machines and doing the same things in a different way. To be effective the automated system, technique or instrument must increase safety, increase efficacy or reduce costs. If the costs are increased, as often is the case, a significant increase in safety or efficacy must be clearly demonstrable. Furthermore, the systems must be simple to use, otherwise they will be bypassed by workers with a resultant potential decrease in safety.

3.8 Environmental health

Appropriate technology, in the context of environmental health, refers to technologies which are environmentally friendly and, at the same time, are suitable for the economic, institutional and social conditions and capabilities of a particular setting. Their application should result in simplicity, efficiency and cost-effectiveness.

The use of appropriate technologies relates mainly to water and wastewater, for example, the use of waste stabilization ponds for treatment of wastewater. Waste stabilization ponds, when designed properly, have a very high efficiency for bacterial and viral kill and are especially the technology of choice for the destruction of helminths and nematode eggs. However, ponds require large areas. If the price of land becomes prohibitive, a waste stabilization ponds system can no longer be considered as an appropriate technology. Other appropriate technologies in wastewater treatment are wetlands, aquatic treatment systems, duck weed and bio-filters, none of which are expensive

and all of which are environmentally friendly. The common appropriate technologies for water supply treatment are slow sand filtration, infiltration galleries near rivers (bank filtration) and groundwater aquifer recharge.

For solid waste treatment, composting of the organic portion of solid wastes is an environmentally friendly and appropriate technology. In pollution control, the use of clean technologies, mass transportation, solar energy, electric trains, electric cars and windmills are the most relevant technology options that are suited for the conditions of the Region.

Housing designs, especially for heating, cooling and ventilation, are critical environmental factors which have a direct and immediate impact on human comfort and health. Housing designs traditional to the Region, with high ceilings, thick walls and air circulating towers which create a natural ventilation, are excellent examples of ingenious use of appropriate technologies. Unfortunately, because of cost, lack of space and other factors, insufficient attention has been given to making traditional architecture an affordable, feasible option in the modern setting.

To reflect on future trends, we need to consider the most pressing environmental concerns in the years ahead. The Eastern Mediterranean Region is in the dry zone and faces, in most parts, a severe water shortage. The main focus for development and use of appropriate technologies must be placed on water-related technologies, pollution abatement methods, clean technologies, the prudent use of chemicals, and models for environmentally friendly cities. The future trends with regard to the use of appropriate technologies can be placed within certain categories, as follows:

- the removal of physical, chemical and microbiological pollutants and contaminants through the use of physical treatment processes and means;
- stabilization of waste material, as far as possible, through complete natural, physical, chemical and biological reactions, where minimal mechanical equipment, fuel and chemical substances are used;
- ecologically sensitive methods and technologies which are suited for the dry areas where water conservation is an overriding imperative;
- application of the concept of the "eco-city" wherein the optimal use of space, transportation facilities, waste minimization techniques, energy saving options, housing design and provision of green areas are carefully considered;
- use of computer techniques for urban management, industrial zoning, pollution monitoring, etc.

3.9 Pharmaceutical biotechnology

"Pharmaceutical biotechnology" is the term used to cover all recent advances in the biological and medical sciences and their exploitation. In the course of the past century these sciences turned their scrutiny from the organ level to that of tissues and now focus upon the level of the molecules involved in controlling the function of tissues and organs.

The explosive increase in knowledge in the biological sciences of molecular genetics, immunology and cell biology over the past twenty years or so has resulted in the discovery

and characterization of the molecules that mediate the effects produced by external agents, drugs or biological response modifiers at the cellular level.

As a result of this tremendous volume of information came the realization that these materials could be manufactured in significant quantities and used as commercial drug substances in their turn. Contribution to the subject can be traced to various factors, of which the following are the most significant:

- recognition and characterization of the endogenous factors that mediate the effects produced by traditional drugs (xenobiotics, or foreign materials affecting life) and identification of the associated mechanisms of activity;
- use of recombinant DNA technology to enable protein mediators to be produced on a large scale by fermentation in fast cells such as bacteria and yeasts;
- production of monoclonal antibodies on an industrial scale following the realization that these extremely sensitive materials could be used for the diagnosis and treatment of certain disease states;
- computer-assisted design of stable derivatives of the endogenous effectors and enzymes; and
- optimization of activity and delivery of these exogenous factors so that they have become, effectively, the new generation of drugs used for the treatment and alleviation of human and animal diseases.

Biotechnology medicines will require sophisticated delivery systems to transport the drug to the site of action in the body. Although many of the biotechnology products currently on the market, and those in development, are administered parenterally, novel drug delivery forms, such as liposomes, microspheres, transdermal and implantable systems, polymers, and other exotic drug delivery systems need to be developed.

The increasingly complex structure and mode of action of the newer biotechnologically-derived biological response modifiers have provided some interesting challenges to the formulator. Over the past decade, biologists, biochemists, and chemists have suddenly realized that the solution of a highly purified and active protein coming off a separation column is not suitable for selling as a new drug and that a lot more work is required. Apart from having to satisfy the needs of the regulatory authorities around the world, there are practical issues to be resolved, such as purity, sterility, and stability.

4. THE TECHNOLOGY MARKET AND THE GROWING INFLUENCE OF INDUSTRY

The development of modern technology and translation of its findings into a workable technology is linked to research. Because of the high costs involved in research and development, it will largely take place in industry, while research by academic institutions will be more or less limited to fundamental aspects, or development in specific areas which are appropriate for a particular country or area. This means that methodologies and equipment are dictated more and more by the suppliers and there is greater commercial pressure to use new technologies. Despite the fact that investment in new medical technology has brought about significant advances in patient care, medical technology is often implicated in increasing health care costs. The matter is not a simple one, as the

commitment to controlling health costs may conflict with innovation and development in medical technology.

Strategies adopted by industry have influenced, and continue to influence, the marketing of technologies. In this connection we will discuss the role of industry in technologies related to laboratory medicine, but as an example it might be applied to almost all health care services.

In industrialized countries laboratory services in hospitals are the largest group of consumers. In general, laboratory tests account for 3% to 5% of national health care expenditure in industrialized countries. As has already been mentioned, the consumption of health care technology is disproportionate between the industrialized and developing countries. This general remark is applicable to expenditure on *in vitro* diagnostic medical devices, including diagnostic analytical equipment and instruments, software and reagents. However the increasing costs of health care will force manufacturers to change their strategies in order to remain competitive and to look for new markets. Developing countries consume only about 10% of the world's production of *in vitro* devices. However, the highest increase in growth of the *in vitro* device market over the next few years is expected to be in developing countries. Industry is expected to use all possible means to increase sales and expand the market in developing countries. It is unfortunate that manufacturers have replaced many items of equipment that were relatively low cost, reliable and simple, and which were appropriate for use in many developing countries, with electronic and microprocessor-controlled equipment, the maintenance and repair of which are more complex and costly. There is a need to assess the possibilities of continuing the production of basic (non-microprocessor-controlled) equipment that has proved to be appropriate for use at the peripheral and district health care levels. Manufacturers should be persuaded to continue the production of robust basic equipment and shown that there is still a market for such. Production could either be undertaken by the manufacturers themselves or could be assigned to developing countries with adequate infrastructure.

The strategies of the manufacturers are also directed towards increasing their profits in the already saturated market in the industrialized countries, for example, with regard to *in vitro* devices. Industry currently gives attention and effort to the development of these "yes" or "no" devices because for medical diagnostic purposes the physician usually converts highly sophisticated quantitative test results into "yes or no" decisions.

A number of technological advances have allowed increased near-patient testing, outside the laboratory, by non-specialist operators. These will have an effect on the organization and responsibility of clinical laboratories. These technologies are based on small instruments and simple disposable non-instrumental systems using either dry chemistry reagent carriers (strips, slides, modules) or cassettes containing all the liquid required for a test. It is expected that by the year 2000 tests for monitoring long-standing conditions, such as diabetes and pregnancy tests, will be performed routinely at home in many industrialized countries. Other tests that may be carried out in community settings are expected to take place in the general practitioner's office. Patients have monitored diabetes at home for many years. Pregnancy tests, drug-screening reagents, stool and haemoglobin tests, and cholesterol-measuring devices are already available over-the-counter in many countries.

Testing outside the laboratory by non-specialist inexperienced operators opens up a huge market for industry and manufacturers are promoting this type of testing. Professionals, however, have some reservations as such testing raises complex issues related to quality assurance. Industry believes that assuring quality is its own responsibility.

The WHO BRS is an example of how industry can influence the continuity of marketing of appropriate technology when there is a conflict of interest. The WHO BRS X-ray unit has demonstrated excellent quality in its production of diagnostic images. At the 1991 meeting of the Radiological Society of North America, the WHO International Society of Radiology Standard Radiographs reported that the highest number of radiographs awarded first place were produced by WHO-BRS equipment. Although the WHO-BRS X-ray unit is technically superior to conventional equipment and costs substantially less, its present price is too costly for many developing countries. The original estimated unit cost in 1978 was about US\$ 17 000. However, the unit represented a real threat to the future marketing of conventional units. By 1982 the price had risen to US\$ 23 000 and by 1984 to US\$ 30 000 (the same as the price of the conventional units produced by Siemens and Phillips). When the US dollar exchange rate decreased dramatically, the price of Siemens and Phillips equipment for both BRS X-ray units and conventional units became equivalent to about US\$ 60 000. Were some developing countries with adequate infrastructure to start manufacturing the BRS X-ray units the per unit cost in production would be about US\$ 10 000 to US\$ 12 000.

5. EVALUATION OF TECHNOLOGIES AND FACTORS TO BE CONSIDERED IN THEIR SELECTION

To avoid costly errors when accepting or rejecting new health technologies greater attention needs to be given to the issue at policy level. As the introduction of new technology may have economic, social and ethical consequences, identification of new technologies and anticipation of the consequences should be made at an early stage in the planning process.

Before becoming widely used, new technology should be evaluated from the point of view of the following parameters:

- technological: determining what is achieved by the “new” as compared to the “old” technology or available alternatives. No test should be introduced into service unless it replaces an existing test or measures an entirely new function.
- clinical: measuring the progress in terms of improvement of diagnosis and patient management.
- health outcome: determining the effect of the technology on the management of the patient, on the length of hospital stay and on the final outcome: cure, death, sequelae, disability and quality of life.
- economic: calculating the total, partial, direct and indirect costs of the disease and the aftercare, and relating this to the benefits.
- psychosocial: assessing the effects of the new technology on patient acceptance, confidence and well-being and taking the performer’s views and the ethical aspects into consideration.

- logistical: investigating the availability of the necessary reagents, spare parts, maintenance facilities and replacement.
- appropriate utilization: assessing whether the technology is relevant and useful and thus appropriate to the specific situation and condition of a health service in a country, region or area and whether it is being overused, underused or misused.
- environmental: assessing performance, costs and management of waste and biological impacts (population, flora, fauna, and nature in general)
- risk: assessing risk and biosafety for materials (reagents, equipment and devices) and people (operators, maintenance engineers, waste disposal workers).

Adequate measures should be identified and adopted by countries for the selection of appropriate technologies. It is particularly important, before embarking on new technologies and looking into the suitability of a technology for a certain level of health service, to find ways of identifying the cost and cost-effectiveness of these new technologies, compared with existing alternatives. The following should be taken into consideration.

- Assess actual and anticipated needs.
- Explore alternative options.
- Consider capital and running costs, estimated on a unit basis
- Assess potential usefulness. What might happen after the introduction of a new technology and what might happen if it is not introduced?
- Study the importance of the technology for epidemiological surveillance, disease prevention, and value in selecting and assessing the effectiveness of control measures.
- Consider local infrastructure, availability of well-trained operators and state of local industrial development.
- Assess reliability, sensitivity and specificity of techniques.
- Assess available technical expertise.
- Look into complexity and maintenance of the equipment required and consider maintenance costs. Consider also maintenance dependence on the manufacturer.
- Consider supply and stability of chemicals and reagents.
- Consider risk assessment and biosafety.
- Consider type and cost of waste disposal.
- Consider environmental consequences.
- Consider twinning as a useful tool for technology transfer.
- Apply on a pilot scale and assess impact.
- Re-evaluate before applying on a wider scale.
- Do not overlook trade policies.

6. WHO PROGRAMME ON TECHNOLOGY TRANSFER

6.1 General

One of the major issues facing the countries of the Eastern Mediterranean Region is the transfer of technology from the highly developed to the less developed countries. The great variation among these countries in political, social, economic and cultural characteristics raises serious issues, which need to be reviewed. Regional diversity

underlines the need for each country to formulate and implement policies relating to the planning, requirements, selection, procurement, standardization, safety, efficiency and maintenance of health technology.

6.2 Programme objectives

The main aims of the WHO programme are:

- a) *policy guidance* to provide guidance to countries on the formulation of national policies and programmes for health technology development, assessment, selection and adaptation;
- b) *development* to promote and monitor the development of health technologies that meet the needs and priorities of countries;
- c) *assessment* to assist countries in laying down criteria for the assessment of health technologies, based on their cost-effectiveness and benefit to the population;
- d) *selection/adaptation* to assist countries in deciding which technologies they wish to select or adapt, on the basis of their prior assessment.

Special attention should be given to the creation of national coordinating agencies for health technology assessment, which is an area where the accumulated experience of more developed countries can be of considerable help.

6.3 WHO programme activities

The principal task of WHO in this area is to help countries to gain access to those technologies which will enhance the health status of all their people. In principle, WHO can assist its Member States by:

- helping to assess their technology needs and their present capabilities;
- providing information and advising on the technologies available to address their health care priorities;
- helping to develop clear policies and programmes for the acquisition and use of necessary technologies;
- assisting in establishing a national infrastructure to guide the acquisition of needed technology, to monitor its use and to maintain it; and
- helping to train essential human resources to organize, manage and operate the technology.

6.4 Challenges to health care technology transfer

Two of the main challenges of health technology development, assessment and transfer in developing countries can be summarized as follows:

1. Lack of access to databases or other sources of information. Articles on technology assessment are difficult to obtain in developing countries. Most libraries have limited resources for subscribing to journals; and journals focusing on efficacy (that is, primary data generation) tend to take priority. Many organizations issue reports on technology

assessment but individuals in developing countries may not know about these unless they are on the organizations' mailing lists.

2. Lack of funding to undertake technology assessments. In developing countries, the few funds allocated to research are usually devoted to public health issues. Even for interested researchers, this is a strong deterrent to undertaking assessments.

Other problems encountered in developing countries are:

- lack of commitment and political support
- weak national health care systems poorly equipped to adopt new health care technology
- lack of national expertise.

6.5 Regional activities in support of technology transfer

Within the area of health care technology, the WHO Regional Office for the Eastern Mediterranean has tried to promote collaboration within the Region and with established institutions outside the Region. These activities, although limited, have proved to be very useful. The main WHO activities in this area include:

- Transfer of technology on the production of hepatitis B vaccine between Japan and the Islamic Republic of Iran through consultancy and training fellowships;
- Technical cooperation among developing countries within the Region between:
 - Pakistan and Tunisia and Pakistan and the Islamic Republic of Iran on the production of rabies human diploid cell vaccine;
 - the Islamic Republic of Iran and Tunisia on the production of measles vaccine;
- Training courses on the use of appropriate technology among various countries in the Eastern Mediterranean Region on polio diagnosis and AIDS diagnosis;
- Collaboration with the Arab Union of Manufacturers of Pharmaceuticals and Medical Appliances in increasing awareness of the importance of health technology transfer.

In addition WHO strongly supports the concepts of twinning and visiting professors between academic and health institutions in developed and developing countries.

7. CONCLUSIONS AND RECOMMENDATIONS

It is evident from the preceding discussion that technology has assumed increasing importance in various fields, including health, and it is true that the astonishing advances that have to be made in health care would not have been possible without modern technology. However such technology can be expensive. Health technology should be carefully evaluated before a decision to acquire is taken. It is surprising that no country in the Region has yet established a mechanism for systematic evaluation of new health technologies, except for the drug industry. Yet such a mechanism represents an essential ingredient for establishing and maintaining up-to-date, cost-effective and high quality appropriate health care services. Member States should therefore establish an efficient national system for appropriate health technology transfer. Of special importance is the

availability of national resources and infrastructure to make the transferred technology viable, cost-effective and sustainable.

In 1996 the Regional Consultative Committee discussed the issue of appropriate technology and made several recommendations. Among these recommendations were the following:

1. Member States are invited to develop national programmes on health technology. The programme should address issues of selection, rational use, developing national capabilities and contributing to modern biotechnology development.
2. Member States should not delay in joining the movement for modern biotechnology.
3. WHO should collect information on available national activities and institutions in the area of modern biotechnology. Information on how other countries have adapted modern technologies should also be obtained. The analysis of these data will be essential in the development of regional programmes.
4. WHO should develop technical guidelines and technical codes on selection and rational use of modern technology.

The Regional Committee is therefore invited to consider these recommendations and advise on practical steps to be taken for the formulation of regional and national policies on appropriate health technology transfer. These may include:

- Designating a national focal point for health technology in the country;
- Assisting countries in making broad appraisals of national needs and priorities, through intersectoral and multidisciplinary workshops and seminars;
- Developing suitable mechanisms for the assessment and acquisition of health technologies;
- Developing means of obtaining access to health technology information systems and databases;
- Reviewing the limitations of existing systems, the various problems encountered and the means of overcoming them;
- Developing more rational approaches to diagnostic, therapeutic, promotive, preventive and rehabilitative technologies;
- Encouraging institutions to develop their expertise in health technology;
- Collaborating with organizations, professional associations and donor agencies to ensure that assistance in health technology is given where it is most needed and likely to be most effective;
- Conducting comprehensive case studies, in collaboration with national authorities and international organizations, to assist the countries concerned and to make this experience available to others.