



**INTERNATIONAL UNION FOR
PHYSICAL AND ENGINEERING SCIENCES
IN MEDICINE**

*Incorporating the International Federation for Medical and Biological Engineering and
the International Organization for Medical Physics*

HEALTH TECHNOLOGY AND TRAINING TASK GROUP (HTTTG)
Appropriate Health Technologies and Training for Developing Countries

Draft Program Outline

October 16, 2007

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1. BACKGROUND

Modern health care relies heavily on a whole range of health technologies. According to the definition commonly used by WHO, these include drugs, devices, equipment, technical, medical and surgical procedures, the knowledge associated with them in the prevention, diagnosis and treatment of disease as well as in rehabilitation, and the organizational and supportive systems within which care is provided. Drugs, which belong to special subsets of health technologies, are not included in the work of the HTTTG. Medical and surgical procedures are within the scope of this program only with regard to devices and technical support. Included into devices and technical procedures are the information and communication technologies.

Health technologies should be efficient, safe, cost effective and available to all people without causing a financial burden to the health care systems too high to make them achievable and sustainable. An important prerequisite to attain these goals is the implementation of health technology assessment, planning and management as an accountable, systematic approach to ensuring that the technologies meet the demands of high quality patient care.

Health technology assessment (HTA) has, in times of rising costs of the health care systems and limited budgets as we see them coincide in most countries, become an important tool and often a political issue, too. The rapid growth of medical knowledge as well as diagnostic and therapeutic techniques and technologies requires a conscientious employment of available resources. Finding appropriate solutions is a major challenge for HTA since a wide range of aspects have to be included into the decisions, such as security, efficacy, cost in comparison to the benefit, as well as social, legal and ethical implications. Decisions in the health sector and in health policy are to be made on the basis of scientific findings, which means that they have to be evidence-based. HTA helps to prevent the uncontrolled dissemination of unsuitable technologies in the health systems, as well as to minimize the financial burden involved and to increase the quality of health care. With an early comprehensive evaluation, HTA also contributes to a fast integration of innovative procedures in the health systems, as well as to a removal of unnecessary, and therefore cost-intensive, methods.

Steadily increasing health care costs have reached crisis proportions in many countries and are coming under close scrutiny from governments, health-care providers, insurers and consumers. Efforts to contain these costs, or at least slow their growth, have been largely unsuccessful as they continue to outpace growth in gross domestic product. Though often blamed for the cost explosion in the health care systems, the cost of medical devices is only about 2-8% of health care expenses in most countries and properly selected technologies can substantially increase the quality of health care and at the same time reduce the overall burden and cost of sickness and health care. Realizing these opportunities is one of the goals of modern health technologies.

In spite of all efforts to make all health technologies available to all countries, an increasing number of countries still can not shoulder the financial burden of acquiring and maintaining all technologies that would be desirable and beneficial for the health care of their people. Therefore it is necessary to establish priorities based on available resources and the burden of disease, a rather complex task for which the World Health Organization (WHO) together with the IFMBE has already developed methodologies and tools such as the WHO Integrated Health Technology Package (IHTP).

One of the prerequisites to make proper use of health technologies is the existence of an appropriate, reliable infrastructure. In order to set up and/or maintain the infrastructure, centers for health technologies should be established as part of the health ministries or at least strongly linked to these. These centers should implement the national strategies and plans for the health technologies, oversee and guide the national health care systems and, where appropriate, regional health care centers with regard to the health technologies as well as collaborate and build partnerships with health-care providers, industry, patients' associations and professional, scientific and technical organizations.

Another important step in improving the quality of health care through health technologies is to build up the necessary health workforce, i.e. medical physicists, clinical engineers and technicians, which is able to manage, maintain and operate the technologies and educate the users, i.e. physicians and nurses, in the safe and competent use of equipment and devices. The industrialized countries should be called upon to

help those countries who cannot afford to provide education and training for a sufficient number of clinical engineers and technicians by offering educational support.

The IFMBE has been an NGO in official relations with the WHO since 1964. It incorporates 58 national and international member societies, representing more than 120,000 professional biomedical and clinical engineers, constituting a unique pool of expertise on the subject matter of the health technologies. The Federation is closely cooperating with WHO in the areas of health technologies, specifically policy and planning, quality and safety, norms and standards, technology assessment and management, education and capacity building. The IFMBE has successfully been working for many years with WHO on projects supporting developing countries in the area of health technology policy, planning and management, education and capacity building, within the broad context of improving health service delivery and health systems performance. Together, WHO and IFMBE have developed several WHO methodologies and tools to support these activities, such as the WHO Integrated Health Technology Package.

IOMP has recently adopted a more proactive approach to support developing countries. In joining with IFMBE to form the HTTTG, IOMP has demonstrated that it accepts a responsibility to developing countries that may deviate somewhat from past priorities. This means that IOMP will support the development of appropriate technologies, rather than those more suited to the western model of health care. This is particularly true in the field of radiation oncology, where patients present with much later stage of disease.

The role of the IUPESM HTTTG, being borne by IFMBE and IOMP, is to:

- help identify needs in health technologies and training for each cooperating country,
- make recommendations for actions to satisfy these needs, and,
- as far as appropriate and possible, support the countries in the necessary actions.

The Task Group will cooperate and coordinate its activities with the World Health Organization and participate in the maintenance and further development of the WHO Integrated Health Technology Package. The HTTTG will collaborate with other relevant national and international organizations, academic institutions and professional bodies which provide support to developing countries in the prioritization, selection, acquisition and use of health technologies. The HTTTG will seek funding for its activities from IUPESM/IFMBE/IOMP and from appropriate funding agencies through IUPESM.

Appropriate Health Technologies

Appropriate health technologies are, according to the WHO Health for All Series' Glossary of Terms, methods, procedures, techniques and equipment that are scientifically valid, adapted to local needs, and acceptable to those who use them and to those for whom they are used, and that can be maintained and utilized with resources the community or the country can afford.

2. THE WORK OF THE HTTTG

The HTTTG will, in cooperation with WHO, organize workshops in all relevant regions and participating countries together with the local Clinical Engineers and Medical Physicists as well as all other relevant professional groups, the health ministries, health care providers and political decision makers to evaluate the health technologies in the countries and to develop plans for the realization of appropriate infrastructures for health technologies.

HTTTG brings to the table a spectrum of skills never before made available to address the technological needs of developing countries. With expert consultants in medical physics and biomedical engineering, HTTTG can identify specific technological needs and recommend technological solutions. Such solutions may be obtained by promoting appropriate R&D with specific endpoints to achieve this objective.

Specific attention will be directed towards education and training. HTTTG will closely cooperate with the WHO Global Health Workforce Alliance which has been established in 2006, with the IFMBE being a founding member, upon a call by African Heads of State, the G-8, the Paris High-Level Forum and the World Health Assembly for urgent and coordinated action on the health workforce crisis with the purpose to assist countries in their efforts to carry out the ten year plan for scaling up the health workforce outlined in the *World Health Report 2006: Working together for health*.

A Strategy for the implementation of appropriate health technologies at country and regional levels:

▪ **Initiation**

○ *Task identification*

- Has the objective for health care technology in the country or region been identified?
- Has political and other support been advocated and secured?
- Has the scope of the process been defined?

○ *Identification of task force*

- Are human and other resources available at country and regional levels for the development and implementation of the strategy?
- Have the terms of reference of the task force objectives been approved?
- Has the task force been appointed?
- Has the implementation schedule been approved?
- Are operational procedures developed?

▪ **Situation Analysis**

○ *Country situation*

- Have needs assessment studies been conducted?
- Are country situation analyses and reports available?
- Are health sector, economic and social indicators and other information available?
- Have other health care technology initiatives and lessons from them been taken into account?

○ *Justification*

- What is the policy basis (resolutions, etc.)?
- What is the social justification?
- What is the economic justification?
- What is the programmatic justification?

Source: Eastern Mediterranean regional strategy for appropriate health care technology, WHO Regional Office for the Eastern Mediterranean

In addition to setting up the HTTTG, IUPESM and the IFMBE have been pushing for a resolution of the World Health Assembly (WHA) towards promoting health technologies around the world. The resolution (see text box) has been brought in by the Mexican WHO delegation under the leadership of the former IFMBE Clinical Engineering Division Chair Adriana Velasquez Berumen and has been approved by the WHA at its 60th meeting in May 2007. The adoption of the health technologies resolution (WHA60.29, see addendum) has brought HTTTG a major step forward in realizing its goals worldwide.

3. THE HTTTG ACTION PLAN

The health technology needs at the village and provincial level in developing countries require the design of appropriate technology and training packages to satisfy those needs, so that the majority of people receive improved health care. The right mix of effective and efficient healthcare delivery depends on the available health care technology. Such technologies must be carefully defined to achieve the widest application to the largest population. The appropriate healthcare technology packages should be defined in accordance with WHO levels of health services of Primary, First Referral, Second Referral and Last Referral levels.

Technology needs are very country-specific, and are determined by the local disease burden, patient demographics, health service delivery models, clinical practice, etc. These may even vary from region to region within one country. WHO has together with the IFMBE developed a methodology and software-based tool called the Integrated Health Technology Package (IHTP). IHTP is designed to assist countries in identifying their individual technology requirements linking and integrating a wide variety of parameters to arrive at locally relevant lists of technology needed to address their specific disease and patient profiles within the existing health service delivery models and accepted clinical practices, and health system capacity and constraints for managing the acquired technology.

The evaluation of the status quo will include:

- Population data and trends
 - Demographics
 - Patient data
- Disease profile and trends
 - Disease priorities
 - Emerging health problems
- Health care system information and trends
 - Regulatory framework
 - Human resources availability
 - Existing/projected
 - Training and education: existing/projected
 - Infrastructure
 - Existing facilities/projected facilities: rural/urban
 - Equipment
 - Other needs, including communication, roads, water, power
 - Service delivery
 - All three levels (primary, secondary, tertiary)
 - Referral system
 - Public/private sector
 - Health information systems
- Financial resources
 - Health budget
 - Other resources

The action plan includes:

- Assessment (using existing tools)
- Based on the assessment, identifying gaps as compared to national, regional and global standards and recommendations
- Setting national priorities based on objectives and national targets
- Developing a national implementation plan and budget for appropriate health technologies
- Implementing the national plan, including:
 - Regulatory mechanisms
 - Procurement policies and systems
 - Maintenance systems
 - Quality assurance systems
 - Risk management systems
 - Training of healthcare professionals, technicians, managers and operators
 - Equipment lists
 - Performance evaluation
 - Cost-benefit analysis
- Monitoring and evaluation

The strategy for the implementation at country and regional levels will be¹:

▪ **Initiation**

○ *Task identification*

- Has the objective for health care technology in the country or region been identified?
- Has political and other support been advocated and secured?
- Has the scope of the process been defined?

○ *Identification of task force*

- Are human and other resources available at country and regional levels for the development and implementation of the strategy?
- Have the terms of reference of the task force objectives been approved?
- Has the task force been appointed?
- Has the implementation schedule been approved?
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○ *Country situation*

- Have needs assessment studies been conducted?
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- What is the policy basis (resolutions, etc.)?
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- What is the programmatic justification?

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The appropriate healthcare technology packages should be defined in accordance with WHO levels of health services of Primary, First Referral, Second Referral and Last Referral levels.

Technology needs are very country-specific, and are determined by the local disease burden, patient demographics, health service delivery models, clinical practice, etc. These may even vary from region to region within one country. WHO has together with the IFMBE developed a methodology and software-based tool called the Integrated Health Technology Package (IHTP). IHTP is designed to assist countries in identifying their individual technology requirements linking and integrating a wide variety of parameters to arrive at locally relevant lists of technology needed to address their specific disease and patient profiles within the existing health service delivery models and accepted clinical practices, and health system capacity and constraints for managing the acquired technology.

HTTTG wishes to assist countries in defining their health technology needs, and identifying and rectifying health system constraints for adequate management and utilization of health technology,

¹ Taken from: Eastern Mediterranean regional strategy for appropriate health care technology, WHO Regional Office for the Eastern Mediterranean

particularly through training, capacity building and the development and application of appropriate technology.

4. LEVELS OF HEALTH CARE

Primary level (first contact level) with a health centre (smaller health centres may be called dispensaries, health stations, health posts) serving a defined community or area - normally several villages (at a single village level, at best there might be some community or auxiliary health workers). A health centre carries out health promotion, protective, preventive, simple diagnostic, curative and rehabilitative activities for ambulant patients, and normally has no beds other than perhaps those needed for emergencies and maternity care. In most instances, it has no physician on the staff, but a physician assistant or nurse assisted by community or auxiliary health workers. The most sophisticated devices at a typical health centre would be syringes for immunization, endoscope, and weight scale for babies.

The provision of new generation, low technology equipment and training, to be defined, could lead to major enhancements at this level, building on the existing traditional medicine at the village level, and enhanced interaction with the secondary level.

First referral level - normally a district hospital that is a recognized referral facility providing a 24-hour intramural medical care which represents a higher level of competence than the source of referral, e.g. health centre. It may be very small with just few beds. In most instances, these facilities have a very limited human resource capacity, a very limited technology base with very basic laboratory services and, if any, imaging equipment, and simple surgery is often done under local anaesthesia.

The technology needs to be defined, so as to enhance the quality of health care delivery. A telemedicine facility is required to leverage the skill basis by drawing on secondary level expertise for consultation and training.

Secondary referral level - a more sophisticated hospital (may be a provincial hospital) providing multi-specialist intra- and extramural care, and serving as a backstop for the first referral hospitals in the hierarchy of technical competence. It may also, on occasion, have special expertise in some particular medical diagnostic and treatment domain, which would qualify it as an institution of last referral for a specific subject.

The technology should allow telemedicine to specialists at the tertiary level. More substantive technology targeted at specific diseases needs to be developed, such as palliative treatment for late presenting patients with advanced cancer, with lower cost therapeutic and imaging requirements compared with that for curative therapy.

Visiting biomedical physicists and engineers to maintain and calibrate equipment.

Last referral level - a most sophisticated hospital located in a national or provincial capital or other big city, typically a University Teaching Hospital, providing the highest level of medical care available in the country or a region.

This level follows the western model of centralized expertise and high technology, and is a resource for education, training and consultation. Specialists in attendance can monitor and communicate with lower level centres by telemedicine.

5. THE BROKERAGE

A brokerage service is under construction. Its aim is to facilitate donation/purchase of appropriate health technology for the developing world, and to reduce the quantity of unsuitable technology arriving there. The initiative is lead by Patricia Coyle, John Loadsmann, John Keneally and Martin Turner, all from Australia.

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acceptable to those who use them and to those for whom they are used, and that can be maintained and utilized with resources the community or the country can afford.

Availability of training will be an important aspect of the brokerage.

The brokerage is not in competition with existing donation guidelines (WHO, ACCE, FAKT, etc) but is intended to serve as a simple means of implementing them. It will be an advisory service only, and entirely online. Potential donors and recipients (“requesters”) will, on entering the website, be invited to access a form to be completed providing certain basic information. This information will then be used by the online volunteer ‘experts’, clinicians and engineers/technicians, to assess the appropriateness or otherwise of the materials for use in areas of limited resources. Items deemed ‘appropriate’ or potentially so, will be recorded, and, when indicated, matching will be attempted, again by the experts.

The experts will be people with knowledge and experience of health technologies, especially that appropriate to limited resource environments, and/or conditions in the relevant areas of the world.

When a potential match is agreed upon, the information will be made available to the 2 parties, and the work of the brokerage is completed. The matter is then in the hands of the 2 parties.

6. BME AND CE SURVEY

7. SCHEDULE OF PLANNED ACTIVITIES

7.1. Regional Workshops

7.2. Activities in Vietnam

8. FUNDING

9. COOPERATION WITH OTHER ORGANIZATIONS

9.1. WHO

9.2. UNIDO

9.3. THE WORLD ALLIANCE FOR PATIENT SAFETY

9.4. THE GLOBAL ALLIANCE FOR THE HEALTH WORK FORCE

9.5. BIOMEDEA

9.6. ACCE

9.7. OTHER, ESPECIALLY MEDICAL ORGANIZATIONS

10. ADDENDUM

10.1. GLOBAL CHALLENGES OF HEALTH CARE TECHNOLOGY¹

Andrei Issakov², Peter Heimann³, Yunkap Kwankam⁴

10.2.1. Introduction

The provision of efficient and equitable high quality health care requires putting together an extraordinary array of properly balanced and managed resources, including healthcare technology, both fixed assets and consumables. Investments of both capital and recurrent character for their generation, purchase and maintenance are enormous. Thus, related decisions must be made carefully ensuring the best match between the supply of resources and the health system needs, the appropriate balance between the capital investments and recurrent implications, and among the different categories of resources and the capacity to manage purchased equipment and devices throughout their entire life cycle.

Technological progress and the way in which assets are managed significantly influence the effective lifetime of health system capital and its impact on service delivery. Old investments quickly become outdated as new technologies emerge or they rapidly deteriorate and become unusable due to poor care and maintenance. Investments are wasted and assets underutilized, if needs assessment and planning are insufficient, technology support and user capacity are inadequate, and the different resource inputs are not properly balanced.

As only a small number of countries are producers of the world's health technology, the vast majority of countries depend on technology transfer. This transfer may require changes in the technology, the context to which it is transferred, or both. While in industrialized nations technology assessment and asset management have notably advanced and have long been well established to control costs and improve access to quality care, in most developing and transitional countries health systems failed to develop the evaluation and support capacity necessary to effectively and efficiently introduce and utilize transferred technology, thus causing serious imbalances.

Health technology has become an increasingly visible policy issue, and health technology management strategies have repeatedly come under scrutiny in recent years. Policy- and decision-makers are deeply concerned, realizing the benefits one can expect from new technologies with regard to potential increase in efficiency and effectiveness of health interventions, but at the same time weighing these benefits against the potential costs and the health system's absorbing capacity. Health authorities are confronted with a bewildering array of technology choices, and find themselves under all kinds of internal and external pressures as they evaluate health priorities and allocate scarce resources.

Clear policy guidance and effective tools for handling complex technology choices are necessary for the decision-makers and managers if they are to adopt efficient healthcare delivery practices in response to health needs and people's expectations.

10.2.2. Why Health Technology Matters

Technology plays a pivotal role in delivering health services and improving people's health. It constitutes the material platform on which the delivery of care rests and the basis for provision of all health interventions, and equips health professionals with indispensable means to perform their functions more effectively and efficiently. Regardless of national culture, level of country development, and degree of health system sophistication, all health care is heavily dependent on health technology, from simple tongue depressors and complex MRI machines to boilers and waste incinerators. The need to address

¹ Published in: IFMBE News, No. 84, pp. 6-9, June 2007

² WHO, Coordinator, Health Technology and Facilities Planning, Department of Health System Policies and Operations

³ WHO, Scientist, Health Technology and Facilities Planning, Department of Health System Policies and Operations

⁴ WHO, Coordinator, E-Health, Department of Knowledge Management and Sharing

technology and its management as a high policy priority is called for from an epidemiological, social, ethical, public health, economical and quality standpoint.

WHO cites as leading contributors to the global burden of disease: infectious and parasitic diseases, maternal and perinatal conditions, respiratory infections, cardiovascular disease, cancers, chronic respiratory diseases and injuries. Technology is central in the algorithms for treatment of all these conditions. Scaling up the response to such major killers as AIDS, tuberculosis and malaria requires a dramatic expansion and improvement of close-to-client services capable of delivering an essential set of health interventions. In addition to medicines and health personnel, these require a number of medical devices and other health technologies without which the desired outcomes would never be achieved.

From a social perspective, the distribution and use of technology is closely linked with equity concern and the gap between the "haves" and "have-nots". Sophisticated tertiary hospitals being heavily concentrated in the largest cities of the developing countries and dominated by indiscriminate use of low-volume, high-cost technology are often available only for a few who can afford them. However, severe shortage of essential services of a higher priority at district level and for primary health care in cities themselves makes those who are most in need - the rural population and urban poor, to suffer most.

Physical resources represent a large investment for the health sector. The worldwide market for medical devices was estimated at USD 145 billion in 1998, and by 2006 it is expected to be around USD 260 billion. The gap in spending on medical devices is staggering. While the USA spent USD 61 billion on medical devices in 1998 or USD 223 per capita and Japan spent USD 21 billion or USD 166 per capita, in some African countries the spending on health was USD 19 per capita. Between 1998 and 2000, the World Bank alone made loans of more than USD 500 million to developing countries, exclusively for medical equipment. And still, the cost of medical devices is only about 2-8% of health care expenses in most countries.

Although investment decisions in physical capital are absolutely critical as they are generally irreversible, committing large amounts of money to interventions which are difficult, if not impossible to cancel, close or scale down, these precious resources are often not spent as appropriately as they should. WHO estimates that in most developing countries in the early 1990's half of the inventory, in some cases as much as 75-80 percent, lay idle at any given time. Figures from the World Bank, GTZ and other agencies concur. The estimated loss of capital in non-functional medical equipment in developing countries under various assumptions, from a best case scenario of 10% to a worst case of 60%, using a simple model which gives estimated stock of equipment in 2002 as USD 709 billion, with a developing country share of USD 85 billion, can be easily computed. For instance, if only 15% of all equipment was out of order in 2002, this still meant a loss of USD 12.8 billion, representing for example around 22% of total health care spending in the WHO African Region.

Poor equipment management is not only costly, but can cause harm to the people served by the health care system. Injection devices, an important subgroup of medical devices, are a case in point. It is estimated that over 90% of all injections are given outside immunization programs, for curative purposes. Unsafe injection practices constitute a huge burden in terms of human suffering and finances - 10.6 million Hepatitis B,C and HIV infections annually, leading to 1.3 million deaths each year which represent 26 million life years lost - and an annual financial loss in direct medical costs of USD535 million.

10.2.3. Persistent Challenges

What is the problem? Why have some countries failed to harness the power of technology to improve the performance of their health systems? There is a large body of analyses of the problems of physical resources, and huge reserves of proposed solutions. Despite general understanding of the problems and clear ideas on the solutions, the problems persist. The inescapable conclusion is that we are missing something. What might that be?

In general, it has to do with low recognition, and in some cases lack of awareness, of the impact of ineffective and inefficient acquisition and utilization of technology on health services - in terms of wasted

resources, lost opportunities, low quality and even harm to patients. Developing and transitional countries face a number of persistent challenges in bringing technology to bear on their health problems.

Experts suggest that poor stewardship is mostly to blame for the problems of physical resources in developing and transitional countries. Many of these countries have failed to put in place viable institutions that assure the six domains of the stewardship function needed for proper deployment and use of technology in their health systems:

- generation of intelligence - collection, analysis and dissemination of information
- formulation of a strategic policy framework for technology
- ensuring formal mechanisms for policy implementation: powers, incentives and sanctions
- building and sustaining partnerships for technology acquisition and utilization.
- creating a fit between policy objectives and organizational structure and culture
- ensuring accountability, responsibility and answerability to the population, and “consumer protection”.

Many developing and transitional countries do not have explicit technology policies that are an integral component of their overall health policies. The acquisition of facilities and other physical resources often is ad hoc, following various pressures of the moment rather than being part of the overall coherent health system development plans.

Health authorities are confronted with a bewildering array of choices when making difficult decisions on investment in medical equipment. The number of different types, brands and models of medical devices offered on the world market in 1994, was estimated at 750,000 produced by around 10,000 manufacturers. These numbers had almost doubled by the year 2000. This unprecedented pace of technology development and transfer has, in many instances, far exceeded the capacity of health systems to track the innovations and to put in place adequate support systems for evaluation, selection and use of new technology.

Appropriate planning and management of physical resources in a holistic manner is the key to efficient provision of quality health services to individuals and to entire populations. Although technology adoption should be driven by health needs, management support capacity, and market preference, and based on technology assessment and forecast, in many instances, there is either a technology surplus or a gap. Much too often other resource inputs needed besides the equipment – human resources, drugs and facilities - are not given enough attention, and are not properly balanced. The net result is that services are not provided, because one or more of the constituents parts of the capital mix are not available.

Typically, only the purchase costs of physical resources are considered. The estimated life cycle cost of an anaesthesia machine, for example, in a developing country setting, shows that the capital cost is only 18% of the total cost of ownership over the lifespan of the machine. Consumables, staff, maintenance and overhead costs contribute 50%, 16%, 13% and 3%, respectively. When provision is made only for acquisition costs, services inevitably cannot be delivered, at least not for long.

There are also imbalances in priorities attached to various resource components. In one Latin American country the stock of equipment was valued at around USD 5 billion, 40% of which was not functional, representing a loss of USD 2 billion. By contrast, the pharmaceuticals program with an annual cost of several hundred million dollars, received significantly more attention than the equipment program. Similarly, in one African country there was, understandably, a public outcry when in one year drugs worth USD 3 million had to be destroyed because they had expired. The stock of unused equipment in the country was around USD 90 million, meaning that similar drug disposals could be carried out over a period of 30 years to equal the value of the assets wasted in unused equipment.

Norms and standards often do not exist, and where they do, they are not routinely applied. The annual allocation for maintenance, in relation to replacement cost, should be about 5-15 per cent for medical equipment, 2-3 per cent for buildings and plants, and 5 per cent for vehicles. This is typically far from being the case, and lack of norms and standards results in excess waste and low quality of services provided.

A significant challenge to health authorities is how to attract and retain competent technologists. Generally, public sector salaries do not compare favourably with those in the private sector, resulting in flight of competent technical staff from the public sector to private enterprise, or even out of the country.

A serious problem in developing and transitional countries, is ensuring that technology resources, including donor support, address the real priority needs of a country, and that technology acquisitions are not directed by external factors. All of these challenges are exacerbated by the need to provide health services to rapidly growing populations, under a crushing burden of disease and in economically depressed environments.

10.2.4. The Way Forward

There is general recognition, globally, that without the right technology, health systems cannot deliver quality health services and improve the health of the people. The global health care technology strategy promoted by WHO aims to contribute to the achievement of health objectives of Member States by strengthening the capacity of countries to optimize the management and use of their technology resources as an indispensable and integral part of the development of health systems that equitably improve health outcomes, respond to peoples' legitimate demands, and are financially fair.

The strategy aims to ensure that each country:

- i. formulates and implements a health technology policy which is supportive of its health policy;
- ii. develops the required capacities for mobilizing stakeholders, and implementing, monitoring and evaluating the policy, including the establishment, where necessary, and reinforcement of a comprehensive human resources development program that provides the health system with qualified personnel to plan, manage, use and maintain health technology resources;
- iii. identifies minimum levels of physical, human and financial resources required for the delivery of well-delineated packages of interventions;
- iv. promotes the use of evidence in decision-making, and encourages operational research and development in the key area of technology assessment and selection, as a rational basis for judicious long-term policy and strategy decisions;
- v. establishes and applies norms and standards in the planning, selection, acquisition and use of high quality and safe health technology and infrastructure;
- vi. puts in place mechanisms to ensure that technology resources, including foreign investments and contributions from partners, are linked to and used effectively to address real priority needs of the country.

The guiding principles for effective implementation of this strategy are:

- i. application of health technology is aimed at supporting the improvement of health outcomes;
- ii. health technology policy should be an integral part of health policy;
- iii. health technology should ensure improved and equitable access of the population to affordable and sustainable quality care;
- iv. health technology and infrastructure management must take into account the needs and aspirations of the population, the environment and available resources;
- v. preference must systematically be given to technological options which are consistent with the local needs and capabilities.

Successful implementation of this strategy will depend, among others, on long-term political commitment, the establishment of real conditions for ownership of the process within countries, continued availability of a critical mass of trained technical personnel, effective resource mobilization and adequate budget provision.

An enabling environment for the strategy includes the commitment of countries and other partners to health sector development, including technology and infrastructure, as an integral component of socioeconomic and human development; reformed health management which introduces more transparency and equity in resource allocation and use, and the assertive will to improve the health status of the population in Member Countries.

Over the years, WHO's strategic vision of optimal use of physical resources in the service of health, has led to the development of technology activities in all six Regions. The work has covered activities that are formally identified as constituting the stewardship and resource generation functions within the new

health system framework. It has addressed the key elements of this strategy, and has led to the development of a number of health care technology management concepts, methodologies and tools. These activities cover five main areas: policy and advocacy, capacity building, improving health care technical services through better technology selection and management, financing, and accompanying measures.

10.2. THE INTEGRATED HEALTH CARE PACKAGE

10.3. WHO RESOLUTION EB120/R21

SIXTIETH WORLD HEALTH ASSEMBLY
Document WHA60.29

Health Technologies¹

The Sixtieth World Health Assembly,

Having considered the report on health technologies²;

Recognizing that health technologies equip health-care providers with tools that are indispensable for effective and efficient prevention, diagnosis, treatment and rehabilitation and attainment of internationally agreed health-related development goals, including those contained in the Millennium Declaration;

Understanding that health technologies in particular medical devices represent an economic as well as a technical challenge to the health systems of many Member States, and concerned about the waste of resources resulting from inappropriate investments in health technologies in particular medical devices that do not meet high-priority needs, are incompatible with existing infrastructures, are irrationally or incorrectly used, or do not function efficiently;

Acknowledging the need for Member States and donors to contain burgeoning costs by establishing priorities in the selection and acquisition of health technologies in particular medical devices on the basis of their impact on the burden of disease, and to ensure the effective use of resources through proper planning, assessment, acquisition and management;

Noting the need to expand expertise in the field of health technologies in particular medical devices;

1. URGES Member States:

(1) to collect, verify, update and exchange information on health technologies in particular medical devices as an aid to their prioritization of needs and allocation of resources;

(2) to formulate as appropriate national strategies and plans for the establishment of systems for the assessment, planning, procurement and management of health technologies in particular medical devices, in collaboration with personnel involved in health-technology assessment and biomedical engineering;

(3) to draw up national or regional guidelines for good manufacturing and regulatory practices, to establish surveillance systems and other measures to ensure the quality, safety and efficacy of medical devices and where appropriate participate in international harmonization;

(4) to establish where necessary regional and national institutions of health technology, and to collaborate and build partnerships with health-care providers, industry, patients' associations and professional, scientific and technical organizations;

(5) to collect information that interrelates medical devices, which deal with priority public-health conditions at different levels of care and in various settings and environments, with the required infrastructure, procedures and reference tools;

2. REQUESTS the Director-General:

(1) to work with interested Member States and WHO collaborating centres on the development, in a transparent and evidence-based way, of guidelines and tools, including norms, standards and a standardized glossary of definitions relating to health technologies in particular medical devices;

(2) to provide support to Member States where necessary in establishing mechanisms to assess national needs for health technologies in particular medical devices and to assure their availability and use;

(3) to develop methodological tools to support Member States in analysing their health technologies in particular medical devices needs and health-system prerequisites;

(4) to provide technical guidance and support to Member States where necessary in implementing policies on health technologies, in particular medical devices especially for priority diseases, according to different levels of care in developing countries;

(5) to work jointly with other organizations of the United Nations system, international organizations, academic institutions and professional bodies in order to provide support to Member States in the prioritization, selection and use of health technologies in particular medical devices;

(6) to establish and update regularly an evidence and web-based health technologies database to serve as a clearing house which will provide guidance on appropriate medical devices according to levels of care, setting, environment, and intended health intervention, tailored to the specific needs of country or region;

(7) to provide support to Member States with vulnerable health-care systems so as to identify and put in place appropriate health technologies in particular medical devices that facilitate access to quality services in primary health care;

(8) to report on implementation of this resolution to the Executive Board and the Sixty-second World Health Assembly through the Executive Board.

Eleventh plenary meeting, 23 May 2007

¹ The term "health technologies refers to the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives".

² Document A60/26.

10.5. THE VIETNAMESE EXPERIENCE

10.6. DEFINITIONS

10.2.1. Health technologies

Health technologies, according to the definition commonly used by WHO, include drugs, devices, equipment, technical, medical and surgical procedures, the knowledge associated with these in the prevention, diagnosis and treatment of disease as well as in rehabilitation, and the organizational and supportive systems within which care is provided. Drugs, which belong to special subsets of health technologies, are not included in the work of the HTTTG. Medical and surgical procedures are within the scope of this program only with regard to devices and technical support. Included into devices and technical procedures are the information and communication technologies.

10.2.2. Appropriate health technologies

Appropriate health technologies are, according to the WHO Health for All Series' Glossary of Terms, methods, procedures, techniques and equipment that are scientifically valid, adapted to local needs, and acceptable to those who use them and to those for whom they are used, and that can be maintained and utilized with resources the community or the country can afford.

10.2.3. Health systems research

Health systems research focuses on the entire health system or part of it, and its object is to ensure that the system is optimally planned and organized and that programs are carried out by the health system infrastructure efficiently and effectively and with appropriate technology. It is often undertaken as part of the managerial process for national health development. Health services research is part of health systems research, but as its name implies, it deals with the health services component of the broader health system.

10.2.4. Technology planning and management

Technology planning and management is an accountable, systematic approach to ensuring that cost-effective, efficacious, appropriate and safe equipment is available to meet the demands of quality patient care. Strategic technology planning encompasses both technologies new to the hospital and replacements for existing equipment that are to be acquired. Acquisitions can be proposed for reasons related to standard-of-care issues, safety, and age or obsolescence of existing equipment. Acquisitions can also be proposed to consolidate several service areas, to expand a service area, to reduce cost of service area or to add a new service area. *Strategic technology planning* optimizes the way the countries or the hospitals capital resources contribute to its mission. It encourages selecting new technologies that are cost-effective, and it also allows the health care provider to be competitive by offering state-of-art services. Strategic technology planning works for a single department, product line, or clinical service. It can be limited to one or several high priority areas. It can also be used for an entire multi-hospital system, geographical region or country.

10.2.5. Health technology assessment

Health technology assessment is any process used for examining and reporting properties of medical technology used or to be used in health care, such as safety, efficacy, feasibility, and indications for use, cost, and cost-effectiveness, as well as social, economic, and ethical consequences, whether intended or unintended.

10.2.6. The Integrated Health Technology Package

The Integrated Health Technology Package (IHTP): responding to the frequent requests of WHO Member States for assistance and support in identifying their technology needs, WHO has developed in

cooperation with the IFMBE and other partners a methodology and software-based tool called the Essential Health Technology Package. IHTP is designed to assist countries in identifying their individual technology requirements linking and integrating a wide variety of parameters to arrive at very precise locally relevant lists of technology needed to address their specific disease and patient profiles within the existing health service delivery models and accepted clinical practices, and health system capacity and constraints for managing the acquired technology.

10.2.7. Standards

A wide variety of formal standards and guidelines related to health care technology exists. Some standards apply to design, development and manufacturing practices for devices, software, and pharmaceuticals; some are related to the construction and operation of a health care facility; some are safety and performance requirements for certain classes of technologies, such as standards related to radiation or electrical safety; and others relate to performance, or even construction specifications for specific types of technologies. Other standards and guidelines deal with administrative, medical and surgical procedures and the training of clinical personnel.

10.2.8. Global Harmonization Task Force

The Global Harmonization Task Force (GHTF) is a voluntary group of representatives from national medical device regulatory authorities and the regulated industry. Since its inception, the GHTF has been comprised of representatives from five founding members grouped into three geographical areas: Europe, Asia-Pacific and North America, each of which actively regulates medical devices using their own unique regulatory framework.

The purpose of the GHTF is to encourage convergence in regulatory practices related to ensuring the safety, effectiveness / performance and quality of medical devices, promoting technological innovation and facilitating international trade, and the primary way in which this is accomplished is via the publication and dissemination of harmonized guidance documents on basic regulatory practices. These documents, which are developed by four (4) different GHTF Study Groups, can then be adopted/implemented by member national regulatory authorities. The relationships between the work of each Study Group can be represented schematically.

The GHTF also serves as an information exchange forum through which countries with medical device regulatory systems under development can benefit from the experience of those with existing systems and/or pattern their practices upon those of GHTF founding members.

10.2.9. Clinical engineering

Clinical engineering means the application of medical and biological engineering within the clinical environment for the enhancement of health care. A Clinical Engineer is a professional who supports and advances patient care by applying engineering and managerial skills to healthcare technology. Clinical Engineers provide educational, research, technical, clinical and managerial services and support to clinicians, nurses, and healthcare managers in a variety of ways.

Such application is undertaken by, or under the supervision of, clinical engineers who bring to health care facilities a level of education, experience and accomplishments which enable them to responsibly, effectively and safely manage and interface with medical devices, instruments and systems, and the use thereof, during patient care; and who can, because of this level of competence, responsibly and directly serve the patient in collaboration with other health care professions.

The clinical engineer is involved at many levels in the safe, appropriate and economical use of technology in the health care system. Supported by clinical engineering technicians, the professional engineer is responsible for areas extending from design and maintenance of hardware to quality control and, where appropriate, the interpretation of signals from medical instrumentation. The work of clinical engineers is directly related to patient safety.

10.2.10. Certification of clinical engineers

Certification promotes the improvement of healthcare delivery through the continuing assessment of competency of Clinical Engineering Professionals. The certification process includes: (i) providing a standard of knowledge necessary for certification; thereby assisting the employer, public, and members of the health professions in the assessment of the clinical engineer. (ii) recognizing formally those individuals who meet the eligibility requirements of the Board and pass the Certification Examination for Clinical Engineering. (iii) requiring continued personal and professional growth in the practice of clinical engineering to maintain certification.

As of today, in most countries anybody can claim to be a clinical engineer or a clinical engineering practitioner and take responsibility for the healthcare technology in a hospital - without the need for certification, i.e. without proof of the necessary qualifications and skills.

10.2.11. Medical Physics

The major contribution of medical physics relates to external beam radiotherapy for cancer, and to a lesser extent, imaging. Non-radiation technologies such as ultrasound are becoming more important as well. However, most research in Medical Physics relates to the development and implementation of new technologies for more precise tumor delineation and dose transfer, whether by intensity modulated radiotherapy, gamma knife, tomotherapy, proton and heavy ion therapy. While these technologies are clearly capable of delivering higher tumor controlling doses of radiation, with lower dose to normal tissues, their cost continues to increase in terms of both capital costs, maintenance and application. Medical physicists adhere to high standards of accreditation and training, and medical physics societies in developing countries continue to emerge.

However, is there any evidence to indicate that the western model of health care, with respect to medical physics, is remotely appropriate to developing countries? This is the challenge for medical physicists around the world, and it is a challenge for the IOMP. The formation of the HTTTG is a recognition of the divergence in the training of medical physicists and the real needs of developing countries. In many such countries, medical physics is carried out by unqualified health workers with little or no training in the many facets of medical physics. It's up to the IOMP, and the regional groups such as AFOMP, to develop and implement a ladder of opportunity for health workers who wish to achieve accreditation in specific tasks.