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Health care technology management

Health care technology policy framework

World Health Organization
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PREFACE

Technological changes in all areas including medical technologies have proceeded, and will continue to proceed, at a rapid pace. Medical technologies usually are associated with diagnostic or therapeutic devices or procedures. With the continuing technology advances, there is a continuously growing gap between developing countries and the rich countries with "established market economies" in appropriate technology use. It is surprising that most developing countries have neither established an efficient national system for appropriate health technology transfer nor established a mechanism for systematic evaluation of new health technologies and their suitability to local circumstances and conditions in the light of available national resources, infrastructure, knowledge and skills. Such a system and a mechanism represent an essential ingredient for establishing and maintaining up-to-date, cost–effective and high quality appropriate health care services. Because of a lack of such a system and mechanism, many developing countries waste precious resources by introducing technologies and purchasing medical devices that are not appropriate to local conditions, substandard, obsolete, improperly reconditioned or have reduced life expectancies.

Many developing countries do not have a comprehensive national health care technology policy that maps out national vision and strategy for rational introduction and application of technology. What is appropriate for one country may not be appropriate for another owing to different needs, policies, priorities and capabilities in health care. In order to make the transferred technology viable, cost–effective and sustainable, there is an urgent need for each country to formulate and implement policies consistent with that country's needs, priorities, resources and capabilities. This document proposes a policy to serve as a stem policy and to provide a framework for the operational and technical policies still to be developed by individual countries.

This is the first in a series of four books. The following volumes cover development of a regional strategy for health technology management, health technology management policy formulation and implementation, and guidelines for conducting a country situation analysis for health technology management purposes. This volume introduces the ideas of and behind health technology management, defines terms relating to and sets objectives for health technology management policy. It examines what should go into such a policy, the national policy framework

and organization. Capacity-building and human resources issues are addressed, and economic and financial implications considered. The book also looks at the roles of legislation and safety issues, cooperation both within a country and with other countries, and concludes with an overview of the essential if sometimes overlooked components of any programme: implementation, monitoring and evaluation.

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The authors are grateful to the WHO Regional Office for the Eastern Mediterranean for taking the lead by inviting them to write this publication and the three other associated publications, which hopefully will form a part of an interregional approach aimed at producing a complimentary set of guidelines and documents to assist countries in health care technology policy formulation and implementation.

DEFINITION AND DELINEATION OF TERMS

> *The definition of health technology used by WHO includes "devices, drugs, medical and surgical procedures—and the knowledge associated with these—used in the prevention, diagnosis and treatment of disease as well as in rehabilitation, and the organizational and supportive systems within which care is provided" [1].*

This definition incorporates:

- organizational/physical infrastructure, including health facilities/buildings, their installations and plant, energy sources and water and gas supplies; and
- supportive/logistical systems, whose components are supply systems, information systems, communication and transport systems, and waste disposal systems.

However, this document *excludes* drugs/pharmaceuticals since these are covered by separate policy initiatives and frameworks. Nevertheless, activities should be linked to ensure, where possible and appropriate, optimized allocation and use of the whole spectrum of health care technologies as promoted by the Essential Health Technology Package concept.

1. INTRODUCTION

Health technology pervades all aspects of modern health care, and over the past decades has contributed to increased life expectancy, more rapid and improved diagnosis and treatment, faster rehabilitation, and generally better health outcomes.

The Alma-Ata Declaration, which was promulgated in 1978 in order to shift world health priorities to the development of health services based on primary health care, promotes the use of appropriate technologies---those technologies which are scientifically valid, socially acceptable and universally available to all individuals and families of the community at a cost that the community and the country can afford at all stages of the country's development in the implementation of primary health care.

However, for varying reasons, developing countries are often unable to apply health care technologies to their fullest extent to improve the health of their peoples.

In an effort to address this situation, WHO has adopted resolutions [*2,3*] related to health care technologies. These resolutions in general call upon Member States (*inter alia*) to:

- develop national programmes on health technology through designating a national focal point for health technology in every country
- develop suitable mechanisms for the assessment and acquisition of health technologies
- develop means of obtaining access to health technology information systems and databases
- take necessary measures to ensure that donor support in the area of health technology is given where it is most needed and likely to be most cost–effective
- raise awareness of health care technology-related issues among decision-makers and health workers in general
- introduce the concept of an Essential Health Technology Package [*3,4,5*] as a management tool to facilitate delivery of appropriate, cost--effective and sustainable health services.

Technology policy is the foundation on which successful use and application of health care technologies reposes. All countries need to have an explicit policy on health care technology, covering all levels of the national health system, as an integral part of their overall health policy.

Regional diversity underlines the need for each country to formulate and

implement policies consistent with that country's needs, priorities, resources and capabilities. Policy should address the totality of physical infrastructure as defined above.

WHO, through its Regional Offices, aims to support countries so that they can gain access to, implement and manage those technologies that will enhance the health status of their people in an affordable, cost–effective, equitable and sustainable manner. WHO will assist its Member States by:

- helping to assess their technology needs and their capabilities
- providing information and advising on the technologies available to address their health care priorities
- assisting in the development of policies and programmes and the establishment of national infrastructure for the needs assessment, acquisition and utilization of technologies
- helping to develop human resource capacity at both strategic and operational levels.

2. BACKGROUND

Many developing countries do not have a comprehensive national health care technology policy that maps out national vision and strategy for rational introduction and application of technology.

In most countries, demands on the health care system are increasing while costs are on the rise, and the gap between needs and resources is widening [*6*]. Health care technology is often associated with these increasing costs, and health care equipment, along with other components of physical infrastructure and technology, often consume the bulk of ministry of health investment budgets. Rational and cost-conscious planning and management of physical infrastructure and technology is the foundation for sustainable provision of quality care to the population.

Many developing countries are characterized by poor management of health care equipment, resulting in significant wastage of valuable resources [*7*]. The efficiency losses resulting from poor selection and maintenance of medical equipment can be very large [*8*]. WHO has estimated that less than half of all medical equipment in developing countries is functional and usable.

Lack of qualified technology management and maintenance personnel in the

public sector [*9*] and lack of managerial expertise among decision-makers and health workers at large, are a serious problem in most regions. The capability for technology assessment and equipment management is therefore very poor.

Free market choice, donations, pressure from manufacturers/suppliers, special interest groups and end-user professional health workers lead to lack of standardization of equipment, making its service and maintenance an extremely difficult and unnecessarily costly task.

The issue of quality of health care service delivery is receiving increasing attention as part of ongoing health system reforms [*10*]. Policy-makers need to pay special attention to the challenges posed by having to meet rising quality of service expectations while health care budgets, in many instances, are decreasing. This has been complemented and strengthened by increasing attention to formal technology assessment activities [*11–15*] and mechanisms to inform decision-making.

Few developing countries have yet established a mechanism for systematic evaluation of new health care technologies, except for the drug industry to some extent. Such a mechanism is an essential ingredient for building and maintaining up-to-date, cost–effective, high quality and sustainable health care services [*16*].

Communications, both within countries and across national boundaries, remain a critical priority for improving the effectiveness and efficiency of health care delivery in general and health care technical services in particular.

As the world moves irreversibly into the Information Age, information and knowledge systems will play an increasingly greater role in all aspects of human existence. Health systems need to harness the power of information and knowledge for the attainment of health goals by including these considerations in health care technology policy.

Limited access to up-to-date information, poor documentation on technology assessments, and the dearth of technology-related information in health management information systems constitute a major obstacle to formulation of sound health care technology policies, and good decision-making.

The challenges facing health systems are exacerbated by the need to provide health services to a rapidly growing population, under increasingly more congested conditions in the cities, and in economically depressed environments. Many of the problems have been identified and examined in WHO regional health care technology strategy documents such as the WHO Regional Office for Africa meeting report addressing health care challenges and new orientations for health care technology in

sub-Saharan Africa [*17*], as well as in part 2 of the present series, Regional strategy for appropriate health care technology. These problems require the urgent attention of policy-makers.

Following the recommendations of an interregional meeting [*18*] in Cyprus in 1986, WHO launched a global action plan on management, maintenance and repair of health care equipment in 1987, directed at the development of effective systems for management of health care technologies. The plan identifies four major obstacles confronting developing countries:

- lack of organizational policy
- ineffective health care technical services [*19*]
- lack of effective human resources development and training
- lack of information support.

To the above list could be added the lack of effective management and decision support tools. The global action plan also calls for adequate funding and provision to support corrective actions, and proposes a coordinated and comprehensive approach to resolving these problems.

Many meetings organized by WHO in different regions [*20–22*] have been held to address these issues and provide a useful foundation and reference for health care technology policy formulation and implementation. Various country specific initiatives [*23*] have been undertaken, and serve to illustrate differences in country environments and constraints.

3. OBJECTIVES OF THIS DOCUMENT

This document proposes a macro policy and is designed to serve as a stem policy and to provide a framework for the operational and technical policies still to be developed by individual countries. It is part of a proposed interregional approach aimed at producing a complimentary set of guidelines and documents to assist countries in health care technology policy formulation and implementation.

Other attributes of the document are as follows.

- Target audience: policy-makers and decision-makers in health ministries, as well as other departments, whose work directly affects health objectives.
- Aim: to provide a framework to assist countries in developing their own national policies and strategies for health care technology, and in formulating plans of

action for their implementation.

- Scope: the document covers the need for health care technology policy and proposes specific topics for policy content.

4. POLICY CONTENT

General

The word "policy" has several connotations. Throughout this document, it is taken to mean an orientation—a guide—for action based on a set of guiding principles or values, aimed at influencing and determining long-term decisions and actions. Even so, it is limited in time and coverage. It is therefore a living document, requiring periodic review and update. Finally, health care technology policy does not occur in a vacuum, but is situated within a context provided by broader policies, such as health policy and development policy.

There is a need to change approaches to policy-making and decision-making so that, rather than take action in reaction to pressure groups, lobbies and emergencies, more rational approaches based on objective criteria should be employed. Scientific evidence—feasibility, cost, cost–benefit or cost–effectiveness—should be used to inform the decision-making process.

Health policy embraces courses of action that affect the set of institutions, organizations, services and funding arrangements of the health care system [*24*]. It goes beyond health services, however, and includes actions or intended actions by public, private and voluntary organizations that have an impact on health.

In formulating policy, it is necessary to identify factors that ensure sustainability of health systems, such as physical assets, human resources, financial resources, political commitment, conducive environment, legal framework, logistics support systems, sociocultural considerations, stakeholder participation, governance, donor policies and public/private sector stances. Failing this, the policy may not have its intended impact.

The following guiding principles, in addition to those listed in the previous section, are recommended for consideration and possible inclusion in the formulation of national health care technology policy. These are not listed in any order of priority or relative importance, since priorities may differ from country to country, and resource constraints may limit the realization of desirable objectives.

National policy framework

To integrate health care technology policy into other national policy processes.

It is essential that health care technology policy be part of the larger policy process in the context of both health system reforms and general socioeconomic development reforms.

Policy should address and promote mechanisms at all levels of health care delivery which encourage the effective provision of health care through establishing scientific, technical, (clinical) health and economic criteria for assessment, and evaluation and selection of technologies appropriate to national health priorities.

Organizational structures

To ensure the creation, operation and sustainability of adequate and appropriate organizational structures at all levels of the health system in support of health care technology needs assessment, acquisition and use.

It is essential that responsible authorities are established and/or designated for implementation and monitoring of policy and management of health care technology as a whole including, where necessary, legislative, regulatory and other mechanisms.

A national health care technology management system should be established for proper integration of health technology resources and processes, including the supportive and organizational infrastructure within which health care technology is applied.

The organizational structures should address the interrelationship of quality, quantity, and economics in support of the stated health care objectives, and should ensure optimal distribution of the limited health care technology resources, facilitate equity in access, improve the quality of health services and enhance positive health outcomes.

These organizational structures should be adequately supported in terms of political support, budgetary allocations and supporting infrastructure to ensure they can fulfil their mandate.

Technology needs assessment

To promote rational, informed and appropriate strategic planning, macro-assessment and/or micro-assessment of health care technologies and their management, taking into account available resources, systemic constraints and technology transfer issues.

The introduction, adoption, distribution and implementation of technologies should be based on defined needs, and the decision-making process should have clearly defined criteria that can be reviewed to incorporate changing needs and resources. Needs assessments should include the impact on performance of health care services and on health.

The Essential Health Care Technology Package concept and strategy should be applied and used as part of this process. The Essential Health Care Technology Package approach facilitates rational and appropriate provision and distribution of health care technologies, within the context of national health system capabilities and service delivery priorities.

There should be ongoing monitoring of technology trends and emerging technologies, and the threat posed to currently deployed technologies and their continued clinical relevance and technical support.

Technology acquisition

To promote the proper and effective selection, procurement and commissioning of health care technologies.

Due consideration of cost-of-ownership issues, human resources and infrastructural requirements and organizational capabilities at facility level, specific to each technology, should be given.

Standardization, normalization and harmonization of health care technologies (including medical devices) should be applied where appropriate.

National guidelines for the systematic and ongoing evaluation of health care technologies (including donated equipment) should be developed, implemented and strengthened.

For donated technologies, due notice should be taken of international guidelines [*25*] facilitating successful transfer, implementation and utilization of health care technologies.

Use of technology

To ensure that policy facilitates the maximization of technology benefits and life-time cost–effectiveness.

To this end, policy should:

- encourage the promotion of quality assurance and total quality management in health facilities, ensuring that patients obtain the best possible care, given the local organizational and environmental constraints
- promote the development and/or implementation of performance indicators, hospital effectiveness parameters and technical efficiency to monitor technology use
- address directly the issue of user training and support mechanisms that should be put into place to ensure adequate competence and proper and safe application of all technologies at all levels of health care delivery.

A national health care technology maintenance (health care technical service) programme should be developed, implemented and adequately supported. As part of this programme, guidelines for maintenance (both preventive and corrective), procedure manual and strategies should be established and implemented.

Performance and cost indicators must be developed and implemented, and associated data collected and evaluated using appropriate information systems.

Quality management and accreditation activities, where appropriate, should be instituted and receive adequate support.

Guidelines and standard operating procedures, covering all health care technology management activities at all levels of health care delivery, must be developed, implemented and refined on the basis of ongoing experience and information.

Formal asset management procedures and systems are needed to ensure that technology assets are utilized effectively and equitably with due consideration to life-cycle costing issues.

Adequate and appropriate instruments, systems and training to ensure proper strategic, logistic and operational management of all technology assets should be provided.

National guidelines on medical device nomenclature (specifically) must be provided and implemented as a precursor to the development of technology databases and supporting information systems.

Capacity-building and human resources strategies

To develop institutional (and individual) capacity and expertise in support of policy formulation and implementation, health care technology needs assessment, acquisition and use.

This objective will be achieved by strengthening the health care technology management system, including promoting appropriate training initiatives. The primary objective in this regard should be the maximization of technology cost–effectiveness.

Orientation and training seminars should be encouraged for policy-makers, decision-makers and other health professionals in order to facilitate the proper formulation and successful implementation of health care technology policy. In future, policy should envisage introduction of the concepts and practice of technology assessment and management into training programmes for all health care workers.

Policy should address and support the development of a corps of health care technology management and maintenance practitioners, with career possibilities and under competitive working conditions. Strategies and mechanisms should be identified for attracting and maintaining well qualified personnel.

Adequate provision should be made for rational management of technical services personnel, and their continuing education should be encouraged, in order to promote professional growth.

An informed and ongoing continuing education programme for health workers should be established to empower individuals with appropriate skills.

Capacity development includes advocacy activities that promote the role of health care technology in health care delivery through sensitization of politicians, health system planners and decision-makers and health workers at all levels of the health system.

Financing and economic issues

To mobilize health care technology resources within given economic constraints, with the need to ensure adequate budgetary allocations for technology management and maintenance activities.

Policy should ensure that:

- adequate allocations of financial, technical and human resources are made for effective technology management
- the process of needs assessment (and, specifically, planning and resource allocation) and budgeting in health ministries is strengthened
- technology acquisition and replacement strategies for institutions conform with the prevailing policies of decentralization and financial autonomy
- there is regular contact and collaboration between different ministries as part of a multisectoral response to health care and related challenges.

The attainment of the above is further facilitated by evaluating and monitoring technology acquisition and use costs and optimizing these within the framework of service provision.

Public–private partnership

To encourage public/private partnerships to maximize the benefit of a country's total health technology resources.

The provision of quality health services at affordable prices is a collective effort involving all sectors of society. "Smart"—mutually beneficial—partnerships between public and private sectors for cost–effective health care service delivery should be explored and, where appropriate, implemented.

Local innovation (research, development and production) of appropriate medical devices, which meet acceptable quality standards and good manufacturing practices, should be encouraged within countries and regions [*26,27*].

Legislation and regulations (including safety and risk management)

To consolidate existing legislation, regulations and incentives as well as formulate new instruments, where required, to ensure proper acquisition, adequate provision, appropriate distribution and safe and effective use of health care technologies.

Appropriate administrative and legal measures, organizational and support mechanisms and appropriate infrastructure within the framework of the policy need to be established and implemented.

The legislation and regulation component of the health care technology policy should support, guide and regulate aspects associated with the provision, acquisition and use of health care technologies.

Safety issues (including hazard notices, notifiable incidents and technology-induced fatalities) must be addressed to ensure effective management of health care technologies, in order to ensure minimal risk to health workers, patients and visitors in the clinical environment.

Sociocultural diversity needs be addressed during the design, transfer and use of health care technologies.

Formal risk and safety programmes, as appropriate to different levels of health care delivery and supported by relevant national and international standards, should be developed, implemented and supported. These programmes should be supported by appropriate information systems with access to international sources of relevant information. Safety and risk management activities should span the period from pre-market appraisal to post-market surveillance.

Regulatory and legislative instruments should be dynamic and responsive to changing circumstances, and should only be applied if they benefit the process of technology adoption and use and health outcomes in general.

Research

To promote research that will lead to improved implementation, monitoring and evaluation of health care technology policy, support the stated outcome of the health care technology management system and facilitate self-sufficiency (or self-reliance) in identified areas.

Research activities to be encouraged within a health care technology policy framework include:

- needs assessment and priority setting through evidence-based investigations and technology assessments
- mechanisms aimed at optimizing health care technology management activities and practice
- tools for improved effectiveness and efficient allocation and distribution of resources, based on scientific evidence
- scientific methods for the evaluation of health benefits for new and existing technologies.

Research activities should identify gaps in the evidence base that need to be filled in order to address priority problem areas in a comprehensive and coherent manner.

Information and knowledge systems

To provide an integrated system for appropriate and effective data collection, storage and analysis as well as dissemination of information and knowledge in support of health care technology management.

Policies should specifically address the introduction, use and distribution of information and communication technologies.

Basic information such as documentation on available health care technology (including equipment), maps indicating existing and operating health institutions, available personnel and epidemiological data should be available.

Measures should be developed to improve the collection, analysis and use of information on health care technology. Information on health care technology should be integrated into health and management information systems, and the mechanisms for dissemination should be strengthened.

Policy should cover the use of artificial intelligence techniques, such as

knowledge-based expert systems and intelligent tutors, which leverage the skills of experts, to improve performance and output.

Telemedicine has the potential to make the best use of expertise available within a health system. Policy should address this issue.

Policy should address the issue of networks at national and regional levels to link health care technology services within and among countries, using modern technology such as computers and satellite-based telecommunication.

International, regional and intercountry cooperation

To promote technical cooperation among countries in order to maximize the effective use of health care technology resources.

This objective should be achieved through ongoing technical cooperation among countries in the respective regions and with international agencies and institutions. Areas of cooperation between relevant national, regional and international partners and institutions should be identified, especially in the preparation of appropriate policies and mechanisms for promoting health technology assessment and operational research.

In a methodical approach to health care technology management, the need for a regional or intercountry approach is underscored. Individually, few countries have the resources and know-how to succeed in this venture.

Within the area of health care technology, WHO promotes collaboration within regions and with established institutions outside regions. Such collaboration should be encouraged through appropriate health care technology policy.

The possibility for group purchases among countries and/or institutions should be encouraged where possible, for selected types of pharmaceuticals, equipment, consumables and other technologies. Among other advantages are, favourable rate contracts, better use of available expertise and more rigorous financial control.

Policy should promote cooperation through sharing of information and other health care technology resources, management systems and tools, promotion of joint initiatives in the establishment of resource centres and the development of human resources capacity development programmes.

The role of professional societies and associations—be they at national, regional or international level—should be duly recognized and effective interfaces established with appropriate such bodies.

Policy should recognize and promote the important role of international partners from the private sector, technical agencies and nongovernmental organizations.

Implementation, monitoring and evaluation

To establish mechanisms for monitoring and evaluation of performance in support of successful implementation of health care technology policy.

There needs to be an analysis of the policy environment in order to assess whether the conditions for successful implementation exist [*24*].

Continuous monitoring and periodic evaluation of the implementation of the policy should be conducted, using well defined indicators. The results of this monitoring and evaluation should be used to quantify needs assessment and inform the decision-making process.

Health care technology policy development and formulation must be a consultative and accountable process which addresses the needs and concerns of stakeholders.

5. CONCLUDING REMARKS

This framework serves as a point of departure for countries developing or reviewing their health care technology policies. It makes no claim to cover all the issues that need to be addressed, as changing needs and special circumstances of individual countries cannot be anticipated. It is important that countries take ownership of the framework and adapt it according to their own needs and overall health policy environments.

Although the framework steers away from being prescriptive it does suggest issues that should be addressed in the health care technology policy process. To this end, the framework serves as a facilitating and consensus-building instrument, both within and between countries and regions. As such, it is a living document and will be reviewed periodically in the light of new challenges and realities.

GLOSSARY

1. Technology innovation and application cycles

The technology innovation cycle includes:

- *needs assessment*—an analysis of what is needed in terms of new technology or improvements to existing technologies
- *research and development*—indispensable activities in the process of innovation, covering aspects from conception of ideas to realization of prototype versions of new products (goods and services)
- *testing*—verification that prototypes of new products perform according to specifications
- *manufacture*—volume production of tested prototypes for commercialization
- *marketing*—developing a clientele for the product, through advertising, sales and other activities
- *transfer*—transfer of technology, from the society or environment in which it is developed to clients elsewhere, generally used to refer to transfer from industrialized countries, where the manufacturers are, to developing countries
- *distribution*—ensuring proper availability of the technology wherever the means for its procurement are available

The technology application cycle includes:

- *needs assessment*—includes planning and technology assessment
- *acquisition*—includes evaluation, selection, procurement, installation, commissioning and initial user/technical staff training
- *use*—includes maintenance (corrective and preventive), ongoing user training, asset and risk management, etc.

2. Health care technology management system

This refers to an appropriate multidisciplinary organizational infrastructure, extending from ministry level to facility level, for the proper integration of health technology resources and processes, including the supportive and organizational infrastructure within which health care technology is applied. The extent of—and resources available within the system—will, naturally, be determined by the policy and environmental constraints of individual countries.

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