World Health Organization

SIXTIETH WORLD HEALTH ASSEMBLY **A60/26**
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Health technologies

Report by the Secretariat

1. The present report reflects comments made by the Executive Board during its discussions on essential health technologies at its 120th session. [1] In particular, it now deals exclusively with medical devices as a major subset of health technologies.

2. Medical devices may be broadly defined as diagnostic and therapeutic equipment, instruments and supplies and ancillary equipment.[2] They are indispensable for health-care practitioners as tools for prevention, diagnosis, treatment and rehabilitation and thus for the effective control of major health problems and the attainment of the health-related Millenium Development Goals. However, the improper selection, management or use of medical devices may lead to a disproportionate rise in the costs of health-care delivery. Several studies indicate a number of problems relating to management of medical devices at a time when the global market for medical devices is growing. Without proper management of demand, through needs assessment, rational procurement, proper installation, preventive maintenance, rational use and quality assurance, it will be difficult for health-care providers to contain costs, particularly in countries with limited economic resources.

ISSUES

3. More than 8000 generic medical-device groups are in daily use throughout the world.[3] The availability of medical devices for use against a wide spectrum of health problems challenges

[1] See document EB119/2006–EB/120/2007/REC/2, summary record of the tenth meeting of the 120th session of the Board, summary record of the eleventh meeting, section 2, summary record of the twelfth meeting, section 3, and summary record of the thirteenth meeting, section 3.

[2] *"**Medical device**" means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article: a) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of: diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation for an injury; investigation, replacement, modification, or support of the anatomy or of a physiological process; supporting or sustaining life; control of conception; disinfection of medical devices; providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and b) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means. Information document concerning the definition of the term "medical device".*
Global Harmonization Task Force, 2005. Document GHTF/SG1/N29R16:2005.

[3] The approximate figures are derived for generic device groups from international collections such as the Global Medical Device Nomenclature and the Universal Medical Device Nomenclature System.

managers to prioritize their selection and acquisition on the basis of their impact on the burden of disease. Each country needs to strike a balance between the largely supply-driven market in devices and the needs of the health system. Both the health sector and individuals need to be protected against unnecessary expenditure and suboptimal use of scarce resources.

4. The global medical-device market alone, currently estimated at more than US$ 150 000 million, is projected to grow to US$ 186 800 million by 2009, expanding at the rate of 4% to 5% annually within the foreseeable future. Expenditure on medical devices contributes to increased health-care costs, which 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.

5. Resources are often wasted on investments in medical devices that do not meet priority needs or are too complex, incompatible with the existing infrastructure and services, or too costly to maintain in service. This wastefulness can undermine the health service as a whole by draining off funds needed for other essential systems inputs. Resources may be further dissipated through irrational or incorrect use of devices, staff shortages, inadequate training, or lack of consumables, spare parts or maintenance plans. The management of medical devices should be recognized as an integral part of public-health policy.

CHALLENGES

6. Assessment should be based on epidemiological and demographic data, indicators of availability and rates of usage of medical devices in health-care facilities, staff capabilities and the resources available for procuring and operating these devices. Interdisciplinary collaboration will help to generate evidence-based information on national needs for medical devices, their suitability to meet identified needs and the cost-effectiveness of different procurement options. Given the limited availability of resources, the prioritization of needs will enable countries to select medical devices in terms of the burden of disease and the level of service that can be provided. Both the recognition of the cross-cutting role of medical devices and planning their use under a sector-wide approach are necessary also. In line with the spirit of the Declaration of Alma-Ata (1978), primary health-care facilities and first-referral-level hospitals should constitute a common base for appropriate health technologies,[1] especially medical devices.

7. The use of medical devices carries a certain risk for patients, medical personnel and the general public. In resolution WHA55.18, the Health Assembly emphasized the importance of improving patient safety and quality of care by strengthening the science-based systems used to assess and monitor medical equipment and technology. Good manufacturing and regulatory practices, pre-marketing evaluation and post-marketing surveillance, and measures to restrict inappropriate use will not only ensure the quality, safety and efficacy of medical devices but also contribute to the fight against counterfeit devices. Donated and second-hand equipment should satisfy the same requirements as new equipment acquired through normal procurement processes.

[1] The WHO Regional Office for the Eastern Mediterranean defines appropriate technologies as those that are scientifically valid, socially acceptable and universally available to all individuals and families in the communities at an affordable price. Document EM/RC44/Tech.Disc./1.

8. Ensuring the sustainability of services and maintaining access to appropriate medical devices must remain an important consideration, and need sound mechanisms for planning and assessment, acquisition and management. Moreover, the health system also needs to be able to identify obsolete devices that could be replaced by new devices that may have a greater impact on public health.

THE WAY FORWARD

9. National policies are needed that cover all aspects of health technologies, but will be successful only if supported by regulatory mechanisms. Regulatory authorities should be grounded in legislation that defines the scope of their powers and their accountability. Regulations should specify that all medical devices, whether imported or locally produced, must meet international norms and standards in order to bring public-health benefits without harming patients, health-care workers or the community. In addition, countries should participate in global and local vigilance networks in order to ensure the effective management of adverse events.

10. National needs for medical devices should be defined in terms of effectiveness, quality, safety, cost-efficiency, availability and access in order to optimize their use and to establish safe and reliable services in health systems. Such needs assessments should take into account national and international norms, standards, guidelines and the conditions in which they will be used.

11. The pursuit of the rational use of medical devices requires innovative, integrated and efficient methods of determining their appropriateness for any level of the health-care delivery system. It also requires the establishment of systems for the assessment and management of both new and existing devices.

12. Effective use of medical devices requires strong collaboration and partnerships between governments, health-care providers, industry, patients' associations, and professional, scientific and technical organizations. Priority should be given to strengthening and expanding those institutions that can work effectively with users to identify needs, undertake biomedical research in order to improve existing devices or develop new ones to meet those needs. Regional and national institutes of health technology play a central role in advocating unimpeded transfer of technology between countries in order to share experience and provide mutual support.

13. Demand, availability, use and impact of medical devices will have to be monitored, with specific indicators, and a sufficient capacity to train specialized health workers and resources available for the operation, maintenance, quality assurance and subsequent development of devices will be necessary.

ROLE OF WHO

14. Through the development of guidelines and tools, including norms and standards, WHO can provide technical support to Member States and donors in assessing and prioritizing national needs for medical devices, allocating resources, implementing national policies and regulations, ensuring their availability and rational use, and promoting good manufacturing practices. Such support will require the continuing input of experts from a broad range of clinical specialties and from the field of health technologies, involvement of interested Member States and WHO collaborating centres, and collaboration with other organizations, academic institutions and professional bodies.

15. Evidence-based assessments of established and new devices are vital in order to ensure their appropriate procurement and optimal use, prevent the dissemination of inappropriate devices and avoid the use of ineffective or potentially harmful ones. WHO should be alert to technological breakthroughs in promoting public health and share information about them with all stakeholders using the unprecedented opportunities offered by advances in access to information and communication technology.

16. As requested by the Board, a consultation of experts on health technologies is to be convened (26 to 28 March 2007) to undertake further work on two concerns in this domain, namely, the scope of health technologies and the drawing up of a list of such technologies.[1]

ACTION BY THE HEALTH ASSEMBLY

17. The Health Assembly is invited to consider the draft resolution contained in resolution EB120.R21.

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[1] See document A60/26 Add.1