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The role of medical devices and equipment in contemporary health care systems and services

Medical devices equip health care providers with tools to perform their functions effectively and efficiently. Several studies indicate a number of problems relating to medical device management, at a time when the regional market for medical devices is growing. Without proper management of demand, through actual needs assessment, adequate procurement, proper installation, preventive maintenance, rational usage and quality assurance, it will be difficult for health care providers to contain costs. The Regional Committee is invited to discuss strategic directions for the Region.

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Executive summary

A contemporary health system relies on the contribution of human resources and health technologies. Medical devices, one aspect of health technologies, equip health care providers with tools to perform their functions effectively and efficiently. Although medical devices provide an opportunity for a better service, the lack of a national system for selection, procurement, use and management may lead to a disproportionate escalation in health care delivery costs. Member States need to establish systems for standardizing and regulating the selection, procurement, use and management of these tools.

The majority of the world's population is denied adequate, safe and reliable access to appropriate medical devices within their health systems. The regional situation is difficult to assess given the current gaps in knowledge and scarcity of data. Nevertheless, several studies indicate a number of problems relating to medical device management, at a time when the regional market for medical devices is growing. Without proper management of demand, through actual needs assessment, adequate procurement, proper installation, preventive maintenance, rational usage and quality assurance, it will be difficult for health care providers to contain the burgeoning costs.

This paper seeks to highlight the need for Member States to develop policies for selection and assessment of appropriate, affordable and/or essential medical devices and technologies. It proposes the development of a regional programme and strategy in order to address the issue of cost increase and inefficiencies related to medical device management. The proposed strategy will focus on updating current data, developing regional guidelines on selection, utilization and assessment, sharing experience and knowledge, and promoting the establishment and use of regional centres of excellence.

1. Introduction

Medical devices[1] are considered to be crucial for the services offered in prevention, diagnosis, treatment and rehabilitation of illness and disease [3,4]. Every day more than 50 000 different kinds of medical devices are estimated to be used in health care facilities and elsewhere all over the world. Most are quite simple, while others are complex and combine different technologies. The global medical device market is worth over US$ 150 billion, with the United States of America, European Union, and Japan having over 65% of the market share [5]. The market is expected to grow steadily by 4% to 5% annually over the next few years implying that this technological revolution in health will continue in the foreseeable future. Member States of the Region often seek guidance from the Regional Office regarding the rational use of medical devices and the establishment of national systems for standardizing their selection, procurement, use and management. Although medical devices provide an opportunity for a better service, the lack of a national system may lead to a disproportionate escalation in health care delivery costs.

Since the Declaration of Alma-Ata in 1978, WHO has highlighted the importance of appropriate technology and has called for better standardization of health and medical technologies. WHO launched a global action plan on management, maintenance and repair of medical equipment [6], promoted affordable basic medical devices such as the Basic Radiology Systems (BRS) and the World Health Imaging System for Radiography (WHIS-RAD), and held several meetings in different regions related to health care technology management, selection and development. In May 2002, the 55th World Health Assembly [7] emphasized the importance of improving patient safety and quality of health care by strengthening the science-based systems used to assess and monitor medical equipment and technology. Subsequently, a follow-up report by the secretariat to the 113th Session of the Executive Board [8] in January 2004 concluded that countries need to develop national regulations, systems for quality assurance, procedures for procurement and risk assessment. These provided a useful foundation and reference for health care technology policy formulation and implementation.

This paper is aimed at raising awareness of the importance of medical technology in general, and medical devices in particular, as one of the major components of health care expenditure growth. The Eastern Mediterranean Region needs to develop a strategy on how to address the issue of burgeoning costs and inefficiency related to medical device management. There is a need to update the data available, improve knowledge and information in this area, develop regional guidelines on medical devices selection, utilization and assessment, and identify regional centres of excellence. Focusing more on medical equipment, the paper explores some of the regional challenges associated with medical devices and proposes ways for Member States to overcome them.

2. General overview of medical devices

2.1 Economic aspects of medical devices

Tracking and explaining the growth in health spending in all national systems has been a prominent concern in governmental, academic and industrial research in both developing and developed countries. Many studies have shown that technological changes in health care, especially medical devices are among the key drivers of growth in health expenditure growth [9]. In Europe, 6.2% of the total health expenditure goes on procurement and maintenance of medical devices, while both the United States of America and Japan spend some 5.1% of total health expenditure on medical devices [10]. Owing to serious gaps in knowledge, figures for the Eastern Mediterranean Region cannot be confirmed. However, crude estimates indicate that Member States spend even more.

[1] The U.S. Food and Drug Administration defines a medical device as: "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them; intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of it's primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes" [1]. Accordingly, medical devices can be classified into the following: diagnostic and therapeutic equipment; instruments and supplies; ancillary equipment; and special service devices (e.g. animal and insect, autopsy and teaching) [2].

There is a need to strike a balance between the largely supply-driven regional market and the actual needs of the health sector based on population size and health problems. The health sector and the individual citizen both need to be protected against unnecessary expenditures. To conserve the already meagre financial resources, countries need very clear evidence-based information on how to a) conduct proper needs assessment; b) assess cost-effectiveness of purchase versus hire of equipment, including donated and second-hand equipment; c) develop policies on rational procurement and use; and d) regulate purchasing decisions in both the public and private sectors.

In an effort to rationalize health spending and curb health care inflation, many countries require health planners to evaluate community needs and institute a Certificate of Need[2] review programme, particularly for heavy medical technology. Although Certificate of Need programmes were intended to control health care spending by limiting service expansion, many studies indicate that they have not lived up to expectations [11,12].

The pursuit of rational use of medical devices requires more than government regulations and Certificate of Need programmes. It requires strong collaboration between private industry and governments; solid information on impact, supply trends and use of different technologies; databases on health technology expenditures for different interventions; institutionalization of health technology assessment (HTA) for new and existing health technologies; and innovative, integrated and efficient methods of determining the appropriate technology for any health care delivery level.

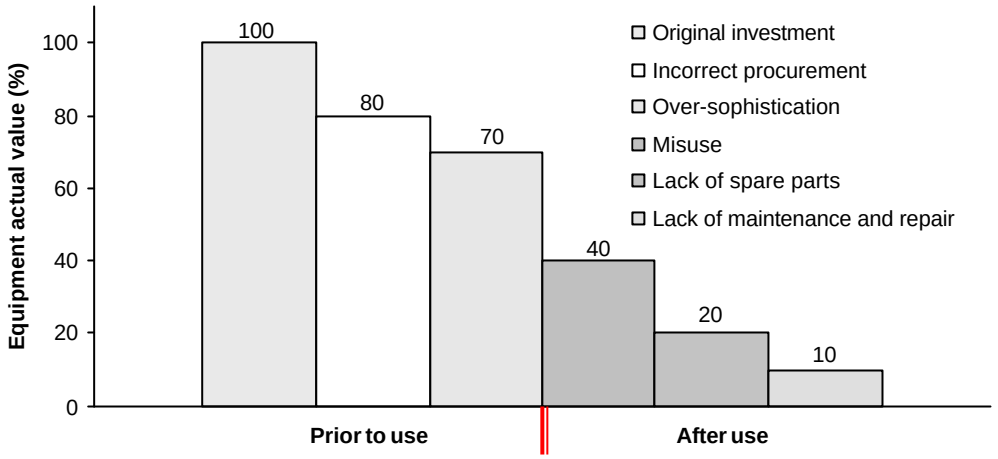
2.2 Management of medical devices

Devices are assets that need to be managed. This is even more evident in the case of medical devices as they usually require considerable investment, directly affect human lives, are highly sensitive, in many cases have high maintenance costs, and some have relatively short life spans. WHO estimates that around 50% of medical equipment in developing countries is not functioning, is not used correctly and optimally, and invariably is not maintained [13]. This has far-reaching implications for health care delivery and represents a deplorable waste of scarce resources. It is critical, therefore, that countries have a medical device management policy.

The problem is compounded by the inability of many countries to utilize the full potential of the available technology. Figure 1 shows the average non-typical depreciation of medical equipment value from procurement to actual use. Excluding normal depreciation, an average depreciation of 30% occurs due to incorrect specifications and over-sophistication before the equipment is used. The value depreciates further once the equipment is used, for reasons such as irrational use, unavailability of spare parts, and lack of inspection, preventive maintenance and contractual repair agreements with suppliers. As a result, the value of the equipment falls to about one tenth of its original investment value.

As an important input to the health care system, medical devices should be properly managed and utilized in order to produce an efficient health intervention. Nevertheless, lack of: appropriate selection and acquisition of knowledge; optimal skills base; maintenance and repair budget; adequate support infrastructure; and adequate managerial skills, result in the waste of already meagre resources in some countries, which in turn leads to a decrease in the quality of health care services [14].

[2] The Certificate of Need (CON) is a regulatory process that requires certain health care providers to obtain state approval before offering certain new or expanded services. The programme is intended to help ensure that new services proposed by health care providers are needed for quality patient care within a particular region or community.



Source: Swiss Centre for International Health, Basel, 2005

Figure 1. Waste of resources from budget to patient

3. Regional situation

3.1 General

Despite the billions of dollars spent each year on an ever-increasing array of medical devices, the majority of countries of the Region still do not recognize management of devices as an integral part of public health policy. WHO estimates that around 95% of the medical devices in developing countries are imported, much of which does not meet the needs of national health care systems and is not used effectively and efficiently [15]. Given the serious gaps in knowledge and scarcity of data, it is difficult to assess the regional situation in regard to use of medical devices, at any level (including primary health care) and especially those used in simple settings (such as laboratories, operating theatres, ambulatory care, etc.). However, several studies demonstrate the importance of rational procurement based on proper needs assessment, medical device management planning, and the dangers of a supply-driven market.

a) Irrational procurement

Procurement of expensive medical devices needs to be based on a clear strategy and actual needs assessment, or sound justification based on comparisons with countries of similar socioeconomic conditions. Irrational procurement leads quickly to oversupply and increased health care delivery costs. The regional situation with regard to diagnostic imaging equipment provides a good illustration of this.

According to WHO, diagnostic imaging is only required in some 20% to 30% of medical cases worldwide, when clinical considerations alone are not sufficient to make a correct diagnosis. Of those cases that require diagnostic imaging, some 80% to 90% of diagnostic problems can generally be solved using basic X-ray and/or ultrasound examinations [16]. The Regional Office conducted a survey of the number of magnetic resonance imaging (MRI) and computerized tomography (CT) scanning units in countries of the Region. Table 1 shows the number of MRI and CT imaging units per million population for both the private and public sectors for four countries of the Region, one from each income group as defined by the World Bank [17], in comparison with member countries of the Organisation for Economic Cooperation and Development (OECD). It is worth mentioning that there was a gap in information with regard to public versus private sector individual CT and MRI figures.

As Table 1 shows, Lebanon has a very high number of scanners per million population compared with some higher income countries. This can be attributed to the private sector domination of the health sector with minimal government regulation, where private providers insist on investing in high technology equipment because of the perceived higher profitability of the service provided [18]. Although Lebanon has one of the highest per capita expenditures on health care in the Eastern Mediterranean Region (10.2% of GDP in 2003) less tha 30% is government spending and 56% is out-

of-pocket expenditure by the citizen [19]. The United Arab Emirates has among the lowest number of scanners compared to countries of comparable or lower income, although it should be noted that two thirds of the population are expatriate. Yemen has the lowest number of scanners, while in Tunisia the number is comparable to several countries of higher income. For OECD countries, figures for CT and MRI per million population ranged from 1.5 to 92.6, and 0.2 to 35, respectively [20].

This clearly shows the level of differential use of medical devices and lack of standardization in each country and across countries of the Region. Irrespective of the income level, there is a need for strategic purchasing of medical devices for countries, which takes into consideration the level of the country's socioeconomic development and economic strength.

Table 1. Number of CT and MRI scanners in selected OECD and Eastern Mediterranean Region countries (per million population)

Country (Reference Year)	CT (Per Million Population)	MRI (Per Million Population)	Income level
Australia (2004)	21	3.7	HI
Austria (2003)	27	14	HI
Belgium (2002)	29	6.6	HI
Canada (2003)	11	4.7	HI
Denmark (2003)	15	9.1	HI
Finland (2003)	14	13	HI
France (2003)	8.4	2.8	HI
Germany (2002)	15	6.2	HI
Greece (2002)	17	2.3	HI
Iceland (2003)	21	17	HI
Ireland (1990)	4.3	–	HI
Italy (2003)	24	12	HI
Japan (2002)	93	35	HI
Korea (2003)	32	9	HI
Lebanon (2001)*	13.7	3.7	UMI
Luxembourg (2002)	37	11	HI
Netherlands (1993)	9	3.9	HI
New Zealand (2004)	12	3.7	HI
Portugal (2002)	13	3.9	HI
Spain (2003)	13	7.3	HI
Sweden (1999)	14	7.9	HI
Switzerland (2003)	18	14	HI
United Kingdom (2004)	5.8	5.2	HI
United States (2004)	13	8.6	HI
Czech Republic (2003)	13	2.4	UMI
Hungary (2003)	6.9	2.6	UMI
Mexico (2003)	1.5	0.2	UMI
Poland (2002)	6.3	1	UMI
Slovak Republic (2003)	8.7	2	UMI
Tunisia (2003)	7.0	0.8	LMI
Turkey (2003)	7.3	3	UMI
United Arab Emirates (2003)	5.5	1.9	HI
Yemen (2005)	1.1	0.3	LI

* Unofficial numbers of MRI and CT scanning units in Lebanon are reported to be much higher than those quoted in the table.

HI high income
UMI upper middle income
LMI lower middle income
LI low income

b) Maintenance and repair

The role of engineering, planning and management of medical devices in the health sector is widely misunderstood and underestimated in the Region, with a passive rather than active attitude being taken. Management is often reduced to the mere acquisition of up-to-date technology and millions of devices have been procured without a clear vision of how to maintain them to ensure functionality, uptime, safety, accuracy and lifetime. A study conducted in one Member State on the annual expenditure of the government for the procurement and repair of endoscopes showed that over a 9-year period, from 1996 to 2004, the government spent on repairs more than 2.5 times what it would have cost to maintain the equipment on standard annual inspection and maintenance contracts [21]. Lack of clear budgetary planning at the time of purchase and procurement is a typical problem in the Region with the cost of maintenance often viewed as an unaffordable expenditure rather than an essential one. The amount saved early on in the lifetime of the equipment is exposed as a false economy in relation to the later repairs that become necessary.

c) Supply-driven demand and inequitable access

By 2009, the global medical device market is projected to be worth US$ 186.8 billion [5,22]. This represents an annual average growth of 4.5% from 2005. Such growth will offer new business opportunities for medical device manufacturers and suppliers, and will pose threats to cost containment for health care providers. Therefore, it is important for governments (in collaboration with the private sector) to collect information and anticipate the impact of technological development on the supply and use of medical devices in order to be able to plan for the future.

Prior to entering a certain market, suppliers usually look for market intelligence reports that reveal possible opportunities, estimate potential demand and forecast profits. A study conducted in 2003 estimated the potential global demand for medical equipment [23]. Using econometric models, which project fundamental economic dynamics within each country and across countries, the demand for 2004 to 2008 was projected from actual demand figures for 1998 to 2003 (Table 2). Although in general, potential demand is typically larger than actual sales in the base years it may also be lower or higher, if a market is inefficient for reasons such as lack of transparency, cultural barriers, regulations, etc. The percentage share of the country's demand as compared to other regional or global figures was also estimated. The term "medical equipment" in the study was defined as any product or service that might fall under or be incorporated within medical equipment[3].

The results show that there is expected to be a steady growth in the demand for medical equipment in all countries of the Region. The three most populous countries account for some 50% of the total regional demand for medical equipment. Countries with small populations, weak socioeconomic situations, unstable political conditions and/or poor health information systems comprise those with the lowest potential demand. However, when the actual demand for 2003 is correlated with population, per capita demand in each country is shown to follow closely its income, with high-income countries accounting for the highest per capita demand (Table 3). Total regional demand for medical equipment does not exceed 2% of the global demand, despite accounting for almost 8% of the world's population [24]. These results indicate that the regional market is appealing to suppliers, but also shows that equitable access to medical equipment will be difficult to achieve under current circumstances.

[3] It is also important to bear in mind that the demand for instruments, consumables and other devices was not included in the study. If included, the demand figures should have been at least 3 fold higher than those reported.

Table 2. Actual and potential demand for medical equipment in the Eastern Mediterranean Region, 1998–2008

Country	Actual demand (million US$)						Potential demand (million US$)					Regional share (%)
	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	
Pakistan	131	173	201	222	243	267	292	320	351	385	422	19.08
Egypt	122	160	185	204	223	245	269	295	323	354	388	17.57
Saudi Arabia	119	155	179	198	217	238	261	286	314	344	377	17.06
Iran, Islamic Republic of	75	100	117	129	142	155	170	186	204	223	244	11.07
Morocco	48	58	64	71	77	85	93	102	112	123	135	6.14
Tunisia	31	36	39	43	47	51	56	61	66	73	79	3.69
Iraq	27	31	34	37	40	44	48	52	57	62	68	3.17
United Arab Emirates	26	30	33	36	39	42	46	50	55	60	66	3.07
Syrian Arab Republic	26	29	32	35	38	42	45	50	54	59	65	3.01
Libyan Arab Jamahiriya	23	26	29	32	35	38	41	45	49	54	59	2.74
Sudan	21	24	26	28	31	34	37	41	45	49	54	2.47
Kuwait	19	21	24	26	28	31	34	37	41	45	49	2.25
Afghanistan	12	14	16	17	19	21	23	25	28	31	34	1.52
Oman	11	13	15	16	18	20	22	24	26	29	32	1.43
Lebanon	10	12	13	15	16	18	20	21	24	26	29	1.29
Jordan	10	11	13	14	15	17	18	20	22	24	27	1.21
Qatar	8	10	11	12	13	14	15	17	19	20	22	1.02
Yemen	8	9	10	11	12	13	14	16	17	19	21	0.95
Bahrain	5	6	6	7	7	8	9	9	10	11	12	0.57
Palestine	1	2	4	4	6	8	8.5	9	10	15	20	0.56
Somalia	1	1	1	1	1	1	1	1	2	2	2	0.09
Djibouti	0.16	0.19	0.22	0.16	0.17	0.18	0.21	0.22	0.25	0.27	0.3	0.01

Source: [23]

Note: Actual demand from 1998 to 2003 is estimated using data collected for relatively efficient markets from independent data source (e.g. Euromonitor, Mintel, Thomson Financial Services, the U.S. Industrial Outlook, the World Resources Institute, OECD, United Nations, industry trade associations, International Monetary Fund and World Bank). Potential demand from 2004 to 2008 is estimated using econometric models.

Table 3. Per capita demand medical equipment in the Eastern Mediterranean Region, 2003

Country	Income group	2003 demand (million US$)	% of regional demand	Population* (2004)	Demand per capita (US$)	Weighted average demand per capita (US$)
Qatar	HI	14.00	1.01	656 000	21.34	10.8
Kuwait	HI	31.00	2.23	2 645 000	11.72	
Bahrain	HI	8.00	0.57	708 000	11.30	
Saudi Arabia	HI	238.00	17.10	22 608 000	10.53	
United Arab Emirates	HI	42.00	3.02	4 210 000	9.98	
Oman	UMI	20.00	1.44	2 651000	7.54	5.9
Libyan Arab Jamahiriya	UMI	38.00	2.73	5 843 000	6.50	
Lebanon	UMI	18.00	1.29	4 370 000	4.12	
Tunisia	LMI	51.00	3.66	9 911 000	5.15	2.8
Egypt	LMI	245.00	17.60	69 323 000	3.53	
Jordan	LMI	17.00	1.22	5 617 000	3.03	
Morocco	LMI	85.00	6.11	30 509 000	2.79	
Iran, Islamic Republic of	LMI	155.00	11.13	66 775 000	2.32	
Syrian Arab Republic	LMI	42.00	3.02	18 200 000	2.31	
Palestine	LMI	8.00	0.57	3 827 000	2.09	
Iraq	LMI	44.00	3.16	26 503 000	1.66	
Djibouti	LMI	0.18	0.01	817 000	0.22	
Pakistan	LI	267.00	19.18	151 816 000	1.76	1.4
Sudan	LI	34.00	2.44	34 512 000	0.99	
Afghanistan	LI	21.00	1.51	22 998 000	0.91	
Yemen	LI	13.00	0.93	21 003 000	0.62	
Somalia	LI	1.00	0.07	8 298 000	0.12	
Total		1392.2		513 800 000		
World total		92 449.8		6 446 131 400		
% of global		1.5%		8.0%		

* Source: *Demographic and health indicators for countries of the Eastern Mediterranean Region*, Cairo, WHO Regional Office for the Eastern Mediterranean, 2005.

3.2 Country-specific needs

There is a lack of systematic reporting on medical devices in the Region. In 2005 the Regional Office distributed a structured questionnaire to Ministries of Health aimed at assessing the initial situation, collecting the necessary basic information and evaluating the impact of medical devices on health care system delivery in the Region. Based on the responses received, several issues can be singled out:

- Strategies, policies and regulations in regard to medical devices are generally weak.
- The attention given to planning and management of medical devices is directly proportional to the attention given by national health services to total quality management (TQM) in health care delivery.
- Countries can be divided into groups as follows:
  - countries with medical device management plans;
  - countries with education and training plans but lacking regulations, systems for quality and management, and procurement procedures;
  - countries with written strategies, regulations and relevant experience but lacking education and training plans; and
  - countries with minimal medical device planning and management and in need of support.

Irrespective of the attention given to medical device management, countries indicated that WHO support in activities such as capacity-building of staff, devising information-sharing protocols, developing guidelines for rational use and designing procurement databases is needed.

4. WHO role and position

4.1 WHO working strategies

WHO is working on new ISO standards and performance indicators, promoting the concept of a list of model essential medical devices, and collaborating with international bodies such as the Global Harmonization Task Force[4] in order to establish internationally accepted guidelines and standards. WHO is pursuing four strategic directions aimed at assisting national health authorities in the selection, procurement, use, maintenance and disposal of high quality medical devices that meet their particular needs [15].

National policies and regulations

Governments need to put in place policies that will address all elements related to medical devices, from their outset, through the manufacturing process, advertising, sale and use, to the disposal of the device. However, policies will be unsuccessful unless they are translated into national regulations that are enforced by laws.

Access to essential medical devices

Access to medical devices is not only about adequate resources. It is about managing the supply chain from selection and procurement to local distribution and rational use. To achieve equitable access and cost-effectiveness, there is a need to develop technology transfer networks among countries. Centres of excellence can be helpful in training and encouraging countries to address and/or deal with many medical device-related problems. To ensure appropriate access, a list of essential devices is required [25].

Quality and safety issues

Medical devices need to be of adequate quality and safety to bring public health benefits without harming patients, health care workers or the community. Thus, regulations should mandate that all devices, whether imported or locally produced, meet international norms and standards. In addition, countries should participate in global and local vigilance networks to ensure the effective management of adverse events.

Management, maintenance and use of medical devices

National management programmes need to be established in order to ensure that trained personnel, facilities and standard operating procedures are in place, together with systems for maintenance and repair of equipment. WHO is developing products and tools, such as policy and procurement guidelines, rapid assessment tools and training programmes, to support Member States.

4.2 Global activities

Concept of "Essential medical devices"

One of the key initiatives in WHO is the development of lists of essential medical devices. A medical device should be considered essential only when its use meets the basic needs of health services, has been proven to be cost-effective, and is evidence-based (i.e. follows well defined specifications and is validated through controlled clinical studies or widely accepted consensus by experts). Medical devices should be selected with respect to their public health relevance based on need, efficiency, safety and cost-effectiveness. A static list of medical devices is neither feasible nor useful. Nevertheless, evidence shows that a template list of essential medical devices can assist countries to plan and manage their needs [26,27].

Global Alliance for Healthcare Technology

The Global Alliance for Healthcare Technology is an initiative of WHO and the World Bank to propose concrete solutions to major problems facing developing countries regarding health technology. The project aims at streamlining health care technology investments so that they match the economic strength of any country. In finding the appropriate match, countries can learn from each

[4] The Global Harmonization Task Force (GHTF), conceived in 1992 in an effort to respond to the growing need for international harmonization in the regulation of medical devices, is a voluntary group of representatives from five national medical device regulatory authorities (European Union, Japan, Australia, USA and Canada) and the regulatory industry.

other by looking at what has actually been established in other countries of comparable economic status. Thus, rather than mimicking the design of health services of high income countries, countries of similar economic strength could benefit from each other's experience [28]. Accordingly, WHO will:

- indicate how a country is doing in terms of health technologies vis-à-vis other countries with similar economic strength;
- generate a set of benchmarking indicators which allow comparison between countries;
- estimate performance indicators, which include coverage and utilization; and
- formulate recommendations on strengthening the use of technologies.

The project will be implemented in conjunction with Fudan University in China, where initial tests and data collection protocols are being investigated. As soon as these initial tests are completed, pilot studies will take place including countries from the Eastern Mediterranean Region.

4.3 Regional activities

WHO, through its Regional Offices, aims to support countries so that they can gain access to, implement and manage medical devices that will enhance the health status of their people in an affordable, cost-effective, equitable and sustainable manner. According to needs, each regional office has focused on the improvement of a certain medical technology aspect or topic.

Eastern Mediterranean Region: appropriate health technology

Inspired by the Alma-Ata Declaration, the Regional Office has been engaged in a number of activities aimed at promoting the use of appropriate technologies, which can be referred to as those technologies that are scientifically valid, socially acceptable and universally available to all individuals and families in the communities at an affordable price. A technical discussion on healthcare technologies [29] took place during the Forty-fourth session of the Regional Committee, in Teheran in 1997. The discussions resulted in resolution RC44/R.3 on appropriate health technology which called upon Member States to:

- Develop national programmes on health technology through designating a national focal point for health technology in the country; developing suitable mechanisms for the assessment and acquisition of health technologies; and developing 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; and
- Introduce the subject of appropriate health technology in medical, pharmaceutical and paramedical education.

Regional professionals in the area of medical technologies worked, together with experts from the Regional Office for Africa and headquarters, on promoting the concept of appropriate heath technologies. Their efforts resulted in publications on health care technology management and management of limited resources [30,31].

The task of developing a dynamic essential list of medical devices was delegated to EMRO in order to benefit from its previous efforts and experience in northern Iraq under the Oil-for-Food Programme, where WHO biomedical engineers were forced to develop a methodology in order to ensure adequate procurement and efficient utilization of medical devices [32]. The Regional Office has been working on the initiative for more than one year now and preliminary results are promising.

Americas: Medical device regulation

Regulation of medical devices is considered a key priority in the Americas and the Regional Office has been committed to working with health authorities of its Member States in Latin America and the Caribbean to ensure and guarantee safety, efficacy and quality of medical devices in the Region. To attain this goal, the Regional Office has been and is still collaborating with regional centres of excellence, the Medical Devices Bureau of Canada, as well as the Food and Drug Administration (FDA) and the Emergency Care Research Institute (ECRI) in the USA.

The regional directing council adopted a resolution (CD42.R10) on medical devices in its Forty-second meeting in 2000 [33]. The resolution called for the formation of an ad hoc group to promote and facilitate the medical device harmonization processes in the Americas; urged Member States to develop and strengthen their programmes for the regulation of medical devices and to promote and

support the Global Harmonization Task Force in its work; and requested the Director to continue to support governments in the development and implementation of programmes to regulate medical devices. Since then the Regional Office has engaged in numerous activities, including issue of publications related to indexing, regulation, harmonization and safety of medical devices [34,35]. These activities are not only needed to enhance public health and promote technological innovation, but to facilitate international trade, ensure commitment to trade-related agreements of the World Trade Organization, and reduce the proliferation of un-harmonized regulatory requirements and practices.

Europe: Health technology assessment

With the current expansion of the European Union, the Regional Office is currently involved in a project that aims at promoting unified structures and processes suitable to produce technology assessments that will be powerful in guiding policy and clinical practice towards the best possible health and cost outcomes [36]. In doing so, health technology assessment activities are integrated with WHO quality assurance and care development concepts; unified through cooperation, communication and networking among health care technology institutions in different settings and countries; and promoted by training and education.

The Regional Office has collaborated with governments of many Member States, several investment banks, the World Bank, technical institutions, and medical schools to form the European Observatory on Health Systems and Policies. The observatory, which supports and promotes evidence-based health care policy systems, has recently produced a policy brief aimed at introducing main concepts, as well as reviewing structures and institutions involved in health technology assessment at the European level [37].

5. Conclusions and the way forward

The Regional Office for the Eastern Mediterranean had some field experience in the area of selection of medical devices, procurement, installation, use, national programme policy formulation, as well as maintenance and repair. This knowledge increased with the experience accumulated during the years of embargo in Iraq. The Regional Office will build on that experience by developing strategies to support the establishment of a regional programme on essential medical devices. An advisory group on selection, use, maintenance and assessment of medical devices, comprising experts in the Region, needs to be established to help in developing a regional strategy and action plan based on their experience and knowledge. The approach will be very similar to that of the regional programme on medicines and will include the following strategic directions.

Updating regional information

The lack of data needs to be seriously addressed. Currently available data are weak and have to be updated with respect to selection, use and assessment of medical devices in the Region. An updated set of economic, technical and managerial indicators is required. A regional database will constitute an essential and important pillar in mapping the regional resources in terms of training, provision of technical experience, education and research. It will define the countries and centres that have potential in promoting the rational use of medical devices in the Region.

Promoting the use of regional centres of excellence

Countries need to pay particular attention to total quality management (TQM) of medical devices and to make use of centres of excellence in the Region for training and provision of technical expertise. The Regional Office will facilitate the transfer of technology, whether from outside or within the Region, in order to develop self-sufficiency in production of some essential medical devices within the Region.

Developing regional guidelines

In addition to drafting an essential list of medical devices, the Regional Office will work on developing guidelines and standards that will guide countries in rational selection, procurement and use of medical devices, taking into consideration the experience and lessons learned in the essential medicines programme. Country-specific norms, standards, guidelines, information and training materials need to be developed to support the establishment of effective national health care technology programmes.

Promoting sharing of knowledge and experience

Through the development of evidence-based advocacy material, experience and good practices can be shared among Member States. A fully integrated database on medical device procurement, selection, training, management and use will be developed by the Regional Office and shared by Member States. The database will serve as a decision-making tool for Member States. Health technology assessment and management systems, including maintenance and repair, will also be developed and shared within the Region.

6. Recommendations

1. Member States should develop and/or modify national master plans for the introduction and implementation of policies and regulations; update their current data; promote total quality management; and establish national centres of excellence. Plans should cover needs assessment, development of national standards, identification of good practices and policies, assuring quality and safety, providing equitable access and use, cost-effectiveness (especially for use of advanced medical devices), training and capacity-building.
2. Financial and human resources should be allocated at the national level in order to support proper implementation of plans.
3. Aided by regional guidelines, awareness campaigns should be conducted to sensitize health care professionals and planners of the importance of medical device management and their specific roles in adaptation.
4. Essential information and indicators on medical devices once collected, should be analysed and shared with other Member States.

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