

TOWARDS A WHO MODEL LIST OF ESSENTIAL MEDICAL DEVICES

THE NEED FOR A POLICY

Medical devices cover a wide range of consumables and equipment, from simple tongue depressors to complex haemodialysis machines, although they exclude infrastructure, such as buildings or power supplies. They are used at all levels of health services and often require substantial capital investment. The right choice of medical devices is crucial to health services and has implications in terms of patient care and in the prevention of disease, disability and death. Yet the management of medical devices is too often relegated to a procurement issue rather than a public health policy requirement.



THE EFFECTS OF INAPPROPRIATE MANAGEMENT

The absence of policy and mismanagement of medical devices can result in infection, injury or death to the patient – or the user – of medical devices. The importance of ensuring patient safety was the focus of World Health Assembly resolution WHA 55.18. Safety of services is an integral part of the quality management of health systems. Safety is also needed for health products, namely medicines, vaccines, blood and medical devices.

¹ The global market for medical devices is estimated to reach US \$260 billion by 2006 (WHO internal document, 1998 estimation)



A WASTE OF PRECIOUS HEALTH CARE RESOURCES

To fight major diseases of poverty, ministries of health are faced with the challenge of scaling up close-to-client services to deliver essential health procedures. The gap between the rich and the poor is also a gap within many developing countries. Medical devices represent a high proportion of health care expenditure¹ and are frequently too expensive for the poor. Despite this investment, information may be unavailable regarding their use and their maintenance and ministries of health often lack a standardized development plan or even an awareness of the medical devices available in the country.

WHAT IS AN ESSENTIAL MEDICAL DEVICE?

Essential medical devices are those that meet the priority health care needs of the population. They are selected with respect to their public health relevance based on their efficacy, safety and cost-effectiveness. A static list of medical devices is neither feasible nor useful. Nonetheless, evidence shows that a template list of essential medical devices can assist countries to plan and manage their needs for health care delivery. The relevance and public health benefit of this approach has been documented through 25 years of implementation of the WHO model list of Essential Medicines.

AN EVIDENCE-BASED PUBLIC HEALTH CONCEPT

The framework to define a model list of essential medical devices is to

- 1) start from major diseases of poverty;
- 2) define appropriate health interventions; and
- 3) list the essential medical devices that will be required for these interventions.

In summary, this is an evidence-based, public health concept where health conditions define which devices are needed, rather than a marketing approach where the availability of new devices justifies new markets.

The following criteria will guide the development of an evidence-based list of essential medical devices.

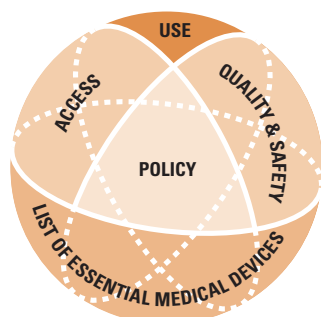
- Devices should be **necessary** to the implementation of a cost-effective health intervention
- Devices should be **effective**
- Devices should be **safe**

The WHO model list of essential medical devices will take into account both the level of health care service delivery (e.g., primary care, district hospital and referral centres); and specific public health programmes and initiatives (e.g., safe motherhood, district surgery, immunization, blood transfusion services). These will be addressed in various subgroups of the master list.

Selection criteria

Levels of health care and specific health programmes

List of essential medical devices as an integral element in the national strategy for medical technology



A list of essential devices at the heart of a national policy on medical devices

Process to formulate a WHO model list of essential medical devices



A national strategy for medical devices should be based on a strong policy, within an adapted regulatory framework. Once consensus has been reached over what set of medical devices is essential, assistance can be focused to:

- 1) Ensure the quality and safety of the devices through norms and standards enforced through national regulations and global vigilance systems;
- 2) Increase access through tools that facilitate procurement and supply management;
- 3) Improve safe, cost-effective and rational use through technical guidance and training.

The process used to formulate the list will be explicit, transparent and consultative through an engagement of key partners (e.g., UNICEF, World Bank and non-governmental organizations). This list will be based on evidence, linked to health outcomes, operational at different levels of health care, include complementary sections (e.g., infection control prevention package) and be adaptable to the morbidity profile of each country.

Key steps include:

1. Formulation and review of existing lists

Lists that exist in WHO (e.g., WHO emergency health kit, medical devices for surgical procedures at first referral level of health care facility) or with selected partners (e.g., WHO/UNDP Compendium of Basic Specifications for Emergency Relief Items, UNICEF Supply Catalogue 2003) will be reviewed for audience, content and the process used to develop them. First, the department of Essential Health Technologies will create a repository of all these lists. Second, mechanisms to update them will be explored.

2. Development and discussion of a blueprint of essential lists

A blueprint of will be prepared of medical devices required at various levels and categories of health care provision and circulated for peer review. The result will be a draft list of essential medical devices that includes interventions of special public health importance.

3. Monitoring and evaluation

WHO will organize annual meetings of experts to review the lists for comments and suggestions before their official clearance and publication.



THE WHO BASIC OPERATIONAL FRAMEWORK

The WHO Department of Essential Health Technologies assists countries to achieve a safe and reliable level of health services in a variety of health technologies through its Basic Operational Frameworks. Below is a summary of the requirements for countries to attain this level of health service for Medical Devices and Equipment, and the products and services that WHO can make available to support this goal.²

It is easy to overlook how medical devices accompany us daily throughout our lives. Whether to monitor the development of an unborn child, protect an infant from measles, diagnose and treat today's killer diseases or to perform keyhole surgery, virtually no health intervention can take place without recourse to a medical device.

Despite huge investment, yet the majority of developing countries do not recognize the management of medical devices as a public health priority. This often means that products are unwittingly produced and procured that do not meet international standards of efficacy, quality and safety. It is also why over 50% of the medical equipment in developing countries is not functioning, not used correctly or not maintained. Some equipment is even unnecessary or inappropriate to fulfil its intended purpose. The misuse of medical devices is another major concern. Each year, for example, unsafe injection practices cause an estimated 260,000 new – and avoidable – HIV infections.

EHT will focus on strengthening national capacity to regulate medical devices so that they meet high quality and safety standards and are used appropriately. Efforts will also concentrate on making appropriate devices and equipment more available and affordable.

Policy

TO BE IN PLACE IN COUNTRIES

Medical devices and equipment are often seen as a mere procurement issue, while they are at the core of public health interventions for the prevention of death or disability or for managing the diseases of poverty. To broaden this vision, a clear policy on medical devices and equipment is required. Key elements include:

- National policy and plan for medical devices
- National policy for the safe and appropriate use of injections
- National Regulatory Authority functional in medical devices, empowered with legislation
- National coalition for injection safety and infection control
- National budget for devices and injection safety, using costing, budgeting and financing
- Assessment of needs
- Inventory of suppliers and medical devices in use

² The Basic Operational Framework for Medical Devices and Equipment can be found on the Internet at www.who.int/eht

Quality and safety

WHO PRODUCTS AND SERVICES TO SUPPORT POLICY REQUIREMENTS

- Aide-Mémoires on Medical Devices
- Medical Device Regulations: Global Overview and Guiding Principles
- *Managing an Injection Safety Policy* document
- Rapid Assessment Tools and Global Databases
- National Regulatory Authority Assessment and Strengthening Tools
- Secretariat of Safe Injection Global Network (SIGN) Alliance
- Documentation on global burden of disease and cost-effectiveness studies
- Costing tools, including maintenance, spare parts, accessories and replacement

TO BE IN PLACE IN COUNTRIES

Medical devices and equipment 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 and equipment, whether imported or locally produced, meet international norms and standards (or WHO specification in the absence of standards). In addition, the coordination of global and local vigilance networks ensure the management of adverse events. Key elements include:

- Good Manufacturing Practices and quality control for local production of devices
- National procedure for licensing/market clearance
- Pre-qualification of suppliers
- National regulations based on ISO standards or WHO specifications
- Post-market surveillance/vigilance system for alerts, notifications and recalls
- National technology assessment centre
- Introduction of syringes with reuse prevention feature

WHO PRODUCTS AND SERVICES TO SUPPORT QUALITY AND SAFETY REQUIREMENTS

- WHO pre-qualification procedures for medical devices
- ISO standards and WHO performance specifications
- Standardized procedures for alerts, notification and recalls
- Participation in the work of the Global Harmonization Task Force
- Standardized assessment protocols for new medical devices

Access

TO BE IN PLACE IN COUNTRIES

Access to medical devices is not only about adequate resources. It is about managing the supply chain from procurement to local distribution. A list of essential equipment and devices is the keystone of a national system that can ensure appropriate access. Key elements include:

- National list of essential medical devices and equipment
- National procurement procedures
- Joint procurement of injectable substances and injection devices
- National policy for acceptance of donations
- Negotiated pricing
- In country production of essential technologies

WHO PRODUCTS AND SERVICES TO SUPPORT ACCESS REQUIREMENTS

- WHO Essential Healthcare Technology package
- WHO model list of essential medical devices and equipment
- Procurement guidelines
- Guidelines on good donation practices
- Collaboration with industry on fair pricing, R&D and technology transfer

Use

TO BE IN PLACE IN COUNTRIES

Health technologies are only effective if they are used in a safe, appropriate and cost-effective manner. Key elements include:

- National guide for management and use of medical devices
- Standard operating procedures and best practices that cover every stage in the life span of a medical device
- Regular training in the management, use and maintenance of medical devices
- National recommendations for injection safety and infection control
- Communication strategy for safe and appropriate use
- Behaviour change for injection safety and infection control

WHO PRODUCTS AND SERVICES IN SUPPORT OF USE REQUIREMENTS

- Assistance and tools on the management and rational use of devices and equipment
- IEC materials and resource toolboxes
- Best practices standards