

بسم الله الرحمن الرحيم



The Republic of Sudan  
Federal Ministry of Health

# **Health Technology Management Policy (Medical Devices)**

**General Directorate of Planning and International relation  
Directorate of Development and Projects**

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## FOREWORD

Medical equipment are essential components of modern health care services, necessary for provision of good standard of treatment and care, and for creation of conditions which will encourage staff to give their best in the interest of their patients. Regrettably however, Federal Ministry of Health, State Ministers of Health hospitals and health Institutions in Sudan are currently full of different types of dysfunctional health equipment, and plants imported from different countries; most of which were neither ordered according to needs nor to specifications.

Inappropriate medical devices selection, its uncoordinated acquisition, its poor maintenance as well as absence of effective regulations are among the major challenges of health care system. This condition led to in-efficient and in-effective planning, management and provision of health care services. It continuously, causes loss of resources and opportunities for provision of high-quality health care services.

This policy Crafting is important step towards reversing this situation. This policy is aimed at ensuring rational and optimal distribution of health technology especially medical devices to improve equity in access to health care. It is proposed that Essential Health Service Packages will provide the context and suggest levels of Health Technology required per region and per health care facility. It is proposed that technology deployment is aligned with health needs, national health plans, regional disease profiles and existing levels of technology sophistication, including logistical support infrastructure. This policy reflects on structures that would best fit the Sudanese context and how Health Technology Assessment evidence produced elsewhere could be adopted and adapted to the Sudanese context. The link between burden of disease, healthcare services, clinical interventions and corresponding health technologies, supporting infrastructure and human resource needs is also addressed. Concept of Basic Health Technology Resources Availability per level of care is realized too.

This document represents the strong commitment of the ministry of health for better utilization of health technology in health care. I'm sure that implementation of this policy at national, state and service levels will change the current medical devices management weaknesses to improve the health system performance. Therefore, I encourage these levels to take necessary steps to assure realization of these policy statements. Finally, I would like to commend the hard working and dedication of the national taskforce led by the health research and policy departments to oversee development of this document. I also thank the WHO for the financial and technical support to this work.

**Mr. Bahar Idriss Abugarda**  
**Minister of health**  
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## **INTRODUCTION**

Health technologies are essential for a functioning health system. Medical devices in particular are crucial in the prevention, diagnosis, and treatment of illness and disease, as well as patient rehabilitation. When used within the context of a robust health system, medical devices improve health outcomes. Through such a system, medical devices can be effectively allocated based on the needs of a particular population. A health system, however, is only as good as the policies, strategies, and action plans that constitute it.

Policies create a framework through which to direct valuable resources. A national health policy framework includes a vision, a situation analysis, policy directions, strategies to overcome challenges, a policy implementation plan, and the leadership and governance required to achieve sustainability. When embedded within a national health policy, health technologies policies can be linked to other health systems components - financing, human resources, information, leadership and governance - that together address the needs of the target population and may result in better health outcomes.

Effective health technology policies address inequity as well as accessibility, affordability and availability of innovative and core medical devices required to target the health needs, particularly those that address the Millennium Development Goals and non-communicable diseases. To do this the four phases of medical devices - research and innovation, regulation for device safety, assessment for better decision making, and comprehensive management - must be considered and adapted to the priority public health conditions, resources and settings.

Once the policies are compiled, organizational structures are required to implement the strategies and action plans contained therein. This includes a regulatory authority and regional and national institutions to optimally assess and manage health technology, with the support of specialized professionals in biomedical engineering and related areas. Monitoring and evaluation of the strategies, objectives or action plans and the use of indicators to trace effectiveness will increase accountability and provide feedback for improvement of the policy and its implementation process.

### **Definition of Health Technology**

Health technology has been defined by WHO as the application of organized knowledge and skills in the form of medical devices, medicines, vaccines, medical and surgical procedures to solve a health problem and improve the quality of lives. This definition is broad enough to encompass traditional medicine, information systems, health promotion and prevention activities, as well as organizational and healthcare delivery support systems.

## **Policy context**

Analysis of health technology management and assessment condition especially medical devices and its related contextual issues revealed very important information. This analysis drew attention to some crucial issues shaped the content and statement of this policy.

### **Health system management and service delivery arrangement**

The country has federal system of governance with three management levels. It is divided politically into 16 states which also divided into certain number of localities. Health is one of concurrent responsibilities in the constitution that power of governance is shared across health system levels. Similar to other sectors, health system structure has three layers. Federal ministry of health represent the apex, it is responsible of policymaking, strategic planning, co-ordination and harmonization of all health actors' actions and plans including national and international players, providing technical support and guidance to states, and monitoring and evaluation of the overall health system performance. The intermediate layer is state ministries of health, they are in charge of health planning, policy making and implementation at state level. They take direct responsibility for the organization of health in the state and support of local health systems. At the bottom we found the localities representing the local health system. The localities are concerned mostly with policy implementation and service delivery. They are based on district health systems. They emphasize the principles of primary health care represented in decentralization, community participation, intersectoral co-ordination and integration of services.

Health system service provision structure is pyramidal with three levels. At the top of pyramid are the teaching and specialist hospitals rendering tertiary care. However, at intermediate level there are state and general hospitals illustrating the secondary care. Finally, primary health care facilities occupy the base of the pyramid to provide the first line of health care.

### **Health Technology situation in Sudan**

Sudan is currently facing a number of problems with respect to medical devices, some of which are highlighted. Much of this information has been obtained from a survey of the various people involved in this area ranging from personnel at the Ministry of Health Sudan, managers, users, biomedical engineers, and other relevant personnel at state, locality and institution levels.

Some of the problems identified include the need for improving the current organizational structure with respect to medical devices, including the need for appropriate dedicated personnel focusing solely on the area of medical devices.

Other problems identified include the lack of a health technology management system, shortcomings in various aspects of the procurement process, including the lack of a systematic approach to needs analysis so that at times medical devices are in place without the specialized personnel required to operate them resulting in the devices not being used for provision of services.

In addition, inadequate attention is paid to budgeting and financing so that there is lack of funds to operate and service the devices after they have been purchased. Apart from this, there is inadequate attention paid to the selection of the medical device so that an inappropriate device is purchased for the institution.

There is no formal health technology assessment being carried out, so that inappropriate technology is sometimes used to deliver the service.

Besides, there are shortfalls in setup preparation; testing and commissioning resulting in some medical devices failing soon after the device is in operation.

The lack of training provisions in the specifications for the device at the time of purchase results in a lack of appropriate training of both the user and maintenance personnel, so that users are not fully conversant with operating procedures, while maintenance personnel are not able to maintain the devices comprehensively.

As mentioned above, users may not be trained to use medical devices, especially when new and sophisticated devices are acquired in place of older models. This is important in life-saving devices like patient ventilators, where operators would need to set various parameters to suit individual patient needs. In addition, users may also not pay adequate attention to safety precautions, and fully appreciate the important of safety features of the devices, for example, the implications when various alarms are set off in the devices. This is compounded by the fact there are many brands and models of the same device, so that users and maintenance personnel may be familiar with handling common brands, but face problems with new brands each time purchase are made.

Another major area of shortfall is repair and maintenance. Most medical devices in Sudan employ sales personnel with few or even no maintenance personnel, and also do not stock even common spare parts of medical devices sold in Sudan. Consequently, these companies are not able to assist

institutions in repairing medical devices when they break down, nor are they able to carry out routine maintenance. This has at time forced institutions to abandon devices which have broken down soon after purchase which local suppliers are unable to repair, lead to purchase new devices to replace them. The lack of local technical support also means that both service personnel and spare parts have to be flown in from the principal companied abroad incurring high repair costs. A system of planned preventive maintenance is also not carried out, so that for example, instead of replacing an X-ray tube when it has reached its optimum life span of 50 000-100,000 examinations or signs of diminishing tube quality, these X-ray tubes are only replaced after the X-ray tube has failed, involving a wait of about 4 to 6 months for anew tube, resulting in interruption of service or new born fault could develop due to shutdown. .

Finally, there are also shortcomings in the decommissioning and disposal of devices. In many institutions, there is no clear procedure or established system for these. As a result, many disused and broken down devices are left lying around, presumably in the hope that they could be salvaged or repaired in future.

### **Strategies for managing Medical devices**

A system for health technology planning, specifically for medical devices, should be carried out at the national level to identify medical device standards for expensive, sophisticated or high risk devices. These can be in the form of population norms or by type of services

The use of the certificate of need in the Sudan National Health Policy for private 'for profit' health sector, 2009 where it a requirement for planning a private facility can also be applied for selected medical devices covering both public and private sectors. Once the numbers of a selected medical device has been determined for Sudan, health facilities can submit a certificate of need to justify acquiring that device for their facility.

There should also be national control of selected medical devices. These could cover expensive, sophisticated, high-risk medical devices as well as those where currently there is already an over-supply or duplication between public and private sectors. This could be by setting financial ceilings based on prices of medical devices at different service levels. It needs to be realized that every investment especially on expensive medical devices would require a return on investment that may result in unnecessary use of the device.

Some of the other approaches that need to be considered are accreditation of hospitals and laboratories as well as other quality assurance activities.

## Scope of health technology policy

While under ideal circumstances it would be desirable to have a health technology policy to cover all aspects of health technology, it may not be practical to do so for various reasons. Most aspects relevant to medicines have already been established with a regulatory system in place, and a system for acquisition of medicines at the national level, and subsequent supply to institutions and health facilities have also been established. Some aspects related to medical devices are being carried out, while there are minimal aspects covered in other areas.

Consequently, it is suggested that efforts be targeted towards the development and implementation of a health technology policy focusing on medical devices. Although the efforts done in the medicines area can provide some guidance to medical devices, major differences exist between these two medical products in terms of regulation, evaluation methods, types of users/operators, storage conditions, testing and commissioning, repair and maintenance, and operating costs (see annex 1 for further details).

The term *medical device* refers to any instrument, apparatus, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used alone or in combination, for human beings for one or more of the specific purposes of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease;
- Diagnosis, monitoring, treatment,, alleviation or compensation for an injury;
- Investigation, replacement, modification, or support of the anatomy or of a physiological process;
- Supporting or sustaining of life;
- Control of conception;
- Disinfection of medical devices; and
- Providing information for medical purposes by means of *in vitro* examination of specimens derived from the human body and 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 by such means. (Global Harmonisation Task Force, 2005)

To enable a common international terminology for medical devices, use of the Global Medical Device Nomenclature (GMDN) is recommended. It is described as a comprehensive system used to generically define and identify medical devices and related healthcare products.



## **NATIONAL HEALTH POLICY FRAMEWORK**

The nature of policy-making is that it is a process, and most often a contested one. This is also true for policy-making in the area of health technology. In recognition of the contested nature of policy-making and the valid interests of a range of stakeholders, the following principles should be applied:

- Base policy-making on the core values of primary health care.
- Ensure a mechanism for endorsement of the process by senior government officials.
- Ensure the process is broadly consultative and involves participation of all major stakeholders.
- Ensure the process is transparent and decisions are reached based on evidence.

An effective national policy is achievable with action at all levels. This entails considering resources and capacities as well as legal and political commitment.

In Sudan, a national health policy has been developed in 2007 taking into account the relevant provisions of the interim Constitution of Sudan, 2005, the Local Government Act, 2003, and other relevant state laws and decrees. The policy focuses on providing healthcare to all citizens of Sudan, especially serving the health needs of the poor and the underserved, disadvantaged and vulnerable. The national health policy focuses on the need for health technology management, as well as working towards ensuring effective health technology management.

The National Health Policy for private 'for profit' health sector also moots public-private-partnership to optimize services in the public and private sectors.

## **RATIONALE FOR MEDICAL DEVICES POLICY**

Planning for health technology should be driven by priority public health needs. It should also be integrated into health sector planning processes, outputs, and cycles at national, sub-national, and local levels. Planning must be comprehensive (cover all areas of activity) and coherent (i.e. compatible with sub-plans). Once again, the plan should cover all aspects of the four major areas of activity: research and development, health technology assessment, health technology regulation, and health technology management.

The existence of evidence-based policy and plans will not result in the desired improved health outcomes without a system of active management. In addition to the existence of policies, plans, and

organizational structures there is the further requirement for the development of suitable organizational structures, associated management processes, and sufficient management and technical capacity.

Management processes must be developed for implementation of plans and must include appropriate oversight, reporting, and monitoring and evaluation. As plans are always imperfect, it is necessary to ensure that mechanisms are also in place to enable appropriate adjustments according to findings as implementation proceeds, while remaining consistent with policy. Furthermore, budgets and plans should be reviewed and updated at regular intervals by a designated governance committee in order to ensure that they always address the current needs of those they are intended to serve.

Strong management capacity alone can result in improved health outcomes in the absence of policy and even plans. However, such an approach is not systematic or balanced and at higher risk of failure and is therefore not advised. Conversely, the existence of policy, plans, organizational structures, and management processes will not result in improved health outcomes in the absence of sufficient and suitable management capacity.

Sufficient and suitable management capacity requires the deployment of financial and human resources. It will be necessary for Member States to allocate sufficient regular budgets, at national and sub national levels, to establish an equipment replacement programme and hire sufficient numbers of qualified and trained staff to implement effective and efficient health technology management. Support from external financial donors may be useful in starting a programme, developing capacity, and providing occasional injections of funds for equipment purchase or further training, but unless Member States commit sufficient regular funds, sustainable improved health outcomes will not be achieved.

A final but important component of an effective management approach will be the integration of all activities into a wider quality assurance programme with a philosophy of continuous improvement and including the necessary safeguards to ensure patient safety and welfare.

## **MEDICAL DEVICES POLICY**

### **THE OBJECTIVE**

Medical device is an essential component of healthcare, as can be seen by the ever increasing expenditure on health technology within the health budget. Apart from this, acquisition of medical devices has long-term impacts especially in relation to ongoing budgets for consumables, reagents, operation, maintenance, and the need for utilities. As well as requiring specialized manpower for operation of the technology. There is also need to ensure safety, efficacy and cost effectiveness of the technology being acquired. To ensure that these are put in place an effective health management system has to be set up which in turn necessitates an effective medical devices policy to complement the national health policy and assist in achieving its aims of provision of healthcare to the people of Sudan.

The overall objective of the medical devices policy is to achieve equitable access to appropriate, safe, effective, cost-effective, efficient and affordable medical devices for all people in Sudan.

### **MEDICAL DEVICE MANAGEMENT SYSTEM**

Medical devices, needs to be managed comprehensively and effectively to ensure that sufficient emphasis is given to the different stages of the device life-cycle (see below for details of the life-cycle). This requires the establishment of a Medical Device management (MDM) system. A good MDM system will ensure the availability of reliable information about medical devices, and involve adequate planning and ensuring the availability of adequate funds. It will also ensure that suitable types of medical devices are acquired and that they are installed effectively. It will also focus on ensuring adequate resources for continued use of medical devices, especially in situations where there high recurrent costs, involving reagents and consumables. A good MDM system will lead to all devices being operated effectively and safely, and that all staff has adequate skills for optimal use of the devices. It will also ensure that medical devices are repaired and maintained well. In addition, MDM will allow a systematic approach to decommissioning, disposing and replacing unsafe and obsolete devices.

## **MEDICAL DEVICE PLANNING SYSTEM**

**MEDICAL DEVICE** Systematic planning needs to be undertaken to ensure that medical devices are distributed optimally to ensure equitable access to all, to support the national health policy objective of providing healthcare to all citizens of Sudan. This will also ascertain optimal utilization of all devices so that their potential can be fully realized.

### **Basic Medical Device List**

This policy recommends development of a basic medical device list by type of facility e.g. a list for primary healthcare facility, health centers, different lists for different categories of hospital depending on the degree of specialization and complexity of services being provided. These device lists should also be discipline specific to be able to differentiate between secondary and tertiary hospital services, as well as teaching hospitals. The MOH shall provide a standard lists for medical devices specifications and technical data to be used at all operational levels of the health system based on the type of health interventions expected to carry out.

It is the responsibility of MOH to ensure that public health facilities are equipped according to established standards. This policy recommends development of a central library of generic equipment specifications that are used across the whole of levels for health service delivery.

### **Medical Device Packages**

For resource planning, data analysis, managing and coordinating project implementation in this area, a software package should be developed as a possible solution.

## **HEALTH TECHNOLOGY ASSESSMENT SYSTEM**

Health technology assessment (HTA) refers to the systematic analysis of the safety, efficacy, cost-effectiveness, ethical, legal, social and organizational implications of a technology, a set of technologies, or a technology related issue, as a means of providing input into decision making or policy formulation. This involves a multi-disciplinary approach to the analysis of information related to the issue in question, rather than the physical testing or analysis of a medical device. While it is applicable for any technology, it is especially useful for expensive or sophisticated technology where decisions to acquire such technologies may have far reaching implications for the institution.

Health technology assessment can be achieved through development of unit that can serve at national, regional, or local (hospital) levels. This policy supports establishment of Department of National Health Technology Management & assessment (DHTM) at federal level of ministry of health and state level as well. At the national level, the department unit has four sections; Medical devices technology section, Medical devices management section, Quality assurance section, Research and health economic. It provides recommendations on public policies regarding medical devices as they relate to the needs of the population and the national priorities. Usually this unit is comprised of interdisciplinary professionals such as epidemiologists, librarians, health economists, biomedical engineers, medical doctors, researchers, and analysts. The major term of reference of the unit is as follow:

- Develops plans, policies, programs and strategies for regulating health and health-related devices and technology.
- Formulates rules, regulations and standards for licensing and accreditation of health and health-related devices and technology.
- Conducts licensing and accreditation of health and health-related devices and technology.
- Provides technical, consultative and advisory services to and develops capability of field offices on licensing and enforcement of laws, rules and regulations pertaining to health and health-related devices and technology
- Monitors, evaluates and ensures compliance of manufacturers, distributors, advertisers and retailers of health and health-related devices and technology to health rules and regulations and standards of quality.
- Advises the minister and the Undersecretary of Health on matters pertaining to regulation of health and health-related devices and technology.
- Conduct research and survey to evaluate and assess the adequate health-related device and technology.
- Manipulate and harmonize the international collaboration in the field health-related device and technology.

The state department has to have the following four units planning unit, Managerial unit, Procurement unit, Research and health economic unit. However, the state unit has to conduct the following activities:

- Implement national policies and guidelines and develops plans, programs and strategies for regulating health and health-related devices and technology.
- Implement national rules, regulations and standards for licensing and accreditation of health and health-related devices and technology.
- Conducts licensing and accreditation of health and health-related devices and technology.
- Provides technical, consultative and advisory services to and develops capability of field offices on licensing and enforcement of laws, rules and regulations pertaining to health and health-related devices and technology
- Monitors, evaluates and ensures compliance of manufacturers, distributors, advertisers and retailers of health and health-related devices and technology to national health rules and regulations and standards of quality.
- Participate and support conduct research and survey to evaluate and assess the adequate health-related device and technology..

Currently, there is a lack of HTA expertise in Sudan. The development of such a facility will require considerable resource investment including capacity building and development of sufficient expertise to be able to carry out HTA. Apart from this, there is a need to develop a suitable model including an HTA organizational structure suitable for Sudan.

In the light of this, this policy focuses on the development of a good HTM system. Once an HTM system is in place, and functioning well, the setting up of a HTA system can then be pursued.

## **GOVERNANCE FRAMEWORK**

An effective governance framework is necessary for the smooth implementation of a medical devices policy. Such a system of governance needs to focus on the areas of legal and financial requirements, medical device regulations and health technology management.

Usually the legal and financial aspects are under the purview of the Federal Ministry of Health, while health technology management will focus on the implementation and monitoring of the health technology policy.

Ideally, medical device regulation should be carried out by an autonomous body, although it can still be within the purview of the Federal Ministry of Health (see section on medical device regulation below for further details). This will serve to outline the separate roles of policy, regulation and implementation, provide varying degrees of autonomy while at the same time maintaining accountability with defined roles and responsibilities.

## **ORGANISATIONAL STRUCTURE FOR MEDICAL DEVICES MANAGEMENT**

An effective medical device policy would require an organizational structure that runs through the whole health system. DHTMA mentioned above will be established down to the level of facilities, these departments are expected to work in coordination with one another. While these entities will be linked as part of a referral network, the roles, responsibilities and activities at each level would need to be clarified to ensure smooth operations. In defining these, it may be appropriate to ensure the necessity as well as the mechanism for provision of specific and clear roles, responsibilities and activities. This policy recommends that the manager of the DHTMA at locality and facility levels become a member of the health management team at each level.

In order to implement policies and strategies on health technologies, this policy recommends development of organizational structures of DHTMAs as locality and facility levels are required. Medical devices management and assessment will follow the decentralized form of health system management. However, the DHTMAs will be dedicated to the major four phases of health technologies; namely, *Regulation*, *Health Technology Assessment (HTA)*, *Health Technology Management (HTM)*, and *Research and Development (R&D)*. Figure (1) shows the 4 areas that will be primarily involved in the implementation of the health technology policies and the support areas of nomenclature and lists of medical devices that are used in many of these processes.

Medical device management working groups can be established from time-to-time depending on needs and should include all relevant stakeholders. These could either be permanent working groups or working groups established for specific functions e.g. for preparation of specifications for acquisition of a specific device. A permanent working group will be responsible for reviewing the medical device situation and institute appropriate planning to meet device needs at each level. All medical devices working groups will report to the DHTMA at that level. This policy recommends that MOH to establish relevant committees to deal with different management phases throughout life-cycle of medical device such as National Medical Devices Planning Committee, National Medical Devices Technical committee as well as Procurement/Tender Committee

A national steering committee on medical devices should be established at the federal level. This committee will function as the policy making body as well as oversee stakeholders coordination and communication and implementation of policies. The national steering committee will be affiliated and led by the national DHTMA; the department is responsible of coordination of stakeholders' efforts to meet the working group recommendations and plans. Similar committees should be established at state, locality and institution level for local policy implementation.

There are several options for developing a service for medical devices management. The key for selecting the right model is to choose one that integrates into the existing health management system and health delivery system model. When creating a medical devices management system, it is suggested to:

- Choose a team for medical devices management at each facility and administrative level.
- Link medical devices management teams as part of a referral network.
- Ensure there are resources in place to perform all necessary management activities.
- Ensure that the management team manager at each level is a member of the relevant health management team.
- At each level, establish a medical devices management working group that reports to the health management team and is responsible for reviewing the status of equipment and for planning future needs.

Medical devices management teams will likely need to work together at national, sub-national and facility levels to ensure coordination and supervision across the entire system. Clarification of roles and responsibilities at each level will greatly facilitate coordination between the different levels and also enable a clearer estimation of human and other resources required to run the system. It is



advisable to encourage information exchange with the health technology assessment agency and regulatory authorities as well.

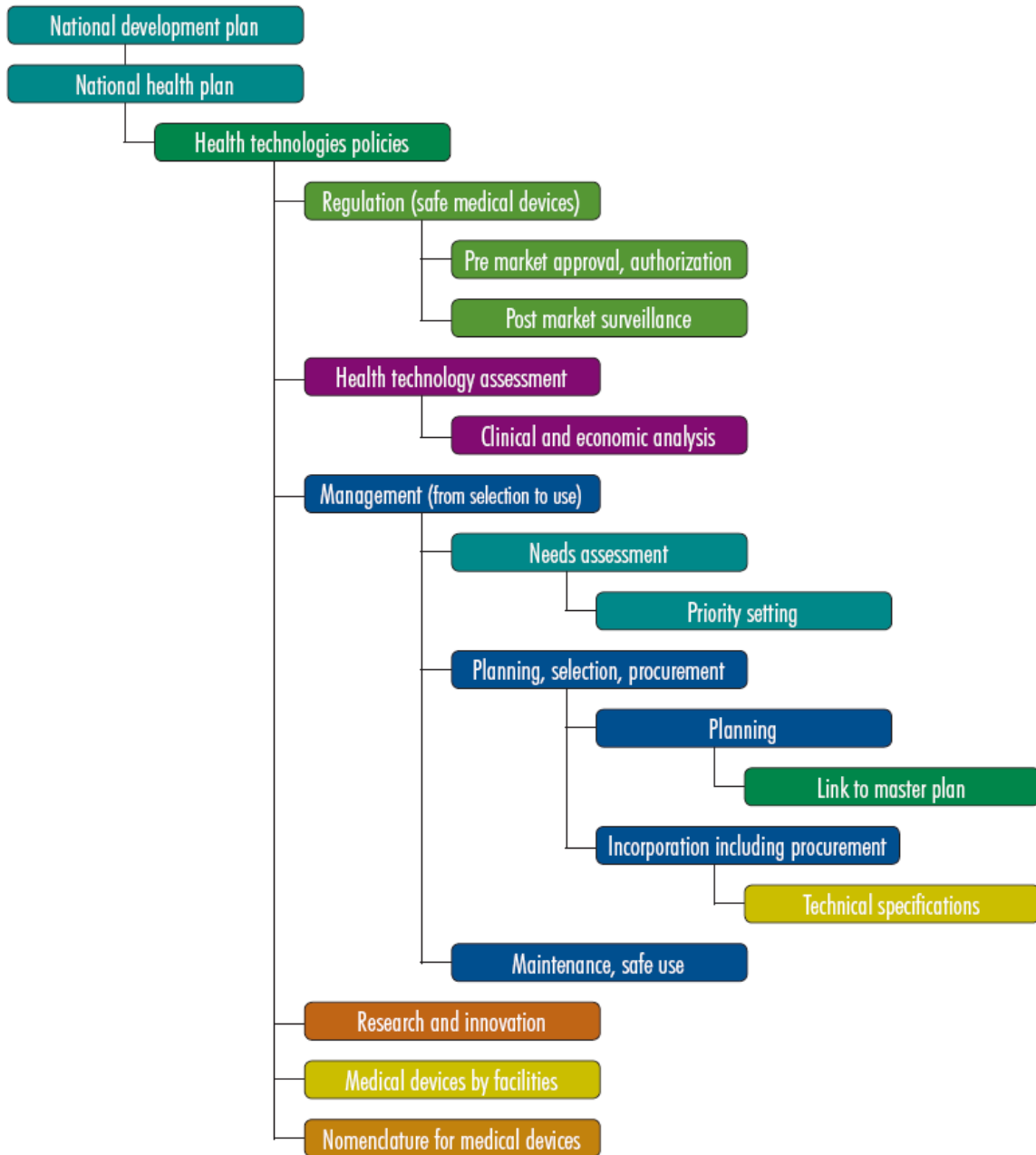


Figure (1). Areas of Implementation for a Successful Medical Devices Policy

## **MEDICAL DEVICE LIFE-CYCLE**

A systematic, comprehensive approach has to be used in acquisition of medical devices as part of the medical device management system. The medical device life-cycle approach has to be used. This involved a step-by-step approach commencing from planning, and managing each subsequent area, until the end of the cycle where the equipment is safely disposed. All steps in the medical device life-cycle should be documented. A schematic representation of the medical device life-cycle is illustrated in Figure (2).

The MOH shall develop regulations on medical devices procurement procedures and should promote accountability and transparency. Procurement actions must focus on compliance with these guidelines. Procurement of expensive medical devices should be based on a clear strategy and actual needs assessment, or sound justification based on evidence (need assessment guidelines).

This policy support procurement of equipment centrally or regionally when there is planned bulk procurement (preferable and more cost-effective). Financial brackets may be used to determine which purchasing method to use in accordance with the government regulations. MOH delegate a relevant public body for procurement of medical devices but deals directly with procurement of foreign funded projects.

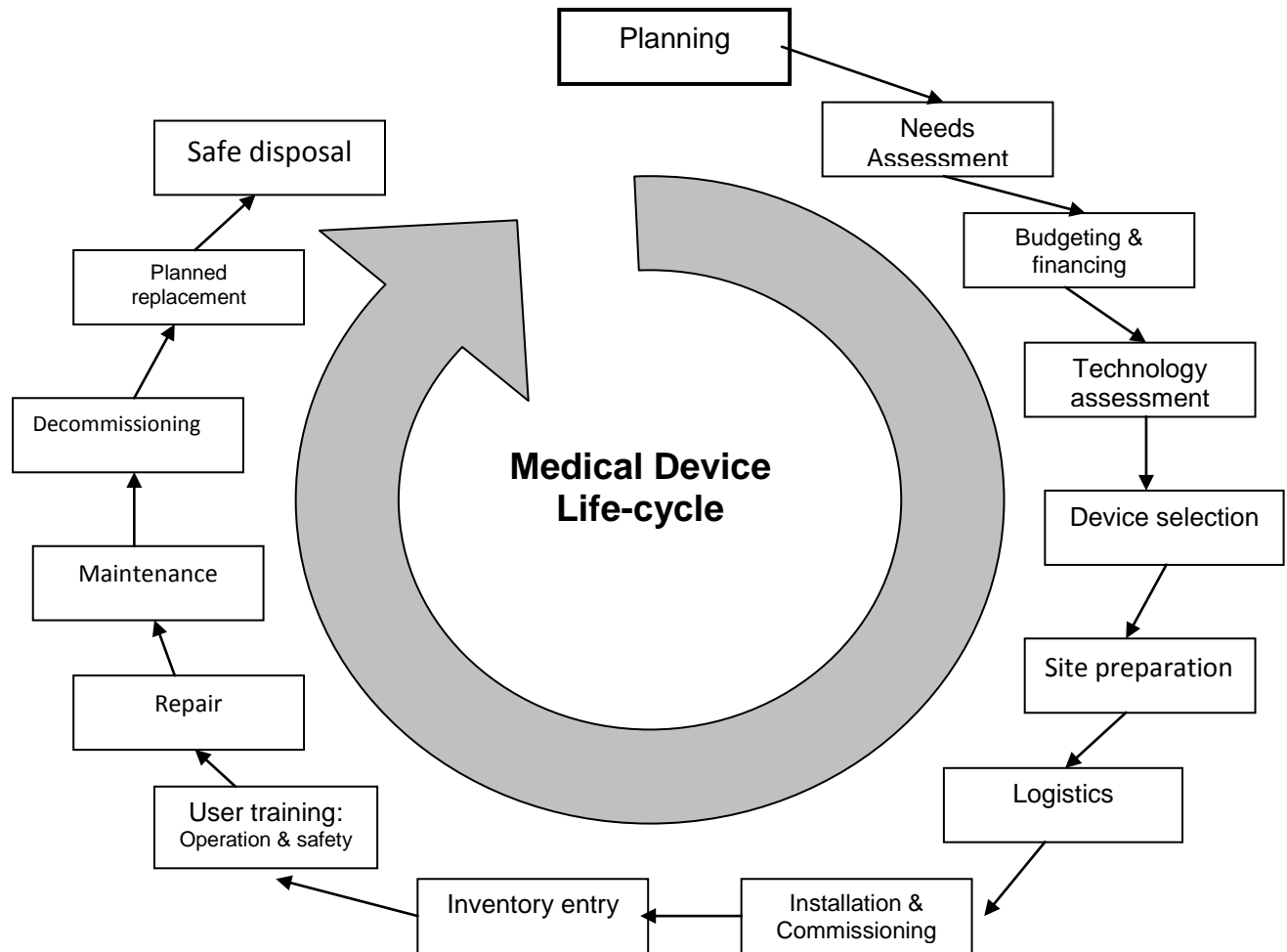


Figure (2): Medical Device Life-cycle

### Planning

Planning for medical devices has to be carried out at every level – federal, state, locality, and institution/health facility. Planning should start early, preferably, about a year prior to a planned purchase of the device. Financial ceilings for limiting purchase of medical devices at various levels based on unit cost of device and other relevant cost should be considered.

### Needs assessment

An in-depth needs assessment should be carried out at facility level prior to decisions to acquire any device. The needs assessment should be formally documented in a request format for application for approval of purchasing any device costing more than a prescribed unit price.

MOH is responsible to develop guidelines for need assessment. In accordance with these guidelines on need assessment, each facility should acquire equipment for valid reasons only and according to an order of priority, as follows

- Replacement of equipment; using scoring mechanism to determine replacement priorities for medical devices & equipment;
- To obtain additional equipment items which are missing from the basic standard requirements for such facility;
- To obtain additional equipment items beyond the basic standard to upgrade the level of health service provided by the health facility;
- To obtain additional equipment items outside the facility's own plans

### **Budgeting and financing**

Budgeting for medical devices to be purchased should commence about a year prior to planned purchase of the devices. Financial provisions for operating as well as repair and maintenance costs have to be made from a year after purchase of the device.

### **Technology assessment**

Technology assessment reports of assessments carried out in other countries can be used as a basis for decisions on whether or not to purchase specific medical devices. This is especially indicated for devices involving technology never used before in Sudan. Technology assessment can be set up in Sudan when there is a demand for the service.

### **Selection of device type**

Specifications have to be drawn up for every device that is planned to be purchased. Equipments should be Appropriate to setting, assured quality and safety, cost-effective, conforms to existing policies, plans and guidelines. Standardized specifications need to be drawn up for commonly used devices which can then be modified (where necessary) at institutional level. This policy recommends Introduction of an element of standardization policy in purchasing medical devices to limit the variety of models in the country especially for equipment commonly used e.g. X-rays, laboratory equipment.

MOH is responsible to establish criteria for prequalification and post-qualification of suppliers (agent) to be used in screening of suppliers before and after the purchasing process. Supplier qualification

(screening) criteria should be specified in the purchase document to enable the suppliers being aware about how they will be judged. MOH should establish list of prequalified suppliers. The manufacturer, especially for sophisticated devices should have a local representative that can undertake the after sale services if needed

General terms and conditions should also be part of specifications which includes stipulations like the local availability of essential spare parts, and the presence of a registered sole agent for the specific brand. Products must be selected based on a thorough need analysis and adjudication system, taking into account the level of the health facility and the skills available. For any new devices / equipment which are high cost / high volume / complex, all suppliers must provide technical evaluation of equipment prior to purchase, then full option assessment should be carried out to reduce uncertainty in respect of future costs and to ensure all operating costs are financially viable. Advanced featured equipment will not be selected unless the basic functions of the device are commonly used. Medical device/s should be identified by the health facility in case of individual purchasing and by bulk purchasing committee, then approved by the managerial committee

In selecting the device type, a technical evaluation should be carried out, where features of each brand of the device being considered is matched against the specifications, so that only those that meet most (if not all) the specifications will be short-listed for further consideration.

A cost-benefit analysis/cost-effective analysis should also be carried out comparing the capital costs, operating costs and maintenance costs.

In decision making, other factors like the technical capability of the local supplier need also be taken into consideration. Standardized format shall be used for selection to include above-mentioned criteria.

### **Site preparation**

The site, at which the device is to be installed has to be adequately prepared, more so in the case of large, sophisticated devices like X-rays, autoclaves. This has to be coordinated with logistics of the device supply so that the site is ready when the device is delivered at the institution.

The associated utilities like appropriate power supply, water, compressed air and the like, as well as other appropriate requirements like radiation protection lab drainage and waist facilities should also be taken into consideration.

In situations where extensive site preparation is necessary like in X-rays or CT scans, site works should be included as part of the acquisition process to ensure comprehensive and coordinated site preparation.

### **Logistics**

A warranty period of at least a year should be made mandatory for all devices purchased for health care.

A purchase contract should be drawn up for all devices purchased to protect the interests of the user. Unless the medical devices are simple, the contracts with suppliers should specify both the medical devices (hardware) and services including training especially in bulk procurement. The contracts with suppliers should at least specify specifications, warranty terms, freighting terms, delivery and penalties for default, installation and commissioning. Other factors to be taken into account are safety, infection control, effective performance, financial requirements, and full life cost. Contract should also include any responsibilities to be undertaken by the suppliers for sophisticated devices regarding the site preparation and pre-installation requirements, if needed.

A maintenance contract with the supplier should be considered for routine maintenance of sophisticated or high risk devices, especially those that cannot be maintained by in-house personnel.

### **Installation and commissioning**

Installation and commissioning should be carried out in the presence of the user as well as biomedical support. Demonstration of the device indicating all its functions should be carried out to the satisfaction of the user and biomedical engineering personnel.

MOH is responsible to develop device acceptance criteria and procedures for unpacking and inspection. All devices from all suppliers should be subjected to acceptance test in accordance with the guidelines developed by MOH Receiving goods on site, official acceptance and training should be undertaken by representatives for the supplier in case of complex items, bulk purchasing, if needed even if the equipment is quite a common item. MOH is responsible for developing guidelines on site preparation for different types of equipment and pre-installation work and installation, qualification of the device. Ministry of Health at state level is responsible for health buildings, plant, and service supply installations, pre-installation according to guidelines developed by MOH.

## **Inventory entry**

This policy supports establishment of MDs information, M&E system along the DHTMA structure to facilitate the collection, collation, analysis and dissemination of information from local and external sources. This system incorporates the equipment inventory, all service history records for equipment in the inventory, a work order system, and the preventive maintenance schedules/procedures. Also this system is used as an administrative tool to track equipment, to initiate work orders, to measure performance indicators, to determine equipment failure trends, to identify training needs, and to produce management reports

DHTMA ensure that system for inventory of equipment developed throughout the health system structure and function according to agreed upon standards. This include details of every device that has been acquired should be entered into the inventory at the facility level as soon as the device has been commissioned. Data base on medical device should also be accumulated at both state and federal level for a prescribed list of medical devices. Information from the database made available for equipment planning, recall, incident investigation, and regulatory activities including compliance. Accuracy of equipment information verified when equipment is seen for routine reasons, e.g., scheduled maintenance, repair. DHTMA ensure annual review of inventory for equipment to ensure records accuracy, all devices are adequately maintained, calibrations have been undertaken, equipment replacement programs are planned and the training required for each item of equipment has been identified.

## **User training**

Training on operation and maintenance should be included in specifications indicating the type, duration, location (on-site/off-site, local/overseas), target personnel i.e. consultants, nurses, maintenance personnel, since differing types and levels of training needs to be provided for each staff category. User training should be provided by an application specialist, especially training for sophisticated or complex devices

Training should also be provided on maintenance including maintenance training to users as well as engineering maintenance training.

Re-training and refresher courses should be carried out at regular intervals. The supplier should also provide skills training to new staff.



## **Operation and safety**

For specialized devices e.g. autoclave, X-rays, the right type of personnel are required to operate these devices. Certification may be a requirement for some specialized devices.

Regular monitoring has to be carried out for certain specialized devices e.g. radiation safety monitoring for X-ray machines.

User manuals should be provided for all devices to enable users to operate all devices safely and effectively, as well as for trouble-shooting for simple problems encountered with devices.

## **Repair**

Simple repairs should be carried out by users. Other repairs should be carried out by biomedical engineering personnel. Specialized or complex repairs should be carried out by suppliers.

## **Maintenance**

Planned preventive maintenance (PPM) should be carried out to minimize down-time of devices e.g. to replace UV lamp at time period recommended by manufacturer rather than when tube fails. This system entails exist of a registry filing system and ensure availability of manufacturer's manual for preventive maintenance of the equipment for each medical device. Nevertheless, PPM require exist and development of certain capacity within the system including Equipment inventory, Definition of maintenance task, Establishing intervals of maintenance, Qualified Personnel, Reminder system, Special test equipment and good Surveillance system

Calibration and testing should be carried out at regular intervals by users or biomedical engineering personnel as recommended by the manufacturer depending on the complexity of the device.

Records of maintenance and repairs of devices should be documented in a maintenance log, while a plant register is to be maintained for sophisticated or specialized devices.

## **Decommissioning**

Decommissioning should be carried out systematically with set procedures and processes of certification, also ensuring that services are not interrupted.

Decommissioning of a device should be carried out when it has attained its optimal life-span or it is beyond economic repair i.e. repair costs are exceedingly high.

## **Planned replacement**

Planning for replacement of a device should commence almost at the time of the original purchase to allow adequate time for budgeting and to prevent interruptions or disruption of services. Planned replacement can be based on the projected life-span of the device locally. This policy supports that national MDMA develop replacement plan, it will be facility-wide, covering all clinical equipment; would utilize accurate, objective data for analysis; would be flexible enough to incorporate non equipment factors; and would be futuristic by including strategic planning relating to clinical and marketplace trends and hospital strategic initiatives relating to technology. The plan will encompass many factors relating to Cost-benefit analysis, Safety, Support, Standardization, Clinical benefit.

## **Patient, worker & Disposal Safety**

It is the responsibility of those involved in equipment management to see that both staff and patients are protected from the potential hazards that exist in the hospital environment. These hazards arise from the use and presence of Chemicals, Radiation, Electricity, and Biological materials.

Disposal of devices should be carried out systematically with set procedures and processes, with safety being a prime concern. Furthermore, additional precautions must be taken for disposal of special devices .g. radioactive devices.

It is the responsibility of the medical service provider (hospital/clinic/medical centre/ etc.) to dispose medical devices in a safe way and complying with the federal policies and local government procedures and keep records of disposed active medical devices.

## **QUALITY ASSURANCE**

Quality assurance and essential assessment protocol has to be established as part of MDM activities .AQ is multidisciplinary taskforce, so committee has to review the health technology device and environment. Protocols such as quality control (QC), occupation health and safety (OHAS) and environment provision should be backbone of any QA protocol.

## **HUMAN RESOURCE STRATEGIES AND CAPACITY BUILDING**

Suitable dedicated personnel who are keen and committed should be appointed to head Medical Devices Management (MDM) units at all levels of healthcare. The head of the MDM entity at federal level should provide leadership and strategic planning and direction in this area therefore, this policy recommends MDM at national and state level headed and led by qualified biomedical engineers. Appropriate training on MDM needs to be provided to all personnel involved in MDM.

Federal ministry of health should identify appropriate personnel for the management of technical problems, finances, purchasing procedures, stores supply and control, and engineering workshops.

The career structures of all these personnel need to be planned as well as continued staff development strategies instituted.

## **REGULATION OF MEDICAL DEVICES**

This policy states that the national medicine and poison board is the national medical devices regularity body. Thus it is responsible of execution and adoption of the medical devices regulations recommended in this policy in full coordination and collaboration with the national DHTMA.

One of the major responsibilities of NMPB is to conducts pre-market approval, registration, and post-market surveillance. The MD regulatory process is similar to that for medicines, food, and other medical products but different technical capacities are required to analyze medical devices, which are classified by level of risk. It is therefore advisable that biomedical engineers trained in regulatory procedures are considered for the purpose of analyzing technical dossiers, verify compliance and that the regulatory authorities have harmonized processes that will enhance safety and the dissemination of innovative devices.

The drug model for regulation should not be adopted for devices; there is a need to focus on regulation of medical devices. A risk approach of regulation of devices should be used, where the higher the risk, the more stringent are the regulatory requirements. A model that minimizes the need for numerous dedicated personnel e.g. the conformity assessment model used in Europe should be considered for adoption in Sudan.

The existing law should be used to provide a legal basis for device regulation in preference to promulgation of a new law which would be time-consuming and resource-intensive e.g. by modifying

the name of the current law, and producing new regulations and guidelines focusing on medical device regulation.

There should be dedicated manpower specifically ear-marked for medical device regulation. Such manpower would require specialized training to enable them to function effectively and efficiently.

Regulation of medical devices should be implemented in a phased manner e.g. by commencing with the voluntary registration of establishments, distributors and suppliers in the first phase.

This policy states that all MD Companies should hold a license to practice all medical devices. Also, they should also hold proof of capability prior its involvement in the supply or service of including the following:

- a. Having a trained and responsible medical engineer.
- b. Having a well trained medical professional under the supervision of a medical engineer.
- c. List and register all devices with the FMOH or FMOH authorized entity.
- d. Have a valid and verified representation or agency agreement with the manufacture.
- e. Update their submitted registration data for the firm or the products within 10 working days of occurrence of change.
- f. Ensure that the products are stored and transported under safe and appropriate conditions as per the manufacture instructions.
- g. Ensure documentation and traceability of devices it supplies to the market and be involved in market surveillance of devices that have been put into service.
- h. Attest for the data that they are submitting.

Local Manufacturers of MD register with NMPB as it is the authorized body for this. They should identify product category they produce according to the GHTF categorization of MDs, register all medical devices that they produce to be placed in the Sudanese market, ensure that MD are stored and transported under safe conditions as required, guarantee that products is labelled with data relevant to the safety and traceability. furthermore, they must be involved in market surveillance of devices that have been put into service.

In addition to the above, this policy recommends that MDs and Accessories to be placed in the Sudanese Market should be registered and coded NMPB. Nevertheless, medical devices companies must be a registered in Sudan and comply with the above stated requirements. Medical devices companies must complete the designated registration form of the products in the Sudanese market.

It has to provide documents in English language that proof that the product(s) production, complies with the regulations of at least one country of the GHTF countries. Also, provide a copy of the labelling associated with the device being a medical device; specify conditions required to accommodate the product in Sudanese environment, and report to the FMOH in written any adverse incidents that they become aware of.

Nevertheless, this policy emphasizes that health Facilities should hold license proving comply with Healthcare construction standards and safe use of medical Devices on patients; operators; and environment;

This policy states that NMPB is the executive authority to issuing a market placement for MDs while the DHTMA in the FMOH is responsible of development of guidelines and regulation that govern this part. FMOH can investigate adverse incidents assumed to be created by medical devices and can instruct recall from market/end-user and even instruct re-export or disposal of the devices.

All Incidents should be investigated to identify product or use problems that can or do result in permanent impairment or injury to the patient or user. Users and facilities should be trained to monitor devices performance and obliged to report encountered problems. A comprehensive incident reporting should be formulated to track and statistically analyze the cause and effect of the incident. Users should consider frequent quality assurance programs to insure reliability and safe use of medical devices. Vendors should keep quick-to-reach database of incidents reported to them or by them to manage adverse reactions and counter actions.

Based on post market surveillance, NMPB can drop the licenses issued to companies/end-users/products that proved to violate registration and/or safe use of medical devices and/or Facility structure layout and/or the environment protection.

This policy recommends that FMOH comply with international rationales governing safe use of medical devices on patients, operators, and environments. FMOH keep a digitized software based record of all medical devices practices relevant to this policy and to create a database of adverse incidents and recalls. Also it issues a national registry number for each establishment and a listing number for medical devices.

All vendors should be obliged to fulfil all commitments with end-users in terms of supply of accessories & spare parts; maintenance; customer support and after sales services. Furthermore, they should be obliged to comply with FMOH or authorized delegate decisions regarding recall of

devices or any other decision aiming to protect the patient or the operators or the environment against reported adverse incidents whether before or after market placement.

## **IMPORT OF MEDICAL DEVICES**

Donated Medical devices can be issued a temporary import license if they are accepted as a donation in the donor country or, they are given with respect to the recipient wishes or, should benefit the recipient and based on need assessment. All donations should respond to an expressed need by the recipient and should never arrive unannounced.

Samples; Urgent needed devices; Home/Personal used devices can be issued temporary import License on case by case basis provided to submit a logical documented justification for the import.

The import of used devices into Sudan should not be allowed. This is due to the fact that adequate replacement or other immediate action cannot be ensured in case of device failure, as well concerns about the quality of used medical devices, especially in relation to areas like disinfection.

MOH develops donation guidelines and standards for donation of medical devices. However, the donated medical devices should meet general criteria covering quality of the equipment, safety, compliance with specifications and standards, non-obsolescence, and appropriateness of the medical device for the user environment. There should be effective communication between the donor and the recipient prior to donation, according to plan formulated by both. Donations should be treated in the same way as paid procurement in terms of preparation, installation requirements, human resources, maintenance and calculation of cost of using the equipment throughout its lifecycle. There should be no double standard in quality. If the quality of an item is unacceptable in the donor country or for any other reason, it is also unacceptable as a donation.

## **INTERFACE WITH THE PRIVATE SECTOR**

The growing private sector is a key stakeholder in the provision of healthcare and should be involved in the formulation and implementation of a national medical device policy. Health technologies should attempt to optimize the use of resources across both public and private sectors to avoid

duplication of services and unhealthy competition e.g. sharing of medical devices or purchasing of medical device services should be considered. The national steering committee is the mechanism for harmonization with the private sector.

## **PROMOTION OF THE LOCAL MEDICAL DEVICE INDUSTRY**

The local medical device industry should be promoted and provided support both by public and private sectors. Government policies favoring locally made medical devices over imported devices may be necessary in the initial period to assure sales of such local devices. This will have the added benefit of preventing outflow of foreign currency.

### **Promoting Self-Sufficiency in Specific Areas**

The local manufacture of medical devices should be encouraged with input and assistance provided by the Ministry of Health. Efforts should be targeted towards developing the medical device industry in small, high-volume items e.g. medical and surgical instruments, syringes so that the country can work towards self-sufficiency in these areas.

### **Medical Device Conversion**

Efforts should also be made to convert existing medical devices to suit local conditions e.g. walking aids, rehabilitation devices. This would also facilitate the development of the local medical device industry, possibly to cater for not only for local, but regional markets as well.

### **Research and Development**

Research and development should be carried out locally to assist in developing medical devices locally. Devices can be designed to suit the local situation and local practices.

## **INTER-DEPARTMENTAL & INTER-SECTORAL COLLABORATION**

There should be inter-sectoral collaboration and cooperation across the many sectors involved in healthcare e.g. education, army, health insurance, private sector. They should be considered as partners in the provision of healthcare to the nation. As well, resources across these sectors should be optimized e.g. by ensuring that the undergraduate and post-graduate educational programs meet the service requirements of the Ministry of Health with respect to health technology.

Inter-departmental collaboration, coordination and cooperation within and with the various public departments and agencies should be strengthened. Rationalization of services provided with involvement and participation of all concerned in particular areas should be aimed for.

## **INTERNATIONAL NETWORKING AND COLLABORATION**

Networking and collaboration should be established with neighboring countries and countries in the region, as well as with other regional WHO offices. Experiences on specific brands/types of devices can be exchanged among different countries. Assistance can be obtained in training and capacity building from countries with the relevant expertise. Input on HTA can also be obtained from specific countries internationally.

## **EVALUATION AND MONITORING**

Evaluation of the effectiveness of the MDM should be carried out. Feedback from users should regularly be obtained to assess suitability and acceptability of devices acquired.

### **Quality and patient safety**

The overall quality of the medical device service should be evaluated at regular intervals. External audits of the service should be considered.

### **Outcomes and indicators**

Outcomes and indicators should be used to monitor effectiveness and efficiency of various aspects of medical device e.g. down-time of critical devices can be used to monitor the quality of the maintenance services of the institution.



# **IMPLEMENTATION OF NATIONAL MEDICAL DEVICES MANAGEMENT POLICY**

The national MDM policy should be implemented by formulating appropriate strategies, procedures and processes, action plans and guidelines for the various aspects of the policy.

## **REVIEW OF NATIONAL MDM POLICY**

This national of MDM policy should be reviewed within five years, or earlier if there are significant changes to the local situation that have a bearing on the policy.

## **ACKNOWLEDGEMENT**

This policy has been developed after long, comprehensive and systematic process. This process started by detailed assessment of health technology regulations, system and practices. This analysis included contextual factor analysis as well. Following this step, a national taskforce supported by international consultant formulated to undertake this document framing and development (see annex 2 for the list of national taskforce). This taskforce has been formulated out of the key concerned national medical devices management and assessment stakeholders.

The Federal Ministry of Health is grateful and appreciates all those, who participated in the development of this policy document. Particularly, in the regard, the members of the Task Force, whose names are mentioned below, collectively as well as individually contributed to the development of this document. The taskforce acknowledge the role of Dr Isra Margani and Eng. Botheina Ibrahim in facilitation of the meetings, reporting, records keeping and regular communication between the taskforce members.

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## Annex 1. A COMPARISON OF MEDICINES AND MEDICAL DEVICES

<b>Aspect</b>	<b>Medicines</b>	<b>Medical Devices</b>
<b>Regulation</b>	Long established legal requirement for regulations in most countries. Usually based on extensive review and testing of all new medicines.	Much newer development, with many countries still not having regulatory mechanisms. Regulations are usually based on risk classification of new devices, the higher the risk, the more stringent the regulatory requirements.
<b>Evaluation</b>	Randomized Clinical Trials (RCT) are a key requirement and serves as basis for regulation as well as evaluation when deciding on choice of drug.	RCT are impractical and, expensive, and usually not carried out for medical devices. Animal and human testing is only done for high risk devices, especially where there is long term contact with skin or tissues. The major constraint is that it is not possible to use a placebo for devices.
<b>Users/operators</b>	Only patients are involved. No operators are required.	Users have to be trained to use most devices, and in some devices require a high degree of skill. There are some devices where the operator is also the patient, but in most cases are different.
<b>Storage conditions</b>	Essential requirement – varies with type of drug e.g. vaccines and biological require refrigeration	Not required if device is targeted for specific country e.g. tropicalised for use in hot weather conditions
<b>Testing, installation &amp; commissioning</b>	Not required.	An essential part of medical device management.
<b>Repair &amp; Maintenance</b>	Not required.	Repairs, servicing, and planned preventive maintenance are essential requirements for most devices.
<b>Operating costs</b>	Not applicable	The costs of reagents and consumables can be considerably high for some devices.

## ANNEX 2. TASKFORCE ON NATIONAL HEALTH TECHNOLOGY POLICY

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2.	Dr. Louran Ali	Policy Department- FMOH (reporter)
3.	Dr. Mustafa Salih	General Directorate of Planning, Policy & Researches - FMOH
4.	Dr. Hassan Abd Elazeez	General Directorate of Quality -FMOH
5.	Eng. Osman Awad	Central Medical Supplies Public Corporation
6.	Dr. Shakir Abd Elrhman	Khartoum state ministry of health
7.	Eng.Emad Edin Mohamed	Planning Directorate - Medical Technology Unit -FMOH
8.	Eng. Abd Alraheem Osman	Curative Medicine Directorate-FMOH
9.	Dr. Nazar Abd Alrhman	General Directorate of Human Resources-FMOH
10.	Dr. Sara Ahmed	Continuous Professional Development -FMOH
11.	Ms. Ibtihag Eltoun	Sudanese Standards and Metrology Organization
12.	Eng.Azza Abd Alhameed	National Medicines & Poisons Board
13.	Eng. Mazin Izeldin	Sudanese Biomedical Engineering Society
14.	Eng.Mohamed Abubakar	Radiation and isotopes center - Khartoum.
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