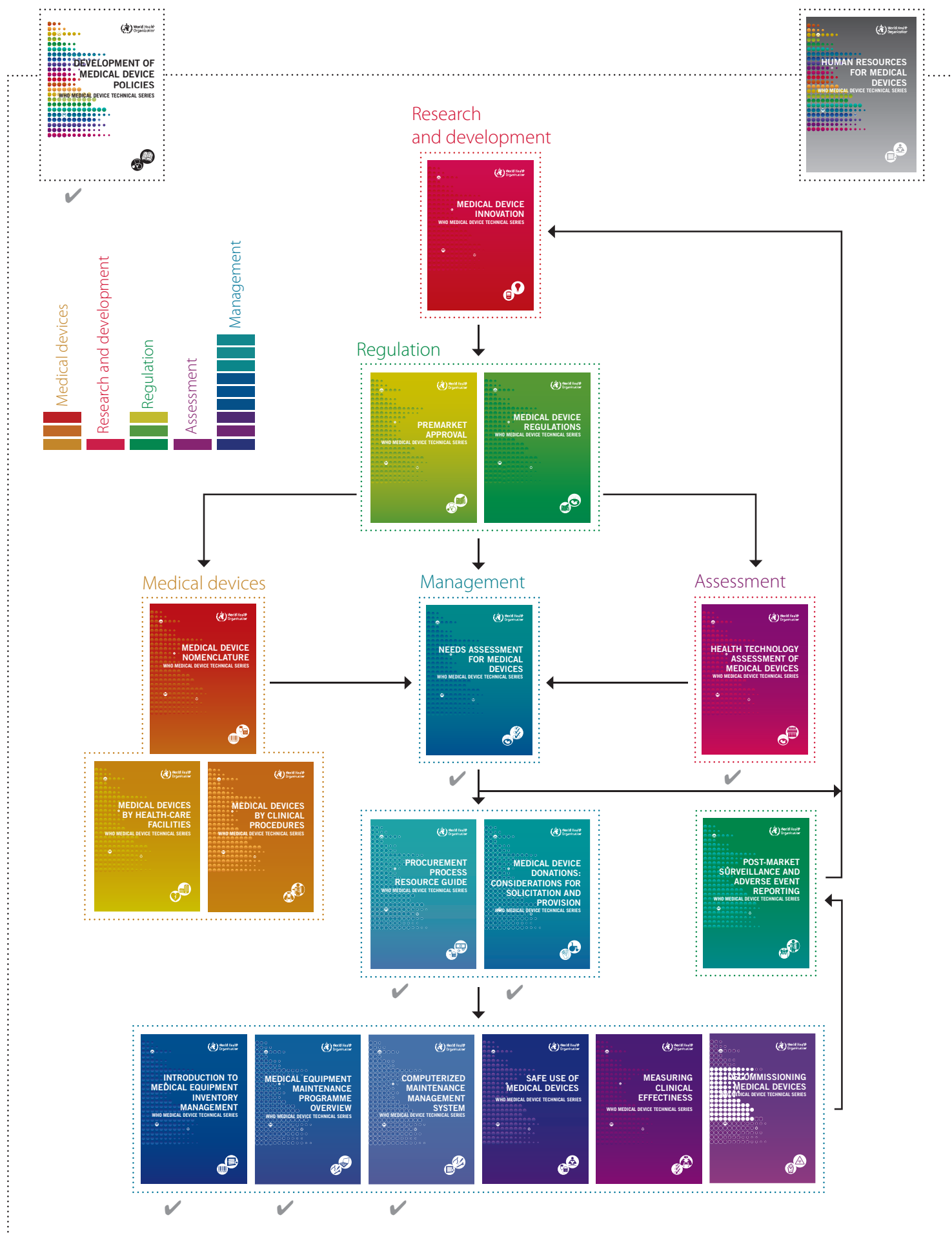


Procurement process resource guide

WHO Medical device technical series





Procurement process resource guide

WHO Medical device technical series



WHO Library Cataloguing-in-Publication Data

Procurement process resource guide.

(WHO Medical device technical series)

1.Appropriate technology. 2.Equipment and supplies - supply and distribution.
3.Technology assessment, Biomedical I.World Health Organization.

ISBN 978 92 4 150137 8

(NLM classification: WX 147)

© World Health Organization 2011

All rights reserved. Publications of the World Health Organization can be obtained from WHO Press, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland (tel.: +41 22 791 3264; fax: +41 22 791 4857; e-mail: bookorders@who.int). Requests for permission to reproduce or translate WHO publications – whether for sale or for noncommercial distribution – should be addressed to WHO Press, at the above address (fax: +41 22 791 4806; e-mail: permissions@who.int).

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by the World Health Organization to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the World Health Organization be liable for damages arising from its use.

Design & layout: L'IV Com Sàrl, Villars-sous-Yens, Switzerland.

Contents

Preface	2
Methodology	3
Definitions	4
Acknowledgements	5
Declarations of interests	5
Acronyms and abbreviations	6
Executive summary	7
1 Introduction	8
2 Purpose	9
3 Approach	9
4 Overview of procurement	10
5 Structure	12
6 The procurement process	14
6.1 Technology assessment	14
6.2 Device evaluation	14
6.3 Planning and needs assessment	15
6.4 Procurement	17
6.5 Installation	18
6.6 Commissioning	18
6.7 Monitoring	19
7 Special considerations	21
7.1 Local regulations	21
7.2 Replacement of equipment	21
7.3 Refurbished equipment	21
7.4 Radiological equipment	22
7.5 Health information technology	22
7.6 Facilities and construction	22
7.7 Emergencies	22
7.8 Sustainability	22
7.9 E-procurement	23
7.10 Grievances	23
7.11 Ethical considerations	23
8 Assessing procurement performance	24
8.1 Definition	24
8.2 System for assessing performance	24
8.3 Indicators	24
9 Concluding remarks	26
Resources	27
Appendix A Summary of elements in the medical device procurement process	32

Preface

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. Recognizing this important role of health technologies, the World Health Assembly adopted resolution WHA60.29 in May 2007. The resolution covers issues arising from the inappropriate deployment and use of health technologies, and the need to establish priorities in the selection and management of health technologies, specifically medical devices. By adopting this resolution, delegations from Member States acknowledged the importance of health technologies for achieving health-related development goals; urged expansion of expertise in the field of health technologies, in particular medical devices; and requested that the World Health Organization (WHO) take specific actions to support Member States.

One of WHO's strategic objectives is to "ensure improved access, quality and use of medical products and technologies." This objective, together with the World Health Assembly resolution, formed the basis for establishing the Global Initiative on Health Technologies (GIHT), with funding from the Bill & Melinda Gates Foundation. GIHT aims to make core health technologies available at an affordable price, particularly to communities in resource-limited settings, to effectively control important health problems. It has two specific objectives:

- to challenge the international community to establish a framework for the development of national essential health technology programmes that will have a positive impact on the burden of disease and ensure effective use of resources;
- to challenge the business and scientific communities to identify and adapt innovative technologies that can have a significant impact on public health.

To meet these objectives, WHO and partners have been working towards devising an agenda, an action plan, tools and guidelines to increase access to appropriate medical devices. This document is part of a series of reference documents being developed for use at the country level. The series includes the following subject areas:

- policy framework for health technology
- medical device regulations
- health technology assessment
- health technology management
 - › needs assessment of medical devices
 - › medical device procurement
 - › medical equipment donations
 - › medical equipment inventory management
 - › medical equipment maintenance
 - › computerized maintenance management systems
- medical device data
 - › medical device nomenclature
 - › medical devices by health-care setting
 - › medical devices by clinical procedures
- medical device innovation, research and development.

These documents are intended for use by biomedical engineers, health managers, donors, nongovernmental organizations and academic institutions involved in health technology at the district, national, regional or global levels.

Methodology

The documents in this series were written by international experts in their respective fields, and reviewed by members of the Technical Advisory Group on Health Technology (TAGHT). The TAGHT was established in 2009 to provide a forum for both experienced professionals and country representatives to develop and implement the appropriate tools and documents to meet the objectives of the GIHT. The group has met on three occasions. The first meeting was held in Geneva in April 2009 to prioritize which tools and topics most required updating or developing. A second meeting was held in Rio de Janeiro in November 2009 to share progress on the health technology management tools under development since April 2009, to review the current challenges and strategies facing the pilot countries, and to hold an interactive session for the group to present proposals for new tools, based on information gathered from the earlier presentations and discussions. The last meeting was held in Cairo in June 2010 to finalize the documents and help countries to develop action plans for their implementation. In addition to these meetings, experts and advisers have collaborated through an online community to provide feedback on the development of the documents. The concepts were further discussed during the First WHO Global Forum on Medical Devices in September 2010. Stakeholders from 106 countries made recommendations on how to implement the information covered in this series of documents at the country level.¹

All meeting participants and persons involved in the development of these documents were asked to complete a declaration of interest form, and no conflicts were identified.

¹ *First WHO Global Forum on Medical Devices: context, outcomes, and future actions* is available at: http://www.who.int/medical_devices/gfmd_report_final.pdf (accessed March 2011)

Definitions

Recognizing that there are multiple interpretations for the terms listed below, they are defined as follows for the purposes of this technical series.

Health technology: The application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of life.² It is used interchangeably with health-care technology.

Medical device: An article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typically, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means.³

Medical equipment: Medical devices requiring calibration, maintenance, repair, user training, and decommissioning – activities usually managed by clinical engineers. Medical equipment is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; it can be used either alone or in combination with any accessory, consumable, or other piece of medical equipment. Medical equipment excludes implantable, disposable or single-use medical devices.

预览已结束，完整报告链接和二维码如下：

https://www.yunbaogao.cn/report/index/report?reportId=5_28855

