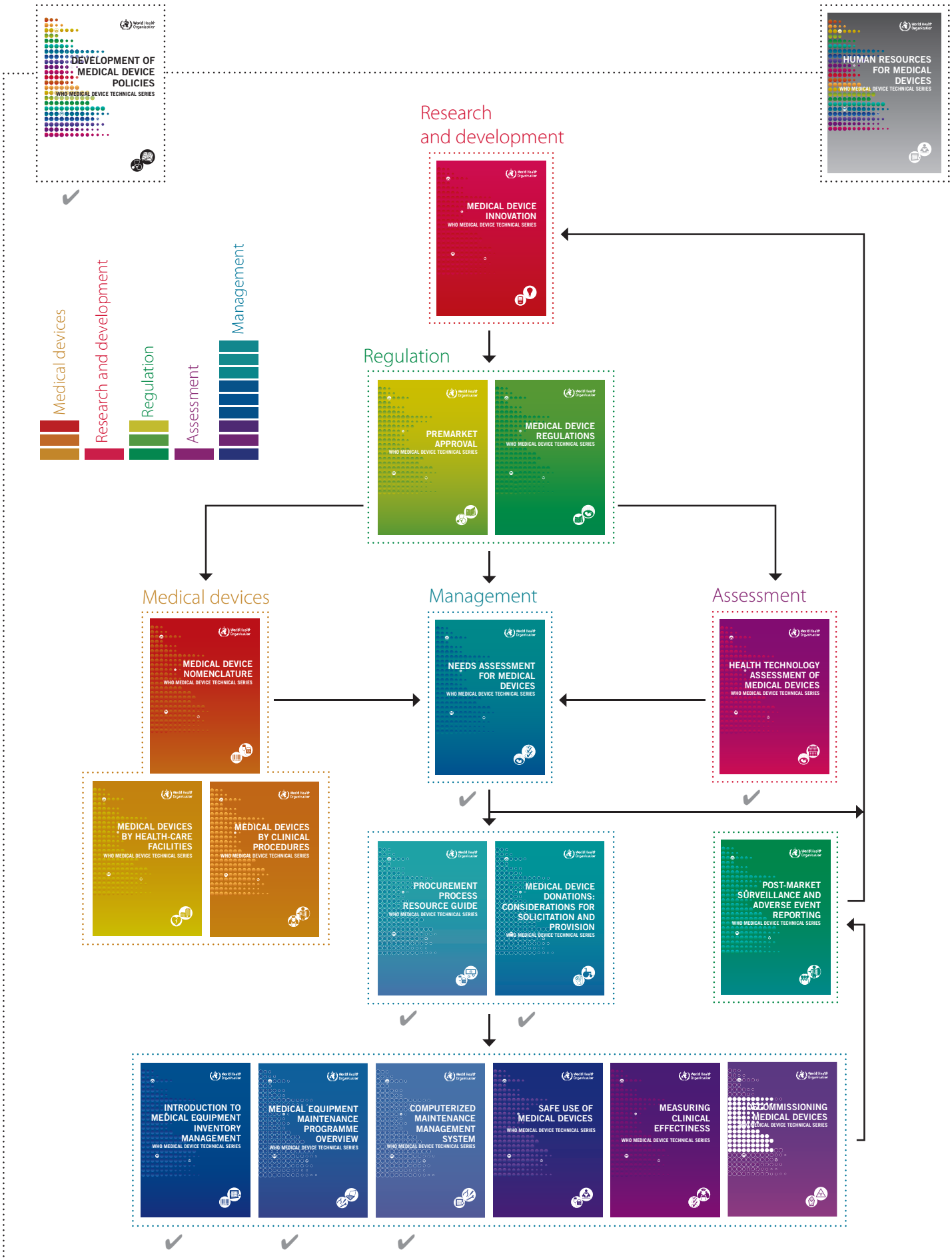
World Health Organization

Health technology assessment of medical devices

WHO Medical device technical series

WHO MEDICAL DEVICE TECHNICAL SERIES: TO ENSURE IMPROVED ACCESS, QUALITY AND USE OF MEDICAL DEVICES



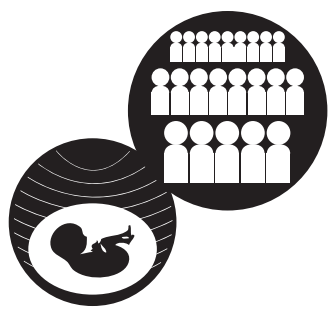
✔ Publications available as of June 2011

World Health Organization

World Health Organization

Health technology assessment of medical devices

WHO Medical device technical series



WHO Library Cataloguing-in-Publication Data

Health technology assessment of medical devices.

(WHO Medical device technical series)

technology. 2.Biomedical technology - standards. 3.Biomedical technology - trends. 4.Equipment and supplies. 5.Technology assessment, Biomedical - methods. I.World Health Organization.

ISBN 978 92 4 150136 1 (NLM classification: WX 147)

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

Contents

Figures and tables

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 will include 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 to help countries 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 discussed further 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.