

Local Production and Technology Transfer to Increase Access to Medical Devices

Addressing the barriers and challenges in low- and middle-income countries



 Intellectual Property and Trade

 R&D Innovation

 Technology Transfer

 Improving Access

 Financing

 Monitoring and Reporting



World Health Organization

Local Production and Technology Transfer to Increase Access to Medical Devices

Addressing the barriers and challenges in low- and middle-income countries



World Health
Organization

Prepared, developed and written by the Medical Devices Unit of the Department of Essential Medicines and Health Products, Health Systems and Services Cluster of the World Health Organization, under the coordination of Adriana Velazquez .

This report forms part of the project entitled "Improving access to medicines in developing countries through technology transfer and local production". It is implemented by the Department of Public Health Innovation and Intellectual Property of the World Health Organization (WHO/PHI) with funding from the European Union (EU).

All reports associated with this project are available for free download from the following websites: http://www.who.int/medical_devices/en and <http://www.who.int/phi/en>

This publication has been produced with the assistance of the European Union. The contents of this publication are the sole responsibility of the World Health Organization and can in no way be taken to reflect the views of the European Union.

Editing and design by Inís Communication – <http://www.iniscommunication.com>

WHO Library Cataloguing-in-Publication Data

Local production and technology transfer to increase access to medical devices: addressing the barriers and challenges in low- and middle-income countries.

1.Equipment and supplies. 2.Appropriate technology. 3.Technology transfer. 4.Biomedical technology. 5.Developing countries. I.World Health Organization.

ISBN 978 92 4 150454 6 (NLM classification: WX 147)

© World Health Organization 2012

All rights reserved. Publications of the World Health Organization are available on the WHO web site (www.who.int) or can be purchased 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 through the WHO web site (http://www.who.int/about/licensing/copyright_form/en/index.html).

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.

Photo: Design That Matters from one of the success stories, on neonatal equipment , see page 52.
Printed in France

Contents

Acknowledgements	1
Abbreviations	3
Executive summary	5
1. Introduction	7
1.1 Background	8
1.2 Medical devices – WHO perspective	8
1.3 Objectives	10
1.4 Methodology	10
1.5 Definitions	11
1.6 Need for this report	14
References	14
2. Scoping study on local production of medical devices	16
2.1 Global medical devices market	18
2.2 Innovation of medical devices	20
2.3 Research and development for medical devices	21
2.4 Local production	23
2.5 Technology transfer and intellectual property	24
2.6 Health system financing	25
2.7 Governance and regulation	26
2.8 Foreign technologies, local business capabilities and economic context	28
2.9 Country case studies	29
<i>a. Brazil Americas Region</i>	<i>29</i>
<i>b. China Western Pacific Region</i>	<i>34</i>
<i>c. Ethiopia Africa Region</i>	<i>38</i>
<i>d. India South-East Asia Region</i>	<i>41</i>
<i>e. Jordan Eastern Mediterranean Region</i>	<i>46</i>
2.10 Success stories	50
References	62
3. Challenges and barriers to local production	70
3.1 Literature findings	70
3.2 Health system challenges	71
3.3 Policy challenges	72
3.4 Organizational challenges	73
3.5 Partnerships and other challenges	74
3.6 Survey on access to medical devices	74
3.7 Relevant findings of the survey	75
3.8 Product development and technology transfer	76
3.9 Policies and partnerships	77
3.10 Regulations and intellectual property rights	77
3.11 Funding and financial mechanisms	78
References	79

4. Measuring the viability for local production of a specific medical device: A feasibility tool	80
5. Way forward: Overcoming barriers	84
5.1 General issues to consider in order to increase access to medical devices.	84
5.2 Stakeholder-specific suggestions resulting from committee discussion.	86
Annexes	91
Annex 1	
Survey on access to medical devices in low-resource settings: results . .	92
Annex 2a	
Feasibility tool: A usage exercise	109
Annex 2b:	
Feasibility tool: Specific sections	125
Annex 3	
Consultation on barriers and opportunities for improved access to medical devices by technology transfer and local production.	133

Acknowledgements

Local production and technology transfer to increase access to medical devices: Addressing the barriers and challenges in low- and middle-income countries is the result of collaboration between the Department of Public Health Innovation and Intellectual Property, and the Medical Devices Unit of the Essential Medicines and Health Products Department of the World Health Organization (WHO). The project is in the context of the *Global strategy and plan of action on public health innovation and intellectual property*. The report was developed and completed from January to June 2012, and was supported with funding from the European Union under EU Agreement PP-AP/2008/172-129. Thanks to Kees de Joncheere, Zafar Ullah Mirza and Robert Terry for guidance and support through the project.


The report was written under the supervision of Adriana Velazquez Berumen, Coordinator, Medical Devices Unit, with the contribution of the following people: Clara Aranda, Jennifer Barragan, Geoffrey Graham, Dr Heike Hufnagel, Einstein A. Kesi, Dr Jitendar K. Sharma, Dr Ricardo Martinez, Albert Poon, Dr Niranjan Khambete, Victoria Gerrard, and support from the following interns: Luz Elena Aguirre Algara, John Akrofi, Dan Azagury, Ashley Crasto, Carolina Lourenco, Cai Long, Matt Kukla, Richard Mudd, Shreesh Naik, Hamza Obaid, Xiaoyu Nie, Xuedan Yuan, Bryan Ranger and Rahul Rekhi.

Thanks to Clara Aranda, Ajanthy Gaya Arasaratnam, Geoffrey Graham, Dr Heike Hufnagel, Dr Ricardo Martinez and Dr Jitendar K. Sharma for their editing.

Thank you to all the participants of the Survey on Access to Medical Devices, as listed in the survey annex.

Thank you also to Einstein A. Kesi, Tony Easty, Rebeca Richards-Kortum, K. Siddique-e Rabbani, Samantha O'Keefe, Howard Weinstein, Gregory Dajer and Rick Kearns for providing case studies to test the medical devices feasibility tool.

We are also grateful to the advisers and participants of the stakeholder meeting convened on 4–5 June, 2012 in Geneva, Switzerland. Participants included: clinical engineers from ministries of health: Nicholas Adjabu (Ghana) and Sam Wanda (Uganda); representatives of innovators in academic institutions: Aya Caldwell, Victoria Gerrard (Singapore); Einstein A. Kesi, Dr Niranjan Khambete, Professor Anuraq Mairal, Dr K. Siddique-e Rabbani; representatives from nongovernmental organizations: John Anner, Rick Kearns, Jorge Ernesto Odon, Howard Weinstein; technical advisers: Clara Aranda, Michael Cheng, Dr Heike Hufnagel, Albert Poon, Dr Jitendar K. Sharma; United Nations organizations: Dr Lutz Mailander (WIPO), Dr Helene Moller (UNICEF), João Paulo (UNCTAD), Ermias Tekeste Biadgleng (UNCTAD); WHO Regional Offices: Dr Adham Ismail (EMRO); WHO headquarters: Dr Kees de Joncheere, Dr Peter Beyer, Dr Mario Merialdi, Francis G. Moussy, Dr Clive Ondari, Robert Terry, Adriana Velazquez-Berumen, Ajanthy Gaya Arasaratnam, Rahul Rekhi, Bryan Ranger, Hamza Obaid,



John Akrofi, Luz Elena Aguirre Algara, Catherine Shih, Shreesh Naik, Jonathan Darrow, and Matthew Novak. Participation via teleconference with Diana Calva from Mexico and Howard Weinstein from Brazil; observers and representatives from medical devices trade associations DITTA and GMTA: Christine Muzel, Tatjana R. Sachse, Maurizio Suppo and Jennifer Brant.

We would also like to thank Chandrika Rahini John, Gudrun Ingolfsdottir, Karina Reyes Moya for administrative support throughout the project.

Abbreviations

ANVISA	Agência Nacional de Vigilância Sanitária
BMVSS	Indian Bhagwan Mahaveer Viklang Sahayata Samiti
BoL	Breath of Life
CDSO	Central Drugs Standard Control Organization
CHC	community health centre
CSIR	Council for Scientific and Industrial Research
DBT	Department of Biotechnology
DITTA	Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association
DRG	diagnosis-related group
DST	Department of Science and Technology
ECG	electrocardiograph
EHT	Department of Essential Health Technologies
EIPO	Ethiopian Intellectual Property Office
EMG	electromyography
EMW	East Meets West Foundation
EU	European Union
FDA	Food and Drug Administration
GCC	Gulf Cooperation Council
GDP	gross domestic product
GHTF	Global Harmonization Task Force
GMP	good manufacturing practice
GMTA	Global Medical Technologies Alliance
GSPA-PHI	Global strategy and plan of action on public health innovation and intellectual property
HIC	high-income country
HIV	human immunodeficiency virus
HTA	Health Technology Assessment
ICMR	Indian Council of Medical Research
IIT	Indian Institutes of Technology
IMDRF	International Medical Devices Regulators Forum
IP	intellectual property
IPPD	Industrial Property Protection Directorate
JFDA	Jordan Food and Drug Administration

LIC	low-income country
LMIC	low- and middle-income countries
MENA	Middle Eastern and Northern African
MIC	middle-income country
MIHR	Centre for the Management of Intellectual Property in Health
MNC	multinational company
MRC	Medical Research Council
MRI	magnetic resonance imaging
MTTS	Medical Technology Transfer and Services
NASG	non-pneumatic anti-shock garment
NCD	noncommunicable disease
NHP	National Health Policy
NICU	neonatal intensive care unit
NIF	National Innovation Foundation
NIH	National Institutes of Health
NRA	National Regulatory Authority
OECD	Organization for Economic Co-operation and Development
PDP	product development partnership
PET	positron emission tomography
PHC	primary health care
PHI	Public Health Innovation and Intellectual Property
PPH	postpartum haemorrhage
PRO	public research organization
PwC	Price Waterhouse Coopers
QSR	quality system requirement
R&D	research and development
SFDA	State Food and Drug Administration
STEM	Society for Technology Managers
SUS	Sistema Unico de Saude
TRIPS	Trade-Related Aspects of Intellectual Property Rights
TTO	technology transfer office
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
USAID	United States Agency for International Development
WHO	World Health Organization
WTO	World Trade Organization

Executive summary

Medical devices are one of the most important health intervention tools available for the prevention, diagnosis and treatment of diseases, and for patient rehabilitation. However, access to these devices is an ongoing challenge, particularly in low- and middle-income countries (LMICs). The 65th World Health Assembly in May 2012 adopted multiple resolutions acknowledging the requirements for medical devices to address the needs of aging populations, and in the areas of maternal, newborn and child health, as well as noncommunicable diseases (NCDs). It is now widely recognized that addressing these – and many other key public health priorities – cannot be achieved without essential, appropriate and affordable medical devices.

In the context of the *Global strategy and plan of action on public health innovation and intellectual property*, the World Health Organization (WHO), with support from the European Union (EU), has developed this report to analyse the barriers to increasing access to safe and high quality medical devices, and to examine the contribution that local production and technology transfer can potentially make, particularly in resource-limited settings.

The overarching goal of this report is to bring together the views of diverse stakeholders from the fields of public health, industry, academia and other relevant sectors, to explore viable pathways to stimulate adaptive strategies to increasing access to medical devices.

The report offers an overview of the current global medical device market, in which only 13% of manufacturers are located in LMICs. A landscape analysis on local production and technology transfer shows that local production potentially offers a cost-effective pathway to improving access to health care and medical devices. However, in settings where innovations are not economically viable, high costs of production may serve to hinder local innovation and development and, in turn, limit their ability to meet local health care needs.

The report analyses local production of medical devices in five countries: Brazil, China, Ethiopia, India and Jordan, and provides examples of successful local enterprises in each of these countries as well as government efforts to promote an enabling environment. Ten specific medical devices are also assessed to offer insights into the opportunities and challenges that local producers face.

In order to document local production barriers, a survey was conducted and collected responses from 47 countries. Survey questions included aspects of product development, technology transfer, policies and partnerships, regulations and intellectual property rights, funding and financial mechanisms. Statistical analysis revealed key barriers of poor governance, weak regulations and policies, high capital costs, lack of properly trained staff, and insufficient information on medical devices to guide rational procurement decisions.

The landscape analysis and survey findings complement deliberations during a June 2012 stakeholder meeting that brought together government, academic, NGO, and industry experts to consider the potential role of local production and technology transfer in meeting medical device needs. Combined with conclusions drawn from previous studies, an evaluation tool was developed to help innovators rationally consider the viability of local production.

Significantly, it remains inconclusive whether local production improves access to essential medical technologies in low-resource settings. Improved access to medical devices requires a supportive business environment to produce economically viable devices; financing mechanisms to connect producers, payers and consumers; and regulations and policies to ensure equitable access to quality devices.

The survey and stakeholder meeting generated the following recommended actions for achieving greatest impact in promoting access to quality medical devices:

- i. Development of a list of 'essential medical devices' based on clinical guidelines;
- ii. Support to the development of technical specifications;
- iii. Encouragement of innovative financing mechanisms and funding sources for medical devices;
- iv. Stimulation of a stronger medical devices market based on health needs and health priorities;
- v. Promote of transparency and international harmonization on medical devices regulations;
- vi. Strengthen regulations to encourage technology transfer rather than hinder it;
- vii. Development of incentives for transfer of technologies from academia to the private sector, and from 'inventors' to 'innovators'.
- viii. Support to professional networking in order to share information about innovative and locally-produced medical devices.

Achieving most of the current global health targets and goals will be impossible without a balanced increase in access to essential medical devices in LMICs. This report recommends a multisectoral approach to promoting such access. The model approach described offers one way to identify, measure and reduce the challenges surrounding access to medical devices as a means to improve health outcomes for all.

1. Introduction

Health technologies (e.g. medicines, vaccines and medical devices) are an indispensable component of effective health care systems. Among these technologies, medical devices provide the foundation for prevention, diagnosis, treatment of illness and disease, and rehabilitation. There are over 10 000 types of medical devices, ranging from basic tongue depressors, stethoscopes, surgical instruments, prostheses, and in vitro diagnostics, to complex medical diagnostic imaging equipment. In 2010, the global medical devices market was estimated to be over US\$ 164 billion (2). It has grown significantly over the past two decades, reaching the most advanced hospital systems in high-income countries (HICs) although many essential medical devices still fail to reach hospitals and health care centres in low- and middle-income countries (LMIC).

The availability, accessibility and effective use of essential medical devices play an important role in the achievement of health system performance goals and the cost and quality of medical care that a population receives. Patients rely on safe, high quality, and affordable medical devices for prevention and early diagnosis of illnesses, as well as curative medical care. Income, geographical location or other variables in access to such medical devices often drive patients to utilize higher cost, lower quality health care or even forego seeking treatment altogether. In low income settings, this is particularly critical for patients who rely on public and community health care systems. Disparities in access to cost effective health services can, in turn, accentuate inequities in financial risk protection and overall health outcomes, while simultaneously driving up overall health system costs.

Addressing disparities in access to medical devices is a complex challenge, as it requires enhancing regulatory, technology, management and procurement assessment systems, and developing innovative and appropriate technologies that more effectively address the needs of individuals in low-resource settings. Additionally, quality education for biomedical engineers and effective training programmes for clinicians and other health care professionals must be available.

While local production of technology is one potential way to increase access to medical devices, additional research is needed to understand how to create an adequate environment that will transfer the benefits of innovations and technologies to the most vulnerable and disadvantaged groups. However, there is little research on the benefits of local production of medical devices in resource-constrained settings and on the obstacles to technology transfer and local manufacturing in LMICs. This report specifically examines the challenges and barriers to medical device access and the potential of technology transfer and local production to increase access, addressing these areas to ensure meaningful results in health systems overall.

1.1 Background

According to the WHO report *Landscape Analysis of barriers to developing or adapting technologies for global health purposes* (2), several factors have been identified that tend to reduce the probability of technologies to be transferred, developed or adapted for health purposes in LMICs. These factors will be reviewed along with this report, and can be summarized as follows:

- i. Inefficient, inadequate or non-existent data-gathering systems and information to understand: population health needs, medical devices required by clinical guidelines and protocols, as well as health care infrastructure and equipment to support health services delivery.
- ii. Lack of capacity development in LMIC markets to encourage local industry models to enter the medical devices segment, coupled with lack of innovation in these models to enable new technologies to meet market needs.
- iii. Low levels of protection and enforcement of intellectual property rights that challenge innovators and producers of medical devices, limiting rather than stimulating in-country innovation, production and delivery of medical products to populations at the 'bottom-of-the-pyramid'.
- iv. Lack or insufficient technically trained and skilled workforce, to ensure effective and safe use, as well as maintenance, of medical devices.
- v. Limited implementation of international standards and regulatory procedures to promote quality products.
- vi. Policies and advocacy to limit unfair competition of medical device producers and promote transparency in procurement and pricing.
- vii. Inadequate financing, required to ensure ongoing maintenance and use during the lifespan of the device.
- viii. Evident lack of information and dissemination networks for innovative devices, to allow selection, procurement and safe use.
- ix. Need to increase attention and incentives to stimulate the creation of partnerships for product development between academic, public and private sectors, in order to ensure that innovations reach their target market and achieve their full potential.

1.2 Medical devices – WHO perspective

The World Health Organization (WHO) is the directing and coordinating authority for health systems within the United Nations. It is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries and monitoring and assessing health trends (3). One of WHO's strategic objectives is "to increase access to safe, quality medical products." As a result, several resolutions have been adopted to address the details of this objective. In 2008 and 2009, the World Health Assembly adopted resolutions WHA61.21 and WHA62.16 on the *Global strategy and plan of action on public health innovation and intellectual property (GSPA-PHI)*. Two of the aims of the global strategy are to (4,5):

- Improve, promote, and accelerate transfer of technology between developed and developing countries as well as among developing countries;
- Improve delivery of and access to all health products and medical devices by effectively overcoming barriers to access.

Furthermore, in recognition of the fact that medical devices represent an economic and technical challenge to the health systems of Member States, in 2007, the World Health Assembly adopted resolution WHA60.29, the first ever specifically focused on medical devices. The resolution outlines the necessary actions for both Member States and WHO to establish mechanisms that will lead to adequate availability and use of medical devices (6).

Since the adoption of resolution WHA60.29, a number of projects focusing on medical devices have been initiated by WHO. In 2007, the Netherlands Government supported the development of a report on *Priority medical devices*, which identified the gaps in available medical technologies and set a related research agenda. In 2009, a further report was developed to address the challenges and solutions experienced by industry in investing in global health priorities: *Landscape analysis of barriers to developing or adapting health technologies for global health purposes* (2). In 2010, the First Global Forum on Medical Devices took place in Bangkok, Thailand, bringing together global leaders from 107 Member States to discuss medical device policies, clinical engineering, regulations, procurement and innovations as well as to provide recommendations on the way forward (7). Also in 2010, a call for innovative technology for global health concerns was launched, leading to the selection of technologies that were in development or commercially available. These technologies were shared with stakeholders. Then later, in 2011, a new call was made. The results led to the publication of the First Compendium of New and Emerging Technologies, which highlights how these promising new technologies can address health priorities (8). Another call has since been launched and over 40 innovations have been selected as appropriate for low-resource settings.

A baseline country survey on medical devices was initiated in 2010, in all Member States, to collect information on policies, guidelines, strategies, health infrastructure and high cost medical equipment available in each country, and to identify a health technology focal point that would facilitate information exchange. A second survey has since been performed to update information and gaps, with the results being published in the WHO Global Health Observatory, a website of health statistics (9). The *Medical Devices Technical Series* is published online and contains information on the development of policies, guidelines and tools to allow better needs assessment, evaluation, procurement, inventories and management of medical equipment in Member States; additionally, guidelines on regulations, innovation and patient safety are under development.

Based on this foundational work, further investigations can be made for increasing access to medical devices. More appropriate technology that responds to the needs of the most vulnerable populations must be developed,

supported and used in order to reach the Millennium Development Goals and reduce the impact of noncommunicable diseases, particularly in LICs. Thus, this report, in line with the aforementioned World Health Assembly resolutions, intends to understand the barriers to technology transfer and local production as mechanisms that can enhance the availability of appropriate medical devices and provides recommendations on overcoming those challenges.

1.3 Objectives

The present report corresponds to the first phase of the project *Local production for access to medical products: Developing a framework to improve public access* from the GSPA-PHI, that aims to improve public health by increasing the availability, affordability and access of medical products. In this phase, the project aims to analyse the main challenges and barriers to local production of and access to medical devices in LMICs.

The objectives of this report are to:

- i. Analyse the current research in technology transfer and local production of medical devices in LMICs;
- ii. Understand barriers and challenges to access of medical devices, particularly in LMICs;
- iii. Develop proposals to overcome barriers to improve access to medical devices; and,
- iv. Comprehend and analyse feasibility to produce medical devices within a LIC context as a way to improve access to them.

1.4 Methodology

In order to achieve the proposed objectives, the following activities were developed to comprise a global situation analysis of the medical device industry, and identification of barriers and challenges constraining the viability of local production of medical devices.

- i. A **comprehensive literature review** was carried out to understand the context of what has been defined as 'access to medical devices', namely the current situation of the medical device industry and market, related processes and elements in the development of medical devices such as research and innovation of medical technologies, and aspects related to financing and regulation of medical devices. An analysis of past research carried out by WHO on medical devices was also performed. To explain the current global situation of the medical devices market and local production, data were firstly obtained by reviewing the existing medical devices literature. This included peer-reviewed journal articles and grey literature, as well as reports published by public international agencies and private nongovernmental organizations (NGOs). All these sources provided a first approach to gathering information for the scoping study. Although information on the topic is limited, effort was made to identify country-specific studies (specifically for five countries from the various

WHO regions) on the local production and development of medical devices. Analysis was performed on the current global market for medical devices, research and development capacity, health systems financing, partnerships and collaboration to support development of technologies, governance and regulations.

- ii. Barriers to production of medical devices were identified in the literature and compared to actual barriers found on the field by **surveying a group of stakeholders**. A survey was designed based on the findings of existing WHO publications on access to medical devices. The survey questionnaire was sent to country focal points for distribution to people linked to the medical devices sector. It was also sent to innovators and developers, to manufacturers, regulators and NGOs. The results were analysed and comments were considered in developing the conclusions of the current report.
- iii. Based on the findings from the literature review and the survey, a first draft of a **feasibility tool** to measure the possibility for a device to be produced and successfully commercialized in a LMIC was developed.
- iv. The **efficacy of the feasibility tool was tested** on various projects and the results were analysed. Other, similar tools were then sought and recommendations for future improvements were compiled.
- v. Finally, a **stakeholder group consultation** was organized to discuss the draft report and the feasibility tool. Successful case studies were also considered as examples of improving access to medical devices and eliminating barriers to their local production in LMICs.

The conclusions of the project include a set of options for eliminating barriers and encouraging the development of policies to enhance local production of medical devices as a means to improve access to medical devices to meet related priority needs.

The timeframe for the activities described above was from January to June 2012.

1.5 Definitions

This section defines some of the terms and concepts used during the research process and throughout the current report.

Health technology

This term refers to 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. It is used interchangeably with 'health care technology' (6).

Medical devices

The definition of 'medical devices' used in this report is as used in the *Medical Device Technical Series*. It is based on the Global Harmonization Task Force (GHTF) definition (10):

Medical devices are defined as an article, instrument, apparatus or machine:

- i. That is intended by the manufacturer to be 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;
 - investigation, replacement, modification or support of the anatomy, or of a physiological process;
 - supporting or sustaining life;
 - control of conception;
 - disinfection of other medical devices;
 - providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and
- ii. That does not typically achieve its primary intended action in or on the human body pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means (11).

Medical devices thus cover the spectrum from in vitro diagnostics, medical imaging, single use devices, surgical instruments, assistive devices to all medical equipment, including diagnostic and interventional imaging, laboratory and all electro-medical equipment.

Medical equipment

Refers to all 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 (12).

Access to medical devices

The term 'access to medical devices' is defined in accordance with an earlier report on local production of medical products (13), as the interaction of different factors that define the degree of access patients have to medical devices and services. The following are six crucial components to improve access to medical devices (10,12):

Availability: Refers to when a medical device can be found on the medical device market; it may also mean whether medical devices are physically available at health care facilities and are usable by medical providers to treat patients.

Affordability: Refers to the extent to which the intended clients of a health service or product can pay for its utilization.

Accessibility: Refers to people's ability to obtain the technology and use it appropriately when needed; it may also refer to whether households or

individuals are geographically able to reach health care facilities that offer necessary medical devices for a specific health condition.

Appropriateness: Refers to medical methods, procedures, techniques and equipment that are scientifically valid, adapted to local needs, acceptable to both patients and health care personnel, and that can be utilized with resources the community or country can afford; appropriateness should include the consideration of available infrastructure and human and financial requirements.

Acceptability: Refers to households' or individuals' attitudes and expectations towards the use of medical devices, specifically whether those devices are socially and culturally appropriate to meet local demands.

Quality: Refers to whether the medical devices found in health care facilities and used by medical providers meet regulatory standards for effective and safe use.

Innovative technologies

In this report, reference to 'innovative technologies' is in accordance to the WHO Call for Innovative Technologies, which defines them as a solution that has not previously existed, has not previously been made available in LMICs, is safer and/or simpler to use than earlier solutions or is more cost effective than previous technologies (14).

Local production

This report defines 'local production' in two ways and in accordance with a previous report (12): First, local production is the domestic production of medical devices by a country utilizing that device to solve a local public health need. Second, local production can be owned by either/both an international or national industry, though the majority of this ownership should be national. A further explanation of the different types of local production will be given later in the report.

Technology transfer

According to a WHO report on the local production of medical products, not including medical devices, there remains no agreed definition of 'technology transfer' (13). This report intends to consolidate these definitions in the context of medical products, suggesting that technology transfer is: "the transfer of technical information, tacit know-how, performance skills, technical material or equipment, jointly or as individual elements, with the intent of enabling the technological or manufacturing capacity of the recipients." Technology transfer for medical devices represents the collaboration of knowledge and resources towards developing medical devices useful for public health needs.

1.6 Need for this report

A wider understanding of the factors that influence access to medical devices in LMICs, and a better assessment of barriers that hinder this process, are essential for initiating an adequate response to the increasing burden of noncommunicable diseases (NCDs), which require a longer and higher degree of medical care, as well as ensuring availability of basic services including prenatal, maternal and neonatal health care interventions. Such an effort would be incomplete unless the knowledge from the current scientific literature is coupled with stakeholder views and an objective assessment of prevalent needs, factors and barriers. This report thus takes a model approach in defining the perimeters of the challenging domain of medical device accessibility in LMICs.

References

1. *Medical devices: Country data. Baseline country survey.* World Health Organization. (http://www.who.int/medical_devices/countries/en, accessed 10 July 2012).
2. *Landscape analysis of barriers to developing or adapting technologies for global health purposes.* Geneva, World Health Organization, 2010 (http://whqlibdoc.who.int/hq/2010/WHO_HSS_EHT_DIM_10.13_eng.pdf, accessed 10 July 2012).
3. *About WHO.* Geneva, World Health Organization, (<http://www.who.int/about/en>, accessed 10 July 2012).
4. Resolution WHA61.21. Global strategy and plan of action on public health, innovation and intellectual property". In: *Sixty-first World Health Assembly. Geneva, 24 May 2008.* (http://apps.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf, accessed 10 July 2012).
5. Resolution WHA62.16. Global strategy and plan of action on public health, innovation and intellectual property". In: *Sixty-first World Health Assembly. Geneva, 22 May 2008.* (http://apps.who.int/gb/ebwha/pdf_files/A62/A62_R16-en.pdf, accessed 10 July 2012).
6. Resolution WHA60.29. Health Technologies. In: *Sixtieth World Health Assembly. Geneva, 23 May 2007.* (http://www.who.int/medical_devices/resolution_wha60_29-en1.pdf, accessed 10 July 2012).
7. *First WHO Global Forum on Medical Devices: Context, outcomes and future actions.* Geneva, World Health Organization, 2011 (http://whqlibdoc.who.int/hq/2011/WHO_HSS_EHT_DIM_11.11_eng.pdf, accessed 10 July 2012).
8. *Compendium of new and emerging health technologies.* Geneva, World Health Organization, 2011 (http://whqlibdoc.who.int/hq/2011/WHO_HSS_EHT_DIM_11.02_eng.pdf, accessed 10 July 2012).
9. *Global Health Observatory: Medical devices.* World Health Organization. (http://www.who.int/gho/health_technologies/medical_devices/en/index.html, accessed 10 July 2012).
10. *Information document concerning the definition of the term "Medical Devices".* Global Harmonization Task Force, 2005 (<http://www.ghtf.org/documents/sg1/sg1n29r162005.pdf>, accessed 10 July 2012).
11. *Medical devices: Managing the mismatch. An outcome of the Priority Medical Devices project.* Geneva, World Health Organization, 2010 (http://whqlibdoc.who.int/publications/2010/9789241564045_eng.pdf, accessed 10 July 2012).

12. *Procurement process resource guide* (WHO Medical Device Technical Series). Geneva, World Health Organization, 2011 (http://whqlibdoc.who.int/publications/2011/9789241501378_eng.pdf, accessed 10 July 2012).
13. *Local Production for Access to Medical Products: Developing a Framework to Improve Public Health*. Geneva, World Health Organization, 2011. (http://www.who.int/phi/publications/local_production_policy_framework/en/index.html, accessed 10 July 2012).
14. *Innovative technologies that address global health concerns. Outcome of the call: Global Initiative on Health Technologies*. Geneva, World Health Organization, 2010 (http://whqlibdoc.who.int/hq/2010/WHO_HSS_EHT_DIM_10.12_eng.pdf, accessed 10 July 2012).

2. Scoping study on local production of medical devices

This chapter assesses and defines the barriers and challenges to local production of medical devices. It offers an analysis of global health trends and an overview of medical devices production in a variety of low-resource settings. The exercise offers insights into key barriers to local production, and the enabling frameworks needed to reduce those barriers. It discusses how local production can be a viable pathway to meet local health needs, but cautions that it is not ideal for all scenarios. The chapter includes five LMIC profiles that analyse regulatory, financial, research and development (R&D), business, and delivery systems, and ten product case studies that target diseases and injuries in low-resource settings.

a. Health trends

Three NCDs – cancer, ischemic heart disease and cerebrovascular conditions – are predicted to become the most common diseases and injuries by 2030 (1). Furthermore, the 2011 *UN Political Declaration on NCDs* underscored the importance of preventing, treating, and monitoring NCDs and noted with profound concern that, according to the World Health Organization, in 2008, an estimated 36 million of the 57 million global deaths were due to noncommunicable diseases, principally cardiovascular diseases, cancers, chronic respiratory diseases and diabetes, including about 9 million deaths before the age of 60, and that nearly 80 per cent of those deaths occurred in developing countries (2). In addition, global demographics are tending towards a growing number of people who are 60 years of age or older, and more must be done to meet the 2015 the Millennium Development Goal (MDG) targets in maternal, child, and newborn health. In light of these contexts and goals, WHO Member States recently passed several resolutions at the 65th World Health Assembly to recognize NCDs, the potential impact of population aging, and the need for a comprehensive, multisectoral response from national health and social sectors. The changing disease burden also influences long-term strategic priorities in the medical device industry while the 2015 MDG deadline presents near-term targets.

b. Medical devices production

The global medical devices industry is evolving. Historically, it was dominated by HICs, although the global burden of disease was felt heaviest in LMICs. Inevitably, concerns arose that HIC-based companies were ill-equipped to understand LMIC needs, and that LMIC budgets were too small to attract their investment. It was not uncommon for multinationals to assess product lines destined for HIC markets and “strip them down” for LMICs instead of developing products specifically designed for their markets.

The past few decades brought a marked shift. Emerging markets were strengthening and new business models emerged where these HIC-headquartered companies opened plants in LMICs or partnered with local

organizations to co-create products for the local context. At times, the partnerships resulted in vigorous technology transfers, while in others, they did little to expand the local knowledge base or increase the local capacity for related R&D. Instances also arose where LMIC manufacturers produced medical devices that could compete with foreign imports in terms of functionality and price. The shift brought new approaches as LMIC innovators were driven to reduce cost and find creative ways around common financial barriers, and HIC manufacturers began developing affordable devices to secure their share of LMIC markets.

Figure 1 *Local health product development*

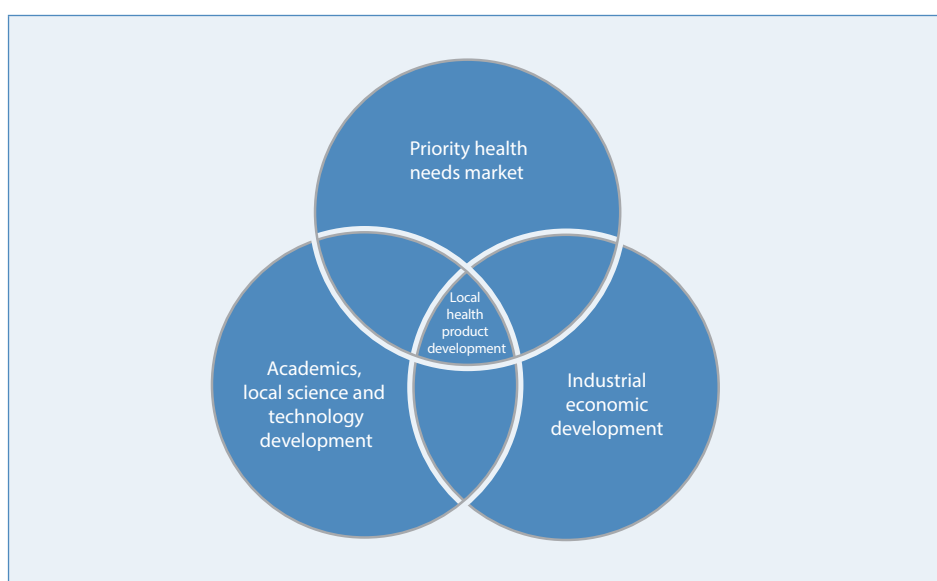


Figure 1 illustrates the intersection where public health priorities, academic interests and industrial development meet to produce innovations that are better suited to the local context.

The literature review indicates that product development partnerships (PDPs) provide unique platforms to facilitate local production and partnerships (3). Creatively employed, PDPs can help facilitate technology transfer, improve local production, and increase access to appropriate and affordable medical devices by operating at the crucial juncture where interests, comparative advantages, and motivations overlap. Key benefits include:

- The innovations are relevant to local health needs;
- They are co-produced by actors who are committed to the outcome;
- They are affordable within the local context;
- They leverage local knowledge and help build local capacity to solve local problems.

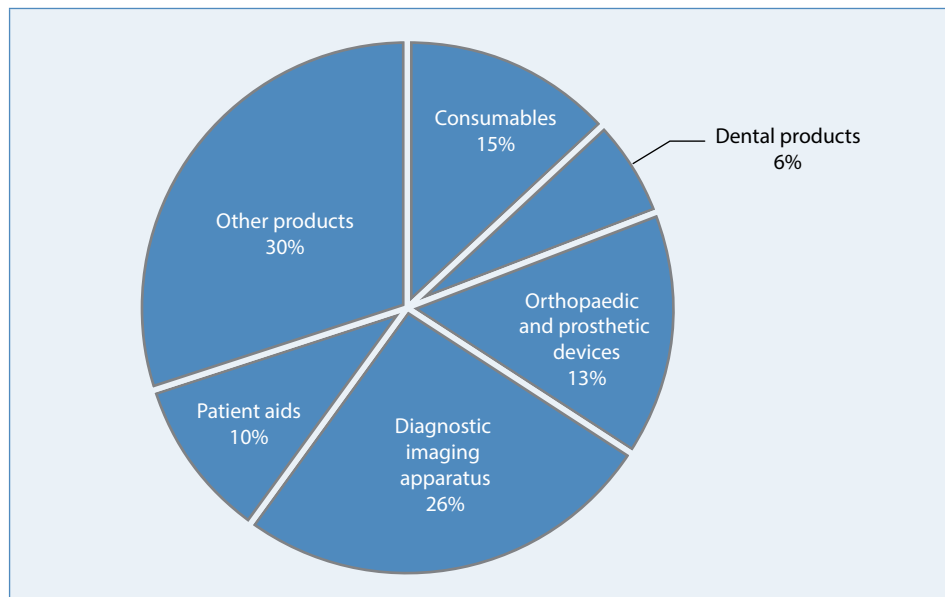
Studies indicate that some locally-produced simple devices can be more affordable than foreign imports. They can also reduce transportation costs (resulting in a smaller carbon footprint), nurture local supplier networks, build health security by increasing the reliable supply of medical products, and contribute to a more robust health ecosystem that meets local health

needs. But it is important to also note the potential pitfalls: Some studies show that local production has not been successful, particularly in instances where it diverts resources from other priorities, and where the resulting innovations do not have the economies of scale to produce batches that can meaningfully decrease per-unit retail prices and do not necessarily address local health needs.

2.1 Global medical devices market

There are estimated to be over 10 000 types of generic medical device groups available through global markets, ranging in complexity, price and life span from single-use catheters to complex equipment for radiotherapy. Figure 2 illustrates the global market share of medical devices by sector. As shown, diagnostic imaging equipment accounts for the largest proportion (26%) of the global market, other electromedical equipment such as monitors, defibrillators, sterilizers, etc, comprise around 30%, followed by consumables (15%) and orthopaedic and prosthetic devices (13%) (4).

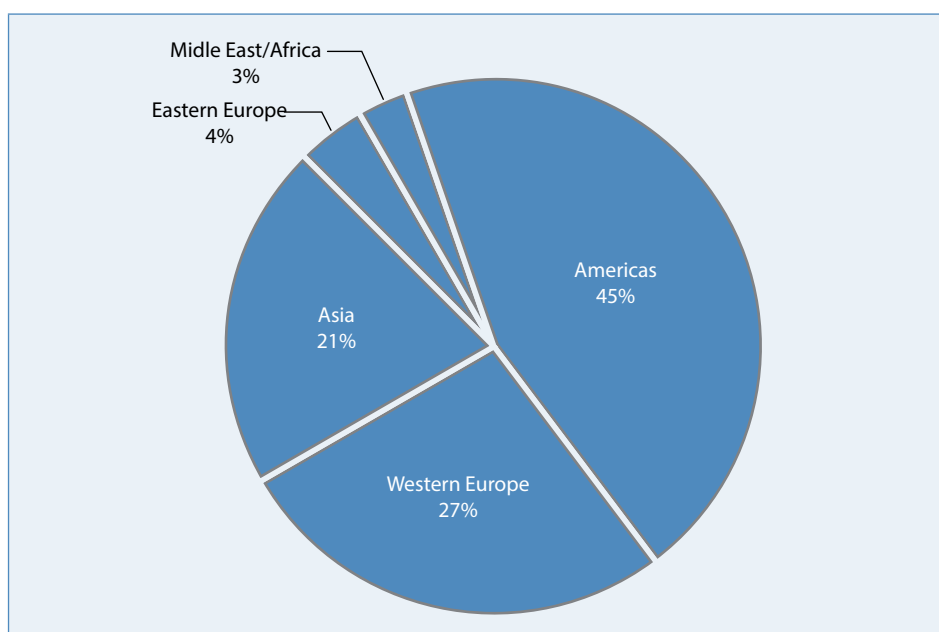
Figure 2 World medical markets, by sector, 2010



Source: *The World Medical Markets Fact Book 2011*

In 2010, the global medical devices market was estimated to be worth US\$ 164 billion and grew faster than the global market for medicines (5). Some conservative estimates predict that it will reach US\$ 228 billion by 2015 (6). The largest regional market was in the Americas (representing 45% of global sales revenue), followed by Europe (31%) and Asia (21%), while the Middle East and Africa represent a combined 3% of sales revenue (Figure 3)(4). The ten countries described in Table 1 represent nearly 77% of the global medical devices market (7):

Figure 3 *Medical device markets, by region, 2010*



Source: *The World Medical Markets Fact Book 2011*

Among all 67 countries surveyed by *The World Medical Markets Fact Book*, LMICs account for nearly 13% of the global medical devices market. In this category, the top five manufacturers – Brazil, China, India, Mexico and the Russian Federation – produce 64% of market needs in LMICs (4). Furthermore, while Asia, Europe, and Latin America are well represented, Africa is conspicuously under-represented in manufacturing capacity. Africa has a wide range of health contexts ranging from Chad’s 1100 maternal deaths per 100 000 live births to Tunisia’s 56 (8). This demands meaningful, customized approaches to medical device production, procurement and delivery that are sensitive to local contexts.

Table 1 *Top ten countries by medical device sales revenue, 2010*

Country	Sales Revenue (US\$ millions)	Percentage (%)
United States of America	100 801	39.0
Japan	29 208	11.3
Germany	19 596	7.6
France	8890	3.4
United Kingdom	8477	3.3
Italy	8360	3.2
China	7811	3.0
Canada	5779	2.2
Russian Federation	5186	2.0
Spain	4602	1.8
Subtotal	198 710	76.9
Total (67 countries)	258 424	100

Source: *The World Medical Markets Fact Book*

Local production may be a viable, cost-effective means to improve access to simple medical devices. However, in instances where local production is insufficient or uneconomical, imports, aid interventions and/or foreign direct investment can help address needs. Table 2 lists the top ten African countries in medical device import and export sales. A large proportion of medical devices are imported from outside of Africa. The leading suppliers of medical devices (by revenue) to the African region are: Germany, France, the United States, China, and the United Kingdom (9).

Table 2 Top ten African countries by value of medical device imports and exports, 2008

Country	Imports (US\$ millions)	Country	Exports (US\$ millions)
South Africa	670.1	South Africa	111.5
Egypt	405.5	Tunisia	98.8
Algeria	307.7	Egypt	40.0
Morocco	171.1	Morocco	14.7
Tunisia	145.4	Mauritius	8.1
Libyan Arab Jamahiriya	141.1	Kenya	4.1
Nigeria	119.4	Swaziland	1.7
Angola	87.8	Madagascar	1.3
Sudan	56.2	Sierra Leone	0.9
Kenya	50.2	Libyan Arab Jamahiriya	0.9

Source: *The African Medical Device Market: Facts and Figures 2010*, which provides an overview of the entire African market for medical equipment and supplies.

It is important to note that neither economic nor health realities are static. Spurred by the MDGs and economic profitability, the international landscape is slowly but visibly shifting towards greater attention to health outcomes and the potential economic gains of producing medical devices.

2.2 Innovation of medical devices

Local production is closely linked with innovation – both in terms of products and the dynamic processes that emerge from the creative identification and assessment of need, and from capitalizing on that assessment to create novel solutions. *Barriers to Innovation in the Field of Medical Devices: Background Paper 6* (2010) (10) offers a detailed briefing on innovation. This report will expand on that paper of the WHO Priority Medical Devices report by contributing three broad ideas:

- i. Innovations offer new solutions. The WHO Global Initiative on Health Technologies considers innovation as:
 - Currently under development or taken into routine use within the last five years;

- Has not previously existed or been previously unavailable in a given country;
 - Is safer and/or simpler to use than earlier solutions;
 - Is more cost effective than earlier solutions (11).
- ii. Frugal innovations offer low-cost, easy-to-use to innovations that are overtaking current technologies on the global market. For example, countries such as China and India are producing portable electrocardiographs stripped down to their essentials for US\$ 500 per unit as opposed to US\$ 5000 (12).
- iii. Medical device innovations are becoming progressively smaller, more specialized, more sophisticated, less invasive and more cost effective. Frugal innovations in particular prove the idiom “less is more” as these innovative devices cost less and reach larger populations. There are a growing number of such case studies where innovations are becoming more affordable and appropriate for low-resource settings.

Above all, local production must have the explicit intention of improving public health outcomes, be sensitive to local needs, and embrace the spirit of local ownership.

2.3 Research and development for medical devices

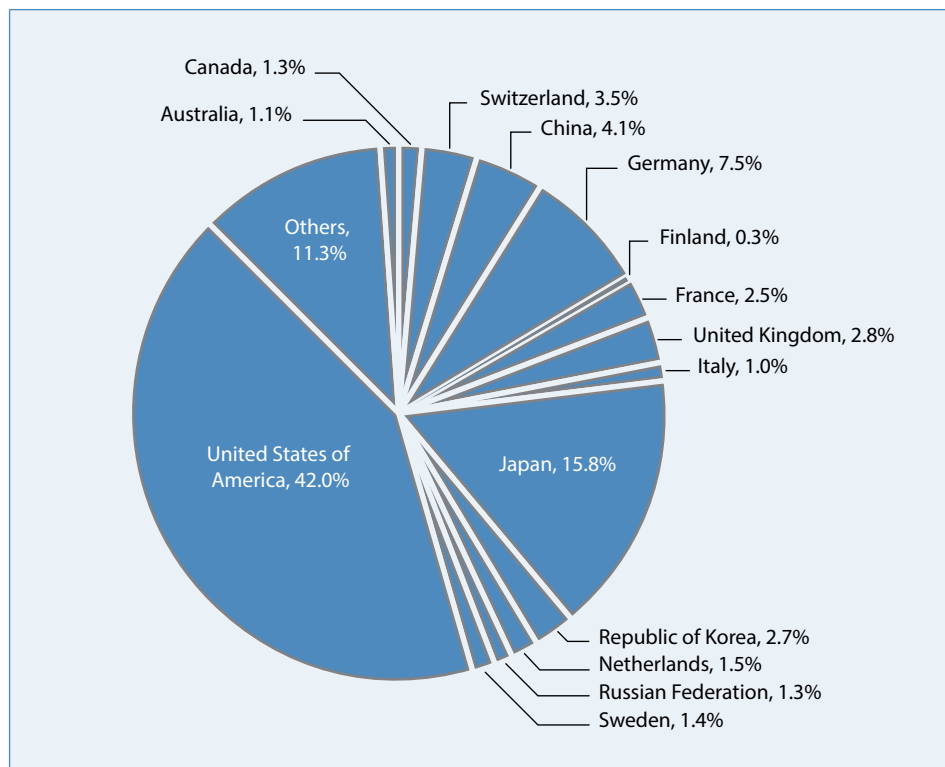
Research and development expenditures by leading medical device manufacturers in Organization for Economic Co-operation and Development (OECD) countries and emerging economies are increasing. In 2010, major manufacturers (e.g. including Johnson and Johnson, GE Healthcare, and Siemens Electronics) collectively spent 9% of their sales revenues on R&D (13); up 2.5% from 2008 (14). Yet, consistent with the innovation process and its accompanying culture of curiosity, these increases do not always translate into patents.

Research suggests that manufacturers headquartered in HICs have historically invested R&D funds towards optimizing current product lines, which often address small global patient populations (typically in HICs) but yield high profits. A health gap thus emerges where 90% of the global disease burden has been typically tackled with only 10% of the world’s research funding. This situation, however, is changing. New models and approaches are emerging where LMIC manufacturers are producing medical devices, and HIC manufacturers are developing more affordable devices to secure their share of emerging, LMIC markets. This change is relatively new but may mark the gradual departure from status quo scenarios where LMIC public health needs and their associated limited budgets could not attract sufficient financial interest.

Undoubtedly, more must be done to reduce the global burden of disease and remedy health care inequities. But the case studies in this report also show that there is room for optimism as diverse stakeholders collaborate to create novel products that meet both public health needs *and* profit targets.

As shown in Figure 4, the 2005–2009 medical device patent applications were dominated by OECD countries, with 42% of patents filed in the United States alone. China’s share (4.1%) deserves special mention. It is roughly half the size of Germany’s, and patent applications are increasing. The Chinese approach to patenting is discussed in further detail in the Country case studies section.

Figure 4 Patent applications in the field of medical technology by country, 2005–2009.



Source: *World Intellectual Property Indicators* (WIPO, 2011)

A growing number of multinational companies (MNCs) are setting up manufacturing sites and research centres in LMICs, particularly in emerging BRIC markets (e.g. Brazil, Russian Federation, India and China) that are becoming powerhouses in producing generic drugs and low-cost health technologies. LMICs boosted their share of R&D expenditure by 13% between 1993 and 2009 (14). However, significantly, LICs without an innovation climate are often spectators in this field and it is common to find a dependence on so-called “off-the-shelf” imported technology.

R&D expenditures in Africa require special consideration. Public funding for R&D as a percentage of total gross domestic product (GDP) averages 0.3% (15). Further, only a small portion of this is invested in health-related R&D. In 2007, the African Union set targets of boosting health-related R&D spending to at least 2% of total health care expenditures by 2015 (16). The target is voluntary and some countries have amended it to reflect local fiscal realities and pressing competing priorities. Egypt, for example, has set a target of 1% by 2017 (26).

Public research organizations (PROs) play a key role in R&D in LMICs. In 2011, the *World Intellectual Property Report* found that MIC governments contribute an average of 53% of all R&D to health-related fields, while their HIC counterparts contribute 20 to 45% (17). In many LMICs, the majority of health-related R&D is public or donor-funded: In China close to 100% of basic health care R&D is publically funded; in Mexico, the figure hovers around 90%; in Chile 80%; and in South Africa: 75% (14). However, despite the large proportion of public funding in PROs, there is a relatively weak link between public R&D figures and national health development in LMICs. A number of challenges contribute to this disconnect, including:

- Lower capacity for rigorous R&D in PROs than in private R&D laboratories;
- A deficit of human capital for science and technology activities;
- Limited collaboration with the private sector;
- A lack of supporting policies and operational structures to aid R&D;
- A drawn-out patenting process; and inadequate funding and resource pools than make it uneconomic to pursue research;
- Low investments in medical device R&D for health priorities.

There is a great variation in R&D expenditures among LMICs and between regions. Discrepancies arise from factors such as regulatory and legal barriers that impede access to technology and collaboration; relatively weak business environments and financing mechanisms in some countries; high import taxes that limit access to important scientific research equipment; and different and changing national intellectual property (IP) and regulatory frameworks that can foster a reluctance to innovate should IP protection disappear.

2.4 Local production

For the purposes of this report, local production categorizes any manufacturer that is located within a national jurisdiction, regardless of whether it is nationally or internationally owned. Significantly, local production must have the explicit intention of improving public health outcomes, be sensitive to local needs, and embrace the spirit of local ownership. Local production is not suitable for all contexts. Chapter 4 of this report, Feasibility Tool, provides guiding questions to help determine if local production of devices might be feasible.

Bennett (1997) (18) defined three broad types of manufacturing stages in pharmaceuticals. These stages also relate to medical devices: tertiary, secondary, and primary, to describe a range of value-added activities from assembling pre-made parts, to developing devices from raw materials, to a combination of the two. These stages can influence the size and vigour of a country's indigenous capacity to identify and meet economic and health targets by defining new markets and developing new devices appropriate to the local context. The latter goal has particular resonance in a current global reality where 70% of complex medical devices brought to LMICs are rendered inoperable at the point of use (11). There are a variety of factors that influence

local production. These factors are listed below and discussed in further detail in the following subsections:

- technology transfer and intellectual property;
- health system financing mechanisms;
- local governance and regulations;
- local business capabilities.

2.5 Technology transfer and intellectual property

Evidence from the present research suggests two key determinants of effective technology transfer:

- the will to acquire new knowledge;
- collaboration and cross-pollination of ideas among diverse corporate, NGO and government stakeholders (19).

Transfer can take place through a variety of configurations including public–private partnerships, private and institutional, and joint ventures. At times, these partnerships will require higher-level facilitation and guidance from governments and international bodies such as WHO and the United Nations Development Programme (UNDP), as well as other global agencies.

Technology transfer in LMICs takes place in resource-limited environments. These limitations can refer to resource and capital, difficulties in selecting initiatives from competing priorities, or to political and skill constraints. Current research tends to suggest that innovation can indeed happen in resource-constrained environments, albeit sub-optimally, as these constraints demand greater creativity and patience in order to overcome even simple barriers, such as access to basic technologies. But some emerging markets have become exceptional, proving that impressive, frugal innovations can happen despite the relatively weak infrastructure that has historically been considered fundamental. Indeed, some business strategists predict that China will reach near parity with European leaders in medical technology innovation by 2020 (20).

In general, medical devices have more patents per device than medicines. A typical drug-coated stent, for example, can have dozens of patents, while a sophisticated blood glucose monitor can have thousands relating to its user interface, software, battery, memory, power management system, integrated circuits and wireless or internet connectivity (21). In contrast, most small-molecule drugs had (on average) 3.5 patents per compound in 2005 although the number is increasing over time (22). Notably, some medical devices patent holders are disclosing their inventions in their patent filings. This might help technology transfer as it allows other companies to build on these inventions and further develop their products. Unlike pharmaceuticals, it is usually possible to invent new medical devices around existing patents. However, manufacturers that fail to employ a rigorous programme to protect, manage and assert their IP rights risk costly litigation, lost revenue and weakened market share.

Discussions on technology transfer tend to happen alongside discussions on IP protection. From a public health standpoint, WHO considers patents as the most relevant expression of IP, whereas other forms such as trademarks (for example, in labels) play a distinct role (23).

At this stage, it is important to note that technology transfer does not, in itself, imply quality assurance, merely that knowledge or product has changed hands. The dialogue on quality – how it is defined, measured, and regulated – must be locally conceived and enforced. It is particularly important that policy-makers monitor and assess changes in innovation and that governments are involved in national innovation systems. Innovation is a key ingredient in health and economic growth strategies. Governments are not only R&D funders, but have the power to incentivize international and local firms to invest in innovation in their communities. Accordingly, governments that are aware of changes to innovation, and have the capacity to regulate and monitor it, are better placed to gauge if current policies are still apt (17).

Global strategies such as the *Global strategy and plan of action for public health innovation and intellectual property* (GSPA-PHI) strive to “improve, promote and accelerate transfer of technology between developed and developing countries, as well as among developing countries,” (24) while the *Trade-Related Aspects of Intellectual Property Rights Agreement* (TRIPS) sets minimum standards for IP protection.

In April 2012, WHO conducted a survey to identify barriers to local production in low-resource settings. The survey was taken by 140 stakeholders from around the world; its questions and analysis can be found in the annex. The findings revealed that local manufacturers approached IP in (broadly) three groups: (1) those who do not understand IP, the patenting process, and the merits thereof; (2) those who appreciate IP and take deliberate steps to guard it; and (3) those who understand IP but treat it as a moral good. The third category is smaller but reflective of new business models and approaches to health care needs where companies such as Brazil’s Solar Ear freely share technologies and business plans with like-minded organizations. There are nuances and complications to this ‘open-software’ approach to innovation, but it is a field that is growing at an important time of challenges to global health delivery systems.

2.6 Health system financing

At its core, health care system financing collects, pools, and redistributes resources among health care payers, consumers and providers, with a goal of effectively, affordably and efficiently achieving health system performance targets.

Notwithstanding other factors, the decision by companies – regardless of location, size or operating budgets – to invest in and supply essential medical devices to countries tends to be driven by economics and the company’s forecasted long-term profitability in a particular country or region. While donor and direct government funding are often sources of revenue for start-up

companies, long-term profitability is driven by system financing and payment mechanisms that link payers, providers and patients.

Research suggests that variations in payers' economies of scale, risk pool sizes and organizational goals impact the size and types of benefit packages offered to patients and subsequently, determines both the type of services that medical providers deliver, and the types of medical devices they utilize to do so. Similarly, how medical care providers are paid for their services can facilitate or inhibit the quantity, quality, cost and type of medical care delivered to patients, and the types of medical devices deployed. As the demand for medical devices rises, so too do revenues for these products and associated R&D.

Health system financing in LMICs confronts particular challenges that are unique to resource-limited environments. Prime among these is a comparatively weaker capacity to generate predictable revenues over a sustained period of time. In these environments, tax systems tend to be regressive and challenges to health financing are compounded by a lack of management capacity; inadequate or incomplete accounts and financial tracking mechanisms; and disbursement or technical inefficiencies.

Symptoms of inefficient health care system financing can be found in health care facilities that cannot be maintained, or are unused – often the result of bilateral agreements or industry–government partnerships where MNCs build infrastructure as part of their economic license to operate. However, when infrastructure is built without a 'social license' that reflects true partnership with local communities, case studies show that health care infrastructure can be ignored. In other instances, even when the infrastructure is agreed upon, there may be inadequate staff to operate the facility rendering it essentially useless for its intended purpose. This is particularly true in rural environments where rural–urban migration can pull clinicians and hospital administrators to urban centres.

A lower capacity to locally finance health care systems can also influence a country's funding sources. In 2005, the World Bank found that government health expenditures would need to grow from 2.3% of GDP in 2000 to an average of 30% by 2015 (25) to successfully meet the child mortality MDGs. In these instances, the additional funding would typically need to come from donors who can sustain support for extended periods. However, large health care budgets do not always correlate with superior health outcomes, nor do comparatively smaller budgets necessarily correlate with inferior ones.

2.7 Governance and regulation

Where appropriately implemented, medical devices regulation can help ensure that the types of devices purchased and used are those that are safe, effective and of a high quality; and restrict the use of technologies that are deemed unsafe. Regulation of clinical trials can also avoid unsafe human trials and protect populations from unsafe and unproven devices.

International standards form a cornerstone of regulation and harmonization. In 1992, the Global Harmonization Task Force (GHTF) was established to encourage convergence at the global level (26). In 1994, the *World Trade Organization (WTO) Agreement on Technical Barriers to Trade* stipulated that all Member States must use international standards as a basis for their product regulations (27). In 2011, the International Medical Devices Regulator's Forum (IMDRF) was established to build on the GHTF, and expedite convergence by focusing on understanding the operational challenges to harmonizing national regulations (28).

Public health initiatives are most effective when there are strong linkages between National Regulatory Associations (NRA), government agencies responsible for health care and industrial development, the private sector and international organizations. A lack of communication between the NRA and government agency responsible for making reimbursement decisions can create a mismatch between the list of devices authorized for sale and those devices listed for reimbursement.

International standards designed for HIC are not always suitable for LMICs. In some instances, they may even act as a barrier to local production. In 2007, an Engineering World Health study (27) found that defibrillators frequently fail due to depleted batteries that can be cost-prohibitive to replenish in LMICs. The study noted that these batteries could be produced locally at a lower cost were it not for stringent operating requirements such as the ability to operate at 0°C – often unrealistic in the location where the final products are used. These requirements, stipulated in international standards and required by the *WTO Agreement on Technical Barriers to Trade*, can inadvertently hinder the emergence of local companies that produce low-cost devices appropriate for the LMIC context, and thereby indirectly limit the availability of essential technologies on the global market. A flexible regulatory strategy for low-resource medical devices must be considered to achieve an optimum balance of safety, affordability, availability and accessibility, on a case-by-case basis (39).

It is important that NRAs act a partner to industry by providing guidance and support for post-market reporting and clinical research (29). A weak or non-existent capacity for post-market surveillance is associated with a lack of systematic data on device-related injury and failure mechanisms (11). If this important feedback mechanism is absent, there is a missed opportunity for continued design improvements; in essence, it is a barrier to innovation. Similarly, it is important that governments have the capacity and expertise to review complex application files. Otherwise, there can be delays in assessment and approval, and increases in the cost of commercialization. Faced with limited and irregular funding, at least one NRA resorted to charging fees for regulatory checks, raising concerns on potential conflict of interest (30).

Innovations require a clear pathway to viable markets in the shortest possible time. This places regulators under pressure to balance two competing priorities: the due diligence needed to reduce potential for harm, and the

pressing need to reduce time-to-market. Current research suggests that medical device manufacturers are deliberately moving towards markets in which they can clear regulations quicker, and where government regulations and procurement rules are transparent and accessible.

Regulations can also influence the number of new businesses that are created. Unsurprisingly, there is a higher incidence of entrepreneurship in OECD nations where processing times are shorter, and where application costs are cheaper. For example, the World Bank Group found that new business formations in the United States take six days to process six steps, and costs 1.4% of annual income per head. In contrast, Haiti takes 105 days to process 12 steps, and costs 314% of local annual income per head (31). The World Bank *Doing Business 2012* rankings (32) reveal a striking and unfortunate correlation: the bottom ten countries also rank low on the UNDP Human Development Index. Chad, ranked last on the *Doing Business 2012* survey (32) also has one of the highest ratio of maternal mortality, with 1200 per 100 000 live births (2010).

2.8 Foreign technologies, local business capabilities and economic context

Most medical devices used in low-resource settings are imported from industrialized countries (19). However, most medical devices designed for HICs are unsuitable for use in low-resource settings where a host of support factors such as access to predictable power and water cannot be overlooked. A more detailed overview of the barriers and challenges preventing the successful dissemination of foreign-produced medical devices is elaborated in *Medical Devices: Managing the Mismatch* (22). Briefly, these barriers are: social context, personnel skills, regulations, enabling infrastructure, total cost for duration of medical device's effective lifespan, and language of instruction.

The global medical devices industry has historically targeted HICs and has become used to the environments within which they operate. LMICs without reliable access to, for example, electricity and water cannot operate a variety of devices during periodic power and water shortages. In other instances, costly replacement parts can reduce the effective lifespan of complex medical devices that cannot be maintained, while costly accessories can transform multi-use devices into single-use products when they are offered with only few accessories.

Economic theories and research underscore the importance of an enabling environment – an ecosystem of inter-dependent services, sound financial markets, meaningful policies and robust infrastructure that work in concert to support local production. Unfortunately, such environments are cost-intensive and time-consuming to properly execute. Yet, notwithstanding this, there are some general guidelines on the core capabilities that communities and countries need in order to sustainably nurture local production in the long term.

Macroeconomic stability is fundamental to local production. In this instance, 'stability' includes both economic and non-economic factors, such as the ability to own land and capital, rule of law, and access to social infrastructure such as schools and hospitals. In this way, enforceable, even-handed laws regulate business practices and entrepreneurship; social foundations help to build a healthy and educated workforce; and sound fiscal and monetary policies that may include instruments such as tax breaks, subsidies and the careful use of interest rates, can create an environment where entrepreneurs have the opportunity to materially benefit from their productivity.

This key capability is joined with five others: sound regulatory environments, health system financing mechanisms, effective intra-governmental and cross-industry partnerships, effective transportation and communications networks to enable to core logistics of buying and selling, and a vibrant innovation culture. These capabilities require substantial investments of time, patience and deliberate policy. Medical device manufacturers must also have the capacity to understand the needs of the market; translate that need into prototypes, and shepherd new products through the various processes and regulations to produce an economically viable, quality product. The case studies in the following subsection spotlight companies that are developing important medical device technologies:

- Brazil:** Local production grows on the back of wider economic development measures;
- China:** Local governments are taking deliberate steps to nurture local production;
- Ethiopia:** Growing interest in local production as the government steadily develop innovation and business environment;
- India:** Local production takes place despite relatively weak regulatory environments;
- Jordan:** Limited local production despite government efforts to increase it.

2.9 Country case studies

Many LMICs have attempted the transfer of new technologies or/and produce medical devices locally. Some of these experiences have been very successful while others have failed to meet population needs. The following section examines a few of these inspiring success stories and, in particular, how medical device manufacturers are developing products while regulations, policies, and infrastructure are being developed in tandem.

a. Brazil | Americas Region

Brazil is an upper middle-income country with a population of roughly 195 million (2010). Its quality of life indicators show steady and modest

improvements, largely aided by impressive economic growth metrics and government determination to reduce poverty in its various measures of income, consumption, social indicators and access to essential services. Its reported number of people living below the national poverty line dropped from 30.8% in 2005 to 21.4% in 2009, while in other health metrics, average life expectancy at birth is 73 years (2010), and the maternal mortality ratio is 58 per 100,000 live births (2010), dropping from 81 in 2000. There are 1.76 physicians, 6.42 nurses and midwifery personnel, and 0.54 pharmaceutical personnel per 1000 inhabitants (2008). While OECD nations tend to have more nurses than doctors, the reverse tends to hold in LMICs (35,67,68). Brazil's leading causes of death are circulatory system diseases, external causes such as poisoning and injuries, and cancers (69).

Health system organization and financing

Brazil's health care system is largely financed by two sources: households, and the Sistema Unico de Saude (SUS), an NHS-styled system that is funded by direct and indirect general tax revenues and aims to provide universal coverage. Household out-of-pocket expenses declined by 6% from 2000 to 2010, while government spending as a percentage of total national health expenditures increased. Brazil's SUS is unique from other Latin American systems in that it separates financing mechanisms from health care provision. It does not separate its Ministry of Health from its social security system such that public funding can be used to finance any provider and health care can be more universal. Furthermore, financing is largely met through public sources, although service provision is mostly handled through the (for-profit) private sector; and the federal government finances health care while municipal bodies provide it (70). Brazil has the second largest private insurance sector in North and South America (71), and the companies offer a range of benefits that complement those offered by the SUS, though services are typically purchased by upper income households (72) and evidence suggests that Brazil's poor are less likely to access health services than the non-poor. Some hypotheses explain the uneven access by attributing low demand (instead of low access) to Brazil's poor, but evidence suggests that Brazil's poor are more likely to self-identify as not accessing health care despite need, and cite financial reasons and distance from health care facilities. External donor funding and social health insurance play a limited financing role.

The SUS employs a diagnosis-related group (DRG)-based payment scheme for hospitals, and capitations for smaller public medical providers. The Brazil Ministry of Health works in concert with regional and local authorities to provide lists and prices of services covered by the public sector. These payment/reimbursement systems have shifted incentives to public (and to a lesser extent private) medical providers to reduce costs and limit the use of less cost-effective technologies. Notwithstanding regulatory and financial constraints that can inhibit the effectiveness of

these systems, Brazil's public payment system has limited cost inflation for medical devices. In parallel to this public sector experience, private insurers who reimburse private health care providers through fee-for-service appear to be a key driver in the demand for medical technologies. While evidence suggests that private insurers have attempted to limit reimbursements to certain medical devices such as CT and MRI machines, small risk pools limit their negotiating power with independent medical providers.

Growth in both public and private sector financing has had significant impact on the behaviour of medical providers and patients. Over the past decade, SUS increased its financing role in preventative and primary care while private insurers increased their contributions to secondary and tertiary medical care, such that there has been a notable increase in the number of private medical providers offering secondary, tertiary and diagnostic services, and public providers offering primary and preventative care (73). Benefit packages among private insurance plans have grown to meet household demand for additional and more intensive medical care. In 2011, researchers found that spending and volumes of services reimbursed by private insurers increased by roughly 350% and 500% between 1990 and 2008 (74).

Regulations

Medical devices are regulated by the Agência Nacional de Vigilância Sanitária (ANVISA) – the Brazil national health surveillance agency. ANVISA was established in 1999 as an autonomous regulatory agency that works with the Ministry of Health through a management contract. The agency strives to promote population health through controlling the production and marketing of health products and services. It is complicated to coordinate ministry decisions to pay for and adopt health technologies in the public health care system, and problems arise as a result of a lack of coordination between ministry decisions to pay for and adopt health technologies into the public health care system, and ANVISA's authorizations on health technology commercialization. While regulation, if properly enforced, can limit the use of unsafe and ineffective medical devices, ANVISA's authorization decisions can create social demand for certain products, and lawsuits have been filed against federal, state and local health authorities that do not provide ANVISA licensed products (73). The mismatch can promote demand for expensive medical devices in instances where cheaper and more appropriate solutions may exist.

Table 3 *Medical device regulation in Brazil*

National Regulatory Authority	Agência Nacional de Vigilância Sanitária (ANVISA)
Key laws/regulations	Brazilian Resolution RDC 185/01
Risk classification system	Four risk classification system similar to EU Directive 93/42/EEC.
Requirements for registration/ importation	Electrically powered devices must be accredited according to RDC 27/2011 Technical file according to Annex 3, Part A/B/C in RDC 185/01 Certificate of Free Sale from country of manufacture Risk management compliance with ISO 14971 for all implants
Vendor registration/ licensing	Company working allowance permit needed to import, distribute, store or sell product in Brazil
Quality system requirements	Biannual audits of manufacturers of Class III & IV devices by ANVISA according to Brazilian Good Manufacturing Practices (BGMP)
Clinical trials requirements	Clinical trials for innovative or high risk products

Intellectual property

Brazil is a founding member of WTO and a signatory to the TRIPS agreement. Its patents are administered by the National Institute of Industrial Property (Instituto Nacional da Propriedade Industrial), and under Brazilian patent law, university researchers and public research institutes are treated no differently from other employee classes with regards to invention ownership. Terms of IP ownership and revenue sharing are further expanded in the Ministry of Science and Technology, No. 88, and the Ministry of Education and Sport (No. 322) laws (49). Brazil maintains a 'first-to-file' system, offering 20 years for invention patents and 15 years for utility model patents. However, patent applications can take up to eight years to process, and the Brazil Government is considering pilots that will considerably speed this process by 2015 (75).

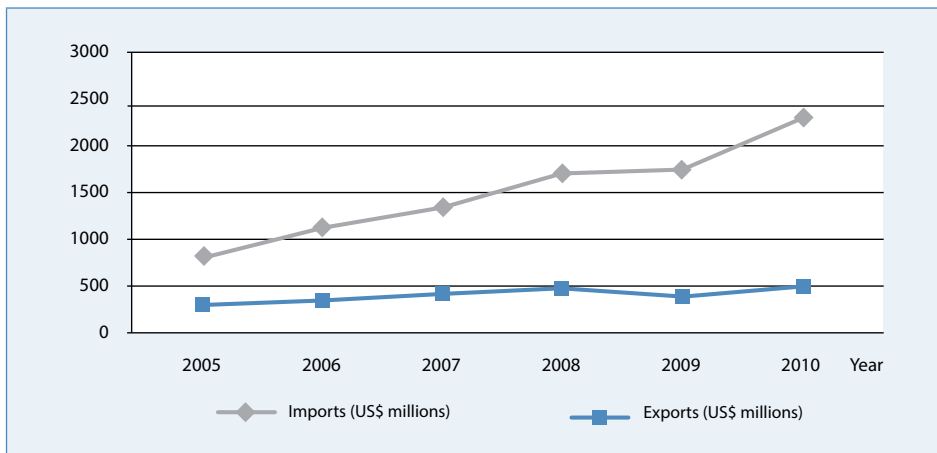
Brazil maintains a central office for technological innovation at the National Council for Scientific and Technological Development. The council promotes innovation at universities and encourage technology transfer to industry. To that end, it helped establish more that 30 TTOs at Brazilian universities to protect IP and facilitate collaboration between universities and industry.

In April 2012, the Brazil Ministry of Health entered an alliance with the Bill & Melinda Gates Foundation to develop innovative solutions to global health concerns. The alliance's signature initiative is the 'Grand Challenges Brazil' which allocates up to US\$ 8 million for health research that can prevent and manage pre-term births (76).

Trade and local production

Brazil ranks 126 out of 183 countries in the World Bank *Doing Business 2012* survey (32). It commands the largest medical device market in Latin America (77). It is valued at R\$ 6.7 billion (US\$ 3.7 billion), and translates to roughly US\$ 18 per capita. These high figures are largely attributed to local demand for consumables and diagnostic imaging equipment in large urban areas relative to rural, although it is significant that spending on basic consumables such as syringes, needles and catheters surpassed high-end medical devices despite growth in private health insurance and a decline in household out-of-pocket spending (78).

Figure 5 Imports and exports of medical devices in Brazil, 2005–2010.



Source: *Medical markets fact book 2011*. Espicom Business Intelligence.

Brazilian medical device imports exceed exports (Figure 5). Imports tend to be high-end devices from the US and Europe, which combined comprise 70% of all Brazil's imported medical devices in 2011 (79). However, unlike China and India, only a small proportion of locally produced medical devices are exported, and imports hold a small share of the local market (79). In this instance, Brazil can be considered the only country analysed in this section that can meet the majority of its recorded medical device needs through local production and development.

Brazil is experiencing considerable economic growth with a 0.3% economic expansion in the fourth quarter of 2011 alone. If inflationary pressure is kept in check, and if Brazil continues to invest in reducing local wealth and health disparities, this growth can translate to higher demand for medical technologies across the wide spectrum of medical devices.

Examples of local production and collaboration

Hearing aids, by their nature, require battery support that can render the device cost-prohibitive to certain populations. In response to growing estimates of the global hearing aid-dependent populations, the Brazilian company Solar Ear worked with local foundations and NGOs to develop a solar-powered hearing aid. The device has a lower environmental footprint than its battery

or electricity-powered counterparts, but above all, is cheaper and deliberately unpatented so that other companies and countries can manufacture similar low-cost, high-impact devices (80).

In 2003, São Paulo-based Pelenova Biotecnologia was founded to develop products for tissue regeneration. The biotech incubator invests heavily in R&D and supports the work of Brazilian biomedical engineers and chemists by assisting them in the commercialization process. Technologies currently under review include latex dressings that can speed the healing of chronic ulcers (81).

b. China | Western Pacific Region

China is classified as an upper middle-income country and has a population of roughly 1.34 billion people (2010). In the past two decades, the country has made significant progress in relation to a variety of both physical and social determinants of health indicators. The reported number of people living below the national poverty line has decreased from 6.8% in 1996, to 2.8% in 2004. In 2011, the China Government revised its poverty line from 1196 Yuan to 2300 Yuan (about US\$ 365) per capita annually, in order to improve the life standard of Chinese citizens (33). The new, revised figure of US\$ 1 per day for rural areas is now closer to the World Bank threshold of US\$ 1.25 per day.

China is also experiencing a growing middle class that will significantly contribute to a medical device market estimated to be worth US\$43 billion by 2019 (34). Average life expectancy at birth is 73.1 years and maternal mortality ratio is low at 38 per 100 000 live births (2010), dropping from 61 in 2000. There are 1.41 physicians, 0.25 pharmaceutical personnel and 1.37 nursing and midwifery personnel per 1,000 inhabitants (2009) (35). The top three leading causes of death are cancers, and cardiovascular and cerebrovascular diseases.

Health system organization and financing

China is changing rapidly. Day-to-day life takes place against a relentless background of strong economic growth strategies, massive rural-urban migration flows, increasing environmental concerns, and growing young and aging populations (36). To keep pace, and in particular to meet its health targets, China's national health care system has undergone major reform efforts but still faces significant challenges.

Although the government had made great efforts, equitable access to health care remains difficult and access to essential medicines is not always guaranteed. To compound issues, health services suffer rising costs as a result of a decentralized financing structure. General government spending on health care lingers at 27.2% of total health expenditures since 2000, as reforms substantially increasing the role of social health insurance schemes in financing medical care. The health reforms include the New Cooperative Medical Scheme for roughly 90% of rural residents, as well as the provision of

benefit packages that vary by local governments and typically including basic and emergency medical care services (37).

Payment systems to medical providers include government subsidies, out-of-pocket payments from patients and fee-for-service reimbursement from both private and social insurers (38). The majority of Chinese patients rely on social insurance and general government reimbursement to public service providers. Combined, these account for 5 to 40% of costs for basic health care services as governments strive to control medical expenditures and ensure improved access to care (39). The remaining costs are met by private insurers, households and public insurers that reimburse providers at higher rates for technology-intensive services. Research indicates that some medical providers have strong incentives to over-provide profitable, high-tech diagnostics and pharmaceutical services while under-providing primary medical care as a result of China's existing financing and payment mechanisms. Espicom 2011 (4) data indicate that diagnostic imaging devices accounted for the largest share of total medical device spending from 2005 to 2010 at roughly 41%, roughly double the expenditures of basic consumables (16%) and patient aids (15%) in 2010.

Despite limited data, the impact of China's financing and payment systems on the investment in and adoption of medical devices appears significant (40–43). Medical device manufacturers appear more willing to enter markets for complex, high-end technologies, including magnetic resonance imaging (MRI) and computerized tomography devices, as well as pharmaceuticals, where potential profits are greater. Studies by Liu and Hsiao (1995), Yip and Hsiao (2008) and Eggleston (2008) (43–45) report that China has more MRI scanners per million population than many other MICs, while other studies indicate that in some rural Chinese village clinics "less than 2% of drug prescription were 'rational'" (43) and at least 20% of hospital expenditures related to the treatment of pneumonia and appendicitis were deemed clinically unnecessary (43–46). However, it is important to note that attempts to curb unwarranted medical device and pharmaceutical expenditures have been largely successful and have started to contribute to the growth of low-end medical devices. High-end diagnostic devices have reportedly slowed between 2005 and 2010 (47,48).

Regulations

Between 1998 and 2003, Chinese health reforms saw the merging of the Department of Drug Administration with the State Pharmaceutical Administration of China to eventually form the State Food and Drug Administration (SFDA). The SFDA oversees all drug- and medical device-associated manufacturing, trade and registration. Its major responsibilities include: drafting laws and regulations, coordinating testing and evaluation, investigating breaches of code, and enforcing regulations.

Table 4 Medical device regulation in China

National Regulatory Authority	State Food and Drug Administration (SFDA) Regulations: http://eng.sfda.gov.cn/WS03/CL0767/61641.html
Risk classification system	Unique three risk classification system
Requirements for registration/importation	Quality system certificate, marketing approval certificates Technical files Chinese registration standard document Import Medical Device Registration Certificate
Vendor registration/licensing	Legal agent and after sales agents in China required for device registration
Quality system requirements (QSR)	Certification according to US FDA QSR or ISO 13485:2003 is required
Clinical trials requirements	Clinical trials needed for some Class II/III devices without approval elsewhere Trials conducted outside China accepted for products with US, EU or other national approval Clinical trials for some high risk devices must be conducted in China
Testing requirements	Testing by SFDA Medical Device Quality Supervision and Inspection Centre

Intellectual property rights

China's intellectual property legislation was recently established with patent laws adopted in 1984, and copyright laws adopted in 1990. While foreign companies and governments have voiced ongoing concerns on protectionist policies and enforcement mechanisms, China's internal political climate has been largely shaped by a desire to join the WTO and it is these internal forces that led to the strengthening of the patent law in 1992 and 2001 (49).

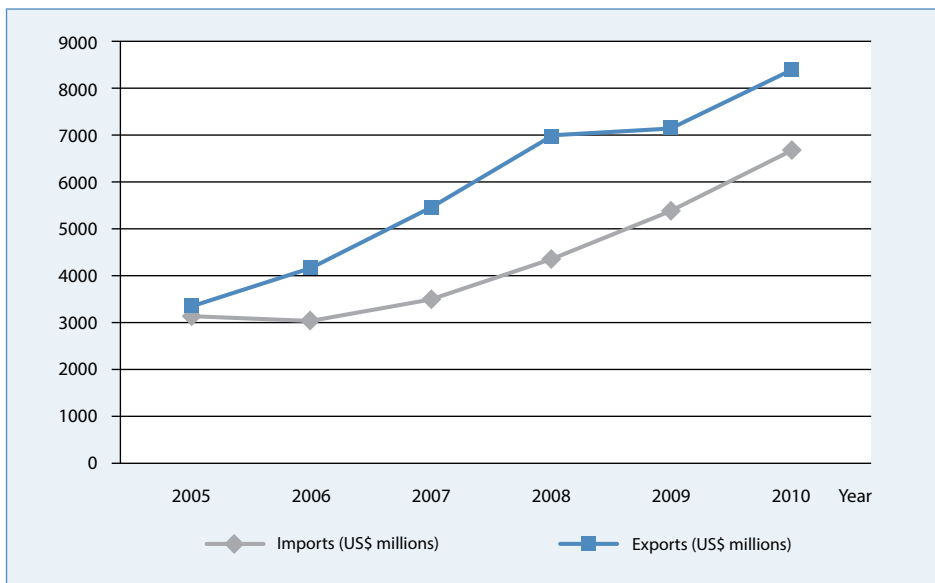
The number of patent applications that are filed by Chinese universities is significant. Between 1999 and 2002, Chinese researchers quadrupled their applications from 998 to 4282 (40). In comparison, US universities reported a more modest increase from 8457 to 12 222 in the same timeframe (49). In 2011, the China Government set a goal of filing two million patents annually by 2015 (50). Some issues to be considered when interpreting these figures are that Chinese academics appear to be adopting patenting as a substitute for publishing research since patent ownership is widely viewed as accepted criterion for academic promotion(49). Significantly, only a relatively small proportion of Chinese university patents have being licensed or commercialized. Still, Tsinghua University reports having spun off more than 38 companies, generating annual sales of US\$ 1.8 billion and actively incubating more than 200 companies at the Tsinghua Science Park in 2003 alone.

Trade and local production

China ranks 91 out of 183 on the World Bank *Doing Business 2012* (32) survey. Its SFDA records over 100 000 medical devices developed by 6324 domestic manufacturing companies, and distributed by 125 382 registered distributors (51). These numbers reflect an economic reality where most manufacturers have small market shares and few profitable products. In 2009, more than four medical device companies were publically traded. On a more macro-level, China's medical devices market grew steadily from 2006 to 2010 (7), with the largest growth seen in diagnostic imaging where sales were almost twice that of consumables and patient aids combined.

China is one of the world's largest producers of medical devices but does not yet command the same authority as its Japanese, American and European counterparts in the field. It does, however, wield considerable competitive advantage in low-cost manufacturing and is on the forefront of frugal innovation. Furthermore, fuelled by health care reforms that can potentially benefit China's local medical device industry, and central government's commitments to invest heavily in R&D, domestic device manufacturers are reported to be developing devices that will cost 30% less than those of foreign competitors (52).

Figure 6 Chinese Imports and exports of medical devices, 2005–2010



Source: *Medical markets fact book 2011*. Espicom Business Intelligence.

Unique to China is an export market that is greater than its imports (Figure 6). China forwards a large number of locally produced devices through export channels.

To some extent Chinese manufacturers operate within a protected business environment where it is common for foreign brands to form local partnerships as a means of harnessing those benefits and entering local markets. Chinese manufacturers tend to compete in low-end, non-sophisticated device markets while foreign competitors duel in the riskier but more lucrative high-end,

such that foreign devices now control roughly 90% of the domestic high-end market for medical devices (52). But China is changing. Its current strengths in simple devices and non-invasive fields may soon evolve as reform, investments and local ambition work in tandem to change the operating environment and status quo (34).

Examples of local production and collaboration

Specialized surgical staples are often used in place of sutures because of greater accuracy and faster recovery times than that with sutures created by hand. Staples however, can be cost-prohibitive in emerging markets. In a creative collaboration between Surgeon Zhao Zhongliang who serves Hebei's farming community, Johnson and Johnson and Ethicon Endo-Surgery, Inc., a producer of medical devices for minimally invasive and open surgical procedures, the surgical stapler was developed and commercialized for alimentary tract cancer patients (53).

Other examples of effective international collaborations include that of Medtronic and Weigao, a Chinese firm, which has co-launched half a dozen inexpensive innovations within the past two years. Significantly, Medtronic created or co-created new products that "it would not have made on its own" by leveraging local strengths and knowledge to build more appropriate devices for the local context. However, while foreign companies enter joint ventures or develop new products, local Chinese firms are racing ahead in developing products suitable to emerging markets. Some of these innovations such as the Brivo MRI and CT scanners, part of GE Healthcare's initiative for more cost-effective and accessible devices, may increase product adoption in other emerging markets or LICs.

c. Ethiopia | Africa Region

Ethiopia is a low-income country with a population of roughly 83 million (2010). It is one of the poorest countries in Africa, and yet, charts notable but somewhat uneven progress in health and social determinants of health metrics. The reported number of people living below the national poverty line fell from 45.5% in 1995 to 38.9% in 2005. Rural access to water supplies has improved substantially from 5% of the total rural population in 1990, to 34% in 2010. Literacy rates are low relative to sub-Saharan Africa, although there are more females in primary schools relative to males (87). Life expectancy at birth was 59 years in 2010, up from 48 in 1992, and the maternal mortality ratio has dropped from 950 per 100 000 live births, to 350 in 2010. There are 0.02 clinicians and 0.24 nursing and midwifery personnel for every 1000 inhabitants (2007) and in 2006, only 6% of Ethiopian births were attended by trained medical personnel (88). The current ratio of maternal mortality is high and unfortunately, not uncommon to the African region. Common diseases are malaria, diarrhoea and intestinal helminthiasis and there are growing concerns regarding acute respiratory diseases and HIV/AIDS.

The incidence of certain diseases increases during droughts. Food shortages associated with natural disasters also increase the incidence of malnutrition and

under-nutrition such that Ethiopia's health system must be able to withstand these disease burdens brought by natural and man-made emergencies. WHO field reports indicate that current utilization of health care services is 0.32 per capita (2011); in part owing to the low availability of appropriate and affordable health care, as well as the high attrition of trained personnel (89).

Health system organization and financing

Ethiopia's health system is largely financed by three primary sources: external donors, general government tax revenues and households. Unique to this scoping analysis, Ethiopia is the only country under review where external donors play an increasingly significant role; contributing 16.5% of total health care expenditures in 2000, and nearly 40% nine years later, during the 2009 global food crisis (90). Government funding dropped slightly from 53% in 2000 to 47% in 2009, and private and social insurance schemes are few. In 2011, Ethiopia ratified a national health insurance programme that is expected to take effect in July 2012. The new programme has raised concerns that health care must be provided by government health facilities in order to qualify for reimbursements (91). The Ministry of Health is investigating opportunities to include private sector health facilities in the future.

Over 70% of all health care facilities are publically owned and are allocated funding through government budgets. Hospital administrators and clinicians are paid on salary (92). An analysis of public sector funding allocations documents notable changes over time. Salaries now represent an increasingly larger proportion of total spending compared to the mid-1990s, but spending on medical devices has fallen from 31 to 25% over the same period (92). However, evidence suggests that this drop in expenditures is mitigated by an increase in external donor financing such that overall medical device expenditures have risen since the mid-1990s. Furthermore, Ethiopia receives a large volume of donated equipment that offer temporary solutions to resolving health system challenges rather than sustainable options for long-term development.

Ethiopia's private sector primarily consists of NGOs that provide preventative care such as vaccines, and for-profit health care providers, that supply pharmaceuticals, drugs and other specialty services. The private sector is generally better staffed and has greater quantity and quality of health technologies, including medical devices, than the public sector. Both public and private providers charge user fees for inpatient, outpatient and diagnostic services. However, unlike private sector providers who retain surplus revenues, public providers send collected user fees to local, regional and federal governments funding pools.

There is a wide discrepancy between the quality and depth of service provision in urban environments relative to rural. High-end devices are more accessible in urban settlements though this may result from greater government and donor funding allocations to urban environments rather than local demand. One study found that while roughly 70 to 85% of urban hospitals had examination and delivery beds, X-ray machines and other high-end devices,

there were significantly fewer rural facilities that owned any of these types of equipment – indeed, many did not own any of them (93).

There is limited research on Ethiopia's health care disparities related to medical devices such that it is difficult to determine how much of the gap can be attributed to financing limitations rather than other factors such as distance to health care and provider absenteeism. Ethiopia's wealthy tend to demand health care from private, formal providers in urban environments while much of the poor self-treats. Research in Ethiopia, Ghana, Nigeria and the United Republic of Tanzania indicate that both quality of care and availability of medical supplies are significant determinants of households' choice of medical provider (94). Without basic devices and other infrastructure, patients have been reported to self-screen and reduce their access to public providers by up to 75% in Africa (64).

The Ethiopia Ministry of Health has developed a national policy as well as strategic plans for collaboration. Its fourth phase covers July 2010 to June 2015, and prioritizes maternal and newborn health, HIV, TB, malaria, and nutrition. There is also emphasis on strengthening the Ethiopia health care system to expand physical access to primary health care units.

Regulations

Medical devices regulations fall under the purview of the Drug Administration and Control Authority of Ethiopia. Regulations are under development (95).

Intellectual property

Ethiopia is developing its IP laws. Patent codes were drafted in 1995 by Proclamation No. 123 Concerning Inventions, Minor Inventions, and Industrial Designs, and instituted in 1997 by Regulation No. 12. The codes served to encourage local innovation and transfer foreign technologies. In 2003, the Ethiopian Intellectual Property Office (EIPO) was established under the Ethiopian Science and Technology Agency, to provide legal protection for IP rights. Ethiopia is negotiating entry into the WTO and is developing its IP laws (96) in preparation.

Ethiopia's largest research institutions for medical device innovation lie in the Ethiopian Health and Nutrition Research Center, and in Addis Ababa University and Alemaya University. Each institution produces locally or regionally marketable research results. The EIPO has received few patent applications from universities in recent years. Those that are filed are primarily in the fields of agriculture, pharmaceuticals and mechanics.

Trade and local production

Ethiopia ranks 111 out of 183 countries in the World Bank *Doing Business 2012* survey (32). Between 2005 and 2010, the country experienced significant growth in medical device imports such as wheelchairs, medical furniture and sterilizers. These imports comprised the bulk of all medical device spending in health care. Espicom (2011) data indicate that only 30% of Ethiopia's medical

device imports come from western Europe, the United States, and developing nations such as China and India.

Examples of local production and collaboration

Local production is somewhat limited and the production that does take place tends to be in low-technology medical devices and furniture. There are notable exceptions. Some medical device manufacturers such as Q-Diagnostics based in Addis Ababa, designs and develops medical devices such as baby incubators for low-resource settings. The devices retail at 30% to 40% less than their imported counterparts, and can be purchased or rented. Others in the health care field such as the Gotland Specialist Higher Clinic work closely with Swedish doctors and medical device manufacturers to stock the clinic with loaned specialized devices for women's health needs (97).

d. India | South-East Asia Region

India is a lower middle-income country with a population of roughly 1.22 billion people (2010). Similar to China, it is experiencing significant change as it strives to meet the needs of its growing population. India's reported number of people living below the national poverty line was nearly halved from 45.3% in 1998 to 29.8% in 2004. Like China, its poverty line of 9,490 Rs. to 11,680 Rs. – approximately US\$ 173 to US\$ 213 – per capita annually for rural and urban settlements, is subject to strong debate. Social determinants of health indicators are uneven but largely promising. For example, while male literacy sits at 82.14%, female literacy trails at 65.46% (2011) (54). In other health metrics, average life expectancy at birth is 65 years, and maternal mortality is 230 per 100 000 live births (2010), dropping from 390 in 2000. There are 0.65 physicians per 1000 inhabitants in India (2009). The top three leading causes of death are cardiovascular, respiratory and diarrhoeal diseases.

Health system organization and financing

India's rising life expectancy and performance in fertility and mortality rates pose dual challenges for simultaneously improving primary and secondary health care services (55). This challenge takes place alongside competing priorities and an economic situation that is shaped by rapid industrialization, environmental risks, new economic liberalization programs, and rising rural-migration waves that have increased the number of urban slum dwellers and raised concerns over equitable access to health in these settlements. Significantly, the latter trend has prompted India's National Health Policy of 2002 (NHP) to respond with a two-tier urban health care system with a primary health centre for 30 000 people, and community clinic for each 100 000 people.

Public health funding is low despite the relatively high number of people living below the poverty line. Federal, state and local governments contribute roughly 25% of total expenditures through general tax revenues, while social health insurance represents a minor portion. Private health insurance contributes an even smaller percentage, and increasingly targets high-income urban households, while community-based insurance schemes are becoming more common in rural areas (56,57). Most payments (approximately 75%) are

out-of-pocket payments for patients, which have marginally declined over ten years with the help of better financial risk protection. Donor funding as a percentage of total health expenditures has been consistently low during this period and plays a limited role in financing India's medical care (55). The NHP recognizes the need to increase public support and contributions to health and is exploring initiatives such as public–private partnerships, voluntary and community health insurance.

Research suggests that inadequate medical device supplies and poorly working devices present greater challenges in India's health systems than it does in China's, and will contribute to widening disparities in household access to affordable medical care (58,59). Like China, the Indian distribution of overall diagnostic and basic medical devices skews towards the private sector and urban areas such that studies have found that 64% of all diagnostic equipment was located in five cities and targeted only 4.5% of India's total population in 2004 (60). The numbers are significant given that 72.2% of India's population live in rural areas. India represents contrasts where world-class doctors attract medical tourists from around the world, and yet, a proportion of Indians cannot afford basic health care.

Insufficient health system financing creates weak payment incentives that do little to improve medical device supply chains. These factors self-sustain such that the Indian public health sector faces acute shortages of basic and high-end medical devices relative to the private sector. Studies by Mavalankar et al (2004) (61) and Mahal et al. (2006) (62) indicate that 45 to 51% of all devices in the public sector were either not functional or not being used. Varshney (2004) (60) further noted that medical device inefficiencies across the public sector have both raised the cost and lowered the quality of care for households relative to the private sector (43). In these instances, those who rely on the public health system because they cannot afford private services, are forced into the informal private sector where the quality of devices and care are uncertain, or they may choose to forgo seeking any medical care. WHO field notes also indicate that private health regulations are generally weak, such that complaints are seen relating to poor quality, high fees and unethical behaviour (55).

Regulations

Medical devices are regulated by the Medical Devices Division of the Central Drugs Standard Control Organization (CDSCO) in the Ministry of Health and Family Welfare. The division primarily acts to disseminate information on registered medical devices and drugs, licensed distributors, and compliance. Information relating to enforcement mechanisms is limited. The CDSCO maintains a distinct division of responsibilities between central and state governments that includes the drafting of device standards and regulations of clinical research (central government) as well as recalls and licensing of drug manufacturing sites (state governments). Medical device manufacturers and importers have access to registration/application forms through the main CDSCO website, though regulations focus on drug manufacturing and medical device clauses are summarily added to the 1940 Drug and Cosmetics

Act and 1945 Drug and Cosmetics Rules. The National Pharmaceutical Policy was introduced in 2002 but does not include mention of medical devices.

Table 5 Medical device regulation in India

Medical device regulation in India	
National Regulatory Authority	Central Drugs Standard Control Organization (CDSCO) in the Ministry of Health and Family Welfare Drugs and Cosmetics Rules Act: http://cdsco.nic.in/Drugs&CosmeticAct.pdf
Risk classification system	No risk classification system Only certain categories of devices require registration
Requirements for registration/ importation	Must be approved for sale in the country of manufacture Device Registration Certificate (Form 40) Schedule D-I and D-II ISI Mark certificate from Bureau of Indian Standards if device is not registered in US, EU, Japan, Canada or Australia Compliance with GHTF member country requirements
Vendor registration/ licensing	Indian authorization agent holding 20B and 21B licenses required for registration, vigilance and inspection activities
Recognized certifications/ approvals	Registration in US, EU, Japan, Canada or Australia can fast track the review process
Quality system requirements	Must comply with quality system standards of country of manufacture
Medical device labelling	Indian Standards Specifications by the Bureau of Indian Standards

Overall, regulations specific to the India medical device industry are somewhat limited and lack clarity and transparency, while low internal quality standards produce wide variances between products on the market. Significantly, certain categories of medical devices require registration as drugs under the Drugs and Cosmetics Act. These devices are: blood/blood component bags; blood grouping sera; bone cement; cardiac stents; catheters; condoms; disposable hypodermic syringes; disposable hypodermic needles; disposable perfusion sets; drug eluting stents; heart valves; internal prosthetic replacements; intraocular lenses; intra uterine devices; in vitro diagnostic devices for HIV, hepatitis B surface antigen and HCV; intravenous cannulae, orthopaedic implants; scalp vein sets; skin ligatures; sutures and staplers; surgical dressings; tubal rings; and umbilical tapes.

Intellectual property rights

Steps are being taken to strengthen IP protection systems and policies (49). India has a strong science and technology base and became fully compliant with TRIPS in 2005. The local medical device sector was among the first to grasp the implications of the new patent regime, the need to reassess internal IP policy, and the value of R&D-focused spending in low-resource markets. In this era, some companies increased their research budgets to as much as 10% of their total budgets. Public agencies such as the Indian Council of Medical Research (ICMR) adopted IP policies to promote R&D, encouraged partnerships with industry, and created incentives for patent filing. More recently, there have been attempts to create a strong force of technology transfer professionals through networking partnerships between the ICMR and agencies such as the National Institutes of Health (NIH) and the Centre for the Management of Intellectual Property in Health Research and Development (MIHR). In 2005, the formation of the Society for Technology Managers (STEM) was a significant turning point in IP management in India (49).

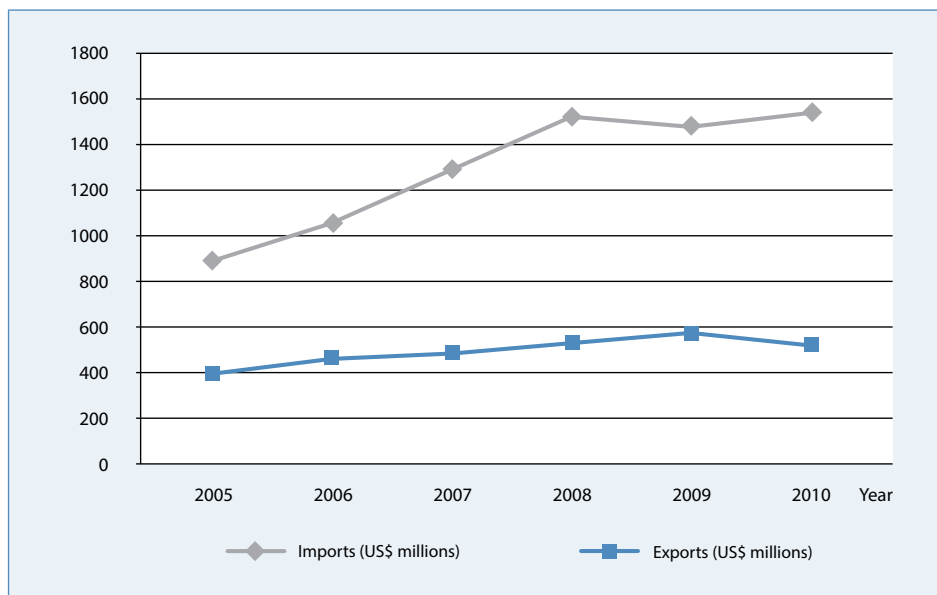
The majority of public sector IP and technology transfer expertise remains in government agencies, particularly in the Council for Scientific and Industrial Research (CSIR), the Department of Science and Technology (DST), and the Department of Biotechnology (DBT) (49). Most academic institutions lack IP management capacity, with the notable exception of leading Indian Institutes of Technology (IITs) and a few other universities such as Delhi University and Jadavpur University. Significantly, a substantial portion of R&D carried out in Indian universities is not IP-protected, in large part because India's university system lacks a sufficient number of technology transfer offices (TTOs) or innovation centres to help university researchers protect and exploit new innovations. Additionally, as a matter of policy, most government agencies own all the IP generated through public-funded research such that inventors have limited incentive.

The Indian government is addressing the IP issue and is considering enacting legislation modelled after the US Bayh-Dole Act that would allow university inventors to own patents generated from federally funded projects (49). Other attempts to spark and sustain innovation include efforts by the DBT to boost public-private partnership efforts, as well as the National Innovation Foundation (NIF) that promotes local inventions and helps to build value chain around them. So far, about 37 000 innovations and traditional knowledge examples have been identified from more than 350 districts.

Trade and local production

India ranks 132 out of 183 countries in the World Bank *Doing business 2012* (32). Its total trade (imports plus exports) in medical devices has steadily risen from 2005 to reach US\$ 2.1 billion in 2010 (7). Local manufacturers forward 60% to 75% of their products through export channels, though on a macro-level, imports outpace exports (Figure 7), largely as a result of current trade laws that indirectly favour imports by charging higher duties on certain raw materials than on finished goods (58).

Figure 7 Imports and exports of medical devices in India, 2005–2010



Source: *Medical markets fact book 2011*. Espicom Business Intelligence

Medical device manufacturers operate in a unique business landscape. India is eager to attract foreign direct investment as a means of reducing its current account deficit yet faces cultural anxiety when it is perceived to open its gates too widely to international businesses. Managing and addressing the politics of these internal anxieties is further compounded by Indian firms who themselves are looking abroad to overcome local bureaucratic hurdles and slow reforms that impede growth, and a growing number of multinational companies eager to enter joint ventures with local companies, establish subsidiaries, employ local agents, or set up manufacturing and assembly units in India (63).

Similar to China, India's medical device industry is fragmented and local producers tend to focus on low-end technologies. However, it too is growing its market share in diagnostic imaging equipment and in particular, in MRIs and positron emission tomography (PET) scanning devices. Technology transfer takes various forms, ranging from imports to joint ventures and/or subsidiaries through foreign direct investment, and local manufacturers. India's domestic production capacity is advancing and local producers are increasingly leveraging state-of-the-art technology to produce locally relevant innovations. Significantly, public health sector providers have responded to weak payment incentives and poor regulations by contracting directly with medical device companies. Researchers Varshney (2004) (60) and Baru (1998) (64) found that companies pay public providers up to 10 to 15% commission on the sale and use of diagnostic devices and services, with commissions as high as 30% for high-end medical devices (60,64).

Examples of local production and collaboration

International companies such as GE Healthcare are developing innovations specific to the Indian rural market, and in so doing, going against a common

industry practice of adapting existing models to rural contexts. In 2007, GE debuted the MAC 400 electrocardiogram as a high quality, simple to use, ultra-portable machine that could be easily carried into patient homes. The device was designed and manufactured in India and cost a fraction of hospital-grade units (65).

Other examples of international, inter-industry collaborations leading to local innovation and production include the Leveraged Freedom Wheelchair developed by American MIT Mobility Lab in conjunction with the Indian Bhagwan Mahaveer Viklang Sahayata Samiti (BMVSS), the world's largest NGO working on devices for people with disabilities. The wheelchair allows users to travel 75% faster (66), while BMVSS produces frugal innovations in its own right, including the 'Jaipur Foot'. The Jaipur Foot was co-invented by craftsman Ram Chandra Sharma and surgeon Pramod Karan Sethi in 1968. It utilises soft, locally available materials such as rubber to create durable prosthetics (foot and above the knee) for amputees. Above all, the prosthetics are offered free of charge. BMVSS now supports 30 institutions by transferring technology and training personnel in the challenges associated with loco-motor disabilities. In 2003, roughly 1% of India's population (i.e. roughly 10 million people) suffered from loco-motor disabilities.

Other local innovations led by Indians include Skanray Technologies in Mysore that produces low-cost x-rays and the Aravind Eye Care System that offers specialised eye care clinics custom-designed, cost-effective devices specific to patient needs. India is home to 10 million cases of blindness. In 1992, imported lenses cost roughly US\$ 200 in India, placing them beyond the reach of most Indians. The Aravind Eye Care System responded with high-quality lenses for US\$ 5, and now produces other ophthalmic devices. WHO estimates that globally 45 million people are blind and that 85% of those cases could be cured or prevented.

e. Jordan | Eastern Mediterranean Region

Jordan is an upper middle-income country with a population of roughly 6 million (2010). Social indicators show slow but steady gains: in 2010, 92% of rural Jordanians had access to potable water, up 2% from 1990; Jordan's reported number of people living below the national poverty line hovered around 13% in 2006 and 2008. Life expectancy is 73 years (2010), consistent with other MICs but slightly higher than that in other Middle Eastern and Northern African (MENA) countries. Its maternal mortality rate is 63 per 100 000 births (2010) dropping from 79 in 2000. There are 2.45 physicians, 4.03 nurses and midwifery personnel, and 1.41 dentists per 1000 inhabitants (2009). Jordan's leading causes of death are: circulatory system diseases, cancers, and external causes, though there is growing incidence of obesity.

Health system organization and financing

Health spending is high relative to other MENA states and its public and private sectors work in tandem to improve and modernize local health care infrastructure. In 2009, the World Bank ranked Jordan as the leading medical

tourism destination in the Gulf region and placed it among the top five medical tourism destinations in the world. Costs for certain procedures such as gastric bypasses are reported to be 10% to 30% of comparable procedures in Europe and the US (82).

Jordan's health system is largely delivered through two public programmes: the Ministry of Health and Royal Medical Services. It is supplemented by a network of NGOs, smaller public organizations, and a large private sector (83). Significantly, while the government is the largest health care provider, it has reduced its financing role over time. Between 1998 and 2003, public expenditures gradually decreased from 51% to 42%, while private expenditures increased from 49% to 58%, indicative of its growing importance and increasing interest among Jordanians to secure health insurance. Several social insurance schemes cover different segments of the Jordanian population and have varying requirements, cost sharing rates, and benefit packages. Jordan's largest public insurance schemes are delivered through the Civil Service Programme and Royal Medical Services Fund and cover both formal sector and low-income groups. Private health insurance represents roughly half of all insurance schemes with companies offering some – though mainly high-end – services for the primary care of wealthier individuals. In 2004, roughly 68% of Jordan's population were covered by a formal insurance programme.

Medical personnel and managers are paid on salary or salary plus bonus depending on the government agency or insurer, while private providers and some public providers are reimbursed from private and public health insurers through fee-for-service. However, unlike traditional fee-for-service schemes, a Medical Fees Committee sets prices for inpatient, outpatient and laboratory services in order to control costs.

On average, household out-of-pocket payments fell from 30% to 29% of total spending between 2000 and 2009, aided in large part by lower cost sharing rates between payers and providers. The bulk of Jordan's external donor funding includes contributions from the United States Agency for International Development (USAID), some European governments and the UNDP though these contributions have gradually fallen relative to overall health spending (84).

From 1998 to 2006, the Jordanian Government undertook a number of health reforms including the following adoptions: a National Health Policy; health strategy (notably, to implement a national health insurance programme and improve health care financing); health insurance reforms (notably to insure the families of female government employees); and pharmaceutical reforms (notably in 2002, the Jordan Drug Policy was adopted to rationalise drug production, procurement, use and distribution.)

Regulations

The Jordan Food and Drug Administration (JFDA) was established in 2003 to regulate medical devices. All imported devices require approval from the JFDA Director General, and medical devices that include a pharmaceutical component are subject to review by a Medical Device Committee. It is yet unclear what requirements, if any, apply to local manufacturers, and

regulations in general, are few. At this stage, most medical devices are not subject to evaluation of safety and performance, and manufacturing sites do not appear to be subject to quality inspections. In 2004, the Joint Procurement Directorate was established to determine the pharmaceutical needs all public health providers and purchase supplies and equipment accordingly. Drug-related costs comprise up to 30% of hospital expenditures.

Table 6 *Medical device regulation in Jordan*

National Regulatory Authority	Jordan Food and Drug Administration (JFDA)
Key laws/regulations	Medical Devices Importation Directives (2003), Food and Drug Law (2003), Drug & Pharmacy Law (2001)
Risk classification system	EU classification according to Directives 90/385/EEC and 93/42/EEC
Requirements for registration/importation	<ol style="list-style-type: none"> 1) Product and manufacturer details 2) JFDA accredited certificates according to risk class 3) Quality control certificate for drug components 4) Certificates for human or animal products 5) Certificates from US FDA, EU, Switzerland, Australia, Japan, Canada and Norway 6) Evaluation of importation request to Medical Device Committee
Recognized certifications/approvals	Certificates from US FDA, EU, Switzerland, Australia, Japan, Canada and Norway
Post-market surveillance requirements	Medical centres and hospitals must report serious/fatal incidents incurred from the use of a medical device
Quality system requirements	No quality management system requirements for medical devices; GMP requirements do apply to drugs
Testing requirements	<ol style="list-style-type: none"> 1) Devices that include a pharmaceutical 2) As indicated by the Medical Device Committee
Labelling requirements	Batch/lot number, expiry date, name of authorization holder, country of origin, storage conditions, CE mark (if applicable)
Advertisement	Not allowed without special approval

Intellectual property

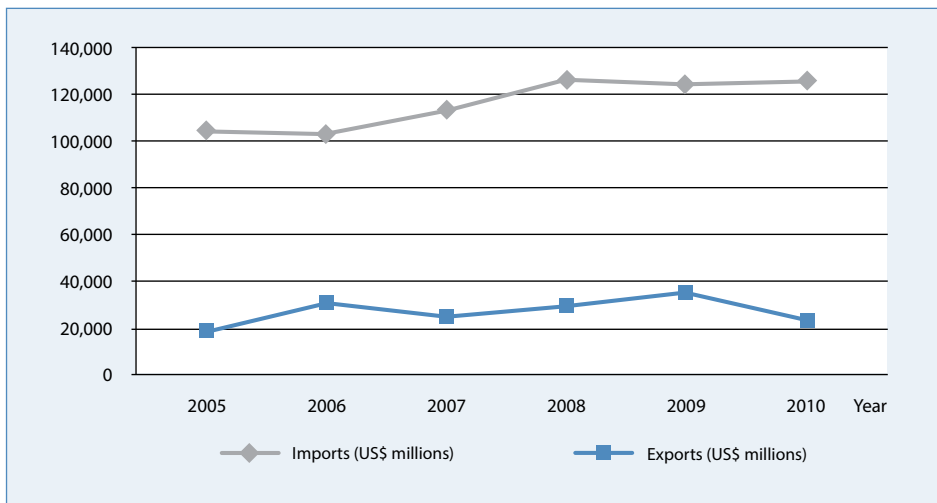
Jordan joined the WTO in 1999 and signed onto the TRIPS agreement shortly thereafter. In 2001, it entered the U.S.–Jordan Free Trade Agreement, which led to further IP reforms. Jordanian law is flexible in its approach to commercializing

technology developed in public sector institutions and patents are issued by the Industrial Property Protection Directorate (IPPD) of the Ministry of Industry and Trade. To date, however, only the Royal Scientific Society, the premier government research institution, reports having established a Technology Transfer Centre.

Trade and local production

Jordan ranks 96 out of 183 countries in the World Bank *Doing Business 2012* survey (32). Its medical device market contributes a relatively large percentage of total health spending, even though the figure fell from 9% in 2005 to 8% in 2010. Consumables represented the greatest overall share of the market and increased by nearly 35% over the same period, followed by diagnostic medical devices, and to a less extent, dental products, orthopaedics, patient aids, and other devices. Initial data suggests that Jordan spends more on medical devices as a percentage of national health expenditures than any other country discussed in this section. Yet medical device spending as a percentage of national health spending declined from 2005 to 2010, from 9.7% to 7.8%, largely due to slower growth in high-end medical devices such as diagnostic imaging (MRI, CT, X-rays), orthopaedic devices, patient aids and wheelchairs. Spending on consumables, including syringes, needles, gloves and other basic medical devices, grew at a much faster pace and ultimately surpassed that of high-end diagnostics by 2010.

Figure 8 Imports and exports of medical devices in Jordan, 2005–2010.



Source: *Medical markets fact book 2011*. Espicom. *Business Intelligence*.

Domestic production is relatively limited such that Jordan is heavily reliant on medical device imports. Most imports are from Germany and the United States. Espicom estimates the Jordanian medical device market to be worth US\$ 178 million in 2011, and will grow to US\$ 268 million by 2016.

Examples of local production and collaboration

Similar to most countries in the Gulf, Jordan has few local medical device manufacturers, somewhat contradicting its ranking as a medical tourism destination and its ranking in the *Doing Business 2012* survey (32) where it fares better than Brazil and India and sits only five steps lower than China. Potential reasons point to indigenous cultural factors such as a relatively young biotechnology entrepreneurial culture and comfort in importing medical goods. However, many companies are actively engaged in distributing devices and Jordan is developing a reputation for being the first country in the region to import and distribute a range of sophisticated high-tech devices such as the cardiac resynchronization therapy defibrillator that enables home monitoring (85). Medical devices that are produced locally tend to be basic equipment and consumables such as syringes and medical disposables.

Jordan offers an interesting case study in local production and collaborations because its government is trying to nurture a nascent local production capacity. Furthermore, unlike Brazil, China and India where on-the-ground medical device innovation is growing in tandem with top-down policies, Jordan offers an example where top-down policies are trying to spark change on-the-ground. In 2011, the Gulf Cooperation Council (GCC) approved Jordan's request for membership. Formal membership is still pending. The GCC strives to promote economic growth and collaboration among its member states. In 2010, in a report on Medical Devices, the GCC noted that:

The GCC medical devices manufacturing sector remains insignificant – meeting below 5% of overall domestic demand – despite government attempts to encourage foreign investment. Production is limited to basic items... [However] given the absence of local manufacturers, [the presence of] a fast growing market and a relatively easy market access, the GCC remains an opportunity for manufacturers of all kind of medical devices with the exception of those at the low end of the technological scale (86).

2.10 Success stories

The following section highlights companies that have led medical device innovations in their field. Collectively, this set of devices addresses communicable and noncommunicable diseases. As shown in these case studies, medical devices are unique from medicines in that they spark innovation in a variety of fields from textile manufacturers that produce water-filtration devices, to car mechanics that developed vaginal assisted-delivery devices. The sheer breadth of innovation in diverse fields poses unique challenges, not least of all for innovators from non-clinical backgrounds who lack credibility until their device is championed by a senior health care official or bureaucrat with significant personal credibility. Other challenging hurdles include limited access to early-stage financing, weak business environments, weak regulatory systems and policies, local perceptions that locally produced goods are inferior to foreign imports, low indigenous skill levels, government bureaucracy and/or corruption, and poor quality resources or large variances in resource quality.

This scoping exercise on the feasibility of local production, together with the survey, and stakeholder meeting contribute to a growing body of research on priority medical devices in the face of the world's evolving disease burdens. The UN Commission on Life Saving Commodities, in particular, recommends 13 commodities for maternal, child, and newborn health. The WHO Medical Devices team adds to this with recommendations to further consider five frugal innovations in low-resource settings. These low-cost, high quality innovations help address:

- MDGs and in particular, maternal and newborn health, e.g. continuous positive airway pressure (CPAP) devices, vaginal assisted-delivery devices and the non-pneumatic anti-shock devices;
- the growing burden of diseases associated with aging: e.g. hearing aids;
- the growth of NCDs: e.g. electrocardiographs.

Four of these devices are analysed in greater detail in the following section, which considers ten devices for low-resource settings:

Neonatal intensive care equipment:	Devices offered through the Breath of Life Programme in eight countries in South and South-East Asia.
Water filter:	A point-of-use water filtration device.
Mechanical heart valve:	Award-winning valves produced in India and exported to neighbouring countries.
Foot prosthetic:	Leg and knee prosthetics made of locally sourced materials. The prosthetics are offered without cost to amputees.
Intraocular lenses:	Lenses developed at less than one eighth of the price of comparable imports.
Telemedicine unit:	Programmes in South Africa to offer services to remote populations.
Non-pneumatic anti-shock garments:	Device controls the impact of post-partum haemorrhage.
Odon device:	Assisted vaginal delivery device.
Solar hearing aid:	A solar powered hearing aid.
Electrocardiograph:	Affordable devices designed and developed by academic researchers and PhD students.

Neonatal intensive care equipment

Introduction

Health care facilities in low-resource countries often lack the appropriate equipment and trained personnel to treat newborn children, such that 98% of infant deaths occur in these countries (98). The East Meets West Foundation (EMW) has successfully introduced neonatal intensive care equipment through the Breath of Life (BoL) programme. To date, the programme is operational in nearly 300 hospitals in eight countries in Asia.

Analysis

EMW, in partnership with the Viet Nam Ministry of Health and a local private medical company, Medical Technology Transfer and Services (MTTS), developed a suite of medical devices for low-resource settings. The equipment is durable, does not require expensive consumables, is easy to use and maintain, and comes with a three-year warranty. EMW delivers the equipment through BoL, a full neonatal care programme that provides intensive technical and clinical training, frequent monitoring, regular follow-up and on-going support, basic supplies for disinfection and infant care, and all necessary ancillary equipment.

Challenges

Key challenges lie in producing highly efficient and affordable medical devices in low-resource settings where locally sourced components are often poor quality; off-the-shelf components are used to allow low volume production; and there is variation in quality provided by local suppliers of outsourced materials. With time, the machines have used an increasing amount of imported components to ensure high standard of dependable quality. New models are made of both locally sourced and imported components and materials.

Steps taken

EMW and MTTS involved local users (mostly doctors and nurses at the lowest level of care) in conceptualizing the devices so that they met local need. Alpha prototypes are shown to the users for initial testing, while Beta prototypes (improved Alpha's) are then piloted in the field. All processes are followed by international and local clinicians and epidemiologists to ensure the highest standard of quality and safety in all phases of product development.

Technology transfer

While at the outset, there were only five ill-equipped neonatal intensive care units (NICU) in Viet Nam, NICUs featuring BOL technologies are now available in every of the 63 Viet Nam provinces, treating more than 50 000 infants per year. EMW has signed a business partnership with GE Health Care (GEHC) that will bring the BoL model to other LMICs.

Success story

EMW equipment is specifically designed to meet local needs. In Viet Nam, the 24-hour infant mortality rate was reduced by 70% one year after the introduction of the BoL CPAP at the National Hospital of Paediatrics in Hanoi, Viet Nam (99). After three years of introducing BoL in Viet Nam, mortality and morbidity rates have been significantly reduced in the hospitals that have received the BOL programme. Viet Nam has had remarkable success in reducing neonatal mortality, from 20.9 deaths per 1000 live births in 1990, to approximately 8.3 deaths in 2010.

Water filter

Introduction

In 2000, WHO reported that 4 billion cases of diarrhoea occur each year, of which, 88% is attributed to unsafe water and inadequate sanitation and hygiene. It also revealed that 1.1 billion people drink highly contaminated water, and that waterborne diseases contributed to mortality among people living with HIV (100).

Analysis

Key success factors to treating water in LMICs are techniques that are accessible, simple, affordable, self-sustaining and decentralized at point of use. These were contrary to the traditional water purification systems that evolved from developed countries but failed.

Challenges

The Danish–Swiss company Vesterdgaard Frandsen developed the LifeStraw water filter to help meet the challenge of low-cost, decentralized water filtration. The concept was novel: a straw with an in-built filter that would filter water as it was being consumed. In developing the product, the company had access to required technology but had to learn LMIC cultural and environmental factors for effective product design. Marketing presented additional challenges: the company needed to educate the market on the new methods to filter water. Finally, the target market did not assure sizeable profit margins and the company was challenged to produce an affordable product for developing countries despite the complex supply chain needed to produce the device.

Steps taken

The company worked closely with Carter Center, USA and NGOs working in different parts of the world to develop and validate the product (101).

To ensure product volume, reduce investments in product education and to reduce investments in a complex supply chain, the company focused on supplying the product through NGOs, donor agencies and an innovative “Carbon for Water” programme (102,103).

The final product was priced at US\$ 3.50 per unit. Measuring 31cm long and 2.9cm in diameter, and weighing 150g, the LifeStraw can filter at least 1000 litres of contaminated water, has a high flow rate, does not involve any chemicals, and does not need an electrical source or replacement parts. It could remove 99.9% of all bacteria, viruses and protozoal parasites at point of use (101,104, 105).

Technology transfer

After initial production and supply through NGOs and donor agencies, the company partnered with leading local companies for increased access through local production of LifeStraw.

Success story

In 2007, this once struggling textile manufacturer was listed as one of the top 50 fastest growing companies. By 2010, it was approximately 20 times the size it was in early 1990s (106). As of 2008 reports, the company has supplied around 200 000 LifeStraw units to LMICs (101). Currently headquartered in Switzerland, the company has offices in Asia, Africa and the US.

Mechanical heart valve

Introduction

In 1978, the Indian Council of Medical Research estimated that over one million children in the country could risk developing rheumatic heart disease (RHD) due to rheumatic fever (RF) (107–111). At the time, the disease was one of the leading causes for mitral valve disease in LMICs. The disease continues to be prevalent today, with 15.6 million million cases reported globally in 2005.

Analysis

Common treatments to address mitral valve disease include: valve repair and the replacement of damaged heart valve with either an artificial mechanical heart valve or a biological valve of animal origin. Yet rheumatic diseases were found to be closely associated with overcrowded, poor living conditions. The causation posed new challenges. Not only were the poor unable to afford expensive surgeries, the disease disproportionately affected people under the age of 30 such that it effectively ruled out the use of biological valves as they had comparatively shorter life spans. Furthermore, the Indian medical device market was largely met by expensive imports that were unaffordable to India's poor. There was a growing need for durable, affordable mechanical heart valves (107,108).

Challenges

India's biomedical engineering industry was quite nascent in 1978. Furthermore, product development was constrained by unique cultural factors such as religious beliefs (which ruled out porcine and bovine transplants), market perceptions, and logistics. Leading surgeons demanded that the products meet international quality and safety standards, while local populations felt that products "made in India" were inferior to foreign imports. Finally, the product needed to be open to new markets outside metropolitan cities. Success lay in building efficient supply chain in to such regions across India for timely accessibility.

Steps taken

The Sree Chitra Tirunal Institute for Medical Sciences and Technology evaluated four models that incorporated different materials (107) over 12 years (112). The final result was a mechanical heart valve with a tilting occluder made of tough and wear-resistant plastic, a metallic cage, and a sewing ring of knitted polyester fabric (107). The device was made entirely of mechanical components, was simple in design, easy to transport, and was manufactured locally. Above all, it was roughly one third the price of comparable foreign imports (113). The product met standards of relevant international protocols for laboratory tests and animal trials and cleared ethics committee review. It debuted in 1990.

Technology transfer

Sree Chitra Tirunal Institute transferred the technology to a leading Indian company. The company had a strong pharmaceutical network across the country and strong supply chains.

Success story

To date, the device is the only locally-manufactured heart valve made in India. It has won awards (114–116) and is used in around 275 centres in India. Approximately 55 000 valves have been implanted since 1990. It steadily supplies a sizable portion of domestic demand for heart valves which is roughly 30 000 per year (108) and is being exported to other countries such as Kenya, Myanmar, South Africa, Sri Lanka and Thailand.

Jaipur Foot prosthetic

Introduction

Twenty to fifty million people around the world are injured in road traffic accidents each year (117), while in LMICs traffic accidents account for the main cause of limb amputation (118). A 2003 survey revealed 10 million people with loco-motor disabilities, while an earlier 2001 census revealed that 75% of people with disabilities lived in rural areas (119).

Analysis

Limb prosthetics have evolved over time. Early, locally-manufactured models were cumbersome, often made of laminated wood and rubber that were heavy to use. The percentage of rejection was high. Furthermore, not only did it take weeks and sometimes months to make the prosthetic, it was cost-prohibitive for most amputees (120).

Challenges

In 1968, master craftsman Ram Chandra Sharma and surgeon Pramod Karan Sethi developed the Jaipur Foot; a leg and foot prosthetic made of soft, locally available materials. However, a key challenge lay in developing a viable business plan that would make the devices free to their target audience: marginalized low-income groups (121).

Steps taken

The co-inventors used different types of rubber, wood and other supporting materials to make a multi-flex foot, as close as possible to the human foot in functional terms. The wooden socket was later replaced by aluminium to make the limb comparatively lighter (120). The co-inventors joined the Bhagwan Mahaveer Viklang Sahayata Samiti (BMVSS) to develop a business model that leveraged roughly 60% of total funding from donations, 30% from government support and the remaining 10% was earned income on corpus (121).

Technology transfer

The Jaipur Foot was aesthetically similar to the human foot, had correct biomechanical alignment and was quick to fit. It was also lightweight (below knee: 1.3 to 1.5 kg; above knee: 2.25 to 2.5 kg), waterproof, could be used bare as well as with shoes, and lasted up to three years (122,123). The Jaipur Knee, made in collaboration with Stanford University, is a self-lubricating, oil-filled nylon prosthetic priced at US\$ 45; considerably cheaper than comparable imported prosthetics that were roughly US\$ 12 000. In 1975, the Jaipur Foot manufacturers began offering free prosthesis in India under BMVSS. During their first year of operation, the Jaipur Foot team fitted 59 limbs (120,121).

Success story

Today, this venture is a non-profit social enterprise staffing 20 centres across India and servicing 65 000 patients each year. Over the years they have served more than 1.2 million individuals, and have set up mobile clinics in 26 countries around the world, including Afghanistan, Iraq and the Sudan.

Intraocular lenses

Introduction

In the 1970's, spurred by WHO initiatives to promote eye health, the government of India worked with NGOs to diagnose and treat cataracts in India's rural areas, in which 70% of the population lived.

Analysis

Domestic need for intraocular lenses was considerable, with estimates suggesting more than 10 million individuals suffered from bilateral cataract, while another 10 million individuals had cataract in one eye (124). Cataract surgery was a viable solution, but imported intraocular lenses were roughly US\$ 200; placing them out of reach of most rural Indians. At the time, private investors and MNCs were reticent to address domestic need because of low profit margins or the potential for economic loss (125).

Challenges

The Aravind Eye Hospital partnered the government project to improve access to eye health in rural areas, but soon faced challenges in offering widespread access to effective cataract treatment. It met the challenge through Aurolab, an NGO it built in 1992 (126).

Steps taken

Aurolab had the necessary capital to produce intraocular lenses, but did not have access to intraocular lens-making technology (126). Efforts to obtain the technology were largely unsuccessful, as large, international medical equipment manufacturers were unwilling to share it. Aurolab thus partnered with Seya Foundation and Combat Blindness Foundation, which identified small companies that were willing to provide the technological know-how to manufacture intraocular lenses in India (126).

Technology transfer

With the help of the two partner organizations, Aurolab transferred technology from a small US-based company. To reduce product price, Aurolab focused on reducing capital investment and leveraged India's comparatively lower labour costs. It also produced large batches of lenses that would help further decrease the per-unit manufacturing cost. Surplus units were exported through the help of an NGO (124, 126).

In 1992, Aurolab produced nearly 35 000 polymethyl methacrylate lenses for roughly US\$ 10. The lower price compared favourable against costly foreign imports. Over time, costs were further reduced to under US\$ 4 (125–127).

Success story

Aurolab has since expanded its product lines to include foldable lenses. This technology helps simplify surgery, offers faster recovery time, less astigmatism, and fewer post-operative complications. The Aurolab foldable lenses were US\$ 22 while foreign imports ranged between US\$ 80 and US\$ 100 (126). Aurolab now produces nearly 600 000 lenses that are exported through various NGO partners to more than 100 countries, and represent 10% of the global market for intraocular lenses (124–126).

Telemedicine unit

Introduction

The 2001 South African census revealed marked differences in population density and 'tele-connectivity' – population density ranged from 432 people to 2 people per square kilometre (128) while 24.4% of households had fixed line phone connectivity, 32.3% had a mobile phone, 8.6% had a computer, 73% were connected by radio and 53.8% had a television (129).

Analysis

The South Africa population density and growing use of telecommunications hinted at potential solutions to reducing access-to-healthcare gaps through telemedicine.

Challenges

Telemedicine is gaining increasing attention in HICs, but is relatively untested in LMICs. In large part, telemedicine trials in LMICs have been hampered by limited capital, resources and organizational culture. Telemedicine demanded core capacities in telecommunications infrastructure, affordable and compactable medical peripherals that were adaptable to rugged working environments, trained personnel, and a socio-political will to try new methods of health care delivery (130,131).

Steps taken

The Medical Research Council (MRC) of South Africa, in collaboration with the Department of Health, established a Telemedicine unit. The unit did extensive studies and successful pilot trials (132). Dr LM Molefi, then director of the Telemedicine unit, started an enterprise that focused on large scale implementation of telemedicine – procurement, supply, maintenance and installation of technology (133).

Technology transfer

Dr LM Molefi entered an agreement with a Chinese firm to distribute telemedicine equipment and technologies in South Africa (132,134).

Success story

In 2011, the company successfully implemented its first large scale telemedicine project in the Limpopo province, connecting 14 regional hospitals (132). The company has been funded by the African Development Bank to work in 14 southern African countries and has also signed an agreement with US-based company to extend its services through mobile phones (133,135). The company recorded 5 million Rand in revenue (around US\$ 600 000) and has grown its staff team from two to eight employees. It has won local and international awards (136).

Non-pneumatic anti-shock garments

Introduction

Postpartum haemorrhage (PPH) continues to be the single most common cause of maternal morbidity and mortality in the world, accounting for approximately 25% of maternal deaths globally. Over 90% of these deaths occur in low-resource countries where the infrastructure and training at primary care facilities are insufficient to handle obstetric emergencies. If not treated immediately, PPH can cause irreparable damage to vital organs or death from hypovolemic shock. In severe cases, when the administration of uterotonic drugs does not stop the bleeding, it is critical to access an obstetric care facility with blood transfusion and surgical capabilities.

Analysis

For women suffering from uncontrollable PPH, it can be life-saving to control the bleeding, reverse the shock, and stabilize the patient for safe transport to a comprehensive obstetric care facility (137).

One method to manage PPH and to manage reverse shock is the use of a non-pneumatic anti-shock garment (NASG). The NASG is a lightweight neoprene garment that resembles the bottom half of a wet suit. It is comprised of five segments that close tightly with Velcro. The NASG applies pressure to the lower body and abdomen, thereby stabilizing vital signs and resolving hypovolemic shock. When fitted correctly, the reusable NASG forces blood to the essential organs – heart, lungs and brain – and allows the woman to be transported to an obstetric care facility (138).

Challenges

Currently, the NASG is not readily available in most low-resource settings. Also, despite recent reductions in price, distribution remains a challenge. Once the NASG is affordable, available, and accessible, the NASG could play an important role in reducing mortality and morbidity among women that experience PPH.

Steps taken

PATH developed a package of quality standards, engineering documents and quality inspection procedures for the NASG and identified a list of potential manufacturers in China and India. PATH met with the prospective manufacturers and, using a quantitative assessment tool, negotiated affordable pricing with a manufacturer in China for the large size garment and a manufacturer in India for the small size garment.

Technology transfer

PATH worked with the Chinese and Indian manufacturers to source raw materials and manufacture a pre-production batch of NASG garments. PATH conducted verification testing on the pre-production batch to establish that all performance and quality requirements were met prior to commercial distribution.

Success story

Due to new garments emerging from China and India, high quality NASG are now affordable at less than US\$ 70. This improvement has been achieved by negotiating affordable pricing and by transferring clear quality expectations to capable manufacturers.

Assisted vaginal delivery instrument

Introduction

Worldwide, 10 to 20% of pregnancies require some form of assistance at the stage of delivery. The most common form of assistance is a Caesarean section. Instrumental vaginal deliveries (forceps and vacuum extraction) account for 2 to 23% of all deliveries and require highly skilled attendants.

A solution

The Odon device was designed to be easy to use, disposable, and above all, to be operated by assistants with relatively low levels of specialized skill. The device consists of a polyethylene sleeve with a cuff-like fold on the foetal insertion edge, which fits the foetal head diameter. The sleeve is introduced into the vagina by two flexible plastic spatulas (3mm thick) that correctly place the device on the foetus' head. Atmospheric air is pumped into the sleeve and is generally sufficient to fix the sleeve around the foetus' head; however, the effect may be further enhanced by insufflating a small amount of air through an insufflation cannula.

Steps taken

Phase 0 of the research was performed in a childbirth simulator (simulator S 575 –'Noelle') at the Obstetric Simulation Laboratory in Des Moines University (DMU), a WHO Collaboration Centre in Iowa, USA. Trials were successful. The device is currently undergoing processes for regulatory approval. A Phase I study to evaluate feasibility and safety is currently being developed in Buenos Aires, Argentina.

Success story

The device offers a host of positive attributes in addition to it being disposable, low-cost, and low specialized skill. It decreases the risk of foetal-maternal injury, contributes to the physiological development of the second stage of labour, contributes to contraction forces and maternal pushing efforts, can reduce prolonged second stage of labour, can reduce postpartum haemorrhage (uterine atony) through a reduction in the second stage, could significantly decrease operative delivery, can reduce the incidence of perineal damage, and can decrease perinatal infections acquired through the birth canal.

Solar powered hearing aid

The problem

In 2005, WHO estimated that about 278 million people had moderate to profound hearing impairments, out of which, 56 million people were estimated to use hearing-aids (139, 140). Hearing aid producers and distributors further estimate that less than 3% of hearing aid needs in LMICs are met annually (142). A large percentage of hearing impairment can be treated through early diagnosis and suitable management. The poor suffer disproportionately because they cannot afford the preventive and routine care to avoid hearing loss. They often do not have access to ear care services and are unable to obtain suitable hearing aids to make the disability manageable. Hearing impairment may also make it more difficult for them to escape poverty by hindering progress in school or in the workplace and by isolating them socially.

Analysis

Solar Ear offers the first digital, rechargeable hearing aid. The rechargeable unit consists of a novel solar battery charger with batteries that cost the same as disposable zinc air batteries but lasts for two to three years. The devices are assembled by young employees who are deaf. In a broader social context, it has the potential to positively impact society views about people with hearing impairment.

Technology transfer and collaboration

The device was invented and manufactured by deaf workers in Botswana and Brazil.

Success story

To date, Solar Ear has created over 40 jobs for hearing impaired youths. It helps less-advantaged children gain access to low-cost hearing aids to help them mainstream into local schools. There are few schools for the deaf in South America, especially in rural areas. The project has been replicated in Brazil, China and India, and within five years, seeks to open fifteen centres with over 3000 employees.

Electrocardiograph

Introduction

In the early 1980s, the Medical Physics Group at Dhaka University in Bangladesh began developing low cost medical equipment because rural populations were unable to access the benefits of modern health care. The group trained students to design, develop, produce, and market innovative medical devices to suit local needs. One such product was a portable electrocardiograph (ECG) equipment that could be connected to a computer.

Challenges

Local production faced three main challenges: (1) Access to technology. Back-end technology was available, but front-end technology involving network switching for standard 12 lead measurements was either unavailable or protected by industry patents. (2) The device needs to be linked to a computer. USB port connections are quickly becoming industry norms, but require expensive foreign licensing. (3) The equipment had to look aesthetically comparable to foreign equivalents in order to better enable product marketing, but Bangladesh did not have the necessary technological and industrial infrastructure.

Steps taken

The group was led by a Primary Investigator, Professor Siddique-e Rabbani. Professor Rabbani worked with PhD students, drawn from physics and engineering disciplines, to develop a prototype of the ECG in about eight months. The students earned modest allowances, and worked on the project alongside their normal research engagements. Bangladesh does not have formal regulations in place for certifying sophisticated medical devices. In its absence, the group obtained informal approval from a committee of national cardiac specialists before sending the devices to the Ministry of Health for evaluation and potential inclusion in a telemedicine programme.

Technology transfer

Development of the ECG prototype was partially financed by Dhaka University and local philanthropy. Dhaka University does not have policies to engage its researchers and academics in commercial manufacture and marketing of developed products, or of leasing out such products to other companies. A business model emerged where the group distributes the technology through the Bangladesh Institute for Biomedical Engineering and Appropriate Technology (BiBEAT), a proprietorship set up by Professor Rabbani and his students that will evolve into non-profit organization that contributes royalty fees to Dhaka University.

Success story

To date, the group has developed seven medical devices including devices intended for telemedicine, a computerized pedograph to measure foot pressure distribution of diabetic patients, a computerised electromyography (EMG) for routine clinical investigation, a muscle and nerve stimulator for physiotherapy, and an iontophoresis device to treat excessive sweating of palms. The devices have been successfully incorporated into clinical use. The EMG, for example, has been in routine use in local hospitals for over 24 years. BiBEAT's ECG would cost between two to ten times less than imported equipment comparable in essential functionality.

References

1. *Global Burden of Disease Report*. Geneva, World Health Organization, 2004.
2. *Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases*. United Nations General Assembly Resolution A/RES/66/2. New York, United Nations, 2011 (http://www.who.int/nmh/events/un_ncd_summit2011/political_declaration_en.pdf, accessed 10 July 2012).
3. Mainsah, BO (2008). *Important factors for the design of medical devices for developing countries. An interactive qualifying project report*. Worcester, Worcester Polytechnic Institute (http://www.wpi.edu/Pubs/E-project/Available/E-project-042408-125959/unrestricted/Important_Factors_for_the_Design_of_Medical_Devices_for_Developing_Countries.pdf, accessed 10 July 2012).
4. *The world medical markets fact book 2011*. Chichester, Espicom Business Intelligence, 2011.
5. Rosen M (2008). *Global medical device market outperforms drug market growth*. Madison, WTN News, 2008 (<http://wistechnology.com/articles/4790/>, accessed 10 July 2012).
6. *Medical Devices Industry*. Villeurbanne, ReportLinker, 2012 (<http://www.reportlinker.com/ci02249/Medical-Devices.html>, accessed 10 July 2012).
7. Espicom Business Intelligence. *The world medical markets fact book 2011*
8. *Maternal mortality ratio, 2010*. Geneva, World Health Organization, 2012 (http://gamapserver.who.int/gho/interactive_charts/mdg5_mm/atlas.html, accessed 10 July 2012).
9. *The African medical device market: facts and figures 2010*. Chichester, Espicom Business Intelligence, 2011.
10. *Barriers to Innovation in the Field of Medical Devices: Background Paper 6*. Geneva, World Health Organization, 2010 (http://www.who.int/medical_devices/access/en/index.html, accessed 10 July 2012).
11. *Landscape analysis of barriers to developing or adapting technologies for global health purposes*. Geneva, Global Initiative on Health Technologies, 2010.
12. How India and China can help western medical bills. *The Economist*, Jan 22, 2011.
13. *Global age-friendly cities: A guide*. Geneva, World Health Organization, 2007.
14. *World intellectual property indicators 2011*. Geneva, World Intellectual Property Organization, 2011.
15. Closing the R&D gap in African health care. *McKinsey Quarterly*, June 2010.
16. *Strengthening of health systems for equity and development in Africa*. Third Session of the African Union Conference of Ministers of Health, Johannesburg, South Africa, 9–13 April, 2007.
17. *World Intellectual Property Report 2011: The changing face of innovation*. Geneva, World Intellectual Property Organization, 2011.
18. *Public/Private roles in the pharmaceutical sector: implications for equitable access and rational drug use*. Geneva, World Health Organization, 1997.
19. *Medical devices: Managing the mismatch. An outcome of the Priority Medical Devices project*. Geneva, World Health Organization, 2010 (http://whqlibdoc.who.int/publications/2010/9789241564045_eng.pdf, accessed 10 July 2012).
20. PWC Medical Technology Innovation Scorecard: The race for global leadership. *Policy and Medicine*, 2011 (<http://www.policymed.com/2011/01/pwc-medical-technology-innovation-scorecard-us-falling-behind-in-the-race-for-global-leadership.html>, accessed 10 July 2012)

21. Johnson, G (2010). Prepare for a clash of IP cultures in medical devices. *Techinsights* (<http://www.ubmtechinsights.com/uploadedFiles/UBM-TechInsights-IP-and-the-Medical-Devices-Sector-Whitepaper.pdf>, accessed 10 July 2012).
22. Oullette, L (2010). How many patents does it take to make a drug? Follow-on pharmaceutical patents and university licensing. *Michigan Telecommunications and Technology Law Review*, 299, 2010 (<http://www.mttl.org/volseventeen/ouellette.pdf>, accessed 10 July 2012).
23. *Intellectual Property*. World Health Organization web site (http://www.who.int/topics/intellectual_property/en/, accessed 10 July 2012).
24. *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property*. Geneva, World Health Organization, 2011 (http://www.who.int/phi/publications/Global_Strategy_Plan_Action.pdf, accessed 10 July 2012).
25. Gottret P and Schieber G. *A practitioners guide: Health financing revisited*. Washington DC, World Bank, 2006.
26. *Ad-Hoc GHFT SC Regulatory Model Working Group*. The Global Harmonization Taskforce Regulatory Model, 2011.
27. Malkin RA (2007). Design of health care technologies for the developing world. *Annual Review of Biomedical Engineering*, 9, 567–87.
28. Trautman KA (2012). *International medical devices regulators forum (IMDRF)* [presentation slides]. (<http://medxu.com/xmedcon/wp-content/uploads/2012/04/Trautman-IMDRF.pdf>, accessed 10 July 2012).
29. Free MJ, Green JA and Morrow MM (1993). Health technologies for the developing world. Promoting self-reliance through improving local procurement and manufacturing capabilities. *International Journal of Technology Assessment in Health Care*, 9(3), 380–96.
30. Kamunyori S et al. (2010) Science-based health innovation in Uganda: creative strategies for applying research to development. *BMC International Health and Human Rights*, 10 Suppl 1, S5.
31. *Starting a business*. Washington DC, World Bank Group, 2012 (<http://www.doingbusiness.org/data/exploretopics/starting-a-business>, accessed 10 July 2012).
32. *Doing Business 2012: Doing Business in a More Transparent World*. Washington DC, World Bank, 2012 (www.doingbusiness.org/reports/global-reports/doing-business-2012/, accessed 10 July 2012).
33. *China increases rural poverty limit to \$1 per day*. London, British Broadcasting Corporation, 2011 (<http://www.bbc.co.uk/news/world-asia-china-15956299>, accessed 10 July 2012).
34. Frugal healing: Inexpensive Asian innovation will transform the market for medical devices. *The Economist* (20 Jan 2011) (<http://www.economist.com/node/17963427/print>, accessed 10 July 2012).
35. *Global Health Observatory Data Repository*. Geneva, World Health Organization, 2012 (<http://apps.who.int/ghodata/?vid=2472#>, accessed 10 July 2012).
36. *China: World Health Organization Western Pacific Region profiles*. Manila, World Health Organization, 2012 (<http://www.wpro.who.int/countries/chn/en/index.html>, accessed 10 July 2012).
37. Yip W, Hsiao WC (2008). The Chinese health system at a crossroads. *Health Affairs*, 27(2), 460–8.
38. Eggleston K et al. (2008). Health service delivery in China: a literature review. *Health Economics*, 17(2), 149–65.

39. Liu X, Liu Y, Chen N (2000). The Chinese experience of hospital price regulation. *Health Policy Planning*, 15(2), 157–63.
40. Bian Y, Zhuang N et al. (2002). Cost and efficiency of use of PET. *Chinese Journal of Health Economics*, 8, 15–17.
41. Sun Q, Ge R et al. (2005). Cost and efficiency of PET/CT. *Chinese Journal of Health Economics*, 2: 37–41.
42. Jin C, Wang L et al. (2002). New fee schedule and the inpatient expenditures for four diseases. *Price and Market*, 9: 37–39.
43. Eggleston K et al. (2008). Health service delivery in China: a literature review. *Health Economics*, 17(2), 149–65.
44. Liu X, Hsiao WC (1995). The cost escalation of social health insurance plans in China: its implication for public policy. *Social Science and Medicine*, 41(8), 1095–101.
45. Yip WC, Hsiao WC (1997). Medical savings accounts: lessons from China. *Health Affairs*, 16(6), 244–51
46. Liu X, Mills A (1999). Evaluating payment mechanisms: how can we measure unnecessary care? *Health Policy Planning*, 14(4), 409–13.
47. Yin A (2004) *The impact of DRG user charge on hospital length of stay and expenditures*. Discussion Paper, Shandong University (in Chinese).
48. Wu A, Li Y et al. (2004). DRG-based payment reform for urban health insurance scheme. *Chinese Journal of Health Economics*, 9, 38–39.
49. Graff GD (2007). Echoes of Bayh-Dole? A survey of IP and technology transfer policies in emerging and developing economies. In: *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). Oxford, MIHR, 2007. (<http://www.iphandbook.org/handbook/ch03/p03/>, accessed 10 July 2012).
50. China's patent strategy worrying firms. *The China Post*, March 22, 2011 (<http://www.chinapost.com.tw/business/asia-china/2011/03/22/295534/Chinas-patent.htm>, accessed 10 July 2012).
51. *Medical devices database*. State Food and Drug Administration [China] (<http://app1.sfda.gov.cn/datasearch/face3/base.jsp?tableId=27&tableName=TABLE27&title=%BD%F8%BF%DA%C6%F7%D0%B5&bclid=1181030635069354841501>, accessed 10 July 2012).
52. *An analysis of medical device industry in China with reference to the Chinese healthcare reform* (<http://www.medicexchange.com/Healthcare-Reform/an-analysis-of-medical-device-industry-in-china-with-reference-to-the-chinese-healthcare-reform.html>, accessed 10 July 2012).
53. *Our responsibility: 2011 Sustainability Report (Summary)*. New Brunswick, Johnson and Johnson, 2011 (http://www.jnj.com/wps/wcm/connect/0634f0004b06d14291deb159991379c9/JJ_OurResponsibility_2011_Summary2_051512.pdf?MOD=AJPERES, accessed 10 July 2012).
54. Census of India 2011: Literacy rises by 9.2 per cent, now 74.04 per cent. *India Times*, 30 march 2011 (<http://economicstimes.indiatimes.com/news/economy/indicators/census-of-india-2011-literacy-rises-by-9-2-per-cent-now-74-04-per-cent/articleshow/7833145.cms>, accessed 10 July 2012).
55. *India: World Health Organization South-East Asia Region profiles* (http://www.searo.who.int/LinkFiles/India_CHP_india.pdf, accessed 10 July 2012).
56. Qadeer I (2000). Health care systems in transition III. India, Part I. The Indian experience. *Journal of Public Health Medicine*, 22(1), 25–32.

57. Peters DH. *Better health systems for India's poor: findings, analysis, and options*. Washington, DC, World Bank, 2002.
58. *Medical technology industry in India: Riding the growth curve*. Deloitte, (http://www.deloitte.com/view/en_IN/in/insights-ideas/india-thoughtware/2e08ee1861f7a210VgnVCM2000001b56f00aRCRD.htm, accessed 10 July 2012).
59. Bian Y, Zhuang N et al. (2002). Cost and efficiency of use of PET. *Chinese Journal of Health Economics*, 8, 15–17.
60. Varshney A. *Medical equipment use patterns in the private and public sector in India: Implications for policy*. New Delhi, National Commission on Macroeconomics and Health, 2004.
61. Mavalankar D et al. Managing equipment for emergency obstetric care in rural hospitals. *International Journal of Gynaecology and Obstetrics*, 2004, 87(1), 88-97.
62. Mahal A, Varshney A, Taman S. Diffusion of diagnostic medical devices and policy implications for India. *International Journal of Technology Assessment in Health Care*, 2006, 22(2), 184–90.
63. Mahal A, Karan AK (2009). Diffusion of medical technology: medical devices in India. *Expert Reviews of Medical Devices*, 6(2), 197–205.
64. Baru R. *Private health care in India: Social characteristics and trends*. New Delhi, Sage Publications, 1998.
65. *Market-relevant design: Making ECGs available across India*. GE Healthcare News, 2011 (<http://newsroom.gehealthcare.com/articles/ecgs-india-reverse-innovation/>, accessed 10 July 2012).
66. *Leveraged Freedom Chair*. Dell Social Innovation Challenge (<http://www.dellchallenge.org/projects/leveraged-freedom-chair>, accessed 10 July 2012).
67. Baldwin C et al. (2011). Why Nurses Should be More Prominent. *Scientific American*, 2010 (<http://www.sa-lives.com/entry/13/why-nurses-should-be-more-prominent>, accessed 10 July 2012).
68. *Health at a Glance 2011: OECD Indicators*. Paris, OECD iLibrary, 2011 (<http://bit.ly/NCLmVM>, accessed 10 July 2012).
69. *Global Micronutrient Project: Brazil Country Profile*. New Orleans, Tulane University (<http://www.tulane.edu/~internut/Countries/Brazil/Brazilxx.html>, accessed 10 July 2012).
70. von Amsberg J et al. *The poverty targeting of social spending in Brazil*. Washington DC, World Bank, 2000.
71. *The medical devices market: Brazil. Medical Market Research Reports*. Chichester, Espicom Business Intelligence, 2012 (http://www.espicom.com/prodcat2.nsf/Product_ID_Lookup/00000535?OpenDocument, accessed 10 July 2012).
72. Uga MA, Santos IS (2007). An analysis of equity in Brazilian health system financing. *Health Affairs*, 26(4), 1017–28.
73. Silva HP, Viana AL (2011). Health technology diffusion in developing countries: a case study of CT scanners in Brazil. *Health Policy Planning*, 26, 385–94.
74. Paim J et al. (2011). The Brazilian health system: history, advances, and challenges. *The Lancet*, 377, 1778–97.
75. *International patent history and laws: Brazil*. Article One Partners, 2011 (<http://info.articleonepartners.com/blog/bid/56219/International-Patent-History-and-Laws-Brazil>, accessed 10 July 2012).

76. *Brazil Ministry of Health and Bill & Melinda Gates Foundation announce strategic alliance to advance innovation in global health.* Seattle, Bill & Melinda Gates Foundation , 2012. (<http://www.gatesfoundation.org/press-releases/pages/brazil-ministry-of-health-global-health-innovation-120416.aspx>, accessed 10 July 2012).
77. *The outlook of medical devices in Brazil, Russia, India and China.* New York, PRNewswire, 2011 (<http://www.prnewswire.com/news-releases/the-outlook-for-medical-devices-in-brazil-russia-india—china-134660973.html>, accessed 10 July 2012).
78. Uga MA, Santos IS (2007). An analysis of equity in Brazilian health system financing. *Health Affairs*, 26, 1017–28.
79. *The Medical Device Market: Brazil.* Chichester, Espicom Business Intelligence, 2012. (http://www.espicom.com/prodcat2.nsf/Product_ID_Lookup/00000535?OpenDocument, accessed 10 July 2012).
80. Parsons, S. *Solar Ear: Affordable, sun-powered hearing aids.* El Segundo, Inhabitat, 2010 (<http://inhabitat.com/solar-ear-hearing-aids/>, accessed 10 July 2010).
81. *After research revealing its healing properties, latex is now being used for new dressing that speeds up regeneration.* São Paulo, Universidade Estadual de Campinas, 2006 (<http://www.inovacao.unicamp.br/english/report/news-newskin.shtml>, accessed 10 July 2012).
82. *Jordan: Modern medical services in the cradle of civilization.* (<http://www.allmedicaltourism.com/articles/destinations/jordan/>, accessed 10 July 2012).
83. Healthcare expenditure and delivery, Regional Health System Observatory (Jordan). Cairo, World Health Organization.
84. Halasa, Y (2008). *Mapping health care financing in Jordan* (Unpublished).
85. Jordan becomes first country in the Levant to successfully implement home monitoring technology, spearheading regional medical evolution. DubaiPR, 2009 (<http://www.dubaipr.com/news/00238-jordan-becomes-first-country-levant-successfully-implement-home-monitoring-technology-spe>, accessed 10 July 2012).
86. *Medical device market: GCC.* OSEC Business Market Switzerland, 2010 (http://www.osec.ch/de/filefield-private/files/6529/field_blog_public_files/7963, accessed 10 July 2012).
87. Ethiopia statistics. New York, UNICEF (http://www.unicef.org/infobycountry/ethiopia_statistics.html#90, accessed 10 July 2012).
88. Kebede-Francis E. *Global health disparities: Closing the gap through good governance.* Burlington, Jones and Bartlett Learning, 2011.
89. Country cooperation strategy at-a-glance. Geneva, World Health Organization. (www.who.int/countryfocus/cooperation_strategy/ccsbrief_eth_en.pdf, accessed 10 July 2012).
90. *Ethiopia's Fourth National Health Accounts, 2007/08.* Addis Ababa, Federal Democratic Republic of Ethiopia: Ministry of Health, 2010.
91. Teklebirhan, M (2012). *Ethiopia's new national healthcare program raises concerns.* Ezega.com (<http://www.ezega.com/News/NewsDetails.aspx?Page=heads&NewsID=3280>, accessed 10 July 2012).
92. *Ethiopia: A country status report on health and poverty.* World Bank and Ministry of Health (Ethiopia), 2004.
93. Ementa, H. *Income redistributive effects of the health care financing system in Nigeria. Poverty Monitoring, Measurement and Analysis Network.* Conference paper, June 2005, Colombo, Sri Lanka.

94. Asfaw A, von Braun J (2005). *Innovations in health care financing: new evidence on the prospect of community health insurance schemes in the rural areas of Ethiopia*. International Journal of Health Care Finance and Economics, 5, 241–53.
95. Drug Administration and Control Authority of Ethiopia (<http://www.ccras.nic.in/country%20wise%20compendium/ethiopia%20120-152.pdf>, accessed 10 July 2012).
96. *Accessions: Ethiopia*. Geneva, World Trade Organization (www.wto.org/english/thewto_e/acc_e/a1_ethiopia_e.htm, accessed 10 July 2012).
97. *A network model for highly specialized medical services in Ethiopia*. Bahir Dar, Gotland Specialist Higher Clinic (www.bahirdar.se/component/content/article/34-main/77-introduction, accessed 10 July 2012).
98. Rajaratnam, J et al. (2010). Neonatal, post neonatal, childhood and under-5 mortality for 187 countries, 1970–2010: A systematic analysis of progress towards Millennium Development Goal 4. *The Lancet*, 376, 686.
99. Ringer, S (2008). International perspectives: Enhancement of neonatal care in Vietnam. *NeoReviews*, 9(10), e439–e446.
100. *Combating waterborne disease at the household level*. Geneva, World Health Organization, 2007 (http://www.who.int/household_water/advocacy/combating_disease/en/index.html, accessed 10 July 2012).
101. *LifeStraw water purifier grows into family size*. Irin Global, 2008 (<http://www.irinnews.org/Report/76548/GLOBAL-LifeStraw-water-purifier-grows-into-family-size>, accessed 10 July 2012).
102. Vestergaard Frandsen SA (<http://vestergaard-frandsen.com>, accessed 10 July 2012).
103. *In Kenya, Vestergaard Frandsen is saving lives with carbon credits*. Sustainable Business Forum, 2011 (<http://sustainablebusinessforum.com/marcgunther/51326/kenya-saving-lives-carbon-credits>, accessed 10 July 2012).
104. Safe drinking water interventions for home and outside use. Lausanne, Vestergaard-Frandsen (http://vestergaard-frandsen.com/carepack/downloads/doc_view/31-lifestrawr-brochure-english, accessed 10 July 2012).
105. *New straw to kill disease as you drink*. London, British Broadcasting Corporation, 2006. (<http://news.bbc.co.uk/2/hi/africa/4967452.stm>, accessed 10 July 2012).
106. *The 6th Annual Fast 50*. Fast Company. (http://www.fastcompany.com/magazine/113/open_31-vestergaardfrandsen.html, accessed 10 July 2012).
107. *Developments in mechanical heart valve prosthesis*. Sadashivanagar, Indian Academy of Sciences, 2003.
108. *Indigenous heart valve makes a difference*. The Hindu, December 2009 (<http://www.thehindu.com/opinion/op-ed/article69694.ece>, accessed 10 July 2012).
109. *What causes heart valve disease?* Bethesda, US National Heart Lung and Blood Institute, 2011 (<http://www.nhlbi.nih.gov/health/health-topics/topics/hvd/causes.html>, accessed 10 July 2012).
110. Choudhary SK et al. (2001). Mitral valve repair in a predominantly rheumatic population: Long-term results. *Texas Heart Institute Journal*, 28, 8–15.
111. *Mitral valve regurgitation; Mitral valve replacement; Mitral valve stenosis: About mitral replacement*. Chennai, MedIndia, 2011 (<http://www.medindia.net/patients/patientinfo/mitral-valve-regurgitation-replacement-overview.htm>, accessed 10 July 2012).

112. 112. *Cardiovascular and Thoracic Surgery Department*. Trivandrum, Sree Chitra Tirunal Institute for Medical Sciences and Technology. (www.sctimst.ac.in/About%20SCTIMST/Departments%20and%20Divisions/Hospital%20Wing/Cardiovascular%20and%20Thoracic%20Surgery%20Department/index.php?hideld=115, accessed 10 July 2012).
113. 113. *TTK Healthcare plans to export artificial heart valves*. Ahmedabad, MediSourceAsia, 2001 (http://www.medisourceasia.com/industrynews/mp7_2001_02.htm, accessed 10 July 2012).
114. Nagarajan M, Muralidharan S and Chandrasekar P (2000). The TTK chitra heart valve – A single centre experience with midterm results. *Indian Journal of Thoracic and Cardiovascular Surgery*, 16, 85–89.
115. Sankarkumar R et al. (2001). Chitra heart valve: results of a multicenter clinical study. *Journal of Heart and Valve Disease*, 10, 619–27.
116. Kumar P et al. (2004). TTK Chitra tilting disc valve: Hemodynamic evaluation. *Indian Journal of Thoracic and Cardiovascular Surgery*, 20, 117–121(<http://medind.nic.in/ibq/t04/i3/ibqt04i3p117.pdf>, accessed 10 July 2012).
117. *Decade of Action for Road Safety, 2011–2020* (http://www.who.int/roadsafety/decade_of_action/en/, accessed 10 July 2012).
118. Road accidents main cause of amputation, says study. *The Hindu*, July 2011 (<http://www.thehindu.com/news/cities/chennai/article2163866.ece>, accessed 10 July 2012).
119. *Facts and figures*. Disability India Information Resources. (<http://www.disabilityindia.com/html/facts.html>, accessed 10 July 2012).
120. *Jaipur Foot History*. Jaipur, Bhagwan Mahaveer Viklang Sahayata Samiti. (http://www.jaipurfoot.org/03_Technology_history.asp, accessed 10 July 2012).
121. *Jaipur Foot: Partnering technology and social entrepreneurship*. Washington DC, World Bank Institute, 2011 (<http://wbi.worldbank.org/wbi/stories/jaipur-foot-partnering-technology-and-social-entrepreneurship>, accessed 10 July 2012).
122. *Haiti earthquake relief*. Rotary District 7020 (<http://haiti-task-force.blogspot.in/p/jaipur-foot.html>, accessed 10 July 2012).
123. Adalarasu K, Jagannath M and Mathur MK (2011). Comparison of Jaipur, SACH and Madras Foot. *International Journal of Advanced Engineering Sciences and Technologies*, 4, 187–192. (<http://ijaest.iserp.org/archieves/10-My1-15-11/Vol-No.6-Issue-No.2/5.IJAEST-Vol-No-6-Issue-No-2-Comparison-on-Jaipur,-SACH-and-Madras-Foot-187-192.pdf>, accessed 10 July 2012).
124. Treating cataracts in India. In: *Case studies in global health: Millions saved*. Washington DC, Centre for Global Development, 2011. (http://www.cgdev.org/doc/millions/MS_case_19.pdf, accessed 10 July 2012).
125. Bhandari A et al. Specialty care systems: A pioneering vision for global health. *Health Affairs*, 27, 964–976 (<http://www.aravind.org/downloads/aravindnewsaug08/4.pdf>, accessed 10 July 2012).
126. Ibrahim M et al. (2006). Making sight affordable (Part I) Aurolab pioneers production of low-cost technology for cataract surgery. *Innovations*, 1, 25–41 (http://www.policyinnovations.org/ideas/policy_library/data/MakingSightAffordable1/_res/id=sa_File1/INNOV0103_p25-41_ibrahim-et-al.pdf, accessed 10 July 2012).
127. Mohr J, Sengupta S and Slater S (2010). Base of the pyramid–Curing blindness among India's poor: Aravind Eye Hospital. In: *Marketing of high-technology products and innovations* (<http://marketinghightech.net/the-book/chapter-4/ch4-aravind>, accessed 10 July 2012).

128. Simelane SE. *The population of South Africa: The overall and demographic description of South African population based on Census '96*. Pretoria, Statistics South Africa, 2002 (<http://www.statssa.gov.za/publications/TechPaperAgeSex/TechPaperAgeSex.pdf>, accessed 10 July 2012).
129. *Key results: Census 2001*. Pretoria, Statistics South Africa, 2001 (http://www.statssa.gov.za/census01/html/Key%20results_files/Key%20results.pdf, accessed 10 July 2012).
130. Molefi M, Fortuin J and Wynchank S (2006). Tele-cardiology. *Cardiovascular Journal of South Africa*, 17.
131. Wynchank S and Molefi M. *Telemedicine's full range of benefits in a developing country: The example of South Africa*. Pretoria, Medical Research Council of South Africa.
132. *Overall winner: Medium companies – Dr Moretlo Molefi, Managing Director Telemedicine Africa*. (<http://www.amdtelemedicine.com/media/documents/DrMoretloMolefi.pdf>, accessed 10 July 2012).
133. Telemedicine Africa (<http://telemedafrica.co.za>, accessed 10 July 2012).
134. *The Limpopo Province Telemedicine Project* (presentation by Dr Moretlo Molefi, Medical Research Council consultant, Med-e-Tel 2009 Conference, 1–3 April 2009, Luxembourg (http://www.medetel.eu/download/2009/parallel_sessions/presentation/day3/telemedicine_as_a_tool_for_equitable_health_services.pdf, accessed 10 July 2012).
135. *Robertson Global Health Solutions announces commercial venture with Telemedicine Africa*. WorldNews, 2011 (<http://www.worldnews.se/news/55496/cleveland-cord-blood-center-participates-in-ohio-third-frontier-wright-projects/>, accessed 10 July 2012).
136. *International Society for Telemedicine and E Health- Newsletter* (January 2012) (<http://archive.constantcontact.com/fs092/1102797716245/archive/1109075644421.html>, accessed 10 July 2012).
137. A “wetsuit” to the rescue: Postpartum hemorrhage kills more mothers than any other cause, but antishock garments may help stop the bleeding. Seattle, PATH (<http://www.path.org/projects/antishock-garment.php>, accessed 10 July 2012).
138. *Compendium of new and emerging health technologies*. Geneva, World Health Organization, 2010.
139. *Deafness and hearing impairment* (Fact Sheet. No: 300). Geneva, World Health Organization, 2010.
140. McPherson B and Brouillette R. A fair hearing for all: providing appropriate amplification in developing countries. *Communication Disorders Quarterly*, 2004.
141. *Guidelines for hearing aids and services for developing countries*. Geneva, World Health Organization, 2004.

3. Challenges and barriers to local production

In 2003, at the fifty-sixth World Health Assembly, it was recognized that the benefits of innovations, even those that were being applied elsewhere, were not reaching people in LMICs, and noted that:

Factors that drive innovation are often biased against conditions that disproportionately affect the populations of developing countries.[...] Innovation to address conditions primarily affecting poor people is held back by a combination of market failure and underinvestment by the public sector. The process of bringing a new product to the market is both expensive and lengthy. Because of the resource implications and the uncertainties involved, creating an environment conducive to successful innovation is essential (1).

Development and manufacture of medical device innovations in LMICs still face several barriers. Although some of these barriers have been described previously by WHO (2,3), there is still little comprehension on how these barriers affect local producers at the micro-level and whether local markets could be incentivized to promote the production of medical devices locally. While in the previous reports, efforts were focused on identifying the situation of access to medical devices, the barriers documented were those that occur at various stages of the production and technology transfer processes, and also at the uptake level. Whereas some of these barriers may be similar and closely related, the current report aims to provide a closer look at those obstacles associated with production and transfer of medical devices from a local perspective.

This chapter discusses the different challenges and barriers to local production based on literature research and on the results of a WHO survey on access to medical devices. A set of recommendations to overcome the barriers and challenges faced by producers and innovators is presented in each section .

3.1 Literature findings

Despite various international efforts, agreements and commitments to promote transfer of technologies to LMICs, in many sectors such transfers are not occurring at a pace rapid enough to support countries to achieve their development objectives. The health sector is not an exception, and in the medical devices industry several barriers and challenges to technology transfer and production of innovations in LMICs have been reported in the literature.

Transfer of knowledge and technologies is fundamental to promote competitiveness and economic growth in world markets. Benefits of transferring and producing medical devices may not only be economic, but also social in terms of health improvements to the populations, particularly in relation to underprivileged and marginalized groups. Furthermore, access

to essential devices plays a vital role in the attainment of the Millennium Development Goals (MDGs).

Nevertheless, the business environment in many LMICs is far from ideal, both for international companies trying to introduce their products into these markets, and for innovators and producers of technologies within these countries. The situation can potentially be changed as technology transfer and local production could offer novel, local solutions to leveraging access to essential medical devices, as means to achieve wider health care coverage. The following paragraphs provide an overview of the main barriers to accessing medical devices and challenges for local production and technology transfer in various regions of the world. A summary of the barriers and challenges in LMICs is presented in Table 1.

Table 1 Summary of challenges and barriers to local production of medical devices

Health system challenges	<p>Poor and limited infrastructure (roads and services, communication network, and even health infrastructure) and equipment.</p> <p>Weak flows of funding between producers, users and payers to signal the economic viability of medical device production.</p> <p>Low levels of trained health workers to treat patients, use or/ and maintain medical devices.</p>
Policy challenges	<p>Weak or non-existent health technology policies, and mechanisms to implement them.</p> <p>Weak or non-existent medical device regulations, and mechanisms to implement them, and a lack of harmonized regulation and requisites across regions.</p> <p>Weak management systems to rationally select, procure, deliver and use devices for the duration of their life span.</p>
Organizational challenges	<p>Insufficient financing and high costs for early-stage entrepreneurs.</p> <p>Low access to early-stage capital.</p> <p>Limited understanding of medical device business life-cycle among investors and credit providers.</p> <p>Weak production capacity and uncertain markets.</p> <p>Unfavourable environment (political, economic, social, technological and legal) for local producers to maximize regional economies of scale.</p>
Partnerships and collaborations	<p>Lack of coordination and collaboration between diverse stakeholders.</p> <p>Competing agendas of organizations for science, technology and innovation.</p> <p>Limited access to and share of knowledge.</p> <p>Lack of incentives that reward new modes of collaborative work.</p>
Other challenges	<p>Lack of an innovation/entrepreneurial culture. Lack of innovation hubs and professional network for sharing knowledge, ideas and experience.</p>

3.2 Health system challenges

- *Financing and payment systems:* The flow of funding between payers and providers of medical care, both public and private, as well as households

and donors is likely to determine the profitability of medical device sales and, thus, whether companies invest in national markets. The resulting supply of medical devices and other technologies will, in turn, influence the capacity of health care providers to deliver high quality, affordable cost medical services to individuals and households.

- *Human resource constraints:* Health systems, particularly in rural areas where medical devices are already in low supply, lack the necessary medical providers to treat patients. Those who do operate in resource-poor settings may be untrained to operate certain medical devices. Similarly, there are limited opportunities for local entrepreneurs and business managers to train health providers or offer professional support and mentoring. This often leads to medical devices, whether imported or locally produced, being inappropriately and inadequately used. The consequences of improper use can negatively influence the quality of care delivered to patients and the resulting costs and/or health outcomes. In the event that medical devices are not used due to lack of personnel training, patient access to care may be impacted. This issue highlights the need for more collaboration and effective PDP's that provide mentorship and build an innovation culture in LMICs, where it may be lacking.
- *Poor infrastructure:* Infrastructure such as roads, reliable access to electricity, and communication networks enable the core logistics of buying and selling products and services to viable markets (local, national and international). The creation of this infrastructure can be highly capital intensive such that they can be hindered by harsh geographical terrain such as deserts and rainforests that make it difficult to develop roads, landing pads, or cellular towers to receive mobile phone or radio signals. However, without a commitment to developing these transportation and communication networks, local entrepreneurs are in danger of trapping local ingenuity within their respective communities, and communities are in danger of not receiving timely access to medical devices.

3.3 Policy challenges

- *Government policies:* Various challenges exist at the national policy level. These include whether a country's national health plan has a health technology policy directed to rational selection, procurement, regulation and management of medical devices; and whether countries have a health technology unit in the Ministry of Health and biomedical engineers or professional staff to implement these policies.
- *Regulation:* Regulation of medical devices plays a major role in the access of safe and effective health technology for the target population. Overly stringent regulatory requirements can complicate local innovation and manufacturing and therefore limit access to safe, reliable and appropriate medical devices. A lack of appropriate regulation can create an unfair market where manufacturers and suppliers of good quality products are competing directly with manufacturers and suppliers of poor quality products. Weak adherence by manufacturers to international standards and regulatory authorities thus result in products of non-assured quality that are not easily

identifiable by providers and patients. Thus a country-specific balance of regulatory measures is a critical component of access to medical devices. It is important to note too, that medical device regulations are different from that of medicines, and that research indicates a relatively lower capacity in LMICs to regulate medical devices. Harmonization of regulatory process can enhance a faster access to medical devices.

- *Resource capacity:* Effective health systems and good governance require that countries have the economic, human and other technical resource capacities in place to ensure that health system performance goals are met. These are necessary conditions to effectively regulate medical device suppliers, set and implement procurement policies, create sound financing, payment and other organizational structures. These are lacking in many resource-limited settings and thus pose a challenge to the local production of medical devices and their resulting impact on patient access to, costs and quality of medical care.
- *Management of medical devices:* The rational selection, procurement and delivery systems for medical devices play a very important role in supporting access. Once a technology has been approved by the national regulatory authority, it can be selected by the assessment units to be placed in the list of approved medical devices for reimbursement, donations or procurement by the public health sector. It then becomes important that the locally-produced device is approved by this process in order to enhance its commercial development and thus its uptake by health service providers.
- *Safe use:* Once the medical device reaches the health unit, it is important to consider installation, user training and continuous maintenance. For locally-produced devices, this can be a very important factor for successful uptake if the local manufacturer provides full support during the lifespan of the technology. Local production of medical devices offers a potential means to reduce supply chain costs and improve access to rural, resource-poor health care providers by being closer to the source of medical delivery.

3.4 Organizational challenges

- *High start-up costs and insufficient financing for early-stage entrepreneurs:* Production and innovation processes are associated with their own range of technological and market-related uncertainties. Start-up companies or initiatives may be seen as high risk; as such, interest rates and the cost of capitalizing a manufacturing plant may be very high and the loan periods too short to realistically allow a manufacturer to generate the return to repay the loan. Rural enterprises in particular tend to be considered risky investments because of investee profiles of relative poverty and limited access to resources. Indeed, access to financing and early-stage capital often figures prominently on the wish list of entrepreneurs, and among the obstacles to becoming an entrepreneur. However, while early-stage financing is important, it is equally important to ensure that entrepreneurs have access to credit throughout the business life-cycle. A robust ecosystem requires financial organizations that understand the various stages of a medical device's business life-cycle and are able to

profitably and sustainably spread their investment risks. It is no coincidence that the nations that offer financial assistance to all stages of business life cycle also have the largest concentrations of large-scale businesses within their borders. These businesses tend to have a relatively greater impact in increasing a nation's GDP than the sum total of micro-, small-, and medium-size businesses combined.

- *Lack of economies of scale:* A combination of weak production capacity and uncertain markets results in limited economies of operation and weak feasibility. For example, manufacturers in sub-Saharan African generally produce at a cost disadvantage compared to the large Asian generic manufacturers (i.e. in India and China). Political, legal and regulatory barriers often make it difficult for local producers to exploit regional economies of scale. It should also be noted that local production facilities often do not operate in favourable environments such as cluster technology parks or special economic zones, and unfavourable environments increase basic operational costs and impede the quality of devices.

3.5 Partnerships and other challenges

- *Lack of collaborative linkages:* Frequently, ambiguous policies and lack of policy coordination between various relevant ministries, departments and institutions, especially between those for trade, science, technology and innovation on the one hand and health on the other hand, are a major barrier to meaningful and sustainable local production. Competing agendas of organizations for science, technology and innovation, lack of a collaborative culture among academia and industry, lack of access to knowledge, forums and lack of incentives that reward collaborations, all further impair interactive learning.
- *Competing motives:* Technology transfer may be very difficult to induce, particularly for products where technology holders and demanders are likely to be market competitors. In such cases, public or public interest actors (such as foundations and NGOs) may need to play a stronger role in providing incentives for sharing, or alternative paths to needed technologies.
- *The lack of an innovation and entrepreneurial culture:* The above factors provide an important framework for local production of medical devices. However, it must also be noted that the professional community's determination to innovate and lead device development are also essential factors.

Understanding the barriers to producing, managing and using medical devices is an important component in realizing universal health care. Further still, considering that many of these barriers are context-specific, local production can be one of several viable ways to improve access while enhancing their capabilities to contribute to overall economic growth in low-income countries (4).

3.6 Survey on access to medical devices

To gain further insights into the most common barriers to local production, WHO also conducted a survey on access to medical devices. Participants with backgrounds and expertise in 46 different countries (Figure 1) – including in industrial, academic and health sectors – provided valuable feedback. The fields of expertise of the respondents covered a wide variety of topics,

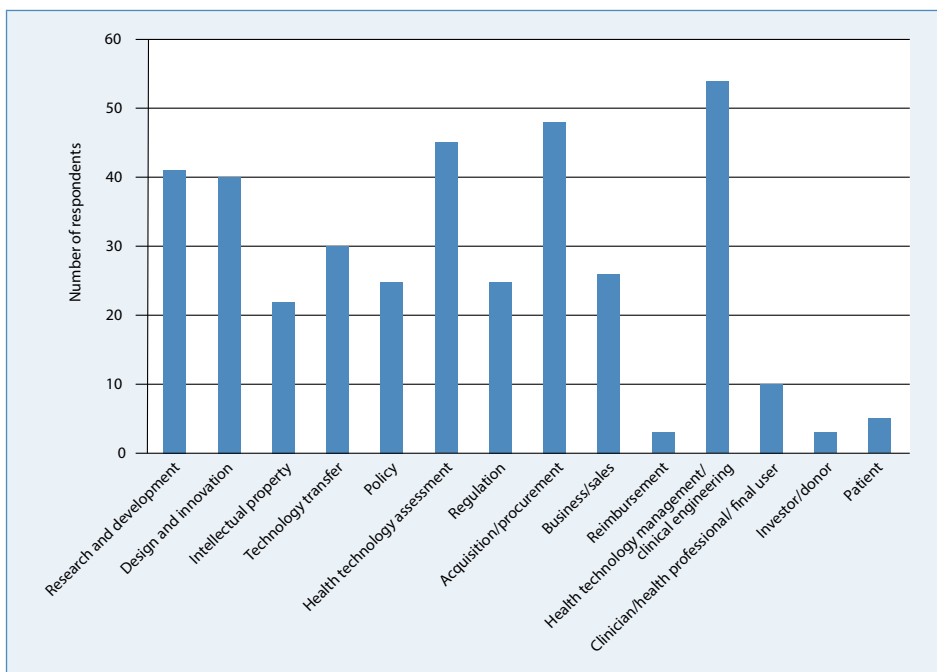
including research and development, design and innovation, technology transfer, health technology assessment, procurement, and health technology management (Figure 2).

Figure 1 *Geographic distribution of survey respondents*



Data Source: Survey on Access to Medical Devices in Low Resource Settings (May 2012).
Map Production: Medical Devices WHO team (DIM), WHO 2012 (All rights reserved).

Figure 2 *Survey respondents' fields of expertise (total responses: 103)*

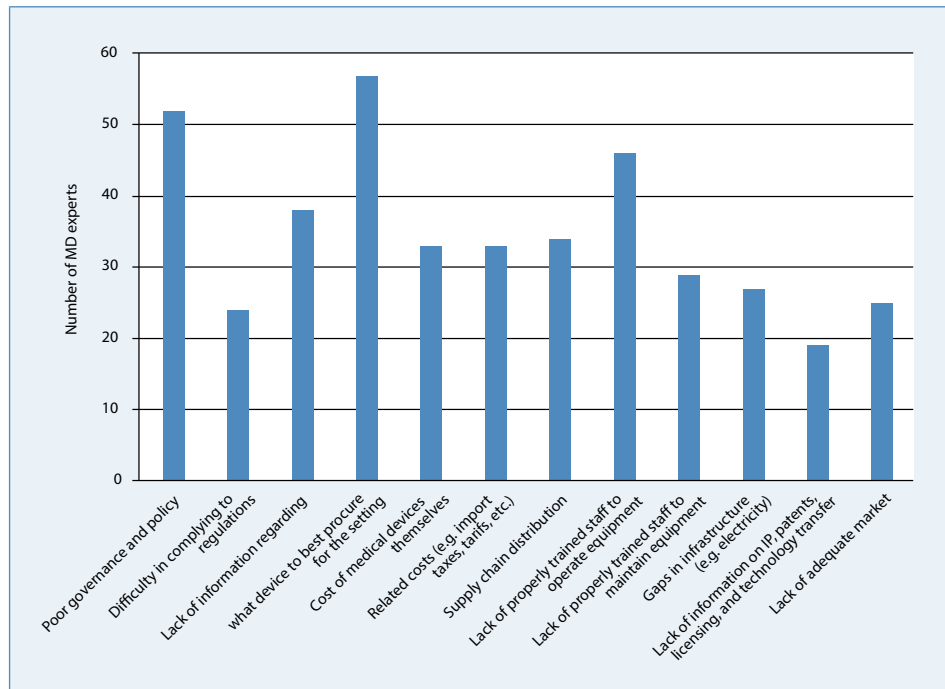


3.7 Relevant findings of the survey

After the completion of the survey, respondents were asked to comment and provide ideas based on their experiences with the medical devices industry. The charts presented in Annex 1 correspond to the relevant themes that were considered as the most prominent barriers and challenges to local production faced by producers in developing countries. Figure 3 shows the main barriers to access to local production, as perceived by the survey respondents. According

to the results, the costs of the medical devices, as well as poor governance and policy are the top reasons hindering access to medical devices, closely followed by the lack of properly trained staff to maintain equipment.

Figure 3 *Main barriers to access to medical devices in low-resource settings (total responses: 103)*



3.8 Product development and technology transfer

The development of a medical device in LMICs appears to be hindered by numerous factors. The majority of participants who considered the major barrier to medical device development was a lack of financial resources for the process were from LMICs (22 of the 29 related responses); all these participants had either a product commercialized or in the development stage. While in some cases, survey respondents reported that they were able to successfully tackle financing barriers, there were persistent concerns on the part of producers, innovators and developers as to how best to fund projects.

In addition to financing issues for product development, clinical trials and safety testing of medical devices are also problematic in many LMICs. While these processes are costly and time-consuming, some countries lack regulatory mechanisms, functioning regulations, or trained human resources. Of producers of medical devices who mentioned they face difficulties measuring the effectiveness of their products (24 of 46), more than half were from LMICs. Identifying and creating solutions in this area will be fundamental to encouraging local production of medical devices.

With respect to technology transfer, other specific barriers were highlighted by the survey. The lack of financing available to support commercialization of locally-produced medical devices and the lack of information available

regarding innovation, were the two main reported barriers to effective technology transfer. Thus, to increase the dissemination of innovations for global health and indigenous technologies, information required for their procurement or donations should be available to all stakeholders both at the country level, and to funding agencies and UN organizations. It is also important to mention that some producers have either transferred or evaluated the possibility to transfer their product to LMICs.

3.9 Policies and partnerships

Some examples of medical devices successfully produced in LMICs are projects developed through collaborations or partnerships between different organizations, highlighting that joint efforts between partners may increase the likelihood that a product will be developed and effectively placed in the market.

Although some of the survey respondents involved in developing and manufacturing medical devices have previously sought or participated in various types of partnership, comments showed that more work needs to be done to put in place the right policies and incentives to stimulate a larger number of partnerships to increase the chances of a device being successfully produced, approved and manufactured in a local context.

3.10 Regulations and intellectual property rights

A frequent aspect of regulation processes mentioned as part of the survey comments was that regulation is a bureaucratic process that frequently requires too much time and resources. These comments underline an evident need to develop regulations suitable for producers in low-resource settings to ensure safety, effectiveness and high quality of their products in order to promote indigenous devices. Also, to reduce the efforts, costs and time spent on regulatory and post-market surveillance, compliance to international guidelines for good manufacturing practices, and the consideration for permission to third parties to provide confirmation of regulatory compliance, were some of the different solutions suggested by participants (5).

Nearly three quarters of 46 survey respondents considered IP rights registration for their products, of which 22 are from an LMIC. While IP rights should be one of the factors promoting innovation, transfer and dissemination of technologies, it is clear that producers and innovators in many countries face challenges to taking full advantage of the opportunities that registration of their products may provide. For instance, countries such as Australia have “strong IP protection laws which provide protection to a manufacturer using its own or licensed IP” (5). Though efforts have been made to stimulate product patenting and IP registration of products, in many countries domestic producers face more stringent regulations, compared to imported products, in addition to prohibitive patent costs and “a great gap of knowledge in the industry and academy regarding patents and license” (5).

3.11 Funding and financial mechanisms

According to respondents, an important barrier to access to medical devices is the cost of such technologies. As many technologies were developed to satisfy a high-end market, most of the medical devices currently on the market are still unaffordable to many LMICs. Medical devices costs may also be described as an “iceberg”: capital costs being just the tip of the iceberg, with some costs related to management of devices hidden (costs of use, maintenance and repair, spare parts and supplies, installation, accessories, training and human resource costs) (3). Financing issues appear to be an obstacle not only at the outset of product design and development, but also while registering, commercializing and licensing technologies.

The survey also highlighted that donors and investors are willing to endorse projects where a technology-related needs assessment has been performed. However, these investments tend to happen for technologies that are already known, have been tested for safe use, and are compliant to regulations. Producers in LMICs may struggle to meet these assessments and can be rendered uncompetitive against MNCs.

Financing was also reported to be a barrier for producers to commercialize their products. From the total number of respondents, 22 were professionals from LMICs working in procurement of medical devices, through international or national tender, donation or direct purchase. Interestingly, the most frequent factor mentioned was price and quality (with ten and five respondents respectively). While a better price may not be affordable to procurers, schemes to finance technologies from the time of purchase to the end of their lifespan need to be ensured in order to harness the full potential of technologies. Information about local medical devices and innovations should be available to be used by buyers. Moreover, to increase affordability of medical devices required for specific or essential procedures, a list of devices needed to be included in the national approved lists for procurement and reimbursement, together with innovative technologies that may substitute traditional high-end technologies. If the technical specifications of these products are also included, then decisions on purchase of various configurations, accessories and spare parts may also be made through a well-informed procedure. Further details of the survey and results can be found in the annexes.

Taking into consideration the various reported barriers and challenges to local production, it is clear that not all medical devices are equally fit to be produced locally in successful businesses. In order to analyse the viability of local production, many different factors have to be taken into account. In order to support such an analysis, a tool was developed to assess the feasibility of local production for a specific device in a given region. The tool is presented in the following chapter.

References

1. *Intellectual property rights, innovation and public health. Report by the Secretariat.* Fifty-sixth World Health Assembly, Geneva, 19-28 May 2003, Document A56/17. (http://apps.who.int/gb/archive/pdf_files/WHA56/ea5617.pdf, accessed 10 July 2012).
2. *Landscape Analysis of Barriers to Developing or Adapting Technologies for Global Health Purposes.* Geneva, World Health Organization, 2010.
3. *Medical Devices: Managing the Mismatch: An outcome of the Priority Medical Devices project.* Geneva, World Health Organization, 2010 (http://whqlibdoc.who.int/publications/2010/9789241564045_eng.pdf, accessed 10 July 2012).
4. *Local Production for Access to Medical Products. Developing a Framework to Improve Public Health (Policy Brief).* Geneva, World Health Organization, 2011.
5. Respondent personal comments collected from the survey. World Health Organization, accessed 10 July 2012.

4. Measuring the viability for local production of a specific medical device: A feasibility tool

One of the potential approaches to improving access to specific medical devices in low-resource settings lies in the establishment of local production. The concept of local production appeals to various groups for different reasons: Innovators and companies aim to produce and sell their technology in a financially sustainable and profitable way; patients and health care workers welcome easy access to essential medical devices; governments seeking beneficial solutions to local and regional health problems are also interested in enhancing national capacity to manufacture and boost economic growth. However, local production of medical devices is a complex endeavour, and success depends on a multitude of factors related to the device itself as well as the local environment.

In this chapter, a feasibility tool is presented that focuses on medical devices addressing health needs in low-resource settings. The tool is a first assessment of the likelihood that a specific medical device can be produced locally. Moreover, the tool helps stakeholders to consider all relevant aspects before starting to plan for development, financing and production.

The tool was developed within the WHO Medical Device Unit and is based on the evidence of barriers to local production described in the previous chapters. It consists of several sets of relevant questions concerning local production and raises critical aspects that must be taken into account when considering local production of a specific device in a given location. Any interested parties using the tool must adapt the questions and especially the relative weight assigned to each question. In Annex 2, an exercise is presented where the tool is employed in a set of case studies that highlight the complexity of such feasibility assessments.

Determining which factors are most critical to the success or failure of medical device local production is an essential but challenging task. This tool gives an estimated measure of success probability for local production of a specific medical device in a given low-resource setting. Moreover, closer analysis of the outcome may indicate possible shortcomings or anticipated difficulties in the venture of manufacturing, selling and using the medical device locally. The tool also serves, therefore, as a basis for reconsidering and improving the strategy for local production of specific devices. The tool was developed with the help of external advisers, and was reviewed by expert committees. The result is a second draft prototype that will need to be refined for further analysis, but it is hopefully a valuable instrument that can help innovators, donors and decision-makers.

In order to develop the feasibility tool, the following steps were taken:

1. Collection of sources for most common issues encountered while estimating the potential of a specific medical device for local production:

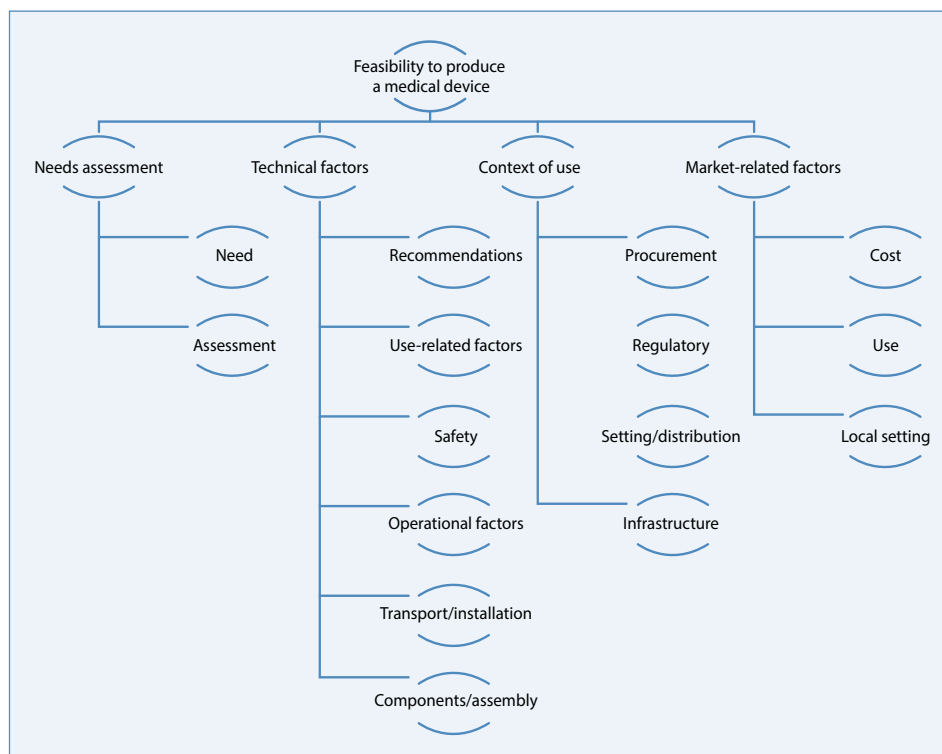
- a. Findings from the scoping study, country studies, and case studies (as presented in Chapter 2).
 - b. Outcome of survey on access to medical devices in low-resource settings with data and comments from innovators (as presented in Chapter 3 and Annex 1).
 - c. Development of first draft of feasibility tool (by WHO) with support of external experts (for the first draft of tool see Annex 2).
2. Presentation of first draft of tool to stakeholders.
 3. Review and revision of the first draft by stakeholders.
 4. Creation of revised second draft presented in this chapter.

The aim was to develop a basic tool to identify medical devices that address a local need and have the potential to be produced and sold locally as part of a successful business model. The tool is suitable for being extended easily to a higher level of detail. The structure and sectioning of the tool are quite generic and allow for easy adjustment to include further aspects.

The feasibility tool should provide a rating to the following question: *“To what extent is medical device X suitable for successful local production in low-resource region Y?”* Therefore, the user needs to know the specific characteristics of region Y he/she would like to analyze for local production of the device.

In order to take the various priority considerations into account, the tool is divided into four sections. Figure 1 shows an overview of the structure of the tool, which is presented in detail in Annex 2b.

Figure 1 Sections and subsections of the Feasibility Tool



Section 1: Needs assessment

The first section focuses on assessing the health care need for the medical device in a given region, and its suitability for manufacturing and use in low-resource settings *at a first glance*. This includes key questions about the tackled health problem as well as the basic characteristics of the device. The two subsections are “Need”, which refers to the local situation of the target health need that the device is intended to address, and “Assessment” which compares the device against technologies meeting the same need that are already in place. The section also looks at the contextual framework and market characteristics into which the device may be inserted.

The purpose of this section is to assess if a given device X seems generally appropriate for local production in region Y. If the sum of points in this section does not surpass a specified threshold, the device should be rated as having “not enough potential” as the fundamental requirements are not fulfilled. Therefore, it is very unlikely that the device can be produced in the given setting.

Most of the aspects introduced in this section are taken into account in more detail in the following sections.

Section 2: Device-related factors

This section looks at the properties of the medical device itself. The purpose is to determine if the device can be easily manufactured, used, installed and maintained. Clearly, a device that is complicated to manufacture could still be potentially produced and used locally, but the employment of external expert technicians for manufacturing could add substantial problems in terms of organization and financing. Equally, greater needs in training for technicians, health care workers and maintenance personnel as well as greater needs for resources (e.g. gas, water or electricity) and infrastructure needs in general, lead to lower ratings. Another important aspect is the risk level for manufacturing, transport, installation, use and maintenance where lower risk levels are favoured.

Eventually, if the device has received awards or is endorsed by UNICEF, WHO or other organizations, it is assumed that a noteworthy assessment of the device has already been performed with positive results that lead to a higher rating by the tool.

Section 3: Context of use (device-in-region related factors)

This section concentrates on the region where the device might be manufactured and used and evaluates the appropriateness of the region. Here, two main aspects are taken into account. The first analyses country-specific government policies and investigates whether there are the adequate structures in place to support local production of medical devices, making business success more probable. It has to be considered, for example, if procurement and regulatory policies are likely to help or hinder local production of medical devices.

The second aspect concerns the infrastructure in the country and evaluates the practicability of manufacturing, transport/installation, use and maintenance in the specific region. For example, if the device is fragile and needs to be transported to remote regions, local use does not seem feasible, leading to a lower rating. Here, a special focus lies in whether there is sufficient local expertise for manufacturing/use/maintenance required for that type of device. Furthermore, a very important factor measured in this section is the availability of consumables and spare parts which is often overlooked but vital for the function of a given device. Cheap, locally produced, low-risk level spare parts and consumables gain higher ratings than expensive or imported alternatives.

Section 4: Market-related factors

This section evaluates the potential of the local market from a pure business point of view. Of course, costs of manufacturing and use play a major role, especially in regions where spending capacity may be very low or where salary disparities in the population are high. Local acceptance and recognition of the usefulness of the device are also taken into account.

The final rating comprises all four sections and leads to one resulting evaluation number or “grade”. The final grade represents the probability that medical device X can be locally produced in region Y as part of a successful business model.

However, it should be noted that not all questions are of equal importance for evaluating the feasibility of a situation. Therefore, they should be weighted according to the impact they will likely have based on the need at hand. Industry has another point of view than developers, so each party using this tool should adapt the weighting to its purpose. In Annex 2, an exercise of a possible weighting method from a public health point of view can be found.

Each section also serves for assessment on its own: the sum of points for each section of the tool gives a distinctive measure for different aspects to be taken into consideration for local production. Therefore, the result of the assessment helps with analysis of where improvements and modifications are needed in order to produce the device successfully in respective regions. A possible outcome could also be the realization that a specific medical device is not suitable at all for local production in a specific region. However, the results might indicate why the region poses a problem and thus suggest ideas in which other regions local production might be more promising.

5. Way forward: Overcoming barriers

In light of the various factors preventing equitable access to medical devices in many regions of the world, WHO has been working to inform and guide relevant stakeholders – governments, private sector, academia, organizations, health workers and patients – in relation to the barriers that prevent the widespread use, transfer and production of medical devices.

The following suggestions have been formulated by 103 survey participants and discussions during the Stakeholders` consultation meeting held on June 4 and 5, 2012 in WHO Headquarters, Geneva, Switzerland.

5.1 General issues to consider in order to increase access to medical devices

- i. **Encourage innovative financing mechanisms and funding sources.** The most relevant factor limiting access to medical devices is the capital cost and financing of related technologies. In addition, medical devices have long-term costs that may make the maintenance and use of the equipment expensive and unaffordable in LMICs.
- ii. **Incentivize and stimulate the creation of a stronger market.** Investors and donors consider public health need as a critical factor in determining whether to fund a project. However, information about the global market for medical devices is not detailed enough to provide accurate data to motivate investment in this field. Moreover, large multinational companies already own a large market share globally, making it difficult for local producers to compete.
- iii. **Determine specific essential or core medical devices by clinical intervention.** Investors and donors are more interested to invest in core technology areas that represent a higher demand and a larger market.
- iv. **Support the development of technical specifications** for medical devices in order to provide information for decision-makers about the minimum requirements needed for a device to be procured. This will encourage medical device producers to comply with specifications from the early stages of development.
- v. **Encourage transparency and international harmonization when strengthening regulations.** Because medical devices need to be safe and efficient, regulations and standards control in manufacturing, distribution and exportation of the technologies are important. Simple and transparent regulations can be implemented that also help to support product and establishment registrations.
- vi. **Develop incentives for transfer of technologies from academia to the market.** Responses to the survey show that the largest incentive in academia for the transfer and production of medical devices is at the R&D level, while less resources are usually allocated to later stages (i.e. patenting,

marketing, etc.). Incentives may encourage collaboration between various medical device stakeholders (i.e. academia, private, public and non-profit sectors) to successfully achieve local production of innovations.

vii. Support professional networking to disseminate information about innovative and locally-produced medical devices. One measure of success for local production of medical devices is that the available technologies are being used to address the intended health need. Nonetheless, information about technologies may be limited, encouraging decision-makers to choose products from well-known international manufacturers rather than local ones. By increasing the support for local professional networks to share knowledge about technologies that are safe, affordable and effective for addressing the health needs of the local community, awareness on the effectiveness of these technologies can be increased.

5.2 Stakeholder-specific suggestions resulting from committee discussion

Based on the discussion of the survey results, the following stakeholder-focused suggestions were put forward by the Stakeholders' Meeting on June 4 and 5, 2012.

		Areas to be addressed		
Stakeholders	Research and development	Regulations	Procurement, logistics and supply chain	Maintenance and safe use
Research bodies, innovators and academia	<ol style="list-style-type: none"> 1. Create pathways for including local health professionals and engineers in product development. 2. Encourage business schools to develop case studies on new business models and frugal innovation methods for medical devices suitable to LMICs. 	<ol style="list-style-type: none"> 1. Incorporate medical devices regulations and intellectual property modules in biomedical engineering programmes. 	<ol style="list-style-type: none"> 1. Establish a means or processes for connecting inventors, engineers and technologies with NGOs/business people/policy-makers who can help disseminate medical technologies. 2. Build confidence in local products. Identify champions based with compliance with good manufacturing practices. 	<ol style="list-style-type: none"> 1. Create an online database or easy to understand information forum for the maintenance of medical devices. 2. Human resource development and capacity building including development of a separate cadre of clinical and biomedical engineers with well-defined career prospects.
Entrepreneurs and industry	<ol style="list-style-type: none"> 1. Develop market intelligence reports and market strategy locally and regionally prior to actual manufacturing. 2. Customize product design to suit local requirements. 	<ol style="list-style-type: none"> 1. Establish better knowledge of the regulatory process 2. local manufacturers to comply quality systems 13485, requesting support from academia, governments or experts. 	<ol style="list-style-type: none"> 1. Capitalize on guidelines defined in previous WHO publications. 	<ol style="list-style-type: none"> 1. Suggest that all instructions for use are translated into local languages and are depicted in an easy to understand way. 2. Reduce consumables waste by deploying appropriate technologies. 3. Ensure proper training of clinicians, health care workers, and users as part of the procurement process. 4. Encourage manufacturers to include on-board power regulator in their power pack for the equipment. 5. Label devices with pre-market approvals to ensure safety, especially class III devices.

		Areas to be addressed		
Stakeholders	Research and development	Regulations	Procurement, logistics and supply chain	Maintenance and safe use
Banks and funding agencies	<ol style="list-style-type: none"> 1. Grants for research. 	<ol style="list-style-type: none"> 1. Soft loans to meet regulatory approvals. 	<ol style="list-style-type: none"> 1. Soft loans to develop supply chain and logistic activities. 	<ol style="list-style-type: none"> 1. Grants for training in maintenance and safe use and for procurement of spare parts.
Governments and WHO	<ol style="list-style-type: none"> 1. Government funding support for product or prototype development. 2. Foster trusting collaborative research environment between academia, industry and government. 3. Reduce import duties on raw materials that are used for manufacturing of essential medical devices. 4. Bridge innovation and product realization through adequate government funding. 5. Develop priority list of medical devices that domestic production can increase access, where appropriate and economically feasible. 	<ol style="list-style-type: none"> 1. Regulate entry of re-furnished equipment in health industry. 2. Local government to simplify clinical trial requirements to encourage local production of medical devices. 3. Strengthening the role of National Regulatory Authorities. 4. Harmonization of regulations at regional level. 	<ol style="list-style-type: none"> 1. Transparent procurement methodologies. 2. An established means/process for connecting inventors, engineers, and technologies with NGOs/business people/policymakers who can help disseminate medical technologies 3. Build confidence in local generic products. Identify champions based on compliance with good manufacturing practices. 4. Advocacy for proven/tested innovations. 5. Rationalization of tax structure to give local manufacturers a 'level playing field' against imported medical devices by adjustment in customs duty. 	<ol style="list-style-type: none"> 1. Establishing an adverse event reporting system and dissemination of the outcomes. 2. Ensure training of clinicians, health care workers, and users as part of the procurement process. 3. Human resource development and capacity building including development of a separate cadre of clinical and biomedical engineers with well-defined career prospects. 4. Identify a local professional and partner with device manufacturers of priority devices. 5. Label devices with pre-market approvals to ensure safety, especially class III devices.
			<ol style="list-style-type: none"> 6. Capitalize on guidelines defined in previous WHO publications. 	

Stakeholders	Areas to be addressed		
	Research and development	Regulations	Procurement, logistics and supply chain
NGO's and international organisations	<p>Research and development</p> <ol style="list-style-type: none"> 1. Establish facilitation centres to address the unmet clinical need for medical device products. Here doctors and health care professionals will assess the feasibility of an idea. Such centres would also propose appropriate business models and commercialization programmes. 2. Identify country-specific disease burden and develop an essential medical devices list, and make this information available in the public domain. 3. Creation of a needs database where clinicians/health care workers in low-resource settings can post their identified medical needs that inventors worldwide can take into consideration. 4. Host knowledge sharing platforms at regular intervals to stimulate innovation and development. 5. Develop priority list of medical devices to which domestic production can increase access. 6. Host a Second Global Forum on Medical Device for dissemination of appropriate technologies. 	<p>Regulations</p> <ol style="list-style-type: none"> 1. WHO to prioritize support/capacity building for LMICs with weak or without regulatory system to strengthen/establish regulatory system for medical devices. 2. Development of internationally accepted regulatory process. Support structure for engineers/investors/innovators to comply with the regulatory process. 3. Depending on a country's situation, identifying universities to give certification to products to encourage local, small-scale innovative entrepreneurs. 	<p>Procurement, logistics and supply chain</p> <ol style="list-style-type: none"> 1. Create central website or catalogue/price charts for all marketable devices approved for sale, procurement and use 2. WHO to include approved devices in published documents or on website. WHO recommendation will encourage adoption of the technology. 3. Establish a means or process for connecting inventors, engineers, and technologies with NGOs/business people/policy-makers who can help disseminate medical technologies. 4. Build confidence in local generic products. Identify champions based on compliance with good manufacturing practices. 5. Facilitate developers to reach markets faster. Create a database of accredited consultants who focus on supply chain development to facilitate the process. 6. Facilitate to use NGOs as supply and advocacy channels.
			<p>Maintenance and safe use</p> <ol style="list-style-type: none"> 1. Online database or easy to understand information forum for repair of medical devices. 2. Awareness campaign about medical device safety among all the stakeholders in the health care system. 3. Identify a local professional and partner with device manufacturers of priority devices.


As evidence indicates, the need for improved access to core medical devices for priority diseases in LMICs is clear. Such technologies, are required to ensure quality, affordable and accessible care in low-resource settings around the world. Building on the previous related work carried out by WHO, a more comprehensive analysis of the barriers and challenges to ensuring widespread access to life-saving medical technologies in LMICs was required. The current project adopted a three-pronged approach to investigating local production and technology transfer as a means to improve access to medical devices: Stating the challenges and barriers impeding health technology access through a detailed survey, literature review and stakeholders' meeting.

In the first instance, a scoping and market landscape analysis laid the groundwork for characterizing the driving factors and forces behind health technology uptake in LMICs. A worldwide survey was also carried out to gather the insights and perspectives of engineers, IP experts, business people, policy-makers, health professionals and activists on the interface of medical devices and public policy – and most significantly, what can be done to improve access to these technologies. By polling key stakeholders in the medical devices arena, key challenges and barriers that require policy attention were identified.

Until now, the various stakeholders in the medical devices area in LMIC, did not have a systematic means of determining the viability of medical device local production and making informed decisions. The draft feasibility tool outlined in this report represents a novel, scalable approach for evaluating specific devices in low-resource settings. While it remains far from a universally applicable solution, it can provide a basic framework through which decisions governing the uptake and implementation of medical devices in LMICs can be made effectively, and in a data-driven manner. The observations and conclusions of the current study, existing research on priority medical devices and related disease burdens, as well as the UN Commission on Life-saving Commodities, have collectively influenced the WHO Medical Devices unit to consider devices for further studies in low-resource settings to help address:

- The MDGs (and in particular, maternal and new-born health), e.g. continuous positive airway pressure devices, vaginal assisted delivery devices and the non-pneumatic anti-shock devices;
- The growing burden of diseases associated with aging, e.g. hearing aids;
- The growth of NCDs, e.g. electrocardiographs.

Finally, a critical and as yet unanswered question posed in the literature relates to the effect of local production on technology diffusion. Though evidence on if and how local production improves access to medical devices is mixed, there exist a clear set of health, technological and industrial policies that should provide solutions to serve this goal. This report identifies a series of concrete steps forward – a list drawn from the consensus of stakeholders spanning health professionals, government, entrepreneurship and academia.



This report serves as a first reference point to further advance research on the benefits of local production of core technologies for public health purposes, and suggests to continue working on medical devices that will address three areas of public health priority: maternal and child care, noncommunicable diseases and ageing population. This report compiles data, tools and actionable policy solutions to address the growing global disparity in access to medical devices. Indeed, with proper coordination of stakeholders across disciplines, including the specific work of biomedical engineers around the globe, the way forward appears clearer. The solutions to address this gap are within possible reach – and with it, the lives of millions of people around the world.

Annexes

1. Outcome and survey questionnaire (Annexes 1a and 1b): This section presents the results of the survey regarding all questions relevant to understand what barriers stakeholders face when developing, manufacturing and selling a medical device in low-resource settings.
- 2a. Feasibility tool – a usage exercise: This section demonstrates how the feasibility tool as described in Chapter 4 can be used to assess the feasibility of local production for a set of medical device examples.
- 2b. Feasibility tool: Specific sections
3. Consultation on barriers and opportunities for improved access to medical devices by technology transfer and local production

Annex 1

Survey on access to medical devices in low-resource settings: results

To gain insight into the most common barriers, WHO conducted a survey on access to medical devices. The primary goal of the survey was to identify the main barriers and challenges that stakeholders in the medical devices sector confront in the countries where their products are intended for use. The survey consisted of 15 sets of questions divided into the following sections:

Box 1 Sections of the survey

- Personal information
- Introduction
- WHO innovation projects
- Product development
- Policy and partnerships
- Intellectual property
- Regulation
- Academia
- Technology transfer
- Acquisition/Procurement/Reimbursement
- Clinical engineering
- Investor/Donor/NGO
- Industry
- End-users
- General

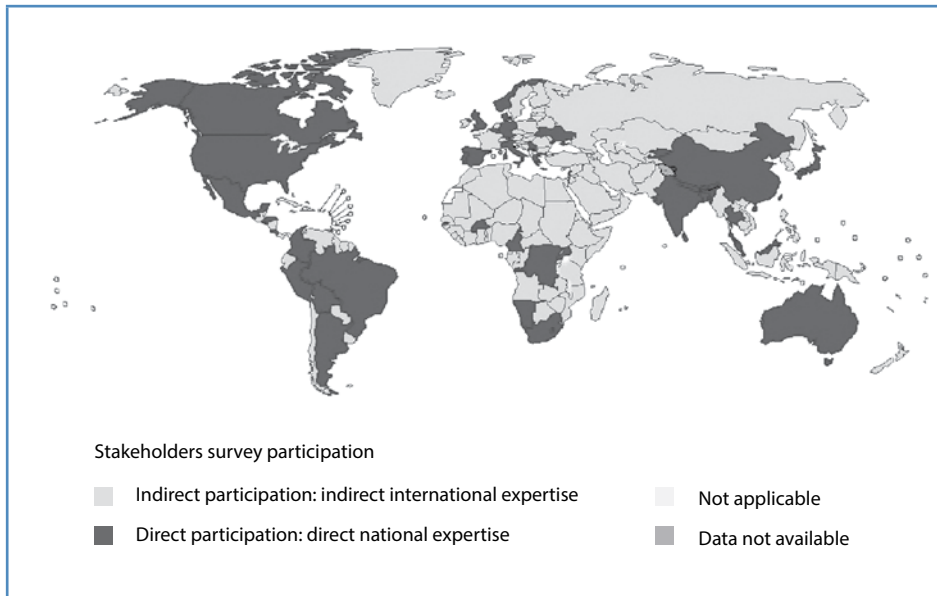
These sets of questions were designed based on barriers to transfer of technology and local production of medical devices highlighted by the literature review, case studies and previous research on medical devices by WHO. The survey was launched in April 2012 using an internet-based tool for data collection (DATACOL). The number of questions per section ranges from 2 to 30 with 146 questions in total, including personal details that have been kept anonymous. The survey was written to guide respondents to questions relevant to their experience, meaning that not all participants would need to answer all questions. The questions requested yes/no or multiple choice responses. Within the survey, there were 52 questions inviting the participants to comment on their choice of answer and give additional background information. Completion of the survey took an estimated 30–60 minutes.

The survey was sent to stakeholders globally. It was sent to the Country Focal Points who were kindly asked to distribute the survey to national developers of medical devices in respective countries, and also to people from various sectors involved with the medical devices industry. At the time of writing the current report, more than 140 people had responded to the survey, of which 103 submitted sufficient data for analysis. The answers to all questions concerning medical device local production and technology transfer were statistically evaluated in order to draw on the valuable expertise of people related to the topic in different roles and professions. The results are presented and interpreted in the remainder of this chapter, followed by a set of topics for further revision to overcome the most relevant barriers commented by professionals surveyed.

Survey outcome

The survey is an ongoing project and remains open for participation and further analysis. However, the deadline of submission for the purpose of the current document was the end of April 2012. Figure 1 shows the participants country profile. It is important to note that most respondents were from low- or middle-income countries.

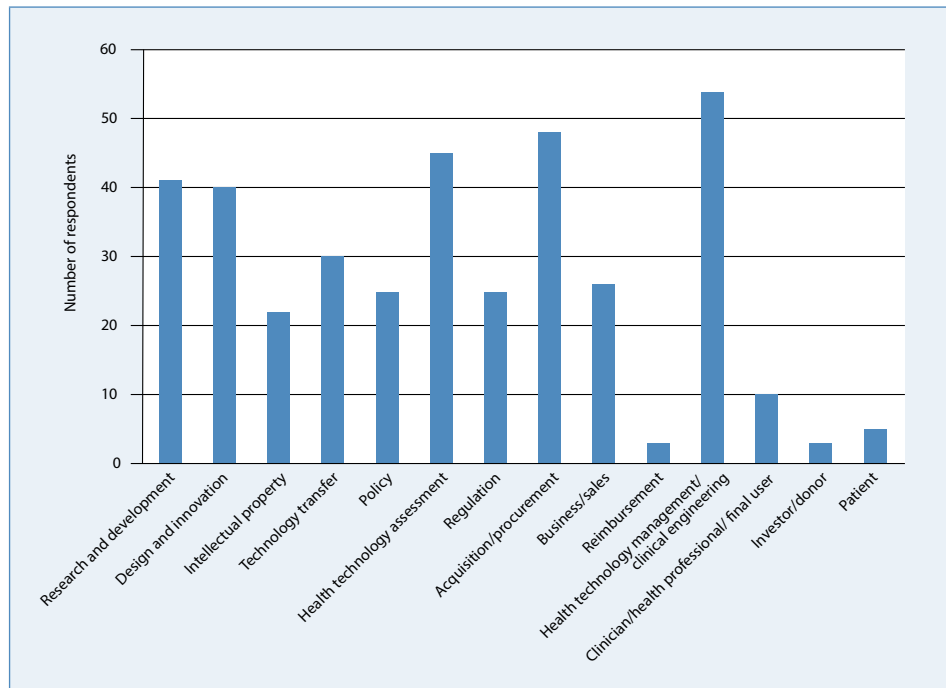
Figure 1 *Geographic distribution of survey respondents*



Respondents' expertise and working sector

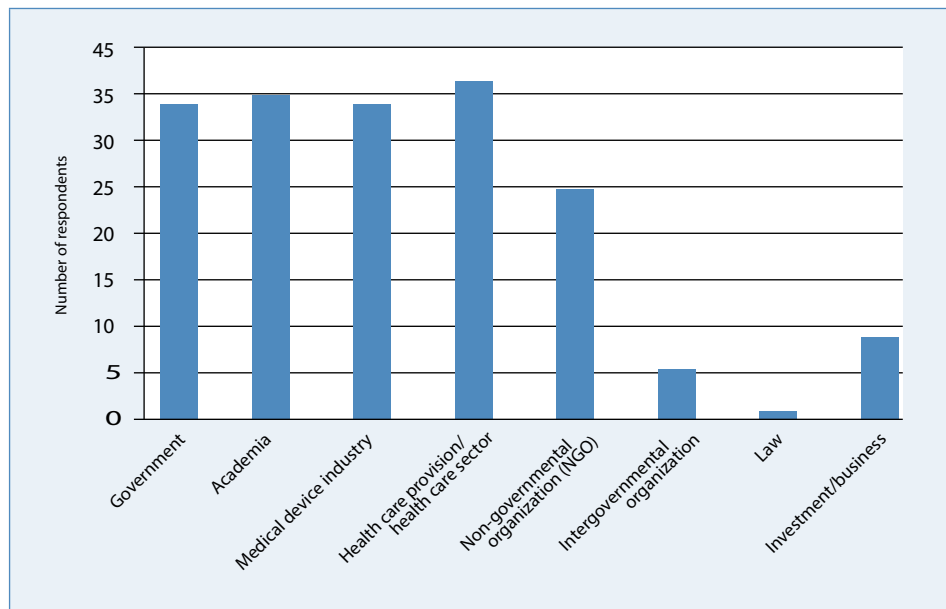
All of the survey respondents were stakeholders involved or associated with the medical devices industry in various ways: research, production, delivery and use. Figure 2 and Figure 3 show their fields of expertise and the sectors in which they work. From the total number of participants, the vast majority (~50%) had directly relevant experience or were working in the clinical engineering field. In contrast, a lower proportion of respondents reported working in reimbursement and financing of medical devices (2%), and donors and investors (2%).

Figure 2 Survey respondents' fields of expertise (total responses: 103)



Furthermore, the questions regarding the respondents' work sector show that the majority work in the health care provision and service delivery sector. Workers in the government and academia sectors were also significant, while a smaller number work in businesses and investment sector, law, nongovernmental and intergovernmental organizations.

Figure 3 Respondents' sectors of work (total responses: 103)

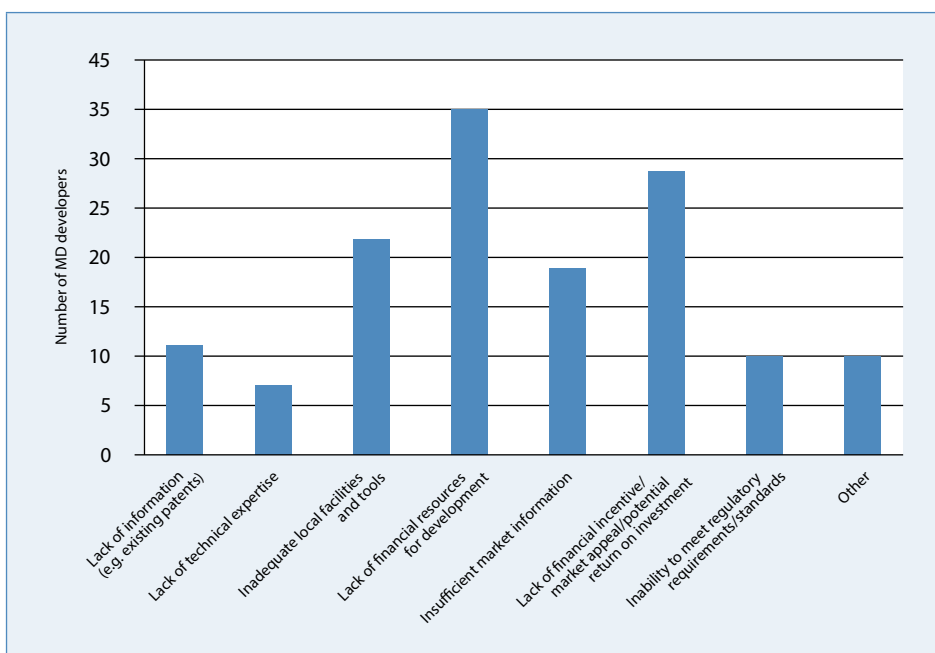


Product development

There is a large spectrum of barriers to developing or producing a medical device for low-resource settings. Furthermore, reaching the market with an innovative device is a difficult endeavour hindered by various factors. The answers to the questions in this section of the survey shed light on the most common problems (Figure 4) which were: the lack of financial resources for product development, lack of financial incentive, inadequate infrastructure, insufficient information about the market, and the inability to meet regulatory standards.

Figure 4 reveals which barriers and obstacles were faced most by developers during product development process.

Figure 4 Barriers faced during product development (total responses: 45)

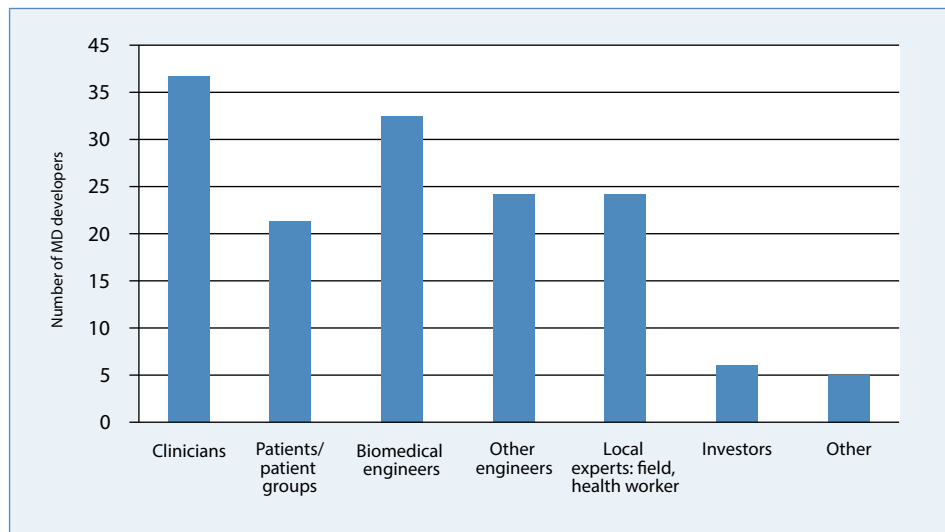


Box 2 Comments from survey respondents on experiences on the field related to Product Development

- “Most low-cost setting needs are not available in the literature [...]” – Engineer (Consultant), India.
- “[...] we first commercialized imported goods to the market, we became close to the users’ specific needs, which lead us to do bibliographic and on-site research which was later backed up with a market research performed by a company specialized in the subject. But our most important source of information came from the final users across the country [...]” – Biomedical Engineer (Industry), Mexico.
- “[...] the understanding of Bolivia’s market was vital to bring on line the specific devices to be designed and built. That is why the research has to be brought together with the personal knowledge, side by side, to give that value for Bolivian’s market [...]” – Biomedical Engineer (Academia), Bolivia.

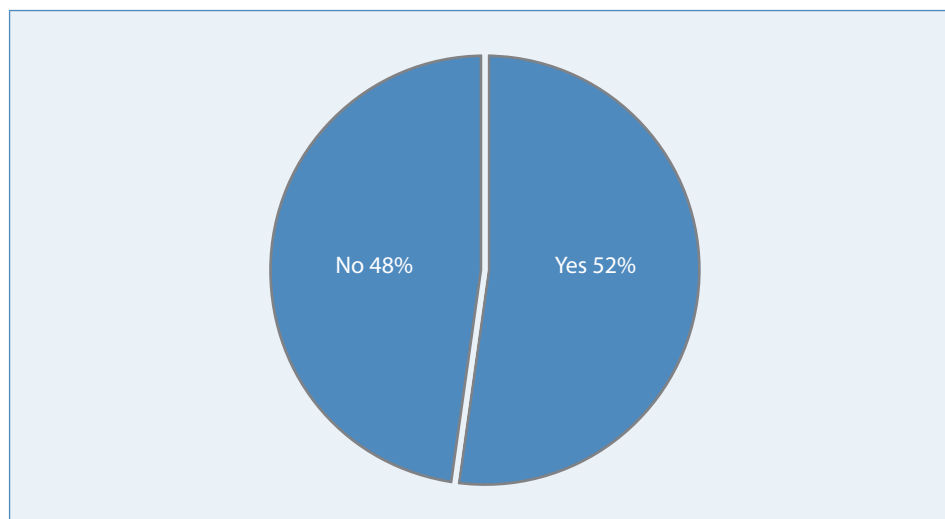
The development of medical devices is a complex process that requires collaboration between people with different professional backgrounds and, often, developers seek these collaborations, partnerships and alliances. Figure 5 shows the additional collaboration developers seek most commonly in the development process. In this regard, the most consulted professionals were clinicians and biomedical engineers: of the total 47 respondents, 37 consulted clinicians to identify the need before developing a project and 32 included biomedical engineers in their consulting processes; however, only 5 included investors or donors in their consultation process.

Figure 5 Stakeholders participating in development process (total responses: 47)



Of a total of 46 respondents, 52% reported that measuring the effectiveness of a medical device can be problematic in low-resource settings as the performance of clinical trials or gathering reliable evidence might be difficult to realize in an environment without stringent standards and functioning regulations, as seen on Figure 6.

Figure 6 Ratio of developers who faced difficulties in measuring medical device effectiveness in low-resource settings? (total responses: 46)

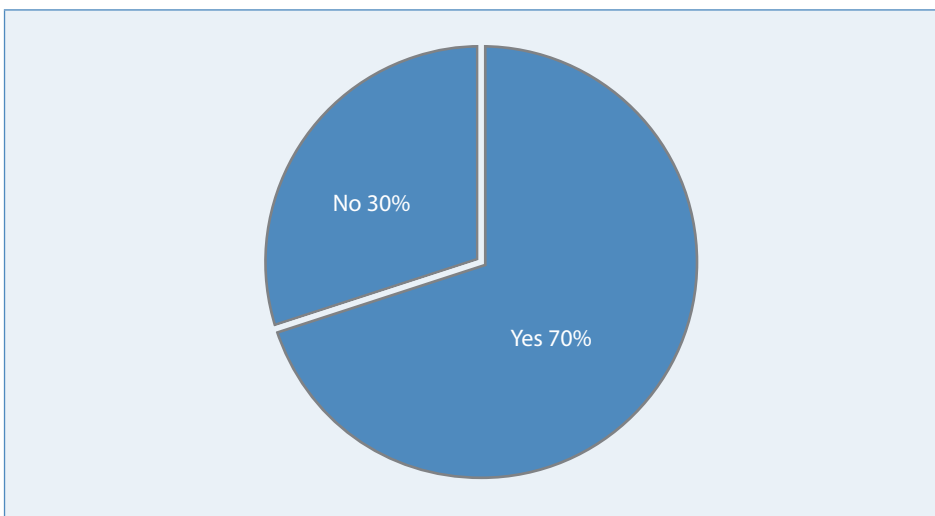


Box 3 *Comments from survey respondents on experiences related to measurement of medical device effectiveness*

- “[...] Regulatory burden is not differentiated between medical devices for low- and high-resource settings. [...] Lack of small-market aggregation mechanisms (each African country, for example, is a new regulatory process—just to conduct the clinical trials).” – Professor of Biomedical Engineering (Academia), USA.
- “Although public health instances are interested in devices that are low cost and solve local problems, there are no mechanisms that make it possible for these new devices to be introduced and tested in the public health system.” – Biomedical Engineer (Industry), Mexico.
- “Common people are very supportive of indigenous innovators. [...] When people find out that I am not working for my own profit only, there is a philosophy of helping people, others come forward to help.[...]” – Biomedical physicist and innovator (Academia), Bangladesh.
- “One of the unexpected challenges we found was working with the customs at the airport. Often our devices and materials would be held for no apparent reason then charged exorbitant fees.” – Programme Manager (Academia), USA.
- “We have strong partnerships with NGOs and academic institutions that have the ability and interest to test the products.” – Mechanical Engineer (Industry), Norway.

Intellectual property rights are handled very differently between countries and can therefore be a support or an obstacle for product developers. Figure 7 shows that 70% of the respondents are developers who have considered intellectual property rights already during the research and design phase, or during the identification of the market needs.

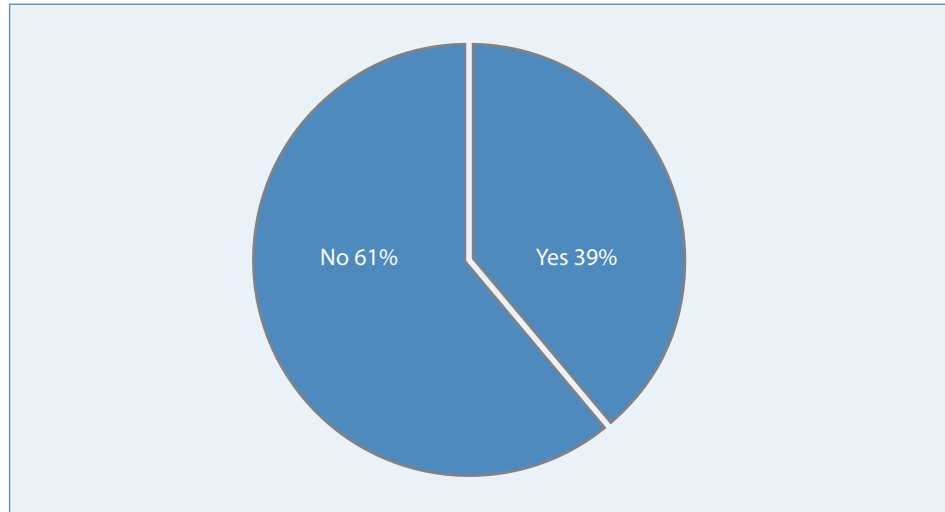
Figure 7 *Ratio of developers who considered IP rights (total response: 46)*



For a number of reasons, the actual manufacturing and production of an effective medical device in a low-resource setting can pose a problem. Figure 8 shows the number of developers who have actually transferred their

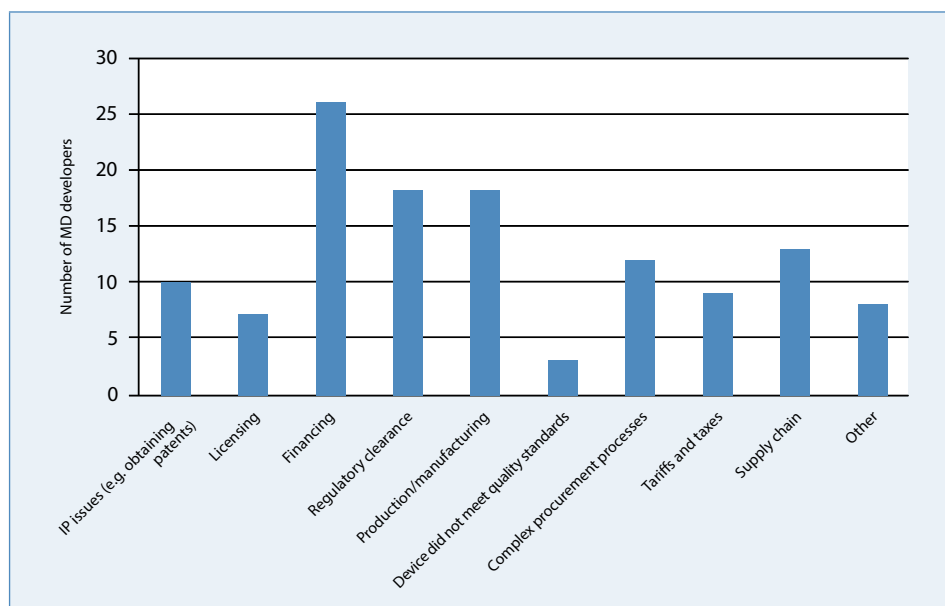
innovative technology for use by industry or organizations in low-resource settings. From a total of 46 device developers who responded to this question, 39% have been successfully transferred their technologies to be produced in low-resource settings.

Figure 8 *Ratio of developers who have transferred medical devices for use in low-resource settings (total responses: 46)*



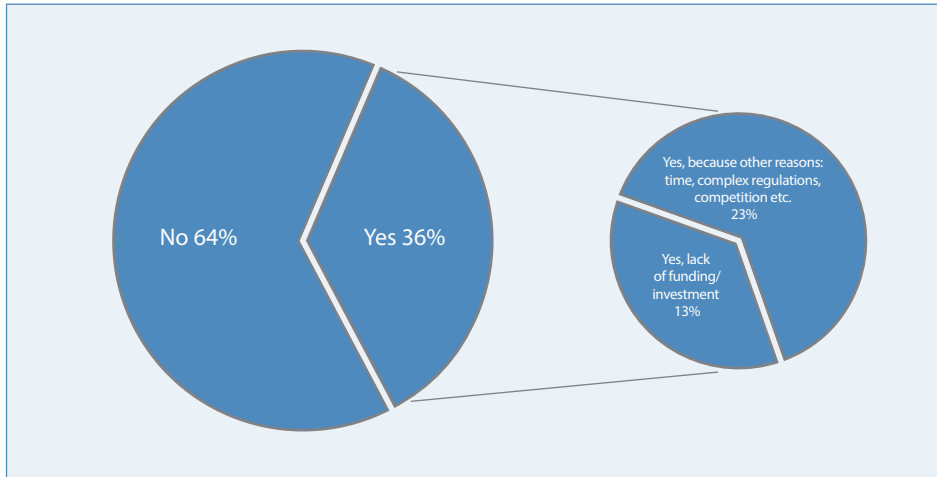
To understand the limited medical device transfer depicted in Figure 8, it is important to identify the obstacles for commercializing and selling medical devices in low-resource settings. In contrast to Figure 4 on barriers to the development of medical device, Figure 9 shows existing obstacles for the *commercialization* of products or for entering the market. The most important barriers mentioned by respondents were: financing, regulatory clearance, and production and manufacturing issues.

Figure 9 *Barriers faced in commercializing/selling medical devices (total responses: 46)*



Moreover, there is also a range of reported reasons why innovative ideas are not transferred into the development of product. Figure 10 shows the most common factors that hinder development of products by innovators with an idea for an appropriate and affordable medical device.

Figure 10 Ratio of innovators with an idea for a medical device for low-resource settings and reasons hindering final product development (total responses: 94)



Box 4 Comments from survey participants on experiences on the field related to technology transfer

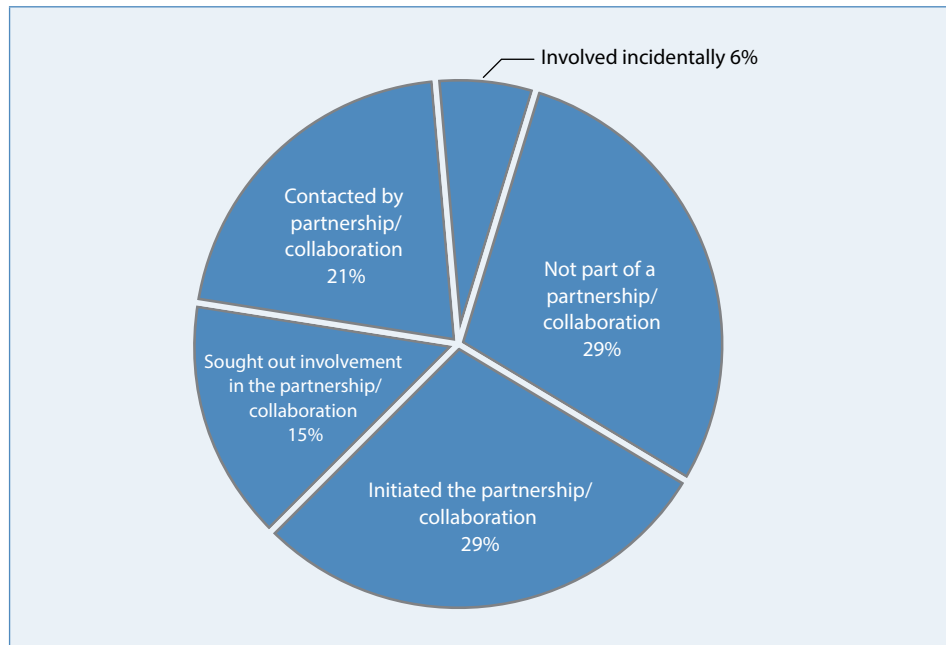
- “[...] we give our technology and business plans away for free to like-minded NGO’s”. – Social Entrepreneur (Non-profit enterprise), Brazil.
- “[...] the spread of knowledge and use for the developing world takes funding and also clinical trials. [...] we are looking for possible producers in mid-cost countries like India, China or Brazil.” – Physician (Academia), Norway.
- “Most of the technologies developed in my Institute have been transferred to industry for scaling up the processes and to manufacture on a commercial scale. Only through an industry partner, the product can be manufactured and placed on the market.” – Scientist/Engineer (Academia), India.

Policies and partnerships

As described in the scoping study (Chapter 2), national policies and incentives can actively support local development, local manufacture and technology transfer of medical devices. Especially centres of excellence, industry and academia collaborations – as well as product development partnerships focusing on medical device innovation and access – often play an important role for successful local production. Interestingly, Figure 11 shows that 69% of the survey respondents sought, initiated or were contacted to create collaborations or partnerships, and the main reason mentioned to not joining was the lack of incentives. However, 29% of respondents are members of these types of collaborations.

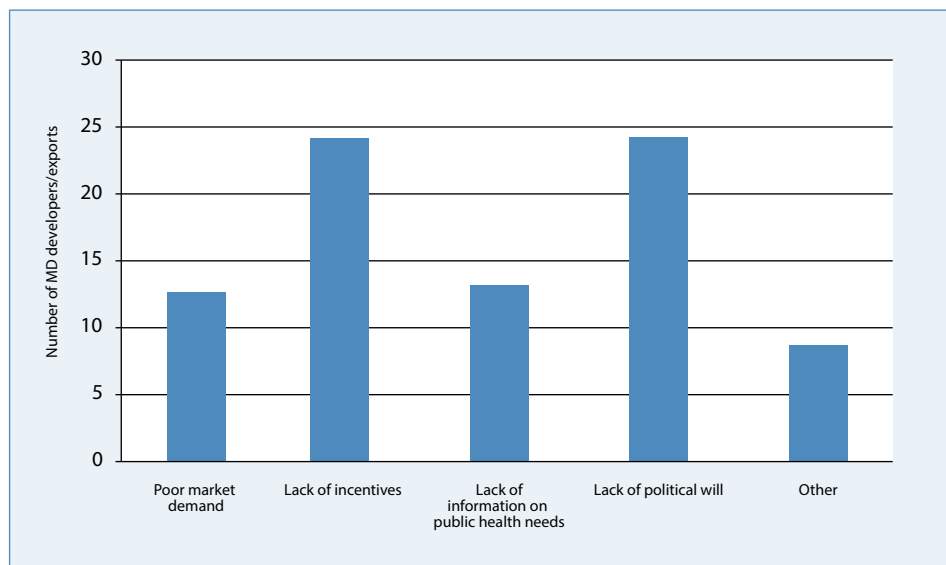
It is important to mention that of those respondents who reported initiating a partnership or collaboration, five have successfully developed a commercialized product and are from a low- or middle-income country.

Figure 11 Ratio of respondents in collaborations and reasons why they got involved (total responses: 48)



Although these collaborations may help increase access to medical devices, there are still some limitations to make them succeed. Figure 12 shows what respondents consider to be the main constraints for such partnerships and collaborations.

Figure 12 Main limitations of collaborations/partnerships in succeeding to increase access to medical devices (total responses: 42)



Box 5 *Comments from survey participants on experiences on the field related to partnerships and collaborations*

Limitations to collaborations

- “Excessive regulation of local manufacturers” – Biomedical Engineer (Clinical setting), Australia
- “[...] health care will not pay for medical devices” – Healthcare Consultant, Thailand

Factors that would encourage collaboration

- “Capacity to understand the needs of the markets” – Entrepreneur (Industry), Brazil
- “Collaboration between expert groups and government lobbying” – Biomedical Engineer (Academia), Australia
- “Less focus on pure profit, more focus on patient care improvement” – Biomedical Engineer (Academia), USA
- “Government and industry jointly identifying mutually useful areas to expand patient access. Government officials and private sector representatives often come with differing backgrounds, needs and expectations. Those have to be recognized and used in ways both find rewarding. So, the first criterion is understanding” – Manager (Industry), USA
- “The first condition should be to have sufficiently trained people in the country, able to form a production structure in the frame of a partnership [...]” – Biomedical Engineer (Non-profit), D.R.C

Regulation

Regulations of medical devices play an important role in most high-income countries, are mostly transparent and harmonized and include ratified regulations to control import, distribution and sale of medical devices as well as enforced industry compliance to medical device regulations. For countries with low-resource settings however, the situation is often not as clear.

Box 6 *Comments from survey respondents on the need for regulations*

- “Regulations are a necessity and do not [...] serve as obstacles or barriers as our population has to be protected from the ever increasing number of counterfeits” - Engineer (Government), Uganda
- “[...] a regulated environment for medical devices is critically needed to ensure quality and affordable health solutions are available. Often these regulations are seen as an obstacle or barrier for manufacturers whose strategic intent is on producing a cost-effective solution but at the expense of quality” - Operations Manager (Industry), South Africa

Box 7 *Respondent comments on experiences on the barriers/obstacles that regulations create for local manufacturing, distribution and sale*

- “Regulations demand extra resources, time and efforts to be spent on meeting requirements [...] which] might include compliance to quality management system (ISO 13485), risk management, clinical tests etc.” - Engineer (Consultant), China
- “It took [...] two years to start a new company in Brazil, [...] very expensive cost of taxes” - Entrepreneur, Brazil

Box 8 *Comments from survey respondents on experiences on the challenges/problems they have encountered with regulations*

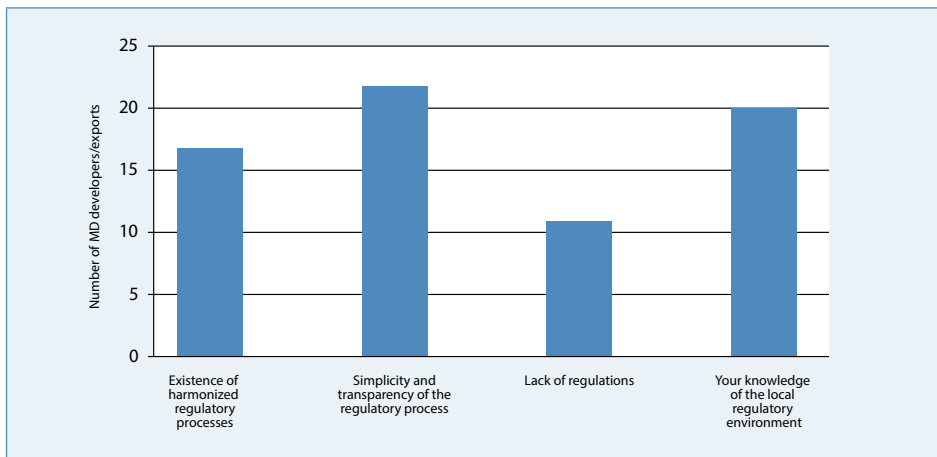
- “Inconsistency in requirements” - Manager (Industry), USA
- “Asian regulation is very dynamic” - Regulatory Affairs, Singapore
- “[...] the barriers of the regulations is the non-existence of written policies and guidelines implementing the new regulatory system [...]” - Engineer (Government), Philippines
- “[...] there aren't local regulations for manufacturing medical devices” - Industrial Engineer, Costa Rica

Box 9 *Comments from survey respondents on discrepancies in regulations for local and foreign manufacturers*

- “Local development and manufacturing subjected to greater and more stringent regulation than imported products” - Biomedical Engineer, Australia
- “Regulations are far stricter for imported items” - Healthcare Consultant, Thailand
- “Domestic manufacturers only receive 0-5 day notification of inspection. Foreign manufacturers usually receive 30+ days [...]” - Manager (Industry), USA

Figure 13 shows significant regulatory issues for medical device developers in the selection of target markets for their products.

Figure 13 Regulation-related market determinants in selection of target markets (total responses: 42)

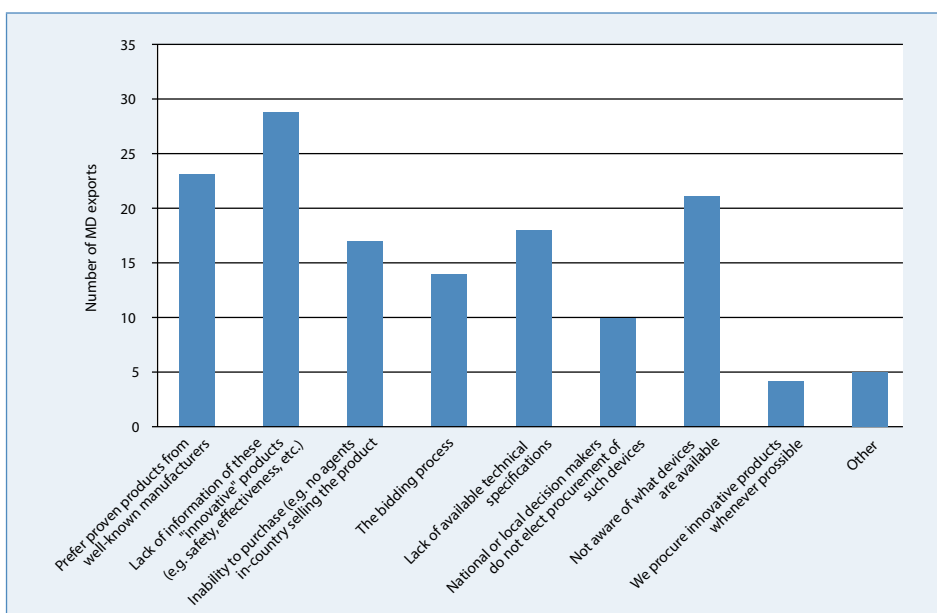


Acquisition/Procurement/Reimbursement

Selling of innovative technologies specifically designed for the developing world is often challenging. In order to find out what the main obstacles are, this section was only answered by stakeholders who actually make medical device procurement-related decisions.

Figure 14 shows the most common barriers to procurement of innovative technologies in low-resource settings. The main obstacles preventing the procurement of innovative technologies are, firstly, the lack of information of these innovations regarding their effectiveness, safety, and even their technical specifications; secondly, the preference to purchase technologies from well-known, commonly used manufacturers; and thirdly, the lack of awareness of the existence of these innovative technologies.

Figure 14 Factors preventing procurement of innovative technologies specifically designed for developing world (total responses: 34)

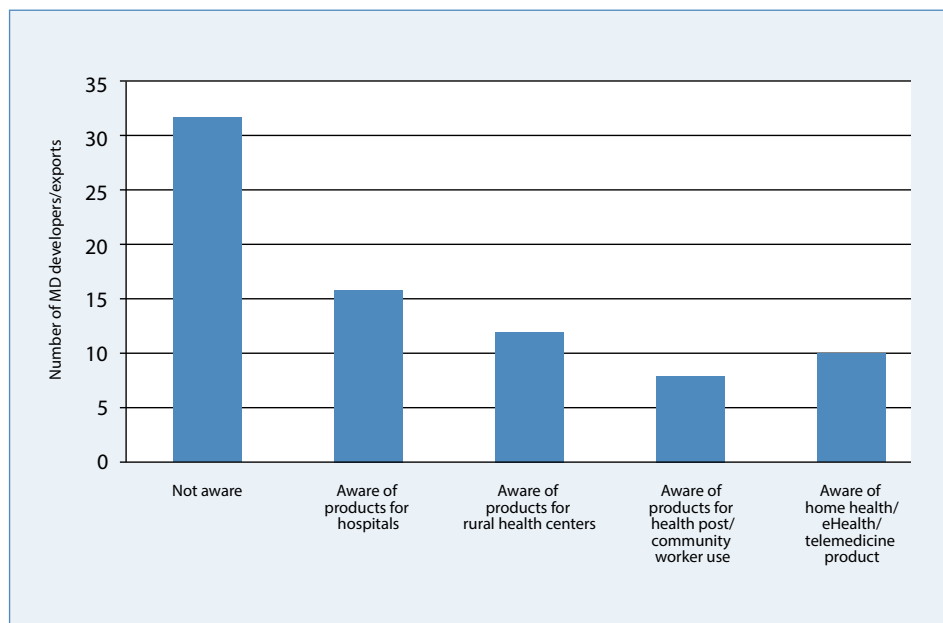


Clinical engineering

Clinical engineers play a vital role at different phases of medical device development (from concept to uptake). Clinical engineers understand the role of technologies in a practical environment; hence, their knowledge of technologies available and innovations is fundamental to encouraging the dissemination and use of available devices. However, there are still a large number of clinical engineers who are not aware of local innovations that are being developed to meet needs in low-resource contexts.

Figure 15 shows awareness among clinical engineers participating in this survey of innovations or products that solve local needs.

Figure 15 *Are clinical engineers aware of local innovations to solve needs in low-resource settings? (total responses: 53)*



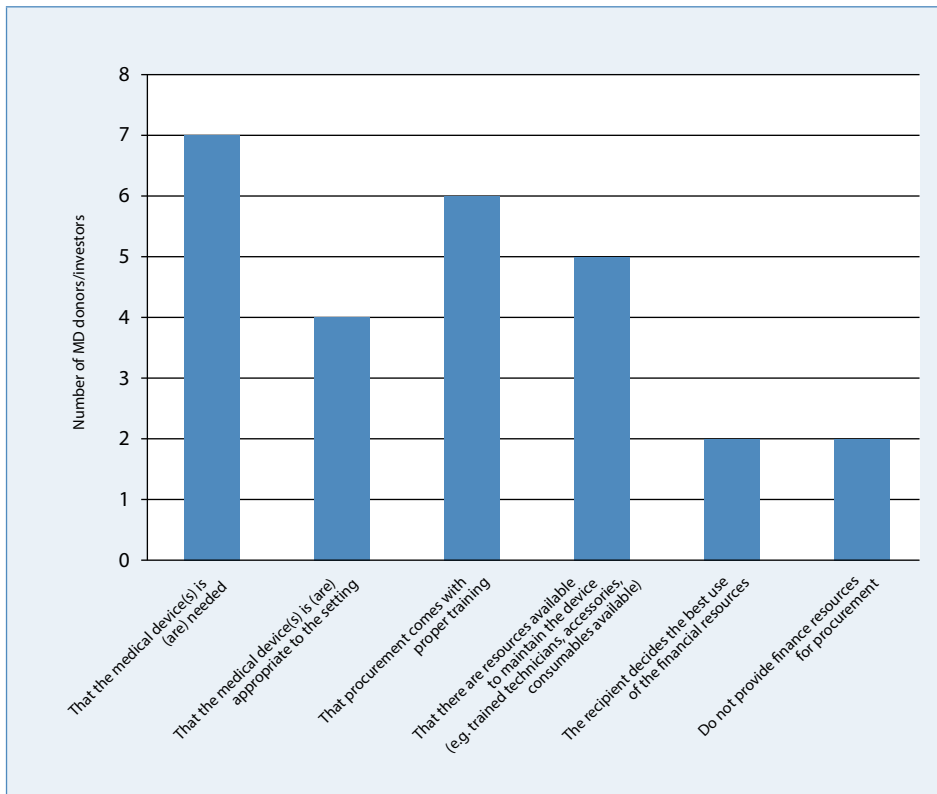
Investor/Donor/NGO

Investors, donors and NGOs provide financial resources for different phases in the development and marketing of innovative medical devices. Responses to the survey showed donor preferences for financing the various phases of development and production. Interestingly, most projects supported by donors and investors seemed to be related to the provision of training to use and maintain of medical devices, rather than on product development and manufacturing.

In addition, investors and donors provide financial resources for procurement of medical devices if they understand and endorse the need for a given device in a specific setting. In the survey, investors and donors were asked the main factors they typically consider before investing in the procurement of medical

devices; Figure 16 shows the responses. The actual public health need for a device, and the requirements for technical training were the most commonly cited factors.

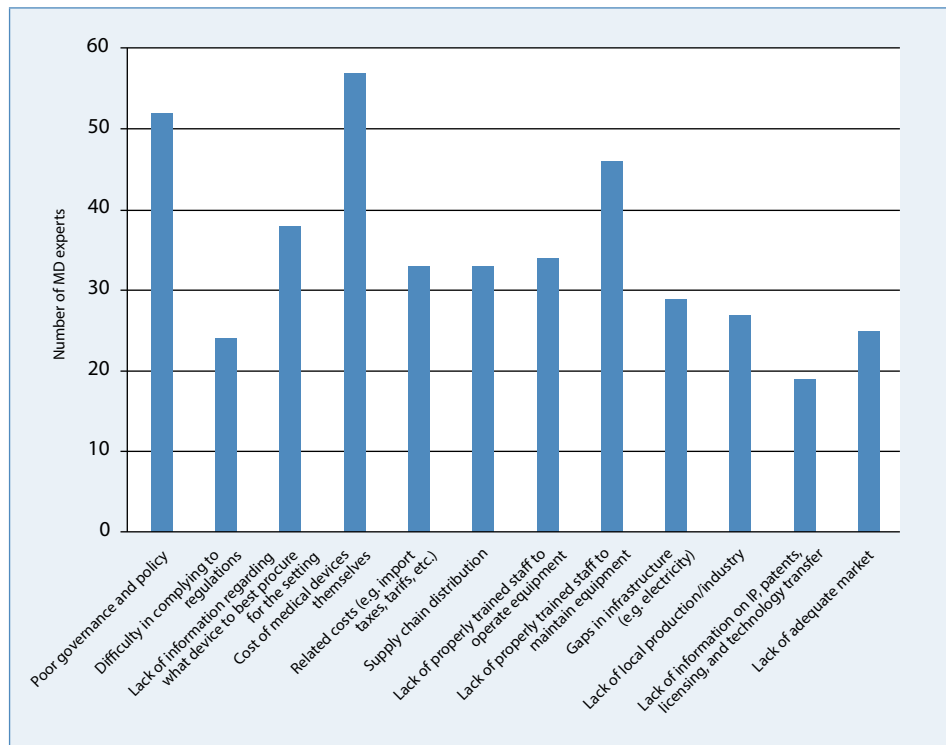
Figure 16 Factors considered by investors/donors before providing financial support to procure medical devices (total responses: 10)



Perception of the main barriers to access to medical devices in low-resource settings

A fundamental question was also asked to understand what stakeholders broadly perceived as the most common barriers to medical devices in low-resource settings (Figure 17). The main barriers to access cited were: capital cost of medical devices, poor governance and policies, lack of adequately trained staff to operate devices, and lack of information available regarding devices to guide procurement.

Figure 17 Main perceived barriers to access to medical devices in low-resource settings (total responses: 103)



Box 11 Comments from survey respondents on changes that can be made to the current regulatory system in order to encourage technology transfer and local manufacturing of medical devices

- “Harmonized submission and post market requirements. Consistency in classification.” - Manager (Industry), USA
- “Compliance to GMP” - Engineer (Government), Philippines
- “[...] consider permitting third parties to provide conformity assessment in the future but to date there have been no regulatory changes. This might improve the speed to market for devices manufactured in Australia.” - CEO (Industry), Australia
- “[...] establish a regulatory capacity and its first priority would be regulation of devices and suppliers in order to promote patient safety [...]” - Biomedical Engineer, Gambia / Canada
- “The National Drug Authority [...] is in the process of being strengthened. As soon as [...] is up and running, it should vigorously work with the Uganda Investment Authority [...] to encourage investment in medical devices.” - Engineer (Government), Uganda
- “[...] For small business type manufacturers, financial assistance might be useful for them to employ staff or manpower or outside consultant to facilitate plan and actions towards meeting various regulatory requirements.” - Electronics Engineer, China

Table 1 Pros and cons of medical device regulation in LMIC according to respondent comments

Pros	Cons
<ul style="list-style-type: none"> • Ensures medical devices are safe, effective and high quality. • Important for innovators, manufacturers and distributors of technologies. • Provides reassurance that the technologies will function according to the specifications. 	<ul style="list-style-type: none"> • Processes sometimes lack transparency and clear governance. • In certain places, local producers and manufacturers face greater and more stringent regulations than imported products. • Resource-, time- and effort-consuming processes to comply with regulations. Since there are no harmonized international regulations, requirements are inconsistent and complex. • In some countries regulatory bodies do not exist; in others, they are inefficient or the body does not have the expertise required for medical device approval and registration.

Table 2 Pros and cons of intellectual property rights in LMICs according to respondent comments

Pros	Cons
<ul style="list-style-type: none"> • Encourages and protects innovation, and increases its appeal to investors. • Awareness of IP landscape before starting product development is essential to identifying competitors, substitutions and possible partnerships, as well as defining markets and opportunities. 	<ul style="list-style-type: none"> • In general, there is limited knowledge of IP regulations, patents and licensing. • Patents and licensing increase costs of production to local manufacturers;

Table 3 Pros and cons of funding and financing mechanisms in LMICs according to respondent comments

Pros	Cons
<ul style="list-style-type: none"> • Reimbursement schemes to procure medical devices may help ensure affordability of capital and hidden costs of medical devices. • Investors and donors can be willing to invest in technologies addressing a clear public health need. 	<ul style="list-style-type: none"> • Funding available is usually not sufficient to increase access to medical devices, and financial mechanisms are not adequate to support expenses related to medical devices.

Survey participants

The survey on access to medical devices in low-resource settings was completed by experts from across industries, and around the world: from Argentina: German Giles, Diego Kadur; from Australia: Alistair McEwan, James Mccauley, Anne Trimmer; from Bangladesh: Siddique-e Rabbani; from Belgium: Saskia Vercammen, Alain Van Den Brande; from Bhutan: Karma Lhazeen; from Bolivia: Wendy Vargas Guzman; from Brazil: Jose Carlos Lapenna, Jair Chagas, Howard Weinstein, Alexandre Ferreli Souza, Eduardo Costa, Warlando Veloso Junior, Ryan Pinto Ferreira; from Brunei Darussalam: Abidin Othman; from Burkina Faso: Rimdella Dominique Tassebedo; from Cameroon: Emmanuel Ismaël Wayanne; from Canada: Margarita Loyola, Klaus Stitz, Gordon Campbell, Shauna Mullally, Gamal Baroud; from China: Albert K F Poon; from Colombia: Alejandro Matiz, Édison Valencia Díaz, Robinson Araque, Tatiana Molina; from Costa Rica: Marvin Herrera, Alfonso Rosales; from the Democratic Republic of the Congo: Roland Hensens; from Denmark: Steen Lindequist; from El Salvador: Luis Barriere; from Germany: Miroslav Bilic, Markus Kraemer, Maurizio Kraemer, Hermann Kranzl; from Greece: Nicolas Pallikarakis; from Honduras: René León; from India: Kesi Einstein Albert, Balram Sankaran, Niranjan Khambete, from Israel: Lior Maayan; from Italy: Antonio Migliore, Annamaria Donato, Danilo De Rossi; from Japan: Shigemi Fujihara; from Kyrgyzstan: Ainura Abalieva; from Lebanon: Sizar Akoum; from Lesotho: Bastiaan Remmelzwaal; from Malaysia: Tajuddin Abdul Latif, Zamane Abdul Rahman; from Mexico: Diana Calva, Santiago Ocejo Torres, Tania Garcia, Sandra, Rocha Nava, Veronica Gallegos, Beatriz Hernandez, Roberto Ayala, Libia Rodríguez, Jesús I. Zúñiga, Laura Patricia Lopez Meneses, Jorge Takenaga, Victoria Eugenia González Gutiérrez, Cuitlahuac, Lopez Vera, Adriana Becerril Alquicira; from Namibia: Belinda Wolbling; from Nepal: Vishwa Shrivastava; from Norway: Lisbeth Taraldsen, Svein Hidle, Leiv Hellefossmo, Knut Erik Hovda, Jens-Petter Ianke; from Peru: Luis Vilcahuaman; from the Philippines: Maria Cecilia Matienzo; from the Republic of Montenegro: Erna Sehovic; from the Republic of Serbia: Vesna, Spasic Jokic; from Singapore: Jack Wong; from South Africa: David Burnstein, Frederik Minnaar, Brian Goemans, Iain Murray, Jsmes Meakings, Terence Moodley, Charl Louw, Simone Rudolph-Shortt, ; from Spain: Setefilla Luengo; from Sri Lanka: Muditha Jayatilaka, from Switzerland: Mario Meriardi, from the Syrian Arab Republic: Mahmoud Abdelwahed; from Thailand: Andy Barraclough; from Trinidad and Tobago: Ronald Koylass; from Uganda: Sam SB Wanda; from Ukraine: Alexander Martynenko; from the United Kingdom of Great Britain and Northern Ireland: John Zeal, Lisa Stroux, Andrew Gammie; from the United States of America: Robert Malkin, Justin Cooper, Frank Painter, Paul Sherman, Ralph Ives, Elisabeth George, Robyn Frick, Ming Jack Po and Aya Caldwell.

Annex 2a

Feasibility tool: A usage exercise

The Feasibility tool was developed based on the findings in the scoping study (Chapter 2) and the survey on access to medical devices in low-resource settings (Chapter 3).

In this annex, one possible approach to weighting and using the tool to evaluate the likelihood of successful local production is presented. The tool is then employed to assess the feasibility of local production for a set of medical device examples in various regions. The results show the advantages and weaknesses of the respective medical devices in terms of local production potential and serve as an indicator of whether local production should be endorsed. The results are linked to the recommendations concerning the selection of appropriate medical devices for local production in low-resource settings in Chapter 5.

This annex is structured as follows:

- i. Development of a weighting method for the tool;
- ii. Employment of tool for a set of medical device examples;
- iii. Limitations of tool and weighting approach presented here;
- iv. Similar tools and recommendations for future work.

Please note that the tool used for the testing phase here is the precedent version of the tool presented in Chapter 4. The structure and main questions are identical, but the updated version integrated all recommendations collected from the experts' reviews during the stakeholder meeting.

i. Development of a weighting method for the tool

In order to test the tool developed for the current project, several successful producers of medical devices in LMICs were contacted to test, assess, comment and provide an understanding of the tool from their perspective. Responses to the evaluation tool and comments on its use were provided.

During initial attempts to evaluate devices and to compare the resulting local production feasibility 'grades', the sum of all the points for each section of the tool did not provide a holistic view or for allow comparison and evaluation. Hence, in a first exercise, a multi-criteria decision analysis was developed to define and 'weight' priorities and scoring for each section of the assessment.

It is important to mention that the development of the weighting factors described below is one example of how the tool may be used in specific contexts. There are other possible applications and weighting methods for the tool that may allow for more flexibility according to context and the user's needs and interests. The points of view of industry stakeholders, for example, might be different to that of a developer, and each user needs to adapt the weighting of the tool to specific purposes.

Questions marking system

There were two problems to be considered when deciding about the weighting system for the tool. The first one concerns the significance of each of the questions. Obviously, not all questions are equally important in evaluating the suitability of a medical device for local production. Therefore, the questions are weighted by importance: The more influence the answer should have on the final evaluation, the higher the weight assigned.

The second problem concerns choices in answering options. For example, a valid question for evaluation in this framework is: *"Is the device used in diagnostics?"*. This question can in all likelihood clearly be answered by "yes" or "no". On the other hand, another valid question would be: *"Is the device required to solve a pressing local health problem/priority disease in your country?"* This is not a simple yes/no question, and to answer it correctly a range of factors may need to be taken into consideration. This implies that for this one example question a separate tool or set of questions could be developed with associated weights.

In order to keep the evaluation tool simple yet useful and meaningful, a combination of yes/no questions, 'grading' questions, and 'umbrella' questions is employed. The grading questions ask the user to rate the validity of a given statement on a scale from 0 to 3. In order to support the user here, example ratings are given together with the questions, see the following example:

Are the necessary consumables available? (Please rate between 0 and 3: 3="no consumables needed", 2="local consumables", 1="consumables imported but generally available", 0="no")

Note: Theoretically, a scale using -1, 0, and +1 might be favourable in some cases as it assigns more importance to the absence of specific properties. However, the final result then would only give an indication resembling a thumbs-up or thumbs-down whereas a rating between 0 and 3 allows for a more precise response and evaluation.

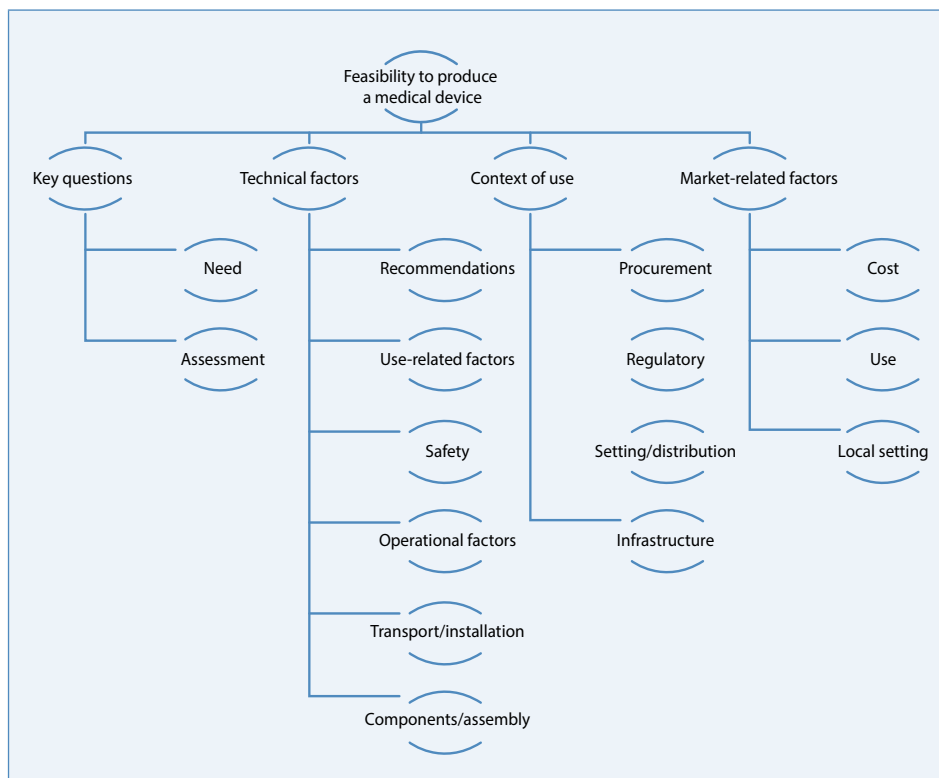
Weighting the sections of the tool: Multi-criteria decision analysis

Assessing the feasibility of producing medical devices within a local context is a complex task, as there are many different variables involved that do not allow a straightforward addition of factors. For this reason, a multi-criteria decision analysis was carried out in order to understand how the different aspects assessed by the tool interact with each other.

Define a hierarchy of the criteria

Each section of the tool: Key questions; Technical factors; Context of use; and Market-related factors included subsections with sets of questions. The overall organization and hierarchy of these tool criteria are shown in Figure 1 below.

Figure 1 *Hierarchy of priorities and criteria of the tool*



Establishing priorities

An important aspect of the tool is that allows assessment of various criteria according to their relevance to successful commercialization and production of medical devices in LMICs. The relative importance of criteria was assigned numerical values as shown in Table 1. This allows for comparison in pairs of elements. For instance, if element A is moderately more important compared to B, then A has value of 10 over B.

Table 1 *Definition of intensity of importance*

Intensity of importance	Meaning
0	Equally important
5	Slightly more importance
10	Moderately more important
15	Strong importance
20	Very strong importance
25	Most important

Each section was thus compared against others in terms of relative importance, and subsections were compared within each given section. The largest priority was assigned to related public health need, followed by the technical aspects of the device and the context in which it will be used; market- and business-related information was regarded as the lowest priority aspect. It is important

to note that intensity of assigned priority may vary if seen from a business perspective, or from other sectors (e.g. regulators, academia etc.).

Paired comparisons of criteria

The four main sections of the tool were compared in pairs in order to define priority factors. Once normalized and averaged, the relative priorities/values for each section were used as weighting ratios (see Tables 2 and 3).

Table 2 *Weighting ratios for sections (level 2) of the feasibility tool*

Section	Weighting ratio	Maximum score for section
Key questions ¹	0.657	66
Technical factors	0.234	23
Context of use	0.082	8
Market	0.027	3

Table 3 *Weighting factors for subsections (level 3) of the feasibility tool*

Section	Subsection	Weighting ratio for the section	Maximum score for subsection
Key questions	Need	0.833	83
	Assessment	0.167	17
Technical factors	Components/Assembly	0.010	1
	Operational factors	0.056	6
	Use-related factors	0.246	24
	Safety	0.119	12
	Transportation/Installation	0.024	2
	Recommendations	0.546	55
Context of use	Regulatory	0.231	23
	Procurement	0.644	64
	Infrastructure	0.085	9
	Setting/Distribution	0.040	4
Market	Local setting	0.057	6
	Cost	0.734	73
	Use	0.209	21

¹ 'Key questions' was changed to 'Needs assessment' in subsequent versions of the feasibility tool, and is referred to using the latter term.

The weighting presented here only takes into account the influence of the sections on the final grade, but do not distinguish between more and less important questions. Therefore, this should not be seen as a final weighting system.

Weighting factors

Tables 2 and 3 provide a reference to the relative feasibility of producing medical devices at the local level, considering the broad range of factors and stages of development and manufacture. The weighting ratios allowed a maximum possible score to be defined for each section/subsection of the tool, based on a total of 100 points. These weighting factors were tested with various device examples and the results are presented below.

ii. Employment of tool for a set of medical device examples

To test the feasibility tool, a questionnaire was sent to producers of medical devices in LMICs. Producers were selected according to preceding WHO initiatives, such as the *Compendium of new and emerging health technologies (1)*. Producers submitted the evaluation form for eight different technologies (Box 1).

Box 1. List of medical devices assessed

- Mechanical heart valve (India)
- Telemedicine unit (South Africa)
- Wound suction device (India)
- NASG project (Nigeria)
- CPaP ventilator (Viet Nam)
- Bubble CPaP (Malawi)
- Computerized ECG (Bangladesh)

The final scoring comprises all four sections of the tool and leads to one resulting evaluation number for each device. However, each section also serves as a stand-alone assessment: the sum of points for each section gives a distinctive measure for different aspects to be taken into consideration for local production. The result of the evaluation supports analysis of where improvements or modifications are needed in order to encourage the production of medical devices. Another possible outcome is the recognition that a specific medical device is not suitable for local production in a specific region or setting. Results might indicate why the region poses a particular problem and thus suggest other regions in which local production might be more promising.

Results from the Needs assessment section

The Needs assessment section is the main 'filter' of the feasibility tool, since it was considered the most relevant. It assesses if the device is actually needed in a given setting, targeting a priority disease or health problem, and if the design suits the characteristics of the setting/region in terms of professional or trained personnel, infrastructure, etc. In this latter point, the analysis is superficial in relation to cases where the probability for technology to fail is high. However, a deeper analysis is provided in the *Context of use* section.

Using this element of the tool, devices are evaluated in terms of their potential to address global health problems; for this reason, the "Need" subsection of the Needs assessment section was the criteria with the heaviest weight. It should be noticed that according to the maximum points per section shown in Table 4, a maximum score for the Needs assessment section is 66.

Note: To compare all the different scorings, a colour code is used. Technologies with a percentage of section compliance lower than 50% will be coloured in light blue (high risk), more than 50% but less than 75% mid-blue (normal risk), and higher than 75% dark blue (low risk). This coding will be used in the total scoring where instead of being percentages are point, though also based in 100 total points.

Table 4 *Scores in the Needs assessment section, by subsection*

	Need	Assessment	Percentage (%) of section	Score from total
Mechanical heart valve (India)	45	6	52%	34
Telemedicine unit (South Africa)	83	11	94%	62
Wound suction device (India)	38	9	47%	31
NASG project (Nigeria)	61	6	67%	44
CPaP ventilator (Viet Nam)	45	14	59%	39
Bubble CPaP (Malawi)	45	7	52%	35
Computerized ECG (Bangladesh)	45	11	57%	38
Blood Pressure Machine (India)	36	10	46%	30

From the eight devices assessed, two of the devices had a scoring in the *Needs assessment* section slightly lower than 50%, and one device with a high mark equal to 94%. When comparing these values, this clear difference means that South African respondents ranked telemedicine highly (in South Africa), while Indian respondents ranked the wound suction device and blood pressure monitors lower, relative to other medical device priorities in India. As shown, Needs assessment rankings – like all categories in this tool – are context dependent, and as such dynamic and dependent on the user.

Results from the Technical factors section

Question sets from the Technical factors section aim to determine if a device can be easily manufactured, used and maintained. The subsections considered were: Components/assembly, Operational factors, Use-related factors, Safety, Transportation/installation, and Recommendations. Final scores from the entire section were generated to define whether the device is technically complex or appropriate to the context in which it will be manufactured or used.

The first and most important factor to consider when assessing Technical factors was to determine whether the device is an essential or prioritized medical device for public health. Hence, the highest scoring was given if the device was included in recommendations, clinical guidelines and technical specifications, or other relevant information to inform how and where a medical device is to be used, particularly if the device has been endorsed by WHO, UNICEF, other international organizations or governments.

If a device is too complex or its assembly parts are not easily replaced, for example, or if specific technically skilled people are needed to make use of the device, then it may not be totally appropriate for a low-resource setting. Hence, Components/assembly, Operational factors and User-related factors are the most relevant subsections to assess. While Safety is vital for medical devices in general, it has been assumed that the nature of these technologies will require low levels of safety precautions during manufacture, installation and use. Transportation/installation is also a relevant section to ensure delivery of medical devices, but under the assumption that the most appropriate medical devices for low-resource settings are the less complex and more effective (2), it has been considered that transportation and installation requirements will be minimal.

Table 5 Scores in the Technical factors section, by subsection

	Components Assembly	Operat. Factors	Use-related Factors	Safety	Transport./ Instal.	Recomm.	Percentage (%) of section	Score from total
Mechanical Heart Valve in India	0	3	3	7	2	18	33%	8
Telemedicine unit in South Africa	0	1	16	7	1	30	56%	13
Wound Suction Device in India	0	3	16	9	2	6	37%	9
NASG project in Nigeria	1	4	21	10	2	6	45%	10
CPaP Ventilator in Vietnam	1	4	11	11	2	36	66%	15
Bubble CPaP in Malawi	1	3	7	12	2	36	61%	14
Computerized ECG Bangladesh	0	4	16	12	2	24	59%	14
Blood Pressure Machine	0	10	18	10	2	6	47%	11

Table 5 shows the collection of data from the Technical factors section from each device considered. For all devices, the highest score in the evaluation of technical factors was given to the CPaP ventilators, in Viet Nam and Malawi, and the Computerized ECG in Bangladesh. The Mechanical heart valve generated the lowest score in this section. It is interesting to note that the device with the highest scoring in the Needs assessment section was the fourth scoring in the Technical factors section.

Results from the Context of use section

Two of the main barriers that came to light in the literature review and surveys were regulations and financing at different phases of medical device development. Frequently, many producers and manufacturers are challenged by inconsistent regulations, complex regulatory procedures, and difficult compliance with established procurement processes. Furthermore, in some low-income settings infrastructure may not be sufficient to enable manufacturing, transporting, installing or commercializing of a given device.

The Context of use section evaluates the context or environment in which the device will be used. For instance, if a device needs to be regulated, or whether there are specific considerations for a device to be purchased (i.e. by governments, organizations, users, etc.). Secondly, the evaluation focuses on human resource capacity to: a) manufacture the device; b) use the device in a health care setting; c) maintain the device; and d) if services, tools and

equipment exist to allow manufacture. Results for this section for each device are presented in Table 6.

Table 6 Scores in the Context of use section, by subsection

	Regulatory	Procurement	Infrastructure	Setting/Distribution	Percentage (%) of section	Score from total
Mechanical heart valve (India)	0	48	5	3	56%	4
Telemedicine unit (South Africa)	0	48	5	2	55%	4
Wound suction device (India)	12	24	9	2	47%	4
NASG project (Nigeria)	23	8	6	3	40%	3
CPaP ventilator (Viet Nam)	23	48	6	2	79%	6
Bubble CPaP (Malawi)	0	32	9	2	43%	3
Computerized ECG (Bangladesh)	12	48	9	2	70%	6
Blood pressure machine (India)	12	32	9	3	55%	4

From the evaluations of this section, the results above show that three devices did not receive a score above 50: the Wound suction device in India, the NASG project in Nigeria and the Bubble CPaP in Malawi. However, this does not mean that the device is not complying with the regulations in the country, but may represent the complexity to gain regulation compliance and registration for the device. For instance, the Mechanical heart valve project in India receive 0 points for the Regulation subsection, and the producer commented that the regulations are under formulation (by the government and regulatory bodies) and are not well defined; however, currently there is a basic registration that the device needs to go through. On the other hand, the devices assigned a higher score from the section were the CPaP ventilator in Viet Nam and the Computerized ECG in Bangladesh. While some of the devices need to be regulated due to the risk they represent to health (for the device itself or the clinical procedure in which it will be used), it is important to mention that devices are expected to be designed appropriately to the context of use. Hence, it may be better to develop devices that require less complex regulations and can be more rapidly and easily approved.

In the *Procurement*, *Infrastructure* and *Setting/Distribution* subsection all of the devices scored more than 50% of the possible points for each subsection.

Results from the Market section

The final section assessed the probability of the business to succeed, by judging and analyzing the type and size of market for the device, and some organizational aspects such as the logistics to manufacture and distribute devices. The sets of questions were divided into three subsections: local setting, cost and use. Firstly, the Local setting subsection is defined by the business environment (in order to understand whether the devices will be used and requested by health workers), if there are existing IP rights protection laws, and whether there are in-country business incubators to support national start-up companies. Then, the Cost subsection deals with questions regarding affordability of the device, considering the capital cost, and the costs of use and maintenance; this subsection includes the cost of production, spare parts and consumables. Finally, the Use subsection questions are related to technology lifespan, and whether it could be reused in the future.

Table 7 Scores in the Market section, by subsection

	Local setting	Cost	Use	Percentage (%) of section	Score from total
Mechanical heart valve (India)	5	59	10	74%	2
Telemedicine unit (South Africa)	5	49	21	75%	2
Wound suction device (India)	2	44	21	67%	2
NASG project (Nigeria)	3	54	10	68%	2
CPaP ventilator Viet Nam	3	73	21	98%	3
Bubble CPaP (Malawi)	2	68	21	92%	3
Computerized ECG (Bangladesh)	3	54	21	78%	2
Blood pressure machine (India)	6	64	21	90%	3

The results of this section are shown in Table 7. The Local setting subsection was weighted with a heavier factor than Cost and Use. Though a country may not have transparent and efficient IP rights protection laws (question 2 of 3), and may not have business incubators or any other type of support to start-ups (question 3 of 3), the reason why this subsection was assigned a larger weighting factor was due to the questions regarding the public health need and demand of the device. Hence, five of the total number of devices evaluated received very high scores in this point. On the Cost aspect of the section, all the devices scored a high grading; an interesting device to evaluate in this section was the Wound suction device, which although having affordable costs, costs related to its use (e.g. surgical procedures) may be high and affect its evaluation. Also, ideally all the devices should have either a long functional lifespan, or should be reusable, as a means to reduce costs of its use and maintenance. The only assessed device that was not reusable in the current assessment was the Mechanical heart valve. All the devices evaluated had a high scoring in the Market section.

Conclusions of the feasibility tool trials exercise

After each device was evaluated, the scoring from each section was added together, since all components have been weighted to give a maximum total value of 100 points (Table 8). Under the same previous consideration, an approved score was equal to 50 or more total points (light blue) and those with a scoring above 75 points were considered as the more feasible devices to be successfully produced within their local context (dark blue). While some of the areas of interest did not get a high score, most devices received a score above 50.

Table 8 Total score for each device, by section

	Needs assessment	Technical factors	Context	Market	Total score
Mechanical heart valve (India)	34	8	4	2	48
Telemedicine unit (South Africa)	62	13	4	2	81
Wound suction device (India)	31	9	4	2	45
NASG project (Nigeria)	44	10	3	2	60
CPaP ventilator (Viet Nam)	39	15	6	3	64
Bubble CPaP (Malawi)	35	14	3	3	55
Computerized ECG (Bangladesh)	38	14	6	2	59
Blood pressure machine (India)	30	11	4	3	48

According to this evaluation, the Telemedicine unit in South Africa, the Computerized ECG in Bangladesh and the two CPaP ventilators are the most feasible to be produced and successfully commercialized in the market they have been developed for. Given the weighting factors assigned to each category, it is not unusual that these devices are also the ones that achieved the largest scores in the Needs assessment sections. There is perhaps a need to reassign the priorities to the respective categories, and to set rules that allow evaluating the importance of specific questions, rather than whole sets of questions for a given subsection. Still, as far as the work for this report is concerned, this assessment seems to be a promising tool to support efforts to encourage local producers to design, develop and manufacture their own national medical device products for the local market to increase and enhance the local public health care delivery.

This evaluation tool is a first approach towards measuring the feasibility of local production of medical devices; the tool has limitations, and will be subject to further improvements.

iii. Limitations of the tool and the weighting approach presented here

Limitations of the weighting system

The weighting system presented in this chapter is a first exercise to demonstrate the use of the tool.

One of the main issues when determining the weighting criteria was the significance or relevance of each question to given subsections: how important is each question in relation to the partial score of the section? In the exercise presented above, the weighting system does not allow evaluation of each question; it collects the information from the whole set of questions and assigns equal weight to all questions in a given section. However, the questions within the same subsection may not necessarily be comparable. For instance, taking a closer look at the Needs assessment section, there are four questions under the 'Need' subsection, one of which is a multiple-answer question that asks if the device is use in: a) prevention; b) diagnostics; c) treatment; d) rehabilitation; or e) support for other devices. This particular question has the option of having all possible answers selected and allocating 1 point per answer, creating a total of 5 points for the single question. It is also possible, however, that a device may be used just for treatment, which will generate a score of 1 point for the entire question. While both responses are correct, the current design of the tool gives a larger value to those technologies that cover a greater number of interventions, however the probability to find a device that covers all options is relatively low.

Furthermore, using the multi-criteria method led to a high weight being assigned to the Needs assessment section. However, this section is the shortest and does not go into as much detail as the other sections. Moreover, some of the aspects looked at here are repeated in the other sections in more detail. Therefore, this section may not be assigned the greatest weight in future iterations of the tool.

Limitations of the tool

There are aspects of the feasibility tool that need to be re-assessed as they do not provide sufficient flexibility in relation to non-applicable or irrelevant questions. One example is the set of questions from the Market section, where in the Cost subsection a question is asked in relation to the costs of operation of a device, but it is not clarified whether the cost of the clinical procedure, along with costs of human resources, other devices and consumables, needs to be considered as a whole. Similarly, the Use section considers it an advantage for a device to be reusable and to have a long lifespan; as shown with the Heart valve example, however, some products may not necessarily fulfil these criteria yet may still be an appropriate technology for the intended public health need.

Nevertheless, the present tool has proven to be a useful approach to assess feasibility of a device to be produced locally, and compare various devices within their own context.

Some areas of opportunity that were identified after initial testing the tool are summarized below.

Increase flexibility of the tool:

Currently, the ranking and scoring systems allow little flexibility of the tool. If a given device is not relevant to a specific question due to its specifications – but still provides an adequate solution to the health need – the tool assigns a “0” score for that question, regardless of the relevance of other factors.

Easier and friendlier scoring:

While a 100 point-based scoring with an approval mark of 50% or more was suggested, there may be ways in which the tool can provide a friendlier and perhaps more visual result. For instance, results could provide an answer to the producers such as “not viable”, “risky business”, “moderate risky business” and “commercially viable”, and a specific colour may be assigned to create a visual impact.

Improve priorities and weighting factors:

Considering that the health benefit is the criteria with the highest weighting, a discussion of these priorities and weighting factors could be carried out with stakeholders to define the best way to objectively prioritize them including all stakeholders’ perspectives.

iv. Similar tools and recommendations for future work

Local manufacture of medical devices may offer opportunities to develop the industry in developing countries, thus enhancing economic growth and supporting the public health sector (3). This opens a window of opportunity to increase access to medical devices and support efforts to achieve universal coverage. Local production has been identified as having indirect economic benefits, including employment and human capital generation, increased exports, and spill-over effects in broader sections of the economy, in the mid and long term.

The feasibility tool may provide additional support to local producers and manufacturers in identifying those factors preventing their products from reaching and entering their intended target market(s).

As defined in the methodology summary, the tool was tested by stakeholders currently developing or producing medical devices in LMICs. While the eight case studies do not fully capture the complexity of producing medical devices in all developing countries and settings, these cases were useful to test and receive comments about the tool.

The tool provides a potential measurement or scoring method that could be used to inform producers before they make a decision to manufacture a given device, or even at the needs identification and screening phases of specific technologies. Given the lack of information available to support producers in making such decisions, this tool is a comprehensive starting point to support capacity building and information gathering, to encourage local production and technology transfer.

Other tools available

During the literature review, an existing tool to measure the feasibility of producing a medical device in a developing country could not be identified. Some high-income countries have the tools and resources available to support producers to analyse their business case; for instance, in the UK, the National Institute for Health Research (NIHR) has a programme called Invention for Innovation (i4i), which aims to encourage innovators to research and develop innovative health care technologies that benefit patients in the clinical environment (4). The programme includes support to progressive development of medical product prototypes, and provides business advice to developers including an industry feasibility study and adoption process (5). Whereas these technologies tend to be high-end technologies to satisfy the demand of a developed country, a similar service as the one offered by NIHR in the UK could not be found in a developing country. However, following the research for the scoping study, some interesting proposals by various universities and organizations related to innovative design and manufacture of medical devices. Of all the proposals reviewed, two of them have been considered worthy to mention as examples of initiatives taken by a university, in one case, and an industry-related organization.

Stanford BioDesign Program

Through its BioDesign Program,² Stanford University offers an approach to encourage innovative medical technologies by recognizing market opportunities and developing a related business model (6). In this framework, innovating in the medical technologies is a process that is considered to have three phases: identification, invention and implementation:

- *Identification* explores the importance of a given device to meeting a compelling medical need, and if it is feasible to be commercialized. This phase is divided in two main stages: Needs finding, and Needs screening. Particularly during the screening phase an analysis of the market is done, giving the whole process an initial business insight.
- *Invention* conceptualizes a solution to the problem detected in the previous phase and tests it. Potential products are designed and tested based not only on how best to solve the problem, but also in terms of the context in which the project will be implemented in relation to the IP rights protection and regulatory environment, reimbursement schemes, and adequate business models. This includes Concept generation and Concept selection.

2 Stanford University BioDesign Program website: <http://biodesign.stanford.edu/bdn/index.jsp>

- *Implementation* develops the most adequate strategy to turn the prototype into a final product and place it into the market through the most effective business model. The stages from this phase are development strategy and planning, and integration. These stages will include the development of several strategies prior to the business plan including strategies in key areas such as: IP property registration or patenting the product, regulation compliance, business strategy, and the combination of all these strategies. The complexity of this phase lays in the overlap and interrelation of these elements.

Stanford University's BioDesign approach assesses similar stages to the Feasibility tool outlined in the current publication.

Inclusive Business Challenge

While the tool presented in this chapter assesses devices in terms of their benefits and contribution to public health, concerns remain how to make a successful business out of a product with lower profit margins in a market, which may not be attractive for the industry. This concern is extended not only to the medical devices industry but also to other industries that support efforts to eradicate poverty, support global health efforts, reduce the burden of climate change, and other issues of global concern. In this regard, the World Business Council for Sustainable Development (WBCSD) (3), an organization that stimulates business globally to create a more sustainable future, has developed a simulation tool to help companies and other stakeholders to detect needs, and implement innovative business models that are inclusive to populations from low-income settings (7).

The tool focuses on raising awareness in the industrial sector regarding the role that business plays in development, and proposes innovative ways to include low-income populations in the business value chain – design, procurement, manufacturing and distribution – and develop products and services that address priority needs. The tool helps companies to identify opportunities and risks while integrating inclusive business into their strategies.

This tool offers an insight into the related opportunities industry have in LMICs, and some medical device companies have been involved in activities to increase access to their products for those populations. The business perspective from WBCSD's tool may suggest additional ways to assess the market and business strategies for local production of medical devices.

The way forward

This annex and the Feasibility tool evaluate access to medical devices in terms of their feasibility to be produced locally in LMICs. Further research is required to understand the context-specific factors conditioning local production, and to encourage producers to successfully place their products in the market. In order to understand the potential of a country to develop and promote their national medical device industry, it is important to learn from successful case studies in developing countries and to support local manufacturers and

producers in the form of information for stakeholders, government support to start-ups, harmonized regulations and other aspects, as discussed.

The Feasibility tool can help to inform innovators of the viability of their products – with a strong focus on whether the product will have a strong benefit for public health. Further development of this tool is required for the second phase of this project.

References

1. Compendium of new and emerging health technologies. Geneva, World Health Organization, 2011 (http://whqlibdoc.who.int/hq/2011/WHO_HSS_EHT_DIM_11.02_eng.pdf, accessed 10 July 2012).
2. Medical devices: Managing the mismatch. An outcome of the Priority Medical Devices project. Geneva, World Health Organization, 2010 (http://whqlibdoc.who.int/publications/2010/9789241564045_eng.pdf, accessed 10 July 2012).
3. Local production for access to medical products: Developing a framework to improve public health. Geneva, World Health Organization, 2011 (http://www.who.int/phi/publications/local_production_policy_framework/en/index.html, accessed 10 July 2012).
4. Invention 4 Innovation: Realising healthcare products for patient benefit. Twickenham, National Institute for Health Research, 2012 (<http://www.ccf.nihr.ac.uk/i4i/Pages/Home.aspx>, accessed 10 July 2012).
5. Feasibility and adoption. Twickenham, National Institute for Health Research, 2012 (<http://www.crnc.nihr.ac.uk/Life+sciences+industry/services/feasibility>, accessed 10 July 2012).
6. Zenios, S, et. al. Biodesign: The process of innovating medical technologies. Cambridge, Cambridge University Press, 2009.
7. The Inclusive Business Challenge. Geneva, World Business Council for Sustainable Development (<http://www.wbcd.org/Pages/EDocument/EDocumentDetails.aspx?ID=12744>, accessed 10 July 2012).

Annex 2b: Feasibility tool: Specific sections

Table 1 Needs assessment section of feasibility tool

* For each question answered with “no”, the follow-up question is: “Can this situation be easily remedied?” In that case, the answer gains 1 point respectively.

1.1 NEED

a) Is the device required to solve a pressing local health problem/priority disease in your country? Please rate from 0 (not at all) to 3 (definitely yes).

b) Is the device used in

- prevention? (1=“yes”, 0=“no”)
- diagnostics? (1=“yes”, 0=“no”)
- treatment? (1=“yes”, 0=“no”)
- rehabilitation? (1=“yes”, 0=“no”)
- support for other devices? (1=“yes”, 0=“no”)

c) Is the device essential in clinical procedures? (1=“yes”, 0=“no”)

d) Is the device an essential support technology for another device that is already available on the respective market? (1=“yes”, 0=“no”)

e) Is the device filling a gap in the region because no similar device is available yet? (1=“yes”, 0=“no”)

1.2 ASSESSMENT

a) Is the device superior to similar devices available in region Y?

- superior effectiveness (1=“yes”, 0=“no”)
- enhanced ease of use and/or maintenance (1=“yes”, 0=“no”)
- reduced training requirements (1=“yes”, 0=“no”)
- labour saving (1=“yes”, 0=“no”)
- improved safety level for patients (1=“yes”, 0=“no”)
- improved safety level for user or environment (1=“yes”, 0=“no”)
- improved safety level for manufacturing (1=“yes”, 0=“no”)
- increased social/cultural acceptability (1=“yes”, 0=“no”)

• **reduced resource requirements** (such as independent of electricity or clean water supply) (1="yes", 0="no")

• **technical superiority** (1="yes", 0="no")

• **improved accessibility** (1="yes", 0="no")

• **better long-term value versus up-front costs** (1="yes", 0="no")

• **better affordability** (1="yes", 0="no")

• **better durability** (1="yes", 0="no")

• **other** (1="yes", 0="no")

b) Is the device adapted for use in the low-resource setting it needs to be employed?*

• **Are there physicians and/or nurses and/or technicians available who will handle the device?** (1="yes", 0="no")

• **Do these users have the expertise needed to handle the device correctly?** (1="yes", 0="no")

• **Is availability of electricity, water, gas and/or other necessary resources ensured?** (1="yes", 0="no")

• **Is resistance against dust/temperature changes/heat/other adverse conditions as found in the hospital/region ensured?** (1="yes", 0="no")

• **Do the local safety standards meet the safety requirements for use and maintenance?*** (1="yes", 0="no")

• **Does the local infrastructure allow easy distribution of the device?*** (1="yes, delivery systems in place", 0="no, people in need difficult to reach")

• **Does the local infrastructure allow easy installation of the device?*** (1="yes", 0="no")

Table 2 Device-related factors

2.1 Components/Assembly

a) Is the device manufactured

• **WITHOUT integration of complex electronic technology?** (1="yes", 0="no")

• **WITHOUT integration of complex biological technology?** (1="yes", 0="no")

• **WITHOUT integration of complex chemical components?** (1="yes", 0="no")

• **WITHOUT integration of complex mechanical components?** (1="yes", 0="no")

b) Are the components made using material locally available? (1="yes", 0="no")

c) Are the components simple to produce?

• can be produced without heavy machinery (1="yes", 0="no")

• can be produced without complex manufacturing process (1="yes", 0="no")

• can be produced without high precision measurements (1="yes", 0="no")

• can be easily imported (1="yes", 0="no")

d) Can the device be produced using a production line already in place for other devices?

(3 = "yes, with the same human resources and machinery";

2="yes, machinery in place, but different human resources needed";

1="yes, human resources in place, but different machinery needed";

0="no, needs special fabrication process that is not available locally")

e) Is the assembling of the device simple?

• can be assembled without heavy machinery (1="yes", 0="no")

• can be assembled without high level expertise (1="yes", 0="no")

• can be assembled without high precision measurements (1="yes", 0="no")

• can be assembled without complex infrastructure (1="yes", 0="no")

• can be assembled by trained aid (1="yes", 0="no")

2.2 Operational factors

a) Is maintenance of the device simple? *(please rate between 0 and 3: e.g. 3 = "no maintenance needed", 2="maintenance can be done by nurse/local technician", 1="needs daily calibration by expert", 0 = "requires maintenance by manufacturer")*

b) Can maintenance of the device be done without complex training? *(Please rate between 0 and 3: 3="no training needed", 2="introduction less than 1 hour", 1="training up to 1 day", 0="training more than a day")*

c) Can the device be used on its own?

• can be employed without cold chain (1="yes", 0="no")

• can be employed without regular safety checks (1="yes", 0="no")

• can be employed without any other additional requirements (1="yes", 0="no")

d) Is the device independent of consumables? *(Please rate between 0 and 3: 3="no consumables", 2="very few and low-cost consumables", 1="few or low-cost consumables", 0="many and/or expensive consumables")*

e) Is the device independent of spare parts? *(Please rate between 0 and 3: 3="no spare parts", 2="very few and low-cost spare parts", 1="few or low-cost spare parts", 0="many and/or expensive spare parts")*

f) Is the device independent of energy sources?

(e.g. 3="no energy required", 2="manual energy source", 1="solar, battery, gas, fuel,...", 0="high voltage/stable electricity")

2.3 Use-related factors

a) Can the device be used safely and effectively without complex training? (Please rate between 0 and 3: 3="no training needed", 2="introduction less than 1 hour", 1="training up to 1 day", 0="training more than a day")

b) Can the device be used in multiple health care settings?

• in home care (1="yes", 0="no")

• by a community health care worker (1="yes", 0="no")

• in a mobile unit (1="yes", 0="no")

• in ambulatory care (1="yes", 0="no")

• within a telemedicine system (1="yes", 0="no")

• in a health post (1="yes", 0="no")

• in a health centre (1="yes", 0="no")

• in a district hospital (offers obgyn., surgery, paediatric) (1="yes", 0="no")

• in a regional hospital (4 or more specialties) (1="yes", 0="no")

• in a specialized hospital (III level university/ research hospital) (1="yes", 0="no")

c) Is the device reusable? (1="yes", 0="no")

d) Is the device suitable for use in low-resource settings?

• works without any type of electricity? (1="yes", 0="no")

• works without any additional resources (gas, water,...)? (1="yes", 0="no")

• can be transported to regions where there are no roads? (1="yes", 0="no")

• is it rugged and resistant? (1="yes", 0="no")

2.4 Safety

a) Is the risk level for the patient/user/health care worker/environment low?

• works WITHOUT radiation (1="yes", 0="no")

• works WITHOUT sharps (1="yes", 0="no")

• works WITHOUT mercury (1="yes", 0="no")

• works WITHOUT gas (1="yes", 0="no")

• works WITHOUT risk of contamination (1="yes", 0="no")

• works WITHOUT implantable parts (1="yes", 0="no")

- remains less than 30 days in the body (1="yes", 0="no")

b) Is the risk level during manufacturing low?

- works WITHOUT turning parts in machinery (1="yes", 0="no")
- only low voltage needed (1="yes", 0="no")
- general safety is ensured without special safety standards (1="yes", 0="no")
- works WITHOUT toxic fumes or similar (1="yes", 0="no")

c) Is the risk level during installation low? (Please rate between 0 and 3. e.g. 3="yes, no health risk", 2="yes, but heavy components and/or electricity connection and/or ...", 0="no, installation workers need special safety training")

d) Is the device usable in an environmentally friendly way?

- works WITHOUT water pollution (1="yes", 0="no")
- works WITHOUT air pollution (1="yes", 0="no")
- needs only sustainable amounts of resources (water/gas/...) (1="yes", 0="no")

e) Has risk assessment been performed on the device? (1="yes", 0="no")

f) Does the device comply with any international standards? (1="yes", 0="no")

2.5 Transport/Installation/Disposal

a) Is the device

- light weight? (1="yes", 0="no")
- resistant against vibration? (1="yes", 0="no")
- sturdy, resistant against blows? (1="yes", 0="no")
- easy to carry by one person? (1="yes", 0="no")
- transported in a single package? (1="yes", 0="no")

b) Is the device transportable and storable without special conditions?

- temperature independent? (1="yes", 0="no")
- pressure independent? (1="yes", 0="no")
- humidity independent? (1="yes", 0="no")
- dust-resistant? (1="yes", 0="no")

c) Is the installation of the device easy?

- can be done without special training? (1="yes", 0="no")

- can be explained by pictorial manuals? (1="yes", 0="no")

d) Is disposal of the device easy?

- is disposal of device and consumables and spare parts risk free for workers and environment? (1="yes", 0="no")

- can it be done without special machinery? (1="yes", 0="no")

2.6 Recommendations

a) Is the device type mentioned as essential in any guideline of WHO, UNICEF, or UNFPA? (1="yes", 0="no")

b) Is the device endorsed or prequalified by a UN organisation? (1="yes", 0="no")

c) Is the device endorsed by one or several NGO? (Please rate between 0 and 3 by number and importance/influence of NGOs.)

d) Has the device won any prestigious awards (for innovation or for low-resource settings)? (Please rate between 0 and 3 by importance of award.)

e) Is the device on a donor list as e.g. Oxfam, US AID, MSF? (1="yes", 0="no")

Table 3 Device-in-local-region/Context-of-use

* For each question answered with "no", the follow-up question is: "Can this situation be easily remedied?" In that case, the answer gains 1 point respectively.

3.1 Regulatory

a) Is the device classified as low-risk?

(according to GHTF classifications in <http://www.ghrf.org/documents/sg1/SG1-N15-2006-Classification-FINAL.pdf>) (1="yes", 0="no")

b) Can the device be produced and sold without regulatory approval in the country? (1="yes", 0="no")

c) Can the device be manufactured, sold and used

- in accordance with the human laws in the country? (1="yes", 0="no")

- in accordance with the labour laws in the country? (1="yes", 0="no")

- in accordance with the environment laws in the country? (1="yes", 0="no")

3.2 Procurement

a) Do public and/or private health sectors have fair and open procurement processes? (Please rate between 0="not at all" and 3="definitely yes")

b) Are locally produced medical devices accepted by health care workers/decision-makers in terms of confidence in quality? (Please rate between 0="not at all" and 3="definitely yes")

c) Has the device been approved for procurement/reimbursement in the country? (1="yes", 0="no")

d) Does the device comply with technical specifications for medical devices issued by the country? (1="yes", 0="no")

3.3 Infrastructure *

a) Is the level of required skill for manufacturing coherent with the engineering setting in the country/region? (Please rate between 0 and 3, e.g.: 3="definitely yes, no additional training needed", 2="some local engineers/technicians in place, education of additional workers easy to do", 1="too few local experts in place, substantial additional education needed", 0="not at all, no local experts in place, education very complex".)

b) Is the level of required skill for use coherent with the health care setting in the country/region? (Please rate between 0 and 3, e.g.: 3="definitely yes, no additional training needed", 2="some local experts in place, training of additional experts easy to do", 1="too few local experts in place, substantial additional training needed", 0="not at all, no local experts in place, training very complex".)

c) Is the level of required skill for maintenance coherent with the health care setting in the country/region? (Please rate between 0 and 3, e.g.: 3="definitely yes, no additional training needed", 2="some local experts in place, training of additional experts easy to do", 1="too few local experts in place, substantial additional training needed", 0="not at all, no local experts in place, training very complex".)

d) Is the local infrastructure suitable for manufacturing the device?

- **machinery available or easy to import?** (1="yes", 0="no")

- **tools available or easy to import?** (1="yes", 0="no")

- **required resources (electricity/water/...) in place?** (1="yes", 0="no")

3.4 Setting/Distribution *

a) Has the device been tested successfully in the setting it should be used in? (Please rate between 0 and 3, e.g. 3 = "successfully tested in exact same setting" or "already in use in similar setting"; 0 = "not tested in low-resource setting at all")

b) Are the necessary consumables available? (Please rate between 0 and 3: 3="no consumables needed", 2="local consumables", 1="consumables imported but generally available", 0="no")

c) Are the necessary spare parts available? (Please rate between 0 and 3: 3="no spare parts needed", 2="local" spare parts, 1="spare parts imported but generally available", 0="no")

d) Can the device be packaged locally using local human resources? (1="yes", 0="no")

e) Can the device be labelled locally using local human resources? (1="yes", 0="no")

f) Is the device easy to distribute in the region?

(Please rate between 0 and 3, e.g. 3 = "yes, similar successful delivery systems already in place"; 0 = "no, device too heavy/fragile/..., access to people in need difficult,...")

Table 4 *Market-related factors*

4.1 Local setting

a) Do physicians/health care workers/decision-makers recognize the need of the device and request its deployment? *Please rate from 0 (not at all) to 3 (definitely yes).*

b) Does the country have a transparent legal and regulatory framework in place covering aspects like finance, investment, IP, and business set up encouragement strategies? *(Please rate from 0 (not at all) to 3 (definitely yes). Please take into account influence of IP to further develop, manufacture or commercialize the product.)*

4.2 Cost

a) Is the device affordable and cost-effective for the intended user-group (patient, funder, govt.)/payer (if payer is not the user)? *Please rate from 0 (not at all) to 3 (definitely yes). Please take into account acquisition costs and service costs.*

b) Can the device be produced locally at lower costs than currently imported ones? (1="yes", 0="no")

c) Are the consumables/spare parts/accessories locally available within an acceptable and pre-determined time frame? (1="yes", 0="no")

d) Are the cost of consumables/spare parts/accessories affordable for the intended user-group (patient, funder, govt.)/payer (if payer is not the user)? *Please rate from 0 (not at all) to 3 (definitely yes).*

e) Are the costs of operation (i.e. service and engineering maintenance) affordable for the intended user-group (patient, funder, govt.)/payer (if payer is not the user)? *Please rate from 0 (not at all) to 3 (definitely yes).*

f) Does the device have the potential to be deployed in a large number of regions/countries with the same needs? (1="yes", 0="no")

g) Is the cost of import of consumable/spare-parts/accessories affordable for (if no import necessary, put "1" to all)

• tariffs? (1="yes", 0="no")

• fees? (1="yes", 0="no")

• "high" taxes? (1="yes", 0="no")

Annex 3

Consultation on barriers and opportunities for improved access to medical devices by technology transfer and local production

Geneva, Switzerland, June 4–5 2012

Agenda

Monday, 4 June 2012

Technology transfer and local production of medical devices

- 09:00** Welcome and objectives of the meeting
Dr Clive Ondari, EMP
- 09:30** Introduction of participants
Selection of Chair and Rapporteur
Dr Nicholas Adjabu (4 June) and Dr Adham Ismail (5 June), Chair
Mr Albert Poon, Mr. Niranjan Khambete, and Mr Einstein A. Kesi, Rapporteur
- 09:45** Improving access to medical devices, background documents
Mrs Adriana Velazquez Berumen
- 10:15** Setting the scene: increasing access to health products through innovation and technology transfer.
Mr Robert Terry
- 10:30** Discussion
- 10:45** Coffee break
- 11:00** Scoping study: Medical devices global market, health financing, regulations and delivery systems for medical devices. Country cases studies. *Mrs. Adriana Velazquez Berumen*
- 11:20** Open discussion
- 11:40** Presentation of the results of the survey on access to medical devices.
Dr. Heike Hufnagel
- 12:15** Discussion
- 12:45** Lunch
- 14:00** Intellectual property for medical products, Dr Peter Beyer
- 14:35** Success stories: what can be learned from a successful medical device development, technology transfer, local production and uptake in low-resource settings?
Neonatal equipment, Mr John Anner
Discussion, lessons learned
Hearing aid, Mr Howard Weinstein (teleconference)
- 14:45** Development of medical devices for priority diseases, low resource settings:
Maternal health: Anti-shock garment, Mr Rick Kearns
Discussion, challenges
- 15:45** Coffee break
Success stories continued: *Assisted delivery tool, Mr Jorge Odon and Mario Merialdi*

- 16:30** Academic, cases: *Stanford University Professor Anuraq Mairal (teleconference)*
Question on survey to Diana Calva (teleconference)
University in Bangladesh, Dr Siddique Rabbani
- 17:20** WIPO tools and gateway, *Dr Lutz Mailänder*
- 17:30** Summary of the day's activities, review of objectives and agenda for the next day
- 18:00** Group photo
 Adjourn
- 19:00** Rapporteurs meeting

Tuesday, 5 June 2012

- 08:30** Introduction to the day's activities
 Presentation on Sree Chitra Tirunal Institute
Mr. Nirajan Khambete
 Presentation of Tool to assess feasibility of technology transfer and local production
Dr. Heike Hufnagel and Ms. Clara Aranda and
Leave for breakout sessions:
- 9:00–10.30** Open discussion on the tool by breakoutgroups:
 Group 1–key questions M31
 Group 2–device related factors M105
 Group 3–device in local context M18
 Group 4–market related factors M13
- 10:30** Coffee break (M105)
- 10:45** Presentation of proposed modifications of the tool, by each group rapporteur.
- 11:15** Fill "post it" notes with ideas on how to bring down barriers by topic Research and development
 Regulations
 Procurement and logistics
 Maintenance and safe use
- 12:15** Place ideas on poster topic and discuss how
 Presentation of priority areas for each main barrier
- 12:45** Lunch
- 14:00** Open discussion, next steps on the : Report
- 14:30** On the Survey
- 14:45** On the Tool
- 15:00** Coffee break
- 15:15** Strategies and actions to be developed.
- 16:00** Way forward
- 17:00** Conclusions
- 17:30** Closure of the meeting
 Mr Kees de Joncheere

Objectives of the Meeting:

- To discuss access to medical devices: barriers and challenges, considering the expertise, the results from survey and literature review.
- To outline the challenges and opportunities at each stage of the innovation process, from idea generation to uptake, in order to propose a list of activities and the stakeholders involved that can enhance access to these devices. Topics to be discussed include: intellectual property issues, regulations, procurement practices, taxes, lists of devices for procurement, and logistics.
- To discuss in which cases the local production and technology transfer could be an option to increase access of medical devices.

Expected outcomes:

- Recommendations on actions to increase access to medical devices in the developing world
- A first version of an assessment tool to analyze if a technology can be produced locally to solve local need.

Appointments:

Co-Chairs:

June 4: Nicholas Adjabu

June 5: Adham Ismail

Rapporteurs: Albert Poon, Einstein Kesi, Niranjana Khambete

Organization:

The meeting took place over two days (June 4/5, 2012) at the World Health Organization, Geneva. The detailed agenda is presented in *Annex 2*.

Welcome remarks:

The meeting was opened by Mr Clive Ondari on behalf of Kees de Joncheere, WHO Director of Essential Medicines and Health Products.

Mr Ondari urged the committee to consider the barriers and challenges to improving access to Medical Devices. After discussing the objectives of the meeting, he spoke of the wider context within which the consultation was taking place. Mr Ondari advised that at the recently concluded 65th World Health Assembly, member states discussed reforms that – by and large – were aimed at achieving efficiencies in how the WHO was structured and how it support member states. The WHA dialogues also touched on universal coverage and the central role of affordability, or “value for money.” Member states agreed on 25% of childhood morbidity in NCDs, and discussed the role of aging in shaping future demographics and current healthcare capacities. Mr Ondari underscored that the consultation’s discussions on local production and technology transfer as a means to improve access to health outcomes, would feed into wider WHA targets.

Medical Devices Unit (WHO):

Mrs Adriana Velazquez Berumen gave an overview of the Medical Devices Unit within WHO. The WHO has six Regional Offices, 147 country offices, and 194 Member States. WHO has identified targets to reach health-related MDGs and reduce NCD disease burden. The global disease burden is changing.

Key findings:

- The WHO has identified targets to reduce NCDs, reach MDGs.
- The Medical Devices Unit works in collaboration with partners and diverse stakeholders to reduce access to medical devices gaps.

The Medical Devices Unit is part of the Health Systems cluster and works in collaboration with UN departments, NGOs and governments, and diverse stakeholders such as industry, to reduce access gaps to medical devices. The unit publishes a variety of reports on Medical Devices (general information), Research and Development, Regulation and Assessment. Key documents include the *Baseline Country Survey of Medical Devices*, and *Managing the Mismatch: An Outcome of the Priority Medical Devices Project*, and the *Compendium of New and Emerging Technologies* and medical devices technical series.

Public Health Innovation, and Intellectual Property Rights:

Mr Robert Terry discussed the Public Health, Innovation and Intellectual Property Rights project (PHI). The project was commissioned by the European Union and seeks to understand where 'local production' fits within the wider discourse of improved access to medical products.

Key findings:

- The report Local Production and Technology Transfer to improve access to Medical Devices was commissioned by PHI. The PHI project is funded by the European Union and seeks to understand where local production fits within the wider discourse of improved access to medical products.
- To date, research does not offer clear evidence of a link between local production and improved access to health outcomes.
- Current research points to the need for greater coherence between industrial and health policies.

1. 'Local production' is defined in terms of geography – i.e. the presence of a manufacturing plant, centre, or unit within a local jurisdiction. It thus includes local and foreign-owned medical device manufacturers that have the explicit intention of improving public health outcomes
2. 'Medical products' are defined as: pharmaceuticals, vaccines, diagnostics, medical devices, blood and blood products

In its first phase, the project commissioned reports from pharmaceuticals and diagnostics on the role of local production in improving access to these products. To date, the research has proven inconclusive: there is no clear correlation that local production improves local health outcomes. A lot more advocacy work is needed.

Mr Terry elaborated that current research points to the need of key capacities such as a supportive government and greater coherence between industrial and health policy. Governments play a key role in linking these goals through initiatives such as (but not limited to) coordination, education, and direct and indirect business supports such as grants, subsidies and facilitated access to foreign markets.

Scoping analysis

Mrs Adriana Velazquez Berumen presented key findings from the landscape analysis.

Key findings:

- The global medical devices market is growing, and market leaders are predicted to change by 2020.
- There are broadly three approaches to intellectual property.
- Discussions on local production do not imply quality. Quality must be locally enforced through the regulations.

The global market for medical devices is growing, and is expected to reach US\$ 228 billion by 2020. By that time, Brazil, China and India are predicted to compete head-to-head with the United States of America, the largest producer of medical devices in 2010, and the largest holder of medical technology patents. She discussed international movements to harmonize medical device regulations, how financing mechanisms such as insurance and government revenues influence medical device production, and the business capabilities required to support local production. Mrs Velazquez Berumen concluded her presentation with a review of five countries: Brazil, China, Ethiopia, India and Jordan.

Survey on barriers to local production

Dr Heike Hufnagel presented the outcomes of the Medical Devices Survey to identify barriers to local production in low resource settings. The survey was sent to 500 experts around the world and received 140 responses.

Key findings:

- Survey was completed by 103 respondents from around the world.
- Key barriers to access to medical devices as well as to development and commercialization in low-resource settings were identified.

Key findings:

- Key barriers to local production: insufficient skilled personnel, capital, incentives, market information, inadequate infrastructure, and regulatory frameworks.
- 39% of developers who responded to the survey were able to transfer their technologies to low-resource settings.
- Public perception of local products versus imported one, foreign competition were identified as main barriers in selling locally manufactured medical devices.

Dr Adham Ismail asked if statistical analysis could identify which of the key barriers were considered to be significantly higher than others.

Success stories

Hearing aid: Local production of hearing aid with rechargeable battery in Brazil

Key findings:

- Cost-effectiveness is a key driver for local production of the device.
- Opportunity should be taken to incorporate re-engineering and design changes to bring about performance and ease of use improvement.
- Local production employing labour force of the same target user population has highly enlightened the end results and the local production process.

Mr Howard Weinstein presented Solar Ear (based in Botswana, Brazil and Palestine), which manufactures, assembles and distributes the first digital rechargeable hearing aid. The low cost solar rechargeable hearing aid battery costs the same as a disposable zinc air battery but lasts two to three years.

In addition, Solar Ear provides employment, training and education programmes for the young, deaf manufacturers of the devices. Since its inception, Solar Ear has sold 10 000 hearing aids, 20 000 solar chargers and 50 000 batteries to more than 40 countries.

Neonatal equipment: Provision of clinical facilities and appropriate medical equipment to developing countries in Asia

Key findings:

- Significant numbers of newborn death (4M) are preventable
- Newborn deaths in developing countries are mainly due to lack of clinical facilities and appropriate medical equipment and might be preventable.
- Companies can participate in support programmes in developing countries to reduce number of newborn deaths.

Mr John Anner, President of East Meets West (EMW), advised that EMW, funded by World Bank, USAID, Irish Aid and other private donors, has been operating in Asia for over 24 years, mainly to provide support programmes in infant health, clean work and sanitation in Asian countries such as Cambodia, India, Laos, Myanmar, the Phillipines, Timor Leste and Viet Nam. Mr Anner explained that annually, there are 5 million preventable deaths of newborn babies and the main reasons are due to lack of clinical facilities and appropriate medical equipment.

Maternal health: Non-pneumatic anti-shock garment (NASG)

Key findings:

- Postpartum haemorrhage (PPH) and resulting shock account for a disproportionate number of deaths in developing countries.
- Reverse engineering and local production can reduce the cost and improve the quality to allow this garment to be more available and affordable in the places that need it most.

Mr Rick Kearns, Technical Officer of PATH, reported on PATH's work on non-pneumatic anti-shock garment (NASG). The use of NASG is an effective means to treat shock and stabilize a woman for transportation to receive suitable treatment she needs. The original NASG is costly at \$300 per garment and quality is unreliable. As patent is ending, PATH did reverse engineering of the garment and greatly reduced the production cost. The reproduced garment now costs around \$50 and total production cost including overheads is about one-third to one-fourth of the imported NASG and better reliability.

Maternal health: Assisted delivery tool – The Odon device

Key findings:

- Innovation and new ideas provide continual improvement on medical devices which in turn lead to bettering human life and health.
- The tool is a low cost, easy to use technological innovation to facilitate operative vaginal delivery when complications occur during second stage of labour and designed to minimize trauma to the mother and baby.
- The invention will make a potentially revolutionary development in obstetrics and it will require some facilitating organization such as WHO to assist introduction.

Dr Mario Merialdi, Coordinator in WHO Department of Reproductive Health and Research, introduced Mr Jorge Odon, the inventor of the Odon device, and explained the background in the idea creation and development of the Odon assisted delivery tool. Mr Jorge Odon elaborated the application principles by extracting a cork from inside a wine bottle and showed a video on how the device assisted a case of baby delivery. Members were impressed that a simple device using a plastic bag can perform the same functions of a tong at less risk. Mr Odon also explained that despite the use of the plastic bag over the head of the baby under delivery, there is no danger of suffocation as the baby still relies on the mother through the umbilical cord.

Chronic diseases: Development of health care devices in Dhaka University, Bangladesh

- Innovations include: Electrocardiogram and pedograph.

Key findings:

- Majority of third world countries are deprived of modern health care technologies.
- Universities and research organizations should assist promotion of health care innovation and to teach technology, manufacture and entrepreneurship to scientists and engineers in LICs.
- The key to success is to share and spread health care technologies and assist local production.

Dr Siddique-e Rabbani, Professor, Department of Biomedical Physics and Technology (BMPT), Dhaka University, presented the engineering works and development of healthcare technology in LICs. Dr Rabbani discussed that the development work in his institution covered five areas of health care: prevention, diagnosis, therapy, rehabilitation and supporting devices. He discussed the local development of computerized ECG/EMG/EP and dynamic pedograph and other medical equipment in the five target areas. From these

success stories, he shared a vision for BMPT to promote health care innovation and teach technology, manufacture and entrepreneurship to scientists and engineers in LICs.

Sree Chitra Tirunal Institute for Medical Sciences and Technology

Key points:

- Sree Chitra Tirunal Institute for Medical Sciences and Technology pioneered medical devices development in India to help technology transfer.
- India is making progress in health indicators despite large population.
- Regardless, further work is necessary.

Dr. Khambete initiated his presentation by giving a quick summary of the key points from the stakeholder meeting (June 4, 2012) and went on to discuss his work in the Sree Chitra Tirunal Institute for Medical Sciences and Technology; this institute pioneered medical devices development in India to help facilitate technology transfer. He alluded to how India is making progress in health indicators despite the large population and asserted that further work needs to be done.

Academic cases: Global Biodesign and SIB & SSB fellowships

Key findings:

- Development of medical technologies could be encouraged through structured training programmes.
- Countries in partnership could promote co-development of affordable and accessible medical technologies that have great values to both partnership countries.

Professor Anuraq Mairal, Director of Global Exchange, Stanford Biodesign, presented his laboratory via teleconference. He discussed Stanford's four-pronged mission to:

- Find and develop "in-country innovators" to become leaders in med-tech innovation.
- Train partner institutions to teach Biodesign process: Identify, Invent, Implement.
- Play an integral role in developing cost-effective and globally relevant solutions to important medical needs across the globe.
- Promote exposure of US fellows and students to global medical technology opportunities.

There are two major programmes: Stanford India Biodesign Programme (SIB) and Stanford Singapore Biodesign Programme (SSB) and there were successful batches of graduates being trained on these programmes. The intended

outcomes are batches of globally-minded engineers and scientists as leaders in the medical technology field to develop affordable and accessible medical devices and technologies that would have great value to the participating countries. The important thing is the graduates are committed to return to their own countries to assist development of local medical technologies.

World Intellectual Property Organization (WIPOs) tools and Gateway

Key findings:

- The Gateway enables access to health-related patent information.

Dr Lutz Mailander discussed WIPO's mission to promote the protection of intellectual property throughout the world. Dr Mailander presented the Gateway as a means to access health-related patent information. The Gateway was built in collaboration with WIPO and the WHO to provide search services to NGOs and UN agencies.

Feasibility tool for local production of medical devices

Key points

- Key questions include whether medical device can be successfully employed in a low-resource setting.
- Evaluation tool is designed as a first probability measure for local production success.
- Evaluation tool is extensive and is divided into four sections that covers all essential questions that need to be considered to answer the key question.

Ms Hufnagel initiated this presentation by pointing out that although success stories suggest local production in resource-poor settings improves health care delivery, this is not always the case. The key question in this situation is whether the low-resource settings offer the necessary resources for manufacturing and marketing the device. A range of related common problems in manufacturing and successful employment were discussed such as a gap between skill level in the country and those needed for manufacturing, a lack of necessary equipment, difficult imports, and a lack of safety standards.

Ms Hufnagel went on to highlight another key question that is often forgotten and needs to be considered: whether the device can be successfully employed in a low-resource setting. For this purpose, a simple tool was developed by various stakeholders and the WHO to serve as a first feasibility measure for local production success.

Ms Aranda then talked about the specifics of the tool and the details of its four sections: key questions, device related factors, device in local region, and market-related factors. She explained the weighting factor associated with each section of the tool and ran the committee through an example of how the tool had been used on specific pre-selected medical devices. She concluded with how the tool would enable manufacturers and innovators to identify key areas they might need to focus on to improve their device's chances of success. Challenges of the tool were mentioned as well such as the difficulty it poses in defining priorities for each section and subsection, the difficulty in establishing a passing and failing score, and the difficulty in explaining numeric scoring.

General discussion on the Feasibility tool

The participants briefly deliberated, at a broad level, the purpose of the tool and what direction the break out session that was to follow should take.

Group breakout session, presentations, and discussions

The participants divided into four groups, each targeting one of the four aspects of the draft Feasibility tool for sustainability of medical devices for local production. Each of the groups discussed changes independently and then presented their findings and suggestions in plenary, which were then further deliberated. The group divisions were: a) key questions; b) device-related factors; c) devices in local regions; and d) market-related factors.

Suggestions were carefully considered and incorporated into version 1 (Annex 3) of the evaluation tool to produce version 2 (Chapter 4).

Proposed action plans on challenges and barriers

The participants deliberated each of the challenges and barrier categories that were mentioned in the draft report and proposed solutions in order of priority. The challenge and barrier categories included: a) needs and development; b) regulations; c) funding; and d) procurement/logistics/supply chain. The specific proposed solutions in order of rank and segmented by stakeholder are tabulated in the Way forward section (Chapter 5).

General discussions and final comments

The participants discussed key aspects of the report, the survey and Feasibility tool, and gave their final recommendations that were carefully considered and incorporated into this document.

Conclusions and closing

The participants finally discussed the outcomes and future directions that resulted from the two-day stakeholder meeting. Dr Kees de Joncheere gave the closing statements.

The participants asserted that countries can accordingly utilize local production and other solutions to improve access to medical devices. Additionally, academia, legislature and investors can cooperate to advance health and industry policy and create conducive environments for medical device manufacturers.

Participants also suggested that future projects could include business case studies to market medical devices and a database from which individuals could assess user needs to develop medical devices.

The participants will be looking forward to the next steps to improve technology transfer and local production of essential priority medical devices in low resource settings as a means to increase access to health care when feasible.



**World Health
Organization**

Medical Devices Unit
Department of Essential Medicines and Health Products
World Health Organization
medicaldevices@who.int
http://www.who.int/medical_devices/en/

ISBN 978 92 4 150454 6

