Towards improving access to medical devices through local production

Phase II

Report of a case study in four sub-Saharan countries

Intellectual Property and Trade

R&D, Innovation

Technology Transfer

Improving Access

Financing

Monitoring and Reporting

World Health Organization

Towards improving access to medical devices through local production

Phase II

Report of a case study in four sub-Saharan countries

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Abbreviations

AIDS	acquired immunodeficiency syndrome
ARIPO	African Intellectual Property Office
BPP	Bureau of Public Procurement
CAGR	compounded annual growth rate
CE	Conformité Européene
CENETEC	National Center for Health Technology Excellence
COSTEC	Commission for Science and Technology
DBE	Directorate of Biomedical Engineering
DST	Department of Science and Technology
DTI	Department of Trade and Industry
ECG	electrocardiogram
EIPO	Ethiopian Intellectual Property Office
FMoH	Federal Ministry of Health
FMHACA	Food, Medicine and Health Care Administration and Control Authority
GDP	gross domestic product
GHI	Global Health Initiatives
GNI	Gross National Income
GMP	good manufacturing practices
HIV	human immunodeficiency virus
HSDP	Health Sector Development Programme
HSSP3	Third Health Sector Strategic Plan
IAFs	International Accreditation Firms
ISO	International Organization for Standardization
LPTTMD	Local production and technology transfer for medical devices
MDG	Millennium Development Goal
MoHSW	Ministry of Health and Social Welfare
MSD	Medical Stores Department
NAFDAC	National Agency for Food and Drug Administration and Control
NCD	noncommunicable disease
NGOs	nongovernmental organizations
NNRA	Nigerian Nuclear Regulatory Authority
PEPFAR	US President's Emergency Plan For AIDS Relief
PFSA	Pharmaceuticals Fund and Supply Agency

SAMED	South African Medical Device Industry Association
SANAS	South African National Accreditation System
SON	Standards Organization of Nigeria
SONCAP	SON Conformity Assessment Programme
TB	tuberculosis
TFDA	Tanzania Food and Drugs Authority
TIC	Tanzania Investment Centre
TISA	Trade and Investment South Africa
WHA	World Health Assembly
WHO	World Health Organization
WIPO	World Intellectual Property Organization

Executive summary

Appropriate, affordable and good quality medical devices are indispensable in healthcare services. They serve for the prevention, diagnosis and treatment of diseases. 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 developed this project report on medical devices access through local production. This report presents the second phase of activities of local production and technology transfer for medical devices (LPTTMD) project, as well as a situational analysis of the challenges in access to medical devices, technology transfer and local production of essential medical devices in four sub-Saharan countries (viz. Ethiopia, Nigeria, South Africa and Tanzania). The objectives of this project were to improve access to priority medical devices, present country case studies and develop a road map on activities to improve availability and consider local production where appropriate. Phase II reviewed the findings from the phase I survey with respect to barriers and challenges to access and applied the feasibility tool (revised from phase I) to enable strategic selection of a device of high public health importance that could be produced locally.

The phase II of the LPTTMD project that began with an April 2013 planning meeting in Geneva had a panel of invited experts who provided inputs on all aspects of the project. The WHO Medical Devices Unit revised and disseminated an updated survey, both online and as physical copies using a WHO mailing list, in June 2013 specifically targeting stakeholders in Ethiopia, Nigeria, South Africa and Tanzania to develop a better understanding of country-specific barriers and challenges.

The feasibility tool developed during phase I was modified by the WHO Medical Devices Unit based on inputs from experts who attended the 2013 LPTTMD planning meeting, staff from relevant WHO units as well as from insights gained from peer-reviewed literature. This tool was disseminated among stakeholders in the four case study countries to evaluate possibilities of local production of specific medical devices. Subsequently, information from the feasibility tool and the survey (evaluating medical devices proposed for development) was used to identify candidate devices for local production.

The detailed analysis of medical devices policies conducted in the four selected case study countries helped identify the landscape related to regulation, use of medical devices and the opportunities for the development of local medical devices. In addition, information from the in-country application of the phase I survey conducted with local stakeholders helped to gain specific local information on barriers and challenges to access including aspects such as an analysis of regulation, taxation, tariffs, maintenance, technical specification, as well as lists of approved medical devices for reimbursement and procurement. An important focus of the work was to support and align with the implementation proposal of the United Nations Commission on Life-Saving Commodities for solutions to decrease maternal, neonatal and child mortality.

Workshops held in the four case study countries in 2014 to discuss survey findings and for application of the feasibility tool to different technologies concluded with an action plan to both increase access to medical devices and enhance local production of affordable, priority medical devices required in the country or region. These in-country workshops proved to be an important initiative to raise awareness of the need to collaborate with

all stakeholders together so that good quality and affordable health technologies could be made available. These provided a place to present national initiatives, challenges and opportunities in manufacturing, regulations, selection, procurement, distribution, management and safe use of medical devices. These workshops also helped raise awareness of the need to increase local capacities with support from the government, academia and the private sector as well as to define and make available the technologies required to target public health priorities.

The following important findings emerged from the four local workshops. All countries had a biomedical engineer focal point either within the ministry or department of health, or in a government institution dealing with medical equipment or health technology management. All case study countries had some initial expertise in regulation of medical devices, although Tanzania had the most developed systems in place. The need for technical specifications for procurement was noted for all case study countries, although Ethiopia had a very robust process and system that included biomedical engineering expertise for procurement officials. In Ethiopia, sixteen of 19 device submissions were deemed feasible for local production; however, there is a need for policy makers, industrialists and investors to collaborate to improve the Ethiopian business development environment to make local production of medical devices a reality. Local production of medical devices in Nigeria showed future potential as no medical device had been produced locally yet. Nearly half of the assessed medical devices were deemed feasible for local production. To increase local Nigerian production of medical devices, special attention should be paid to improving business development, market strategies and supply chain factors. South Africa showed the greatest capacity to support a strong local production environment – all the four device submissions were deemed feasible for local production and many medical devices were already being produced. Many programmes and organizations, including the Medical Device Manufacturer's Association of South Africa and South African Department of Science and Technology's Innovation Agency, promote technical innovation, research, development and commercialization of medical devices. Tanzania was in the lead in regulating medical devices (among the four case study countries) with its regulatory agencies (including biomedical engineers) and a regulatory process. Nine of 13 submissions were deemed feasible for local production in Tanzania, although factors such as poor business development and market strategies were considered obstacles to local production.

Conclusions drawn from the report indicate that there is a very important need to increase access to medical devices to meet healthcare needs. The actions to be taken would include: increasing the awareness of the role of varied priority medical devices in healthcare delivery; promoting initiatives that will encourage education of biomedical engineers locally; designing better products as per local requirements with the support of other professionals who would help with innovation, research and development; regulating medical devices appropriately so as to have a better process to select, procure and distribute medical devices and train the users; and depending on the setting and willingness of the government, academia and private sector, consider local production of some priority appropriate medical devices to target local needs.

It is hoped that this WHO study and the local workshops that brought together all stakeholders (including government, academia and private sector), would have prompted them to work together towards increasing access to appropriate medical devices to meet local health priorities. It is anticipated that other countries learn from these experiences and use it to develop their own action plan that would lead to better availability of good quality medical devices, which will help deliver enhanced healthcare and thus increase the well being of their population.

PART I | Global perspective

2013 survey on development of appropriate, affordable, quality medical devices for low-resource settings and feasibility tool

1. Introduction

Health technologies are an indispensable component of effective healthcare systems. Among these technologies, medical devices provide the tools to diagnose, treat and rehabilitate people living with illness and disease. WHO cites over 10 000 existing medical devices ranging from lancets to complex imaging equipment, in vitro diagnostics and implantable devices. Globally, the medical devices market had an estimated worth greater than US$ 250 billion in 2010. Though the medical devices market has grown enormously over the past two decades, it is primarily concentrated in advanced healthcare systems of high-income countries and only minimally impacts the less advanced rural and primary care centres of low- and middle-income nations.

A medical device is defined as an "article, instrument, apparatus, or machine that is used in the prevention, diagnosis, or treatment of illness or disease, or for detecting, measuring, restoring, correcting, or modifying the structure or function of the body for some health purpose" *(1)*. These devices have the potential to fulfil critical global health needs from rapid diagnostic testing to prevention and complex treatment. Supplying medical devices can involve transferring existing devices, also known as technological "diffusion", from developed to developing settings in the form of low-cost sales or donations *(2,3)*. Almost 80% of health technologies in low-resource settings were donated *(3)*; however, these transfers have not been entirely successful *(2)*. One study noted that 40% of medical equipment in low-resource settings was nonfunctional in contrast to high-income countries where less than 1% of medical equipment was nonfunctional *(4)*.

Lack of spare parts, required consumables, reliable power, water and public infrastructure are major barriers plaguing healthcare technology in the developing world *(5)*. A recent survey of health workers in Africa and Asia showed significant gaps in available essential health technologies to assist maternal and infant health in rural settings *(6)*. A report by the Lancet Commission on global health technologies states, "more frugal technology, specifically designed for the world's poorest people, is needed. Such technology also has the potential to disrupt healthcare in high-income countries" *(4)*. Capacity building and focusing on improving local workforce knowledge have the greatest impacts for attaining full operational capacity *(7)*. Given the current challenges regarding medical device utilization in low-resource settings, technology donation would be ineffective. Hence, there is a well-defined need to design, develop, produce and implement (commercialize) frugal, appropriate and innovative devices. This need should be met via a process which considers local and regional limitations, cultural contexts and stakeholder needs while enhancing the capacity of the local healthcare workforce *(5,6)*.

1.1 Medical devices – WHO perspective

In 2014, one of WHO's six strategic objectives was to "increase access to safe, quality medical products". This objective started out from the 2007 World Health Assembly (WHA) approved resolution WHA60.29 to specifically address the need to regulate, manage and assess medical devices. It mandates the WHO to carefully review and consider the global medical devices landscape. Since the WHA60.29, the WHO has initiated a number of high impact projects on medical devices. In 2007, the Priority Medical Devices project was developed to identify gaps in availability and future needs of medical technologies. In 2009, *Landscape analysis of barriers to developing or adapting health technologies for global health purposes* was prepared to guide industry investment in global health priorities *(8)*. In 2010, the WHO launched a call for innovative technologies addressing global health concerns, leading to the yearly publication of the *Compendium of new and emerging technologies*. The Compendium highlights promising, affordable and appropriate technologies to address health priorities, specifically for low-resource settings *(9)*. In 2010, the first Global Forum on Medical Devices took place in Bangkok that brought together global leaders from 107 Member countries in areas of clinical engineering, regulation, innovation, assessment and policy development. In the same year, all Member countries performed a baseline country survey to collect information on medical device policies, guidelines and strategies. Each year, these country surveys are updated and the results are presented in both World Health Statistics and Global Health Observatory publications. In 2014, 174 Member countries submitted their survey data.

The "Medical Devices Technical Series" includes policies, guidelines and tools published in English, French and Spanish to allow for better needs assessment, evaluation, procurement, inventory and management of medical technologies in Member countries. A Second Global Forum on Medical Devices, focusing on "*priority medical devices for universal health coverage*", was held in Geneva from November 22–24, 2013 and included over 500 participants, 120 presentations and 39 workshops. The forum focused on the role of the industry, academia, innovators and WHO in increasing access to appropriate technologies globally. Phase II of the "local production and technology transfer for medical devices (LPTTMD) project", focused on issues (barriers and enablers) related to local manufacturing, production and commercialization of specific medical devices in the four sub-Saharan case study countries.

1.2 Objectives

This report aims to identify the current issues, challenges and opportunities in low-resource settings regarding the production and lifecycle of medical devices. It builds on the findings from phase I, which elaborated on the general barriers and challenges to accessing medical devices in low-resource settings.

The WHO launched an internet-based survey to gather information surrounding the needs in the medical device production environment from countries around the world. Additionally, the WHO launched a feasibility tool to evaluate production and manufacturing viability of selected medical devices in a given setting. Case study countries – Ethiopia, Nigeria, South Africa and Tanzania – implemented the feasibility tool using several country-specific cases. The aim was to systematically evaluate the current capacity, policy and infrastructure to locally produce and manufacture selected medical devices both globally and within the

four case study countries. These objectives stem from the greater objective set by WHO to improve access to selected medical devices by facilitating local production.

To achieve these objectives, a group consisting of WHO staff, external consultants and field advisers performed the following activities.

- Administered a comprehensive revised phase I survey among the stakeholders to garner knowledge of specific local barriers and challenges to medical device access.
- Revised, implemented and tested the feasibility tool (designed during phase I) to systematically evaluate selected devices in each of the four case study countries.
- Identified devices with high potential for local production in the four case study countries.
- Provided capacity building activities regarding medical device lifecycles to a variety of stakeholders in the four case study countries. Topics of interest included manufacturing, needs selection, management and safe use of medical devices.

1.3 Findings from phase I

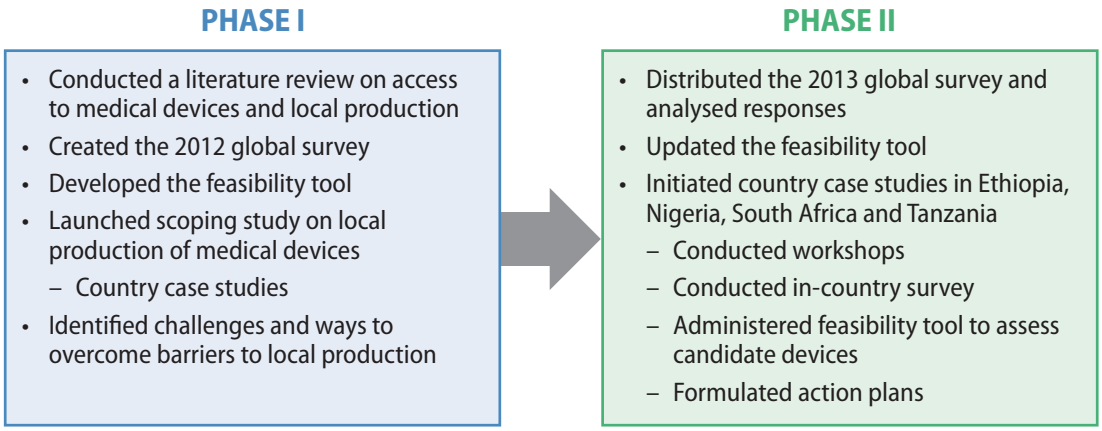
Phase I was conducted in 2012 and consisted of a scoping study that conducted an extensive literature review to compile and discuss barriers and challenges to local production and technology transfer of medical devices. Information and findings that supplemented this scoping study included:

- Market data on medical devices at both the country and industry levels.
- Geographical distribution of global investment in research and development.
- Global patent trends related to health technology.
- New devices and markets to address emerging needs in low-resource settings.
- Health system financing and payment mechanisms for medical devices in public and private sectors.
- Government regulation and policies for medical technology in low- and middle-income countries.
- Examples of product development partnerships in Brazil, China, Ethiopia, India and Jordan.

To evaluate and account for multi-level issues associated with design, development and commercialization of medical devices for low-resource settings, an analytical tool (feasibility tool) was developed during phase I to assist with strategic decision-making on the feasibility of locally producing medical devices.

Phase I outcomes were presented in a comprehensive 2012 report, titled *Local production and technology transfer to increase access to medical devices: addressing the barriers and challenges in low- and middle-income countries (10)*.

***Figure 1** Phase I (2012) and phase II (2013–14) outcomes*



1.4 Planning phase II

A phase II project-planning meeting was held from April 29 to May 1, 2013 at the WHO headquarters in Geneva. Participants included representatives from the academia, industry, non-profit organizations and United Nations-affiliated organizations.

The meeting objectives were to:

- inform country representatives, team consultants and advisers about the major objectives, deliverables and timeline of phase II of the LPTTMD project and to develop a comprehensive work plan;
- review the 2012 feasibility tool and collect feedback from participants to further refine the tool; and
- review the 2012 WHO medical devices survey to develop a baseline status of medical devices and biomedical engineering fields in various countries and prepare the survey for implementation.

The major outcomes were:

- a work plan based on each country's needs and capacities for phase II of the LPTTMD project;
- feedback from participants to update the feasibility tool to version 2013;
- feedback from participants to update the 2013 survey on medical devices; and
- a work plan for in-country workshops.

The outcomes resulted in the following action items.

- Specifications of general project directions
  - Prepare an activities timeline.
  - Formulate a specific list of deliverables.
  - Draft the table of contents for the final report.
- Suggestions for use of the country survey instrument
  - Choose only respondents with relevant expertise.
  - Obtain a minimum of 20 responses in target countries.

  - Target respondents from a variety of stakeholder groups (e.g. end-users, government representatives, academics, clinical engineers, manufacturers).

- Suggestions for modification and deployment of the feasibility tool
  - Assess user qualifications to improve the accuracy of reported data.
  - Define clear and specific objectives, expected outcomes and a target set of respondents to facilitate an optimal set of questions.
  - Implement an online feasibility tool to improve accessibility and ease of score reporting to the user.
  - Clarify and frame the needs assessment section using a (i) disease-oriented approach with questions on major health problems of the country; and a (b) device-oriented approach that explores current competing devices.
  - Select expert country consultants in medical equipment development to support in-country activities. Some consultants should be chosen from among the academics, WHO country office representatives and local biomedical engineers.

Based on the action items defined in the planning meeting, participants and consultants updated the survey and planned feasibility tool administration and country workshops.

This report includes the following.

- Definition of the 2013 version of the feasibility tool.
- 2013 global survey on development of appropriate, affordable, quality medical devices for low-resources settings.
- Results of the global survey and specific results of case study countries.
- Specific results of the feasibility tool used for new technologies that are locally developed or currently under development in the four case study countries.
- Country profiles of medical devices of the four case study countries, particularly addressing local production.
- Country workshops and devices action plans.
- Way forward to increase access to medical devices or local production and technology transfer, particularly in low-resource settings.

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2. 2013 survey on development of appropriate, affordable, quality medical devices for low-resource settings

The "*2013 survey on development of appropriate, affordable, quality medical devices for low-resource settings*" was updated following the April 2013 planning meeting. This updated/revised survey was disseminated to health technology focal points around the globe through the WHO Medical Devices Listserv.

The survey aimed to establish respondents' knowledge of both WHO projects regarding medical device innovation as well as in-country policies, regulations, intellectual property, procurement, academic units and engineering programmes related to local production and technology transfer of medical devices. Specific questions targeted responses from donors, investors, industry members and end users to gain a wide perspective on the medical device landscape.

The survey was conducted in all case study countries to gather information regarding the local production and technology transfer landscape within the country. The survey was designed to address barriers and obstacles to local production of medical devices and all survey respondents were asked relevant questions.

The four case study country coordinators ensured that at least 20 responses were received from their respective countries. Survey design and analysis are presented below. Specific responses of case study countries are presented in sections 4.7, 5.7, 6.7 and 7.7.

2.1 The revision process

The revised/updated phase I survey evolved through the following steps.

- Feedback was gathered from respondents and experts during administration of the phase I survey (2012–13).
- Feedback was collected from WHO consultants and experts who attended the 2013 LPTTMD planning meeting (Annex I).
- Feedback was collected from practicing experts in fields associated with different aspects of medical devices commercialization ranging from design and development to implementation and surveillance.

The revised survey aimed to elicit information on specific topics concerning medical devices (see the list in section 2.2 below and the complete questionnaire in Annex I). Each of the steps included in the survey is critical to design, develop and commercialize a medical device.

2.2 Survey overview

The survey consisted of sets of questions designed to gather specific information and was divided into the following sections.

1. Personal Information (mandatory): Name, affiliation, country of domicile and contact information.
2. Introduction: Respondent's expertise and experience.

3. WHO Innovation Projects: Respondent's knowledge of WHO projects related to medical device innovation.
4. Product Development: Respondent's experience developing products for low-resource settings, with an emphasis on the types of barriers faced during development.
5. Policy and Partnerships: Respondent's knowledge of in-country policies for procurement and partnership promotion between the academia and industry.
6. Intellectual Property: Existing policies regarding patents, trademarks and design registries, as well as the respondent's knowledge of these policies and use of these services in their business operations.
7. Regulation: Respondent's knowledge of regulations and their impact.
8. Academia: Academic units related to medical devices in respondent's country and unit role in the medical device industry.
9. Technology Transfer: Technology transfer activities and public–private partnerships in the respondent's country.
10. Acquisition/Procurement/Reimbursement: Policies in the respondent's country regarding medical device acquisition, procurement and reimbursement.
11. Percentage of devices procured by category.
12. Biomedical/Clinical Engineering: Biomedical engineering programmes, clinical engineering practices for equipment specifications, and maintenance and medical equipment donations.
13. Investor/Donor/NGO: Questions to investors, donors and nongovernmental organizations (NGOs) regarding their approaches to medical device purchase and deployment, as well as their approaches to medical device production.
14. Industry: Question to the medical device industry regarding their activities. Also asked industry members about barriers to initiating or expanding local production.
15. End users: Questions to end users regarding their perceptions of and approaches to using locally produced medical devices.
16. General: Questions regarding barriers to local production and the potential for local production to have an impact on access to medical devices.

2.3 Survey distribution

The survey was distributed globally in June/July 2013 via Datacol (WHO's online survey mechanism) to contacts of the WHO Medical Devices Unit and those in the contact lists of other relevant WHO units. Notification on listserves, web postings and targeted email notifications were used to solicit responses from the global community.

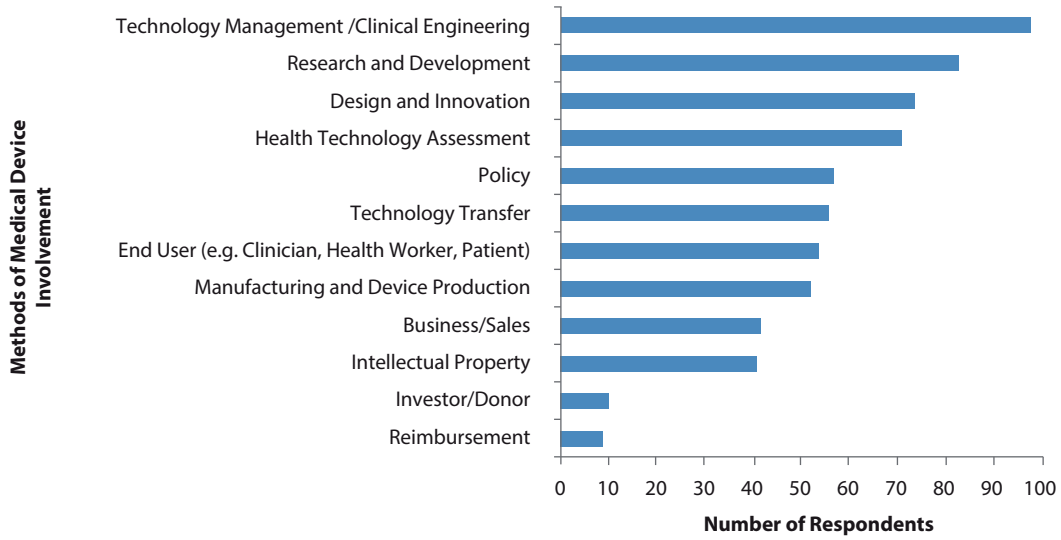
Country focal point persons selected during the planning meeting for each of the four case study countries reached out to local professionals from different backgrounds and areas of expertise to gather more evidence based and accurate information from the case study countries. Country representatives used both online and offline versions of the survey to accommodate a wide variety of respondents. Paper copies of the survey were made available to those with limited computer access. The country focal point person was a key component in identifying local innovators.

2.4 Survey respondents

A total of 205 stakeholders, involved with the medical device industry in various ways including design and innovation, policy, business and sales, completed the survey. An initial set of questions was aimed to gather information about respondents' experience and expertise. The responses to some of these questions are briefly summarized here.

The greatest numbers of respondents were involved with technology management and clinical engineering (88 respondents), research and development (83 respondents), and design and innovation (74 respondents) (Figure 2). Many respondents reported expertise in multiple areas related to medical devices.

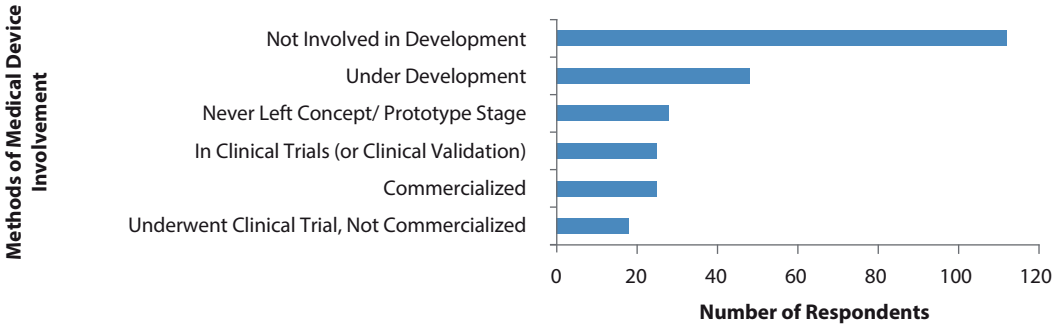
Figure 2 *Survey respondents' fields of expertise related to medical devices*



n=205 respondents

Nearly 60% of survey respondents (112 respondents) were not directly involved in developing medical devices for low-resource settings. The remaining 40% of respondents were involved in various stages of medical device development, ranging from the concept stage to fully commercialized products. Figure 3 illustrates survey respondents' involvement in medical device development. Note that some respondents were involved in multiple stages of medical device development.

Figure 3 *Percentage of survey respondents involved at stages of medical device development*



n=196 respondents

One survey question gathered information on the methods used to identify and validate the need for a product and the appropriateness to the target market. Figure 4 presents the responses to this question. Personal observation and knowledge of the target market was the most commonly used method to assess product need. Interviews and/or focus group discussions with potential end users and stakeholders were also commonly used. The least used methods to determine product need were interviews and/or focus group discussions with those who had prior knowledge of the target market and clinical studies/ investigations. Many respondents indicated several methods used to identify and validate the need for product(s) and appropriateness to the target market.

***Figure 4** Methods used to identify and validate need for product(s) and appropriateness to target market*

n=103 respondents

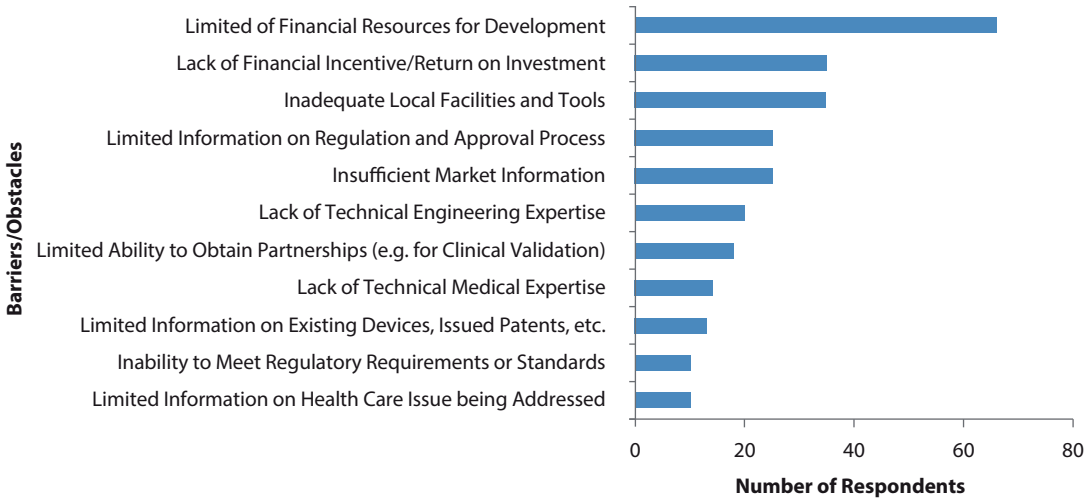
Background/experience in technology transfer of medical devices

In response to the question regarding technology transfer, 74% of global respondents indicated that they did not have any background or experience in technology transfer of medical devices.

2.5 Survey results

Survey responses indicated several perceived barriers to medical device development in low-resource settings. The most commonly reported obstacles to medical device development were 'limited financial resources for development' (66 respondents), followed by 'inadequate local facilities and tools' (35 respondents) and 'lack of financial incentive/ market appeal/potential return on investment' (35 respondents). Figure 5 displays the obstacles faced by survey respondents during the product development process. Many survey respondents reported facing multiple barriers and obstacles to medical device development.

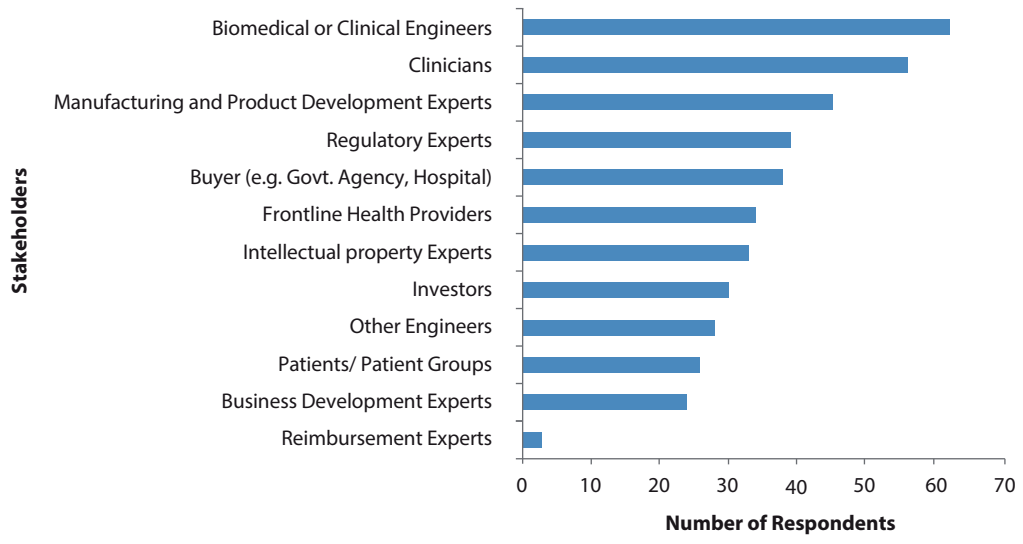
Figure 5 Barriers/obstacles to medical device development



n=85 respondents

Due to the complexity of commercializing a medical device, numerous stakeholders with a range of expertise and interests must be involved in the commercialization process. Figure 6 sheds light on the most common stakeholders with whom developers collaborate. Globally, the most commonly consulted stakeholders were biomedical or clinical engineers, clinicians, manufacturing and product development experts, regulatory experts and buyers (e.g. government agencies, hospitals). Reimbursement experts were least commonly consulted. Multiple survey respondents reported consulting with different groups of stakeholders throughout the medical device development process.

Figure 6 Stakeholder participation in the medical device development process



n=95 respondents

Role of intellectual property rights during research/design or target market identification

Of the 80 respondents who answered questions regarding intellectual property, 65% indicated that they considered the role of intellectual property rights during research/design or target market identification for medical devices. Of these, 45% indicated that patents and licensing encouraged local manufacturing, while 41% indicated these had no

effect on local manufacturing. The remaining 14% of respondents indicated that patents and licensing discouraged local manufacturing potential.

Government provision of special funding for research and development of medical devices at institutions

Approximately one third (20/56) of the respondents indicated that the government provides special funding for research and development of medical devices at the individual institution level.

Factors preventing procurement of innovative technology designed specifically for the developing world *(92 respondents)*

Below is a list of the most commonly identified factors preventing overall procurement (≥15% of respondents):

- Lack of information on types of innovative products (for safety, effectiveness, etc.).
- Preference towards proven products from well-known manufacturers.
- Unawareness of available devices.

Below is a list of answers least commonly selected overall (≤8% of respondents):

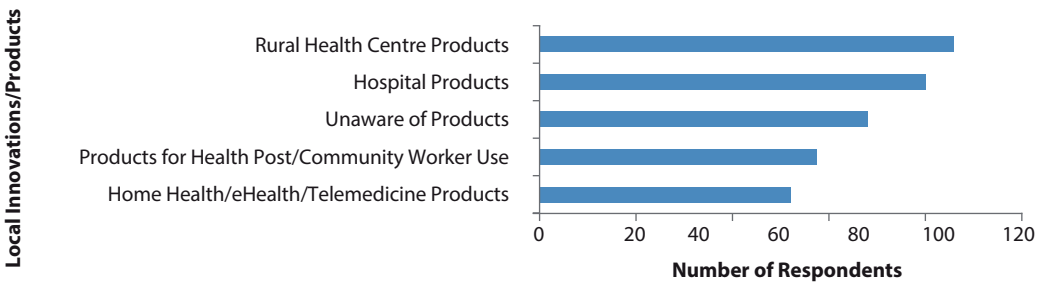
- The bidding process.
- National or local decision-makers not procuring such devices.
- Procuring innovative products whenever possible.
- Other.

Additional options included 'lack of customer support', 'lack of available technical specifications' and 'inability to purchase'.

Awareness of local innovations/products to solve local needs in rural and low-resource settings

Almost half of the respondents (48%) reported they were aware of products intended to solve local needs in rural health centres. Of these 89 respondents, only 26 reported that they were aware of l home health/eHealth/telemedicine products (Figure 7). The respondents listed examples of existing local innovation/product they were aware of that was used to address local needs in rural and low-resource settings.

Figure 7 Awareness of local innovations/products to solve local needs in rural and low-resource settings



n=89 respondents

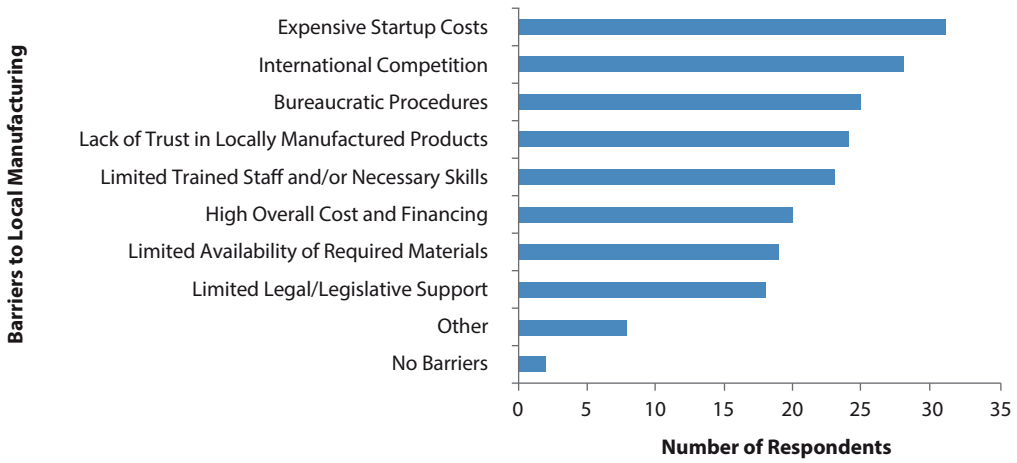
End-users

Of the 72 respondents, 57% had no preference for local or imported devices, while 25% reported a preference for imported devices.

Main barriers to local production

The most commonly cited barriers to **manufacturing** devices locally were expensive start-up costs and international competition (Figure 8). Multiple respondents reported more than one barrier to production of locally manufacturing medical devices.

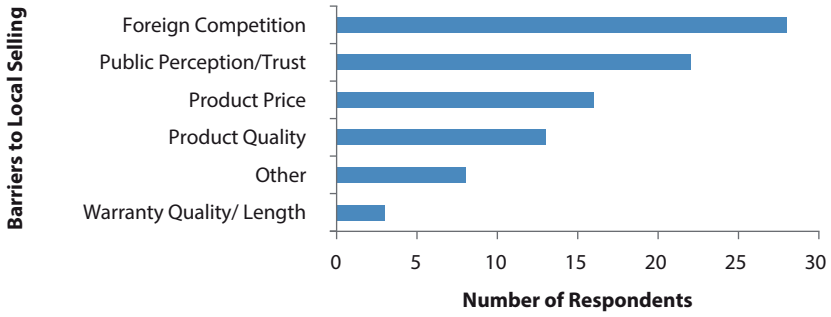
Figure 8 Barriers to manufacturing medical devices locally



n=52 respondents

The most commonly cited barriers to **selling** locally manufactured products were foreign competition (28 respondents) and public perception/trust (22 respondents) as displayed in Figure 9. Respondents selecting 'Other' identified barriers such as lack to market access, politics, corruption and regulatory costs to selling locally manufactured foods. Many respondents indicated multiple barriers to selling locally manufactured products.

Figure 9 Barriers to selling locally manufactured products

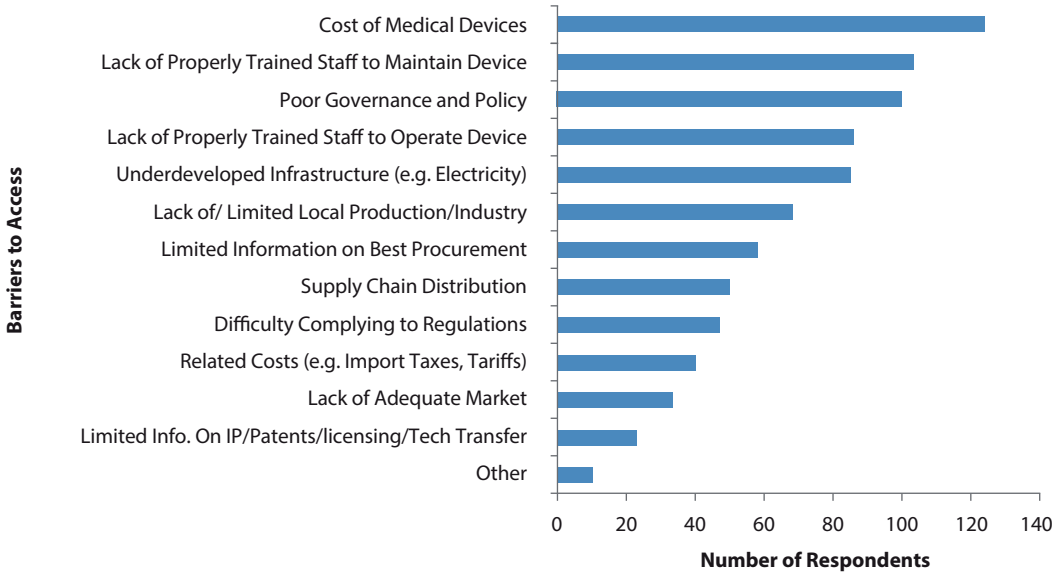


n=49 respondents

Of the 52 respondents who indicated they were involved in product development, 29% reported there were no issues preventing the **sale of their products into the desired target market**. Of the 21% respondents who selected 'Other', many indicated lack of product commercialization as a barrier to access.

The most commonly cited barriers to **access** among 197 respondents were cost of medical devices (124 respondents), lack of properly trained staff to maintain device (103 respondents), poor governance and policy (100 respondents), underdeveloped infrastructure (85 respondents), and lack of or limited local production/industry (68 respondents). All cited barriers are presented in Figure 10; multiple respondents cited more than one barrier to access to medical devices in low-resource settings.

Figure 10 Barriers to access to medical devices in low-resource settings



n=197 respondents

The survey results were compared to local in-country standards and used as discussion inputs during in-country workshops. Global survey results will help WHO and Member countries address knowledge and information gaps on areas of affordability, regulations and management of medical devices.

3. The feasibility tool

The WHO Medical Devices Unit developed a feasibility tool (version one) during phase I to foster an evidence-based systematic approach to evaluate the feasibility and efficacy of local production of any given medical device in any given setting. This was a much needed step in improving access to essential medical devices in low-resource settings knowing that the local production of medical devices can play a key role in improving access to essential medical devices in low-resource settings.

The tool was the first of its kind to assess the likelihood of success to locally produce a selected medical device. The tool included questions designed to gather information within four categories: (i) needs assessment, (ii) technical factors, (iii) context of use, and (iv) market-related factors. The selected medical device was then evaluated based on responses to feasibility tool questions.

To capture the intricacies and develop a more comprehensive analytical approach to local production and commercialization of medical devices, the feasibility tool was further refined, evaluated, revised and implemented in each of the four case study countries in phase II. The phase II feasibility tool is a multi-faceted aid designed as a checklist for stakeholders involved in developing medical devices, a decision-making aid to evaluate local medical device production feasibility, an educational instrument to outline potential challenges from the development to implementation stages of medical devices, and an investigative tool to identify key barriers to manufacturing and commercializing medical devices in low-resource settings. Section II of the feasibility tool can be used to conduct categorical analysis of candidate devices including questions related to needs assessment and evaluation, design and user-related factors, regulation and safety, intellectual property and technology transfer, and manufacturing, production, maintenance, business, market and supply chain factors. Devices with a Feasibility Index score greater than or equal to 75% were deemed feasible. Feasibility Index scores of candidate devices and results are explored in the following section.

The revised feasibility tool, implementation process and results are described in detail below.

3.1 Objectives of the feasibility tool

The updated feasibility tool was developed to serve multiple purposes (see Annex II). The tool was primarily intended to aid as a **checklist** for stakeholders involved in developing and commercializing medical devices, from needs assessment to design, production and distribution in low-resource settings. The tool however could also be a **decision-making aid** to evaluate both the implementation potential and feasibility of local production of a medical device in a given setting. Additionally, the tool could serve as an **educational instrument** to inform medical device designers, innovators and developers about issues to consider when developing, testing, manufacturing and implementing medical devices. The tool may also be used as an **investigative tool** to identify key barriers with regards to manufacturing and commercializing medical devices in low-resource settings.

3.2 Development methodology

A variety of approaches were deployed to revise and evaluate the feasibility tool, including literature reviews, interviews with experts from different fields involved in design, development, production and implementation of medical devices and consultation with academia, government and international agencies and industry representatives. The feasibility tool underwent several iterations to be optimized for its intended objectives. Several previously commercialized devices in low-resource settings were used to test and evaluate the relevance, importance and accuracy of the feasibility tool questions.

3.3 Structure of the feasibility tool

The feasibility tool was designed to gather information from individuals (or small groups) that were considering producing a specific medical device locally. Each respondent selected a medical device for consideration based on personal experience with and/or interest in producing the device, or on perceived needs, or perceived likelihood of success in pursuing local production.

The first section of the feasibility tool gathered data on the respondent's personal information and about the device selected for consideration. Personal information included respondents' level and type of training, current employment and employer and areas of expertise (Annex II). These questions provided information regarding overall expertise of the respondent pool.

The feasibility tool was designed to assess the basic requirements for successful scale-up and implementation of the device through five critical questions concerning the tool itself: need for a candidate tool, whether the tool has significant value added, meets regulatory requirements, meets technical requirements and is suited for use. If these basic, yet critical, requirements were met, then the user was prompted to continue on and answer the six parts in the second section of the tool, i.e. "categorical analysis" (see Figure 12).

i. *Needs assessment and evaluation:* to estimate whether there is a need for the device based on the public health status of the target setting.
ii. *Design and user-related factors*: to evaluate the device's engineering design and usability related issues.
iii. *Regulation and safety*: to evaluate the device's regulatory status and safety related concerns for both device users and beneficiaries.
iv. *Intellectual property and technology transfer*: to evaluate intellectual property related issues of the device, and policies and capacities related to technology transfer and intellectual property in the target setting.
v. *Manufacturing, production and maintenance*: to evaluate the local manufacturing capacities to produce the device in a given setting.
vi. *Business, market and supply chain*: to evaluate the local setting's market-related policies and factors related to enhancing medical device implementation.

The six aforementioned sections were selected to cover a range of relevant topics related to local production. Each part included several questions designed to gather information from the respondent regarding his/her perceptions on specific issues related to the feasibility of

local production. For each question, available responses were: 'yes', 'no', 'don't know', or 'not applicable'. Additionally, respondents could opt out of responding to a question ('blank').

Each question was worded such that a 'yes' answer would indicate a respondent's positive perception to the factor regarding feasibility of local production. Therefore, a 'yes' answer positively contributed points to the total feasibility score for that submission.

Each question also carried a specific weight. When constructing the feasibility tool, questions deemed most important were allocated a high point value (5 points) and other questions were given a low point value (3 points).

***Figure 11** Structure of phase I feasibility tool*

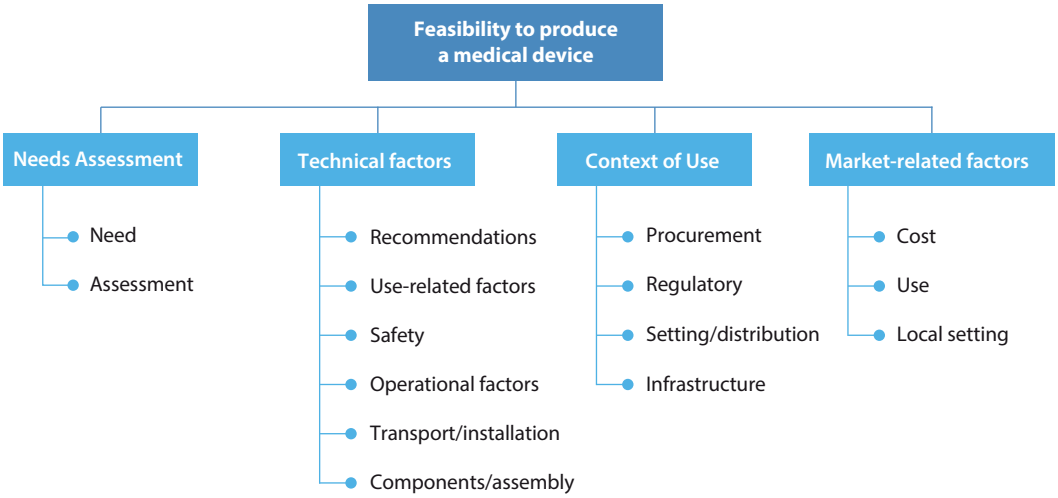
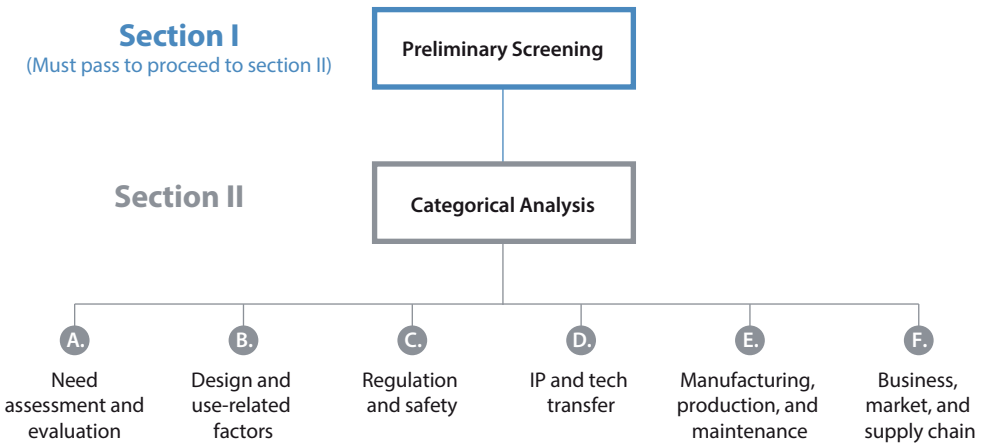


***Figure 12** Structure of phase II feasibility tool*



3.4 Procedures for completing the feasibility tool

In each of the participating countries, a focal point person was established to coordinate data collection using the feasibility tool. Each focal point person recruited participants who were either involved in medical device design and/or had relevant expertise in aspects of local medical device production, including clinical, engineering, policy, regulatory and entrepreneurial work.

Focal point persons and respondents used varied methods to complete the feasibility tool. Some respondents completed the feasibility tool on their own while others either met with the focal point person or communicated over the phone to complete the tool. Groups of respondents considering producing the same medical devices locally occasionally completed the tool together.

3.5 Deployment strategy

After the WHO Medical Devices Unit engaged with field experts to internally review and evaluate the feasibility tool, the tool was disseminated among the study representatives of the four case study countries. WHO targeted stakeholders involved in medical device design, development, production and commercialization. Study representatives within the respective countries contacted the stakeholders and administered the tool based on following two objectives:

i. To determine a list of needed medical devices, based on public health issues and country status, to consider for local production.
ii. To evaluate local production feasibility of the device using the feasibility tool.

3.6 Scoring

The Feasibility Index served as the primary measure for both an overall and sectional score of the feasibility tool. A high Feasibility Index score indicated greater local production possibility for a device as perceived by the respondent. A secondary measure, termed Response Rate, was calculated to determine the percentage of questions answered within each section. A high Response Rate score indicated that the respondent had answered the majority of the questions. The detailed calculation of each of these indices is described below.

For each question, five possible responses: yes (Y), no (N), not applicable (NA), don't know (DK) and blank (B), were available. A 'yes' response indicated a respondent's positive perception of the factor relating to local production feasibility of a specific medical device and therefore contributed positive points (3 points or 5 points) to the Feasibility Index.

For each section of the tool, the total number of points for each response was calculated:

- Y_t: total (sum) of points allocated to those questions answered 'yes'.
- N_t: total (sum) of points allocated to those questions answered 'no'.
- NA_t: total (sum) of points allocated to those questions answered 'not applicable'.
- DK_t: total (sum) of points allocated to those questions answered 'don't know'.
- B_t: total (sum) of points allocated to those questions left blank (not answered).
- The Feasibility Index was defined as: $Y_t / (Y_t + N_t)$

This Index was devised to give an overall impression of respondents' ratings in each section. Note that the Feasibility Index does not consider questions answered as NA, DK or B. This formulation was devised to avoid discounting feasibility for issues that respondents' perceived as inapplicable or for which the respondent had insufficient knowledge. For each section, a Feasibility Index ≥ 0.75 was interpreted as 'feasible' for that section.

Response Rate was defined as: $(Y_t + N_t + NA_t) / (Y_t + N_t + NA_t + DK_t + B_t)$

This Index was devised to give an overall impression of the respondents' ability to answer questions.

3.7 Analysis

Primary data analysis focused on the Feasibility Index for each section. Each device was classified by counting the number of sections with a 'feasible' rating (Feasibility Index ≥0.75). Each submission was placed into one of the following three classes:

i. Feasible: all sections with scores ≥0.75
ii. Single obstacle: all but one section with scores ≥0.75
iii. Multiple obstacles: more than one section with scores >0.75

The values for the Feasibility Index were excluded in the analysis for those sections in which the respondent did not answer a sufficient number of questions, i.e. Response Rate <0.75.

Analysis of Feasibility Index values for each of the sections can indicate the types of perceived obstacles to local production. For example, a submission with high Feasibility Index values for five sections but a low Feasibility Index value for business factors would indicate anticipated obstacles in the business environment to local production of that device.

Feasibility tool analysis by category was done using a 'spider plot' representation to score for each section of the feasibility tool survey on one spoke of the web. Values close to the outer boundary of the plot (100%) indicate a favourable set of responses to that section; values nearer to the centre of the plot (0%) indicate a less favourable set of responses to that section.

In addition to analysing individual submissions, trends across the set of submissions were also analysed. Consistently identifying perceived obstacles across the set of submissions, either from a given country or a region, is likely to indicate important obstacles that may hinder the local production of any device, and not just for the identified candidate device.

The feasibility tool was used to evaluate all proposed technologies in the four target countries. Results and analysis are discussed in sections 4.8, 5.8, 6.8 and 7.8.

Part II | Country case studies

Ethiopia, Nigeria, South Africa and Tanzania

The following four chapters address the demographics and healthcare environment as well as the medical device industrial landscape, market, regulations, innovation environment and intellectual property of the four case study countries – Ethiopia, Nigeria, South Africa and Tanzania. The survey and feasibility tool results of in-country medical devices assessed for local production and technology transfer potential are also included in the four subsequent chapters.

Workshop introduction

Capacity building workshops were held in the four case study countries in 2014 to provide training, capacity building and/or technical support activities in manufacturing, regulations, selection, management and safe use of medical devices. The workshop attendees included policy makers, regulators, academics, local manufacturers, biomedical engineers, clinical engineers and other concerned stakeholders. The objectives of each workshop were to:

- promote an exchange of ideas between representatives of government agencies, academia and the industry;
- identify country-specific needs for medical devices;
- identify opportunities and roadblocks to local production of medical devices; and
- develop a roadmap to promote local production of medical devices.

The workshops included presentations by WHO staff on the country survey on medical devices, the LPTTMD project and related WHO activities as well as presentations by in-country experts on user needs, design and use, regulations and safety, intellectual property and technology transfer, and manufacturing and business development. Both workshop days included presentations by local innovators in which ideas for local production were described and extensively discussed. The workshops concluded with small group-interactive sessions and a reconvention of the entire group to produce the following primary workshop outcomes.

- An action plan for key stakeholders to increase access to medical devices.
- A set of devices/ideas for local production that could provide the greatest benefits to the country.
- A roadmap and recommendations for turning these ideas into reality.

In addition to presentations and interactive sessions, each participant was asked to complete the feasibility tool questions (Annex II) on the first day of the workshop to gather information to help foster discussion. In the questionnaire, each attendee identified up to three important unmet clinical needs, up to three unmet needs for assistive technology or rehabilitation-type devices, and up to three eHealth solutions with potential to increase access to quality healthcare. Similarly, each attendee identified up to three major access barriers to medical devices, up to three reasons for optimism in local production, and up to three actions that could improve the local production environment. All responses were compiled and then consolidated to eliminate redundancy. On the second day of the

workshop, the consolidated list was presented and reviewed by the participants to help establish a foundation for discussions regarding barriers and action plans.

The action plans were developed in small group discussions and then a list of action items was established and consolidated in a discussion involving the entire group. At the end of the workshop, the participants were also asked to complete an evaluation form. The outcomes of each of the workshops in each country are provided in the following chapters: Chapter 4 Ethiopia, Chapter 5 Nigeria, Chapter 6 South Africa, and Chapter 7 Tanzania.

4. Ethiopia

4.1 Country indicators

DEMOGRAPHICS AND DISEASE BURDEN

ECONOMIC CLASSIFICATION	LOW INCOME COUNTRY
POPULATION (2015)	98.9 MILLION *(1)*
NATIONAL LANGUAGES	AMHARIC, TIGRIGNA, OROMINGA, GUARAGIGNA, SOMALI, ARABIC, ENGLISH, OVER 70 OTHERS
GROSS NATIONAL INCOME (GNI) PER CAPITA (US$, 2013)	470
HEALTH EXPENDITURES PER CAPITA (US$, 2013)	69
HUMAN DEVELOPMENT INDEX (2013)	.435
LIFE EXPECTANCY AT BIRTH (YEARS, 2012)	65
MEDICAL EQUIPMENT AND SUPPLIES (US$, 2008)	29 MILLION *(2)*

The main causes of death in Ethiopia are lower respiratory infections, cancer, diarrhoeal diseases, malaria and tuberculosis (TB) *(3)*.

4.2 Healthcare environment

The Ethiopian healthcare system operates largely under the Federal Ministry of Health, which publicly owns over 70% of healthcare facilitates. In 2012, the government owned 138 hospitals, 635 health centres, 5955 heath posts and 1206 health stations *(4)*.

Since the introduction of the new National Health Policy in 1993, Ethiopia has implemented a series of Health Sector Development Programme(s) (HSDPs) and delivered healthcare through a four-tiered health service system. Level I consists of primary healthcare units, networks comprising a health centre and five health posts connected to each other by a referral system, in each woreda (district). Level II includes a general local hospital. Level III involves regional hospitals, while Level IV centres consist of specialized referral hospitals *(5)*.

Ethiopia's private healthcare sector consists mainly of NGOs that provide preventive care, such as vaccines, and for-profit healthcare providers that supply pharmaceuticals, drugs and other specialty services. In 2012, there were 2264 private clinics, 246 private pharmacies, 476 drug shops and 1754 rural drug vendors in Ethiopia *(4)*. Both the private and public sectors charge user fees for inpatient, outpatient and diagnostic services. Public providers in Ethiopia use a consolidated revenue collection and budgeting system in which all public institutions that collect revenue are supposed to channel their revenue to the central treasury and receive their operational funding from the government *(6)*. This system has led some public health facilities to lack a sense of ownership. Public health facilities also tend to face resource shortages to cover operational costs. The private sector, which charges higher fees, is generally better staffed and has greater quality and quantity of health technologies, including medical devices, than the public sector. There is a discrepancy between the quality and depth of service provision in urban environments compared to rural areas. High-end devices are more accessible in urban settings, which

may result from greater government and donor funding allocations to urban environments rather than from greater local demand in urban areas compared to rural areas *(4)*.

The government's 48.4% contribution and the private sector 51.6% contribution to the expenditure, almost evenly funds Ethiopian healthcare. Nearly 80% of private sector expenditures are out-of-pocket expenses *(7)*.

The Ethiopian healthcare system is currently in its fourth HSDP stage, which ends in June 2015. This phase prioritizes maternal and newborn health, human immunodeficiency virus (HIV), TB, malaria and nutrition. Additionally, the African Development Bank oversees an ongoing primary healthcare project, which began operating in 2000, with the goal of boosting the provision of primary care facilities in selected parts of the country *(2)*.

4.3 Medical device industrial landscape and medical device market

In 2008, Ethiopia imported US$ 29 million worth of medical equipment and supplies, making medical equipment the 11th largest import market in Africa. India supplied the most medical equipment to Ethiopia in 2008, followed by China and the United States. However, these countries accounted for just 14.3%, 14.1% and 13.7% of total 2008 medical equipment imports, respectively. Ethiopia exported a mere US$ 74 000 worth of medical equipment and supplies *(9)*.

To encourage private investment and promote inflow of foreign capital and technology, investors in Ethiopia are completely exempt from import custom duties and taxes levied on all investment capital goods including plant machinery, equipment and construction materials worth up to 15% of the investment value in imported capital goods. In addition, Ethiopian products and services destined for export are exempt from any export tax *(11)*.

National registration is required for imports and preimport approval is granted to applicants who wish to import a registered product. Unless there is an in-country emergency, a product generally cannot be imported if the Ethiopian Food, Medicine and Health Administration and Control Authority (FMHACA) has not registered the product. The FMHACA implements procedures and guidelines to control the import of medical products and requires that all imports correspond with an import license. If a discrepancy arises between an approved preimport permit and the actual consignment, the product is returned to its origin *(10)*.

The principle medical device importers in Ethiopia are the Pharmaceuticals Fund and Supply Agency (PFSA) and Medtech, both located in Addis Ababa. Nearly 60% of Ethiopia's need for medical devices and medicines is covered by PFSA. Ethiopia is also home to approximately 100 additional active medicinal drug and medical device importers, almost all of whom are located in Addis Ababa *(10)*.

4.4 Medical device regulation

Ethiopia's medical device regulation is overseen by the FMHACA, which ensures all regulatory activities are functional throughout all regions and woredas (districts) of the country. The FMHACA is structured into managerial and enforcement wings to follow up on different directorates.

In accordance with Proclamation No. 661/2009, the FMHACA regulates healthcare practices, premises, professionals and products in Ethiopia *(12)*. This mandate also extends to healthcare products, specifically medicines and medical devices.

The FMHACA includes registered medical device manufacturers in the list of registered medical devices. There is no national list of medical devices for different types of healthcare facilities, nor is there a list of devices for specific procedures *(12,13)*. The FMHACA uses an established checklist to approve devices or medical device manufacturers by ensuring that they meet country requirements. This device registration checklist includes preset classification methods based on device invasiveness, use, material, etc., as well as technical specifications and quality assurance requirements. The FMHACA has prepared guideline requirements for medical device registration to ensure that manufacturers submit proper documentation when applying for approval from the FMHACA *(14,15)*.

The medical devices registration system is based on dossier submission, and quality and safety information assessment. The FMHACA also includes a medical device and in vitro diagnostic registration guideline. The registration process takes between 12–24 months after submission and is valid for four years. Assessments completed by other agencies cannot be used to facilitate local medical device registration. However, fast track registration is available for devices used for HIV, malaria, TB testing and other products considered vital *(10)*.

A FMHACA mechanism can grant conditional, expedited or provisional approval for medical devices. The FMHACA may register a product with a minimum requirement if the product is already registered and marketed in the member countries of International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. The FMHACA also registers products with a minimum requirement that have been prequalified by the WHO *(10)*.

In December 2012, a Medical Equipment Donation Directive was established to address policies regarding medical device donation. The Directive ascertains that donated devices meet preimport, point-of-entry and postentry requirements, and oversees the requirements surrounding the reporting and disposal of donated medical devices in the country *(16)*.

Generally, the FMHACA does not follow-up with post-market surveillance guidelines for medical devices. However, there is a standard operating procedure and protocol in place for collecting samples of male condoms biannually from the market *(10)*.

The FMHACA offers a free yellow postage that can be filled in by prescribers and dispensers, a pharmacovigilance system with market authorization holders and a free call service so that anyone can inform the FMHACA about problems relating to quality *(10)*.

Challenges include inadequate regulatory function coverage involving medicine registration, inspection, clinical trial authorization and monitoring, quality control laboratory testing (premarketing), actual consignment and postmarketing surveillance. Technical capacity gaps also exist to assess the quality, safety and efficacy of product dossiers, establish essential medical device lists, execute good manufacturing practices (GMP) inspection, establish a database for a regulatory information system and administer

surveillance activities and consignment-based drug quality testing for drugs that are used to manage communicable diseases *(10)*.

4.5 Innovation environment

Ethiopia is the fastest growing non-oil African economy with an annual real gross domestic product (GDP) growth rate that stabilized around 10.5% between 2004 and 2012. Increased public and private investment, improved macroeconomic management and increased focus have propelled Ethiopia's growth in manufacturing and services in recent years. The World Bank *Doing Business* 2012 ranked Ethiopia as 125 out of 189 economies *(1)*. The report identifies lack of access to finance, land and practices in the informal sector, as well as corruption and deficiencies in the judicial system, as major obstacles to conducting business in Ethiopia.

In the past decade, Ethiopia established institutions for biomedical/clinical engineering education and research. In 2008, Jimma University's Institute of Technology established Ethiopia's first biomedical engineering degree programme, while Tegbar-Id Polytechnic College has been the preeminent biomedical technical vocational training institution in Ethiopia since 2006. In recent years, the Addis Ababa University also established biomedical engineering degree programmes and biomedical technical vocational training.

In 2013, the American International Health Alliance launched the first US President's Emergency Plan For AIDS Relief (PEPFAR)-supported programme to strengthen biomedical engineering training in Ethiopia. Through a partnership between two US-based institutions with Jimma University and Tegbar-Id Polytechnic College, the programme aims to facilitate curricula and faculty development and improve practical training opportunities at both preservice and in-service levels *(17)*.

4.6 Intellectual property

Patents. The Inventions, Minor Inventions and Industrial Designs Proclamation 123/95 *(18)*, henceforth referred to as the "Proclamation", established the framework governing the patent system. The rules are implemented by the "Inventions, Minor Inventions and Industrial Designs Regulations" *(19)*, henceforth referred to as the "Regulations". Patents were previously administered through the Ethiopian Science and Technology Commission; however, the recently established Ethiopian Intellectual Property Office (EIPO) now files all patents.

Agents are assigned to patents if the patent applicant is neither a resident nor has a place of business within the country. The applicant can claim priority to an earlier filing of a patent if the patent was filed within 12 months in another jurisdiction. The application is subject to a formal examination regarding form and unity of the invention. If an application is deemed acceptable, then the patent will undergo substantive examination *(16)*.

Granted patents are published in the Official Gazette and grant certificates are issued to successful applicants. Patent protection is initially granted for 15 years with a possible five-year extension subject to proof of "working" the invention in Ethiopia *(17)*. A patent of introduction indicates that a patent was patented abroad, has not expired and is not patented within the country. The same requirements must be met for regular patents filed in-country; however, the length of protection granted for this is 10 years *(18)*.

The Proclamation sets out a fair use exception for acts of noncommercial purposes and when the patented invention is used solely for scientific research and experimentation (i.e. wherever the invention serves the public interest) *(19)*.

The Proclamation provides for compulsory licensing for nonworking patents for three years. To enable the effective working of an invention, a compulsory license can be issued for working either an earlier related invention or a later invention *(20)*. Proof of failure to conclude a licensing contract on reasonable terms is required to grant a compulsory license. Grants of compulsory license are registered in the Official Gazette.

Utility certificates. Utility certificates protect minor inventions under the Proclamation *(21)*. Novelty and industrial applicability form the grounds for utility protection. The term of protection lasts five years with a possible five-year renewal on the condition that the invention is worked in Ethiopia.

Industrial design protection. An industrial design will be protected if it is new and has practical applicability. Industrial designs that solely obtain a technical result are not protected under the Proclamation. Industrial design protection is initially conferred for five years, which can be protracted for two five-year extensions on the condition that the design is used within the country *(22)*.

Trademarks. The Trademark Registration and Protection Proclamation No. 273/2012 governs trademark acquisition in Ethiopia.

The international classification of trademarks provides the basis for goods and services registration *(23)*. An applicant can claim priority for a trademark filed within six months from the date of first filing *(24)*. The Proclamation sets out eligibility requirements for trademark registration (distinctiveness) and reasoning behind failing to admit trademarks for registration *(25)*.

Once an application is received, the patent is examined for form and substance. Once a trademark is examined, either the Intellectual Property Gazette or a widely circulated newspaper publishes a notice for invitation of opposition for sixty days at cost to the applicant *(26)*. If there is no opposition, the trademark can be registered and a certification is issued. The trademark protection period lasts seven years with possible consecutive renewal for another seven years. Renewals are republished and circulated at cost to the applicant.

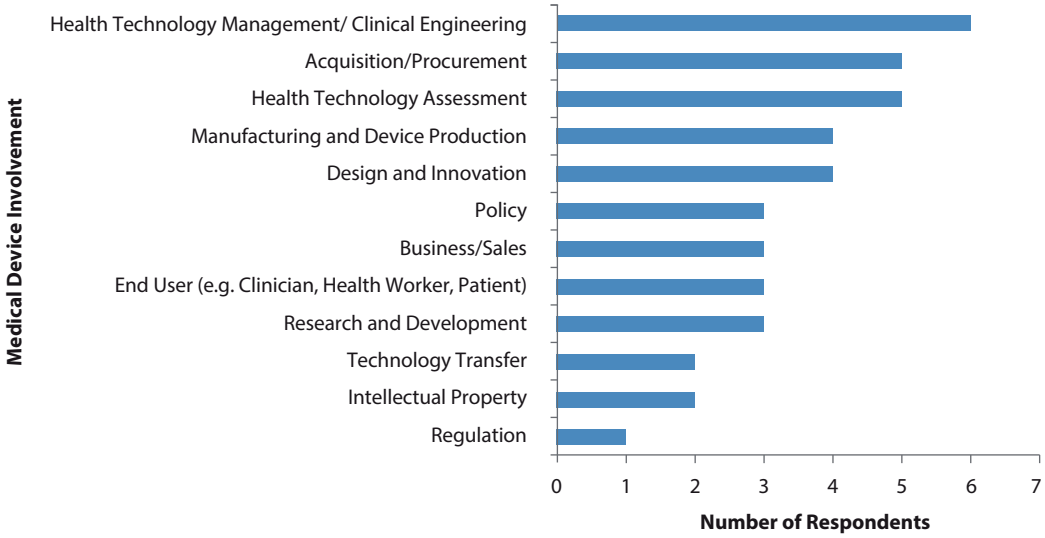
A licensing contract for a trademark should be made in writing and registered with the trademarks office. The proprietor should indicate whether the trademark is for all or part of the goods and services and be registered with the trademarks office *(27)*.

No electronically verifiable patent data exist for medical device patents in Ethiopia. An extensive legal framework protects intellectual property administered through the EIPO. Ethiopia will update its intellectual property laws in preparation for its accession to the World Trade Organization. Ethiopia currently has technology transfer regulations in place to govern technology agreements between persons and domestic and foreign enterprises, as well as between persons and private and public institutions *(27)*.

4.7 Results of the 2013 phase II survey on access to medical devices: Ethiopia

Of the 13 who responded to the survey on access to medical devices, six were involved with health technology and clinical engineering, five were in acquisition and procurement, and five were in health technology assessment. No investor/donor or reimbursement experts responded to the survey. Figure 13 displays respondents' answers regarding their involvement in the medical device industry, which were generally similar to global responses. Many respondents were involved in multiple areas of medical devices.

***Figure 13** Ethiopian respondents' involvement in medical devices*



n=13 respondents

Only four of the 13 respondents from Ethiopia were involved in the developmental stage of any medical device. These four respondents reported that the device was either under development or never evolved beyond the concept/prototype stage. The reasons cited for the lack of progress were dearth of components, limited design and development capacity, unavailable resources and poor connections to end users. In response to a question regarding barriers, four of five respondents reported that inadequate local facilities and tools were a barrier to product development and three of five respondents reported having limited financial resources for development.

In response to a question regarding the types of experts included in the development process, all six Ethiopian respondents reported consulting biomedical (or clinical) engineers. None of the respondents consulted a business development expert, reimbursement expert or a end-user.

The top barriers and obstacles respondents faced in **commercializing/selling** their medical device products included a lack of seed funds, limited supply chain, limited local manufacturing capabilities and lack of business expertise. A significantly higher percentage of Ethiopian respondents reported these barriers compared to global respondents.

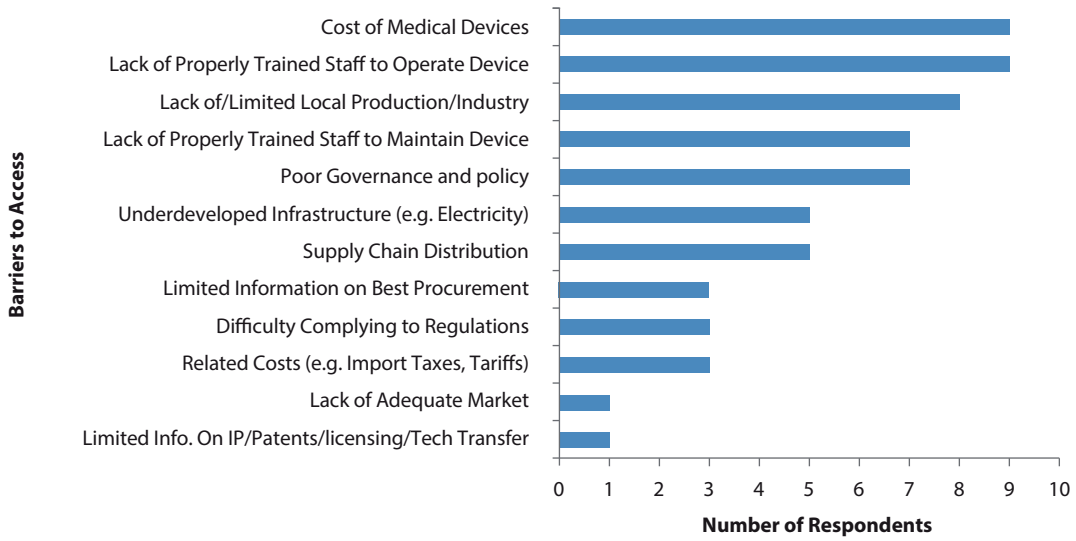
For product developers (five respondents), regulation, existing harmonized regulatory processes, simplicity and transparency of the regulatory process, and knowledge of the local regulatory environment played a significant role when selecting their target market.

The most important criteria that eight respondents selected as impacting their medical device procurement decision were price, compliance with technical specifications, quality and safety. Other cited criteria were available local distributors and compliance with norms and standards.

Of the eight respondents who answered a question regarding preference for imported versus local devices, five (63%) preferred using imported medical devices. This response was significantly higher than the global average of 25%. Furthermore, 75% of these same respondents in Ethiopia said they trust that locally manufactured devices are safe to use, indicating there are concerns other than safety that lead Ethiopians to prefer using imported medical devices.

Among the 13 Ethiopian respondents, more than half cited cost of medical devices, lack of properly trained staff to operate the device, lack of properly trained staff to maintain the device, poor governance and policies, and lack of or limited local production/industry as barriers to accessing medical devices in low-resource settings (Figure 14).

***Figure 14** Ethiopian view on barriers to access to medical devices in low-resource settings*



n=13 respondents

4.8 Application of feasibility tool to Ethiopian candidate devices

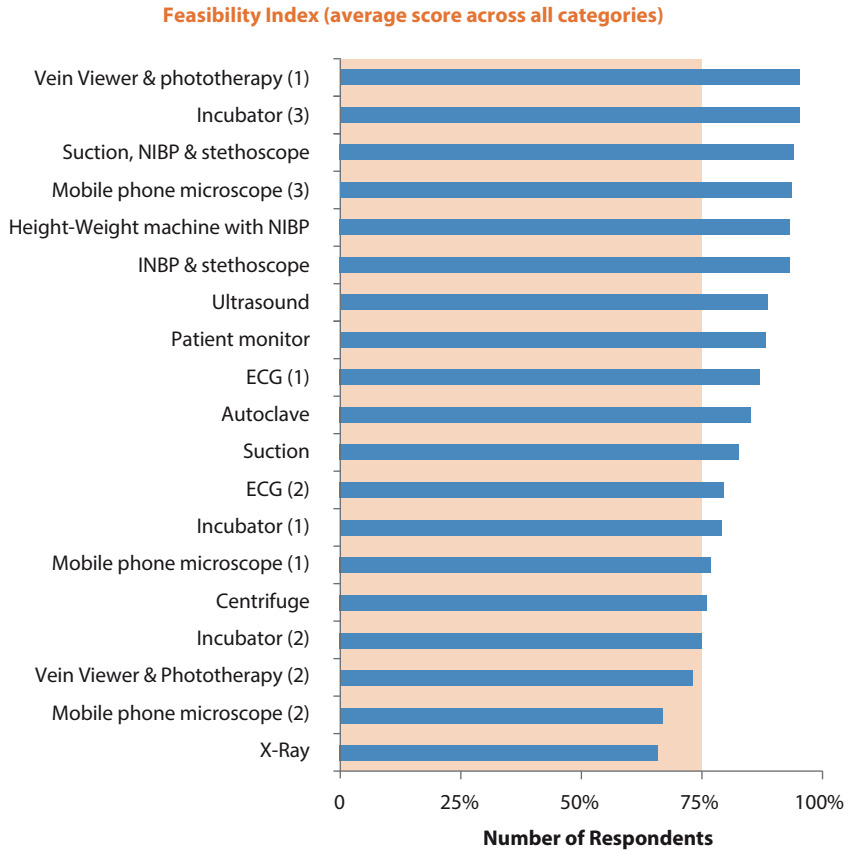
Administration of the feasibility tool. The feasibility tool was sent to the in-country project consultant, Mr Mulugeta Mideksa, who coordinated all aspects of administering the tool. He recruited 19 participants of whom more than 75% were engineers or technicians, more than 50% had education at the post-graduate level and more than 50% were based at a university. Group expertise was strongest in 'medical device design and user analysis' where 95% of participants indicated having expertise. Among the participants, 74% cited expertise in 'need identification and assessment'. Mr Mideksa administered each instance of the feasibility tool in meetings with small groups of participants.

Candidate devices. The in-country project coordinator consulted with participants to develop a list of candidate devices for evaluation. The list was developed based on an initial perception of perceived need and device complexity. With respect to product need, the coordinator and participants primarily considered: (i) whether or not the device addressed

Millennium Development Goal (MDG) 4 or MDG 6; (ii) whether or not the device could be used in potentially life-saving procedures; and (iii) current availability. With respect to complexity, the coordinator and participants primarily considered the complexity of the device itself and resource availability for device production. The coordinator and participants produced a list of 13 devices during the initial selection process that were then evaluated by one or more participants. Nine participants each evaluated a separate device; two-participant teams evaluated two separate devices; and three-participant teams each evaluated two separate devices. Figure 13 provides a legend for all evaluated devices.

Feasibility Index and Response Rate scores. Across the set of submissions, the overall scores for the Feasibility Index and Response Rate were very high. The average Feasibility Index score was 83%, ranging from 66% to 95%. Six of the 19 submissions indicated a Feasibility Index greater than or equal to 90% and only three submissions received a score less than 75%. The average Response Rate score was 93%, ranging from 69% to 100%, and only one submission had a Response Rate below 75% (incubator (1), Response Rate = 69%) (Figure 15).

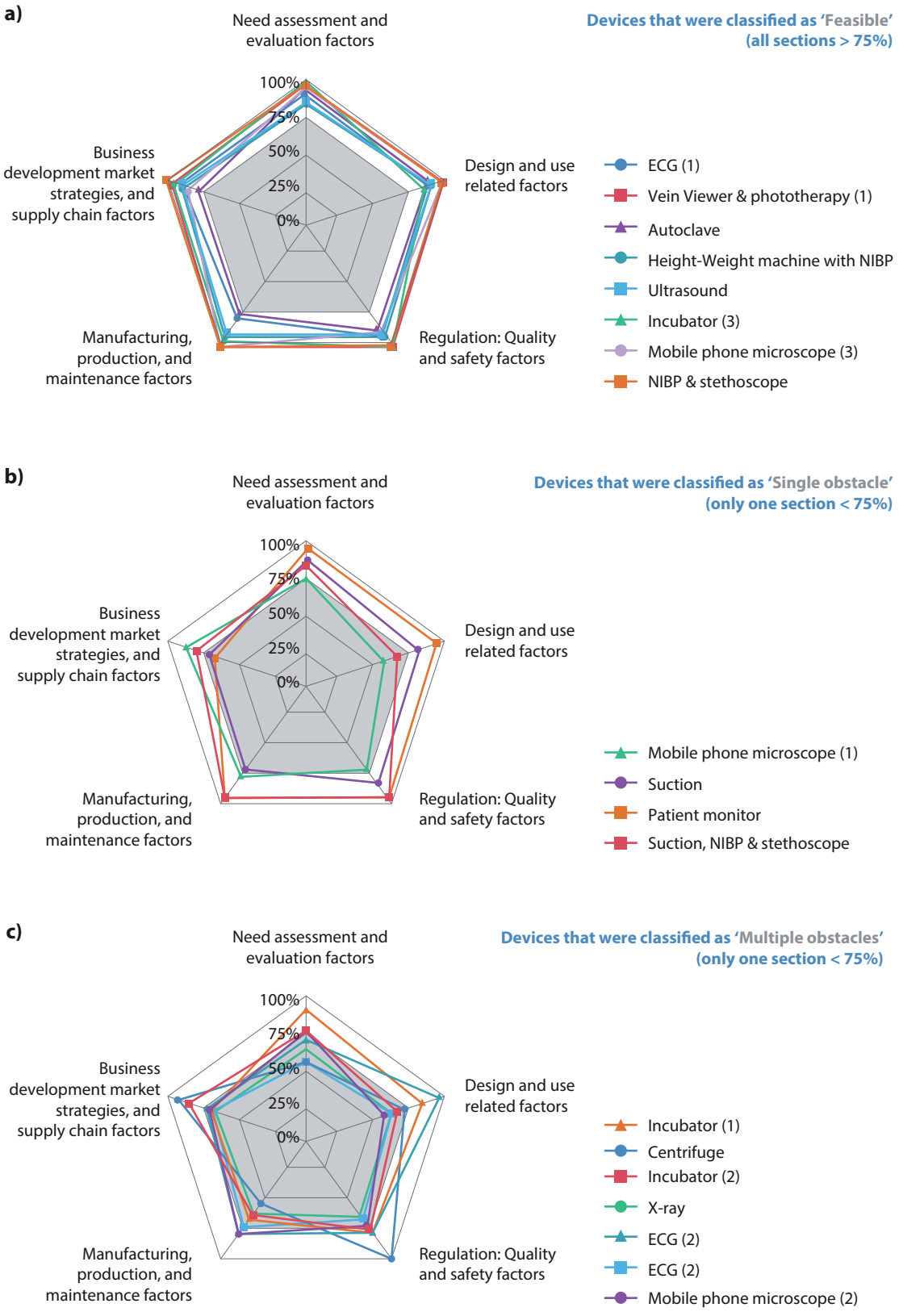
Figure 15 Feasibility Index scores, average across all categories



Note: Scores greater than 75% (outside of shaded area) were interpreted as 'feasible' when using the overall score. Numbers after the device name are used to indicate multiple device evaluations from this group.

While the total score for a given submission can provide an overall sense of feasibility, the ratings on each individual section of the feasibility tool may provide further insights regarding feasibility. For each submission, the scores for the individual devices on each of the five sections are given in Figure 16.

Figure 16 Feasibility tool analysis by category



Note: Scores less than 75% (inside of shaded area) for a given category were interpreted as an 'obstacle' for that category.

Device classification and identification of obstacles. Of the 19 submissions, eight were categorized as feasible (Figure 16a), four were categorized as 'single obstacle' (Figure 16b), and seven were categorized as 'multiple obstacles' (Figure 16c).

The list of eight devices that received at least one 'feasible' classification included some devices that would require fabricating relatively simple components and could be low-cost (e.g. non-invasive blood pressure and stethoscope) and devices that would require fabricating or acquiring rather sophisticated instrumentation for measurement and/or display (e.g. ultrasound or electrocardiogram (ECG)).

It is interesting to note that there was a high degree of variability in the classification of devices across submissions. The ECG, incubator, mobile phone microscope, vein viewer and phototherapy devices were each classified as 'feasible' on one submission, but as having 'multiple obstacles' on another submission.

Of the devices that were classified as having a 'single obstacle', obstacles indicated by the feasibility tool were in 'Design and Use' and 'Business Development'. Across the entire set of 19 submissions, obstacle identification was distributed nearly evenly across the sections of the feasibility tool. 'Design and Use' and 'Business Development' were each identified as obstacles on seven submissions, 'Manufacturing, production, and maintenance factors' was identified as an obstacle on five submissions and 'Need assessment and evaluation factors' and 'Regulation: Quality and safety factors' were identified as obstacles on four submissions.

Discussion of results. Feasibility tool submissions from this group of participants indicate a general sense of optimism for local production in Ethiopia. This optimism is most strongly reflected when observing that 16 of 19 submissions had an overall Feasibility Index score greater than 75%. This observation is supported, at least in part, by the categorical analysis which indicated that eight of the submissions had Feasibility Index scores greater than 75% in all categories and four submissions had only one category that fell below 75%.

A set of 'Business Development' factors was one of the most commonly identified obstacles to local production, potentially indicating an opportunity for policy makers, investors and industrialists to institute changes that could have a broad impact on supporting local production capacity in Ethiopia.

4.9 Workshop summary

Introduction. The LPTTMD Workshop in Ethiopia was held at the Elilly International Hotel in Addis Ababa on 17–18 July 2014. Attendees included representatives from the Ministry of Health, the FMHACA, other government agencies, several academic institutions and hospitals, the WHO country office and WHO headquarters. A full list of participants and their affiliations is provided in Annex IV. Figure 17 illustrates the distribution of participants' employment.

Workshop attendees identified and discussed a number of unmet clinical needs, important assistive technology devices and opportunities for eHealth solutions. The group identified a range of needs that included devices for diagnostics and imaging, maternal and child health, frontline health workers and assistive technology devices that would aid in overcoming impairments in mobility, vision and hearing. Opportunities for eHealth solutions mainly focused on capacity building, database development and consultation.

The roadmap for creating a strong local production environment emphasized the importance of creating new policies and programmes that could promote innovation and facilitate growth in the manufacturing sector. The workgroup identified opportunities to encourage partnerships, stimulate knowledge and technology transfer and build human resource capacity. Participants strongly recommended policies and programmes that would encourage communication and collaboration between public and private institutions and between engineers and health workers. These recommendations sent a clear message regarding the need for teamwork to address the complexities involved in fostering medical device industry growth.

Occupations of workshop attendees. The occupation of workshop attendees is presented in Figure 17. Multiple Ethiopian workshop respondents reported working in more than one field related to medical devices.

Figure 17 Occupation of Ethiopian workshop attendees

n=13 respondents

LPTTMD workshop outcomes: needs, barriers and action plans. Action plans were developed in small group discussions and then a list of action items was established and consolidated in a full group discussion. Participants in the first session produced a list of needs and opportunities for medical devices that could be acted upon to improve access to quality healthcare (Table 1). Participants in the second session developed a roadmap for creating an environment that would be conducive to local production (Table 2).

Table 1 Identified needs and opportunities for medical devices

Most important unmet clinical needs
Test kits (malaria, TB, HIV/ acquired immunodeficiency syndrome (AIDS)
Imaging equipment (especially ultrasound, chest radiograph)
Early detection of noncommunicable diseases (NCDs) (e.g. diabetes, cardiovascular diseases, cancer)
Maternal and child health (diagnostic and treatment equipment)
Devices for frontline health workers

Most important assistive technology or rehabilitation-type devices
Hearing aids
Wheelchairs
Prostheses
Intraocular lenses
Technology for those living with visual impairments
Best opportunities for eHealth solutions
Capacity building
Database maintenance and access
Tools for people living with disabilities
Diagnosis and treatment consultations

Table 2 Recommendations to create an enabling environment for local production

Develop policies and programmes
Update policies to achieve coherence across agencies
Create government guidelines for mandatory medical devices in local health institutions
Produce guidelines for manufacturing centres
Establish incubation centres
Provide incentives for local innovators
Provide loans or grants to well-organized local production teams
Encourage partnerships
Between public and private institutions
Between engineers and public health workers
Promote knowledge and technology transfer
Improve human resource capacity by providing high quality training for engineers, regulators, and entrepreneurs

Summary and conclusions. The workshop provided an active discussion forum among participants from a variety of sectors, each of whom could play an important role in advancing local production. Across all sectors, participants demonstrated a great interest and enthusiasm for local production while identifying significant barriers that would need to be addressed. The roadmap would provide a way for various actors to contribute to the success of efforts to locally produce medical devices.

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5.1 Country indicators

DEMOGRAPHICS AND DISEASE BURDEN

ECONOMIC CLASSIFICATION	LOWER MIDDLE-INCOME
POPULATION (2015)	183.5 MILLION *(1)*
NATIONAL LANGUAGES	ENGLISH (OFFICIAL), HAUSA, YORUBA, IBO, FULANI, AND MORE THAN 200 OTHERS
GNI PER CAPITA (US$, 2013)	5,360 *(1)*
HEALTH EXPENDITURES PER CAPITA (US$, 2013)	217 *(1)*
HUMAN DEVELOPMENT INDEX	0.503 *(1)*
LIFE EXPECTANCY (2012)	55 *(1)*
UNDER 5 MORTALITY RATE (2011/2001)	124.1/181.3 PER 1,000 LIVE BIRTHS *(1)*
REGULATORY AGENCY	MINISTRY OF HEALTH
NATIONAL MEDICAL DEVICE REGULATORY POLICY	PROVISIONS OF ACT CAP F33 LFN 2004 (FORMERLY DECREE 19 OF 1993) AND ACCOMPANYING GUIDELINES *(2)*

5.2 Healthcare environment

In 2004, the top five causes of death in Nigeria were malaria, lower respiratory infections, HIV, diarrhoeal diseases and road injuries *(3)*.

The national health system is organized into a three-tier structure – federal, state and local – with all levels involved in managing and financing the healthcare system, as well as providing health services. The federal level is responsible for overarching policy and management of the entire health system and for healthcare delivery at the tertiary level hospitals. At the next level, each of the 36 Nigerian states has a State Ministry of Health, which is responsible for secondary hospitals and management and policy of the primary healthcare system *(4)*. The local level, broken down into local government and community levels forms the primary healthcare system. Each level of governance is given a relatively high level of autonomy in financial and policy decision-making, leading to unclear division of responsibilities and duties within the hierarchy *(4)*.

The Nigerian healthcare system is financed through both public and private sources and operates under the Federal Ministry of Health. Healthcare expenditures are funded through three major sources: (i) out-of-pocket (60.4%); (ii) the government (36.7%); and (iii) private insurance (1.96%)*(5)*. The percentage of GDP spent on healthcare has steadily decreased from 7.0% in 2007 to 5.3% (or US$ 79.56 per capita) in 2011 *(5)*. External resources contributed to only 5.4% of healthcare expenditures *(5)*.

The high out-of-pocket expense for healthcare limits its availability *(4)*. 65% of physicians in Nigeria work in private hospitals, which are concentrated in certain regions of the country, resulting in a physician shortage in rural settings. Only 12% of the nation's physicians work in primary care *(4)*. Nigeria ranks 38 among 50 African countries in the number of hospital beds per 1000 people, and 14th in the number of physicians per 1000 people *(6)*.

5.3 Medical device industrial landscape and medical device market

The major industries in Nigeria are agriculture (31.2% contribution to GDP in 2008), crude petroleum and natural gas (28.7% contribution to GDP in 2008), and wholesale and retail trade (18.8% contribution to GDP in 2008) *(7)*. Nigerians primarily produce and export palm, peanut (oil), cotton and rubber. Nigeria is the tenth largest oil producer worldwide and the third largest oil producer in Africa *(7)*.

Incentives exist to stimulate small and medium enterprises. Examples of investment incentives for businesses outside the oil and gas sector include the Nigerian Investment Promotion Commission Decree of 1995, which allows foreign investors to fully own a business, and the Nigerian Export-Import Bank, which provides commercial bank guarantees and direct lending to these businesses *(8)*. The Nigerian Export Processing Zone Authority, operational in Calabar and Onne ports, provides duty-free import of equipment and raw materials for at least 75% of exported products. To increase local production, businesses may receive a 30% tax concession for five years if 60–80% of the raw materials used in production are procured locally. Businesses qualify for an additional 10% tax concession if the device is fabricated locally rather than just assembled locally *(9)*. Research and development is also eligible to receive tax relief *(9)*.

Due to its large population size, Nigeria has the largest market potential in Africa, but there are many challenges to establishing a successful business. The World Bank's *Doing Business 2013* report ranks Nigeria 131 out of 183 countries, citing the major obstacles to doing business as poor access to electricity, difficulty in registering property, high taxes and frequent trading across borders *(10)*. Corruption, lack of infrastructure and inconsistent trade policies contribute to a challenging business environment *(8)*. Nigeria scored well on the ability to obtain credit for starting a business and is relatively open to foreign investors *(8,10)*. In the Global Innovation Index, Nigeria ranks 120 out of 142 counties *(11)*. From June 2011 to June 2012, Nigeria implemented a new labour tax that employers are required to pay, making it more difficult to do business in Nigeria *(11)*.

In 2008, Nigeria imported US$ 119.4 million (US$ 0.80 per person) and exported US$ 270 000 worth of medical equipment and supplies, making it the seventh highest importing country in Africa for medical equipment *(6)*. The import and export of medical devices has continued to increase with a compounded annual growth rate (CAGR) of 23.2% and 7.8%, respectively *(6)*. The leading suppliers of the imported medical equipment are China, Germany and the United Kingdom *(6)*.

Nigeria is currently developing a model to improve procurement and distribution capacity. At the national level, external agents are sometimes used to benefit from international procurement in terms of quality and price. Some states (Kano and Bauchi) have established drug management agencies as parastatal companies to combine the procurement processes for multiple programme areas and decrease political influence. Pooled procurement was introduced as a concept and may be attempted in certain states if enough interest is shown. Some states (Jigawa and Kano) have established different types of "drug revolving funds," the most centralized of which handles all procurement at the state level and supplies healthcare facilities in exchange for payment. Less formal drug revolved funds are set up between a community and its local health facility to assist procurement at the facility level *(12)*.

5.4 Medical device regulation

Table 3 displays regulatory agencies for the Nigerian medical device market, and summarizes the relevant organizations necessary to achieve regulatory approval for a medical device.

Table 3 Key organizations in the Nigerian national regulation of medical devices

Regulatory Organization	Key Role
Federal Ministry of Health (FMoH), Registration and Regulatory Affairs	• Directs national legislation for regulation of medical devices • Can administer approval certificate for medical devices
National Agency for Food and Drug Administration and Control (NAFDAC)	• Formulates national legislation for regulation of medical devices • Can administer approval certificate for medical devices
Nigerian Nuclear Regulatory Authority (NNRA)	• Can administer approval certificate for medical devices with radiation sources
Bureau of Public Procurement (BPP)	• Formulates national list of approved medical devices and their manufacturers for procurement by tertiary hospitals
Standards Organization of Nigeria (SON)	• Coordinates SON Conformity Assessment Programme (SONCAP) certification
International Accreditation Firms (IAFs)	• Independent organizations that assess the quality of a manufacturing process and/or product with an International Organization for Standardization (ISO) 17025 certified laboratory
Programme management companies	• Can administer SONCAP certification on behalf of SON

The Provisions of Act Cap F33 LFN 2004 (formerly decree 19 of 1993) and accompanying guidelines form the national regulatory framework for medical devices *(2)*. This policy dictates that a medical device cannot be manufactured, imported, exported, advertised, sold or distributed without registration. Device registration, which is a different process for imported versus locally produced devices, can be approved by the National Agency for Food and Drug Administration and Control (NAFDAC), Ministry of Health, or Nigerian Nuclear Regulatory Authority (NNRA). Registration entities generally assess manufacturing quality and ensure that the necessary legal documentation is present. However, the final registration decision is at the discretion of the relevant regulatory body. If approved, the device obtains a NAFDAC identification number.

The Bureau of Public Procurement (BPP) compiles and publishes a national list of preferred medical devices and manufacturers. To gain BPP approval, the medical device must pass a more rigorous screening, including the aforementioned registration, and garner approval from the Standards Organisation of Nigeria Conformity Assessment Programme (SONCAP). SONCAP is an independent quality and safety assessment by approved International Accreditation Firms (IAFs). Programme management companies administer the certification. Table 4 provides a full list of requirements for BPP approval.

Nigerian medical device registration involves reviewing a dossier and assessing quality and safety information. The dossier has 26 sections that contain the name of the product, the marketing authorization holder, the manufacturer, pack sizes, formulations, pharmacology

of the product, etc. Registration is valid for one to five years. Documentation review is completed to grant authorization to some classes of medical devices for which the resources to test the device are unavailable in Nigeria. Canada, the European Union, the United Kingdom and the United States of America complete assessments that are used to facilitate local registration of medical devices. This registration process takes three to six months *(13)*.

For life-saving commodities and other important public health products, a documentation review is used to expedite the registration process. When conditional approval is granted, the NAFDAC follows up using the Pharmacovigilance and Post-Marketing Surveillance Directorate. However, WHO-prequalified products are eligible for an expedited process that takes about three weeks *(13)*.

Medical devices must be registered with the NAFDAC prior to importation and all imports are required to have an import license. Pre- and post-shipment inspections are completed. If a discrepancy is found, the company is informed and products are kept on hold until all regulatory requirements are met. A compliance directive may be issued *(13)*.

Table 4 Medical devices registration requirements of the Nigerian Bureau of Public Procurement (BPP)[a]

Requirement	Notes
SONCAP certification	• Requires (i) a product certificate; (ii) test report; and (iii) certificate of conformity • Administered by SON with evaluation by IAFs
ISO 13485	• Evaluates quality of manufacturing (other certification bodies may be sufficient)
Approval certificate	• Granted by the Ministry of Health, NAFDAC or NNRA
Guaranty certificate	• Must be in English
Evidence for in-country servicing/ repair capacity	• Requires in-country centre for servicing and repair of device and trained personnel
Electricity requirement	• Rated on 220–240 V and applicable safety regulations

[a] *Applies to all medical devices, including those that are donated*

Note: A system for postmarket surveillance for medical devices exists. Products are randomly selected for testing, unless a complaint has been filed that necessitates immediate follow up. Testing occurs monthly (13).

The Pharmacovigilance Rapid Alert System of Consumer Reports allows consumers to report food and drug-related complaints *(13)*. Complaints regarding quality of medical devices are recorded. NAFDAC provides the public with adverse drug reaction reporting forms. The Mobile Authentication Service is a short code also used to report adverse drug reaction *(13)*.

Private providers are subject to accreditation and regulatory oversight. NAFDAC trains both the public and private sectors on how to report adverse drug reactions and patent and proprietary medicine vendors. Public information programmes are also conducted in this regard *(13)*.

5.5 Innovation environment

Nigeria ranked 120 out of 142 countries worldwide in the Global Innovation Index in 2013 *(11)*. Nigeria has established institutions for both undergraduate and graduate biomedical/clinical engineering education and research, and is currently increasing training programmes for clinical engineers through the Nigerian Institute for Biomedical Engineering *(14)*. According to the WHO Global Survey of Teaching Units and Associations, biomedical/clinical engineering training exists at the following institutions: Ahmadu Bello University, Nigerian Institute for Biomedical Engineering, University of Benin, University of Nigeria, and the African Union of Biomedical Engineering and Sciences *(15)*. Additional institutions include the Federal University of Technology, which offers doctoral degree programmes in biomedical technology *(16)*. The Nigerian Institute for Biomedical Engineering is currently developing the National Postgraduate College of Biomedical Engineering, which will be a national professional development programme offering a range of certifications through collaboration with the Federal University of Technology *(17)*. While these programmes are promising, Nigeria still lacks the biomedical capacity needed to maintain and repair medical equipment in hospitals, as well as the capacity needed to develop new medical devices throughout the country.

5.6 Intellectual property

Patents. The Patents and Designs Act 1971, henceforth referred to as "the Act," governs patent and design protection in Nigeria. The Industrial Property Office of Nigeria manages patent administration. Patent applications are subject to examination as to the form and unity of the invention. Patents are granted at the risk of the patentee without guarantee of their validity; the law does not require a substantive examination *(18)*. Upon granting the patent, the patent is entered into a register and published in the Federal Gazette *(19)*. Patent protection is initially granted for 20 years from the date of filing, subject to payment of annual fees *(20)*.

The Act provides for compulsory licensing for 'nonworking' inventions, either three years after the grant or four years after the date of filing *(21)*. Grounds for nonworking include refusals to grant licenses on reasonable terms, in order to enable working of later patents, or authorized use by government agencies if it is in the public interest *(21)*.

Design protection. According to the Act, an industrial design can be registered either if it is new or has not been made public by means of description and use *(22)*.

Applications are made to the Registrar and an applicant can claim foreign priority within three months of filing for registration in Nigeria *(23)*. The Registrar examines the application as to conformity and if the application meets the requirements, the industrial design will be registered, issued a registration certificate, and recorded in the Register of Industrial Designs *(23)*.

An industrial designer can request that the registration be kept secret not exceeding 12 months from the date of application, notwithstanding other provisions of the Act *(24)*. The period of protection initially lasts five years from the date of application and may be renewed for two further consecutive five-year periods on payment of relevant renewal fees *(25)*.

Trademarks. The Trademarks Act of 1967 governs trademark acquisition in Nigeria. Trademarks are registered in respect of goods only *(26)*. The requirements for registration (distinctiveness), including geographical indications and matters prohibited from registration, are described in the Act *(27)*.

Any person applying for a trademark can apply for advice from the Registrar regarding the registrability of the trademark on the grounds of its distinctiveness. If an application is made within three months based on such advice and the mark is found nondistinctive, the applicant is entitled to withdraw the application and receive a refund for any application fees *(28)*.

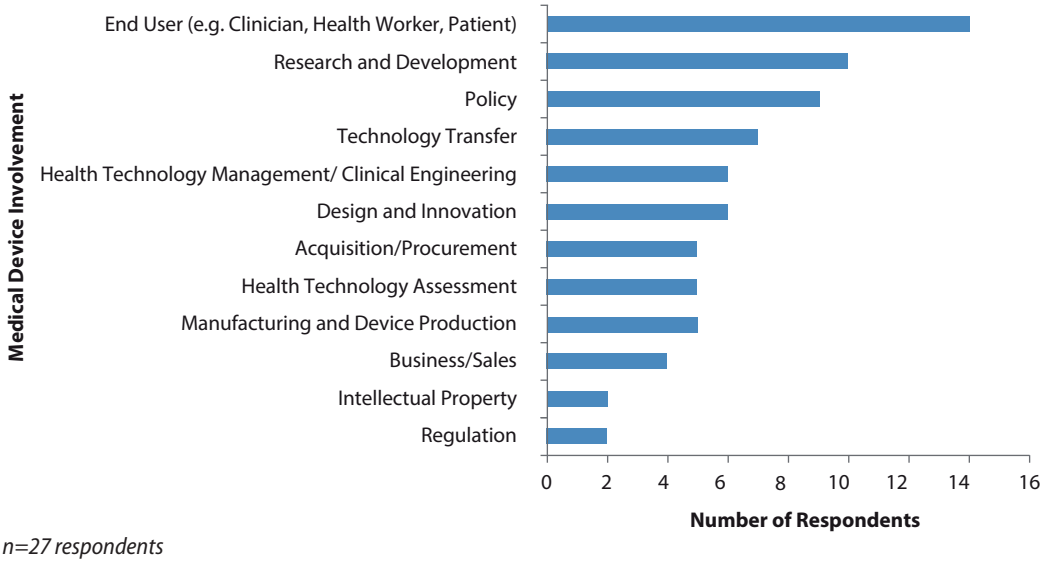
Once an application is received, the submission undergoes an initial conformity and registrability examination. The application is conditionally accepted if the trademark is published in the Trademark Journal *(29)*. If no opposition is filed within sixty days, the trademark is registered. An initial registration period lasts for seven years with a possible extension of 14 years subject to conditions for renewal *(30)*.

Currently, no easily accessible verifiable patent data for medical device patents exists in Nigeria. However, an extensive legal framework protects intellectual property through both the Nigerian Industrial Property Office and the Patent Cooperation Treaty administered by the World Intellectual Property Organization (WIPO).

5.7 Results of the 2013 phase II survey on access to medical devices: Nigeria

Twenty-seven people from Nigeria completed the survey on access to medical devices. Of these, 14 were end-users including clinicians, healthcare workers and patients. Ten respondents also reported involvement in research and development and nine respondents were involved in medical device policy. None of the respondents were investors/donors or reimbursement experts. The least number of respondents reported involvement in intellectual property and regulation of medical devices (Figure 18). Multiple respondents identified involvement in multiple sectors related to medical devices.

***Figure 18** Nigerian respondents' involvement in medical devices*



n=27 respondents

Only five of the 27 respondents were involved in any stage of medical device development. Respondents involved in product development noted the top barrier/obstacle they faced when developing their products was limited financial resources for development (cited by four of five respondents), inadequate local facilities and tools (cited by three of five respondents), and limited information about what actually exists (cited by two of five respondents).

During the development process, four of six respondents consulted a biomedical engineer, only one respondent consulted regulatory and intellectual property rights experts, and none of the respondents consulted reimbursement experts.

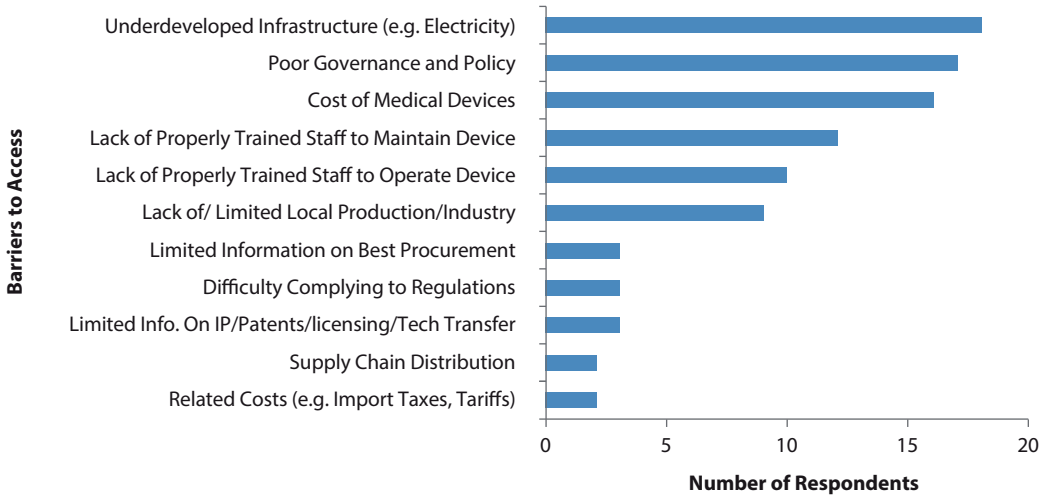
Of the five respondents involved in product development two cited lack of seed funds and limited local manufacturing capabilities as barriers to medical device commercialization and sales.

Respondents most frequently cited quality and safety (nine of ten respondents), price (nine of ten respondents) and compliance with technical specifications (six of ten respondents) as criteria used to make medical device procurement decisions.

Eight of 14 respondents indicated they had no preference between local versus imported devices, which is consistent with the global response rate. Of these 14 respondents, 11 also indicated that they trust that locally manufactured medical devices are safe to use.

Respondents were allowed to select more than one barrier to accessing medical devices in low-resource settings. Of the 26 respondents, most cited underdeveloped infrastructure (69%), poor governance and policy (65%) and cost of medical devices (62%) as barriers to accessing medical devices in low-resource settings (Figure 19).

***Figure 19** Nigerian barriers to accessing medical devices in low-resource settings*



n=26 respondents

5.8 Application of the feasibility tool to Nigerian candidate devices

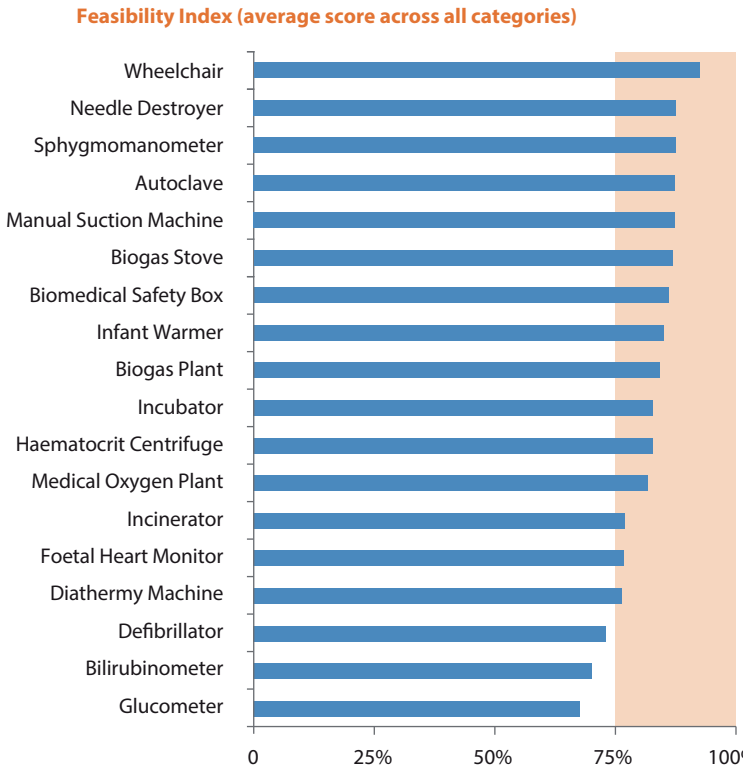
Administration of the feasibility tool. The feasibility tool was sent to the in-country project coordinator, Dr Ogori Taylor, from the WHO country office, who administered the feasibility tool to 27 participants. Approximately 50% of participants identified themselves

as engineers or technicians. The group also included participants from a variety of institutions including hospitals, universities, government, associations and industry.

Candidate devices. The in-country project coordinator consulted with participants to develop a list of candidate devices for evaluation. The coordinator and participants produced a list of eighteen devices that were then evaluated by two or more participants. Reported below are the average scores across the set of participants that evaluated each device (see list of devices in Figure 19).

Feasibility Index and Response Rate scores. Across the set of submissions, overall scores for the Feasibility Index and Response Rate were high. The average score for the Feasibility Index was 82% (range 67% to 92%). Twelve of the eighteen submissions indicated a Feasibility Index that was greater than or equal to 80% and only three submissions received a score of less than 75%. The average score for the Response Rate was 95% (range 91% to 100%).

Figure 20 *Feasibility Index scores, average across all categories*



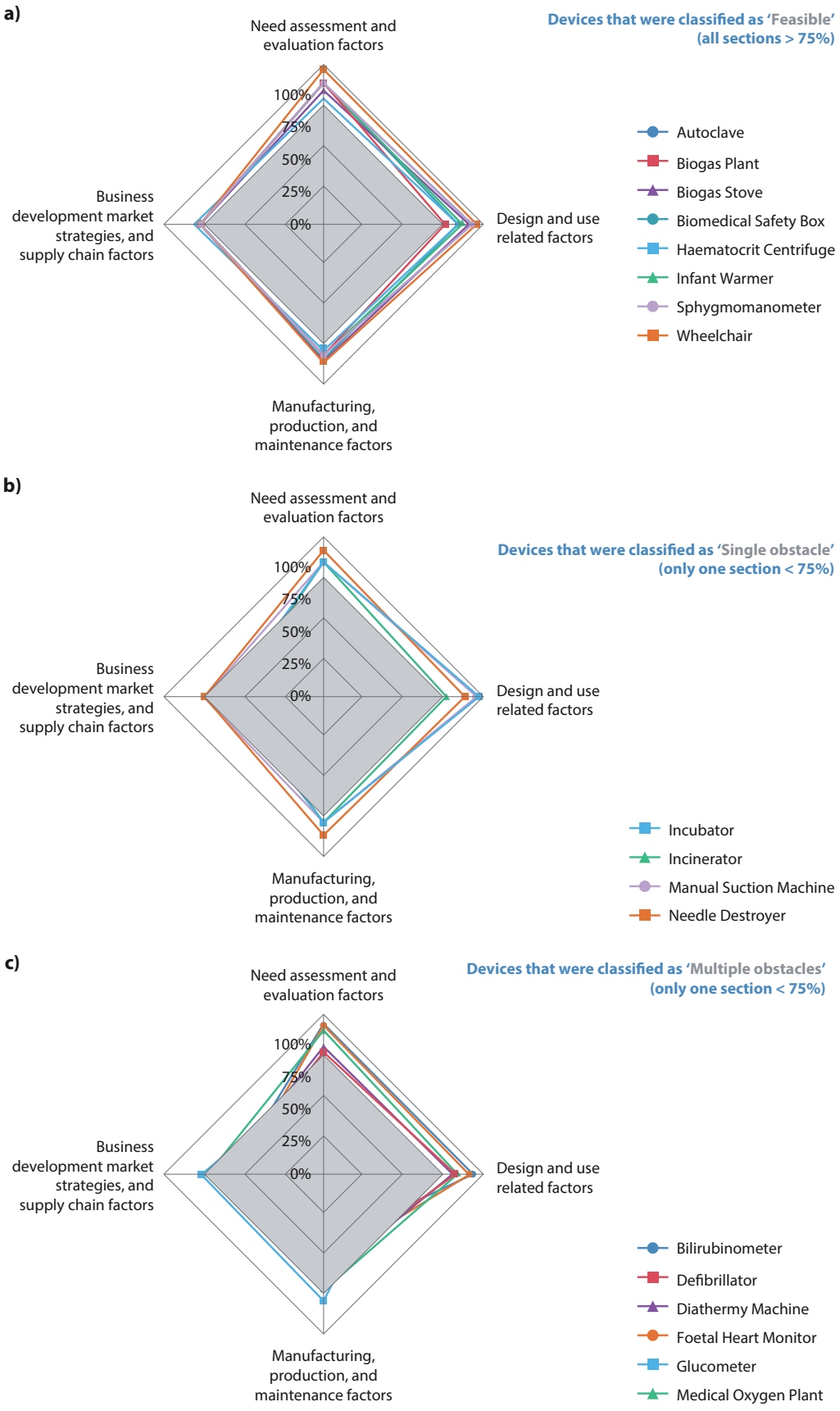
Note: Scores greater than 75% (outside of shaded area) were interpreted as 'feasible' when using the overall score.

The ratings on each individual section of the feasibility tool may provide further insight. The scores for the individual devices for each of the four sections for each submission are given in Figure 21.

Device classification and identification of obstacles. Of the 18 submissions, eight were categorized as 'feasible' (Figure 21a), four were categorized as 'single obstacle' (Figure 21b), and six were categorized as having 'multiple obstacles' (Figure 21c). The eight devices that received at least one classification as 'feasible' included one assistive device (wheelchair), one diagnostic device (sphygmomanometer), one simple treatment device (infant warmer) and several devices to support laboratory services or hospital infrastructure. The

four devices that were classified as having a 'single obstacle' also mainly included items that support laboratory services or hospital infrastructure. All of these submissions fell short on the 'Business development, market strategies and supply chain factors' section of the feasibility tool. Of the six devices that were classified as having 'multiple obstacles', five fell short on 'Business development, market strategies and supply chain factors' and 'Manufacturing, production and maintenance factors', while only one (glucometer) fell short on 'Needs assessment and evaluation factors' and 'Design and use-related factors'.

Figure 21 Feasibility tool analysis by category



Note: Scores less than 75% (inside of shaded area) for a given category were interpreted as an 'obstacle' for that category.

Discussion of results. The feasibility tool submissions indicate a general sense of optimism for local production in Nigeria. Nearly half of the medical devices that the participants selected to assess were deemed feasible and suitable for local production. Notably, the devices evaluated by this group and those that were classified as 'feasible' were mostly devices or equipment that would be used in a hospital laboratory or would constitute part of the hospital infrastructure.

Since the most commonly identified obstacle was in the 'Business development, market strategies and supply chain factors' section, strategies targeted to improving these factors may help to advance local production of medical devices in Nigeria.

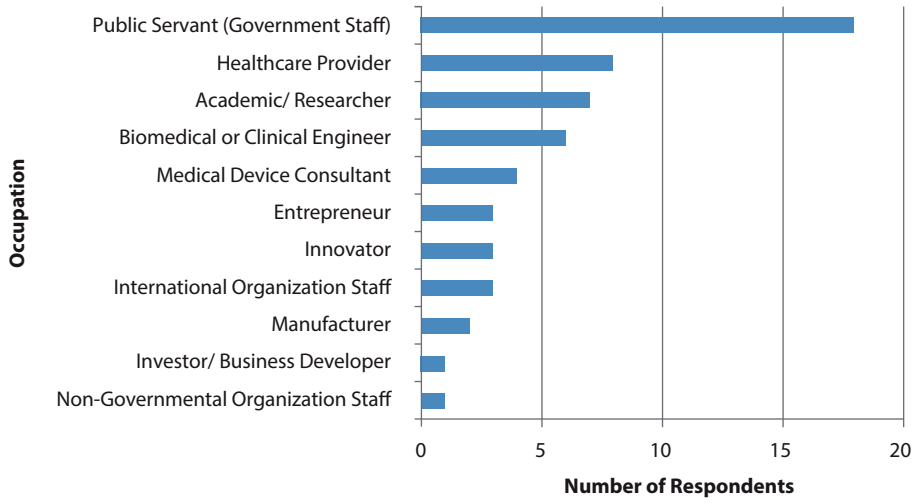
5.9 Workshop summary

Introduction. The LPTTMD Workshop in Nigeria was held at the Reiz Continental Hotel in Abuja on 1 July 2014. Attendees included representatives from the Federal Ministry of Health, NAFDAC, other government agencies, several academic institutions and hospitals, the WHO country office and WHO headquarters. The complete list of participants and a summary of their affiliations is provided in Annex V. Figure 22 illustrates the occupational distribution of the Nigerian workshop participants.

The meeting was officially opened by Dr Rui Vaz, representative of WHO country office of Nigeria, and by Ms Adriana Velazquez Berumen. Both WHO representatives emphasized the importance of medical devices for health service delivery to increase access, availability, regulations, selection and safe use. Local production is a new opportunity that could be initiated in Nigeria, particularly for devices in high demand.

Occupations of workshop attendees. Note that multiple Nigerian workshop respondents reported working in more than one field related to medical devices.

Figure 22 Occupations of Nigerian workshop attendees



n=26 respondents

LPTTMD workshop outcomes: needs, barriers and action plans. Action plans were developed in small group discussions and a list of action items was established and consolidated in a full group discussion. Participants in the first session produced an action plan to increase access to medical devices (Table 5). Participants in the second

session created a list of devices that address important needs and hold potential for local production (Table 6). Participants in the third session developed a roadmap to create an environment conducive to local production (Table 7).

Table 5 Recommended actions to increase access to medical devices

What
Collect relevant existing policies and guidelines (to facilitate development of new policies or update existing policies)
Conduct situational analysis/national assessment for medical devices in Nigeria
Optimize processes for life-cycle management and procurement of medical devices
Advocate for and obtain buy-in from key stakeholders
Perform gap analysis: inventories/integrated needs assessment
Develop priority medical device lists for all healthcare settings to aid planning, procurement, maintenance, replacement and decommissioning
Build capacity of key players among all stakeholders
Increase collaboration between academia, government, industry and professional societies
Increase evidence-based maintenance options

Table 6 Priority medical devices for local production

Maternal and child health
Basic obstetric equipment
Nonpneumatic antishock garment
Cord clamps
Resuscitator-bagsMucus extractors
Baby warmers
Weighing scales, height measuring scales, tape measures
Disposables
Disposable gloves
Syringes/needles
Condoms
Hospital equipment
Stove-based sterilizers
Vaccine cold box
Diagnostics
Rapid diagnostic kits, including rapid HIV test kits
Sterile sputum receptacles
Microscopes
Sphygmomanometers
Urine test kits
Slides/slide covers

Other
Insecticide-treated nets
Kidney dishes
Covered bowls

Table 7 Recommendations to create an enabling environment for3roduction

Provide a list of devices to the Ministry of Health (MoH) and suggest criteria for selection
Establish a process to identify met and/or unmet (poor access) medical device-related needs of the MoH that could be candidates for LPTTMD
Set up a Medical Device Innovation Forum (with sub-committees for specific devices), begin pilot on five selected devices, identify infrastructural and other challenges (e.g. cost of production, needed competencies, incentives) that must be overcome to create an enabling environment
List all agencies supporting LPTTMD (e.g. NAFDAC, FMoH, etc.) and their roles and 'rules of engagement'
Create funding options for local production in Nigeria
Promote inter-ministerial discussion and alignment around LPTTMD issues; share report with ministries
Involve private sector (organizations and individuals) as partners in developing new government policies
Remove intellectual property/patent bottlenecks
Develop a business case for LPTTMD

The action plan for increasing access to medical devices strongly endorsed improvements in information gathering, communication and policy development. The workgroup identified the need to understand and coordinate policies, increase communication across sectors and develop new policies and programmes to streamline procedures involved in the production and use of medical devices.

Workshop attendees identified and discussed a number of devices that could be suitable for local production and identified key obstacles that must be overcome. The workgroup cited Nigeria's existing capacity for producing various technologies and particular strengths that could be better leveraged for producing disposables. The group also noted potential opportunities to address acute needs for equipment and supplies related to maternal and child health.

The roadmap for creating an environment conducive for local production emphasized identifying unmet needs and emerging opportunities for local production, establishing policies and improving communication among all stakeholders. The group cited the potential value of establishing a forum to promote innovation that would advance ideas and identify challenges faced in locally producing medical devices. Other proposals focused on promoting collaboration across sectors and streamlining procedures for protecting intellectual property.

Summary and conclusions. The workshop provided an active forum for discussion among participants from a variety of sectors, some of whom met at the workshop for the first time. Participants included industrialists, regulators, Ministry of Health authorities, medical equipment managers, selection and procurement officers, and technology users along with WHO country office representatives. A wide range of proposals for advancing local

medical device industries were presented and extensively discussed. Across all sectors, there was great interest and enthusiasm for local production, but significant barriers to medical device access were identified.

No medical devices are produced in Nigeria, but production potential now exists through government policies supporting innovation and local production. The roadmap provides a way forward for various actors to contribute to the success of efforts to locally produce medical devices. Primary recommendations focused on the importance of identifying unmet needs and emerging opportunities for local production, establishing policies and improving communication across sectors. Participants suggested that workshop members meet every six months to follow up with the action plan.

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6. South Africa

6.1 Country indicators

DEMOGRAPHICS AND DISEASE BURDEN

ECONOMIC CLASSIFICATION	UPPER-MIDDLE INCOME
POPULATION (2015)	53.5 MILLION *(1)*
NATIONAL LANGUAGES	ISIZULU, ISIXHOSA, AFRIKAANS, SEPEDI, ENGLISH, SETSWANA, SESOTHO, XITSONGA, AND OTHERS
GNI PER CAPITA (US$, 2014)	7190 *(1)*
HEALTH EXPENDITURES PER CAPITA (US$, 2013)	1121*(1)*
HUMAN DEVELOPMENT INDEX	0.658 *(2)*
LIFE EXPECTANCY (2012)	60 *(1)*

6.2 Healthcare environment

In 2004, the top five causes of death in South Africa were HIV/AIDS, cerebrovascular disease, ischaemic heart disease, lower respiratory infections and violence *(3)*.

The healthcare system in South Africa is financed through public and private sources and operates under the National Department of Health. South Africa is divided into nine provinces, each of which has a health department responsible for local policy and healthcare delivery under the national framework. Healthcare is delivered through a four-tier system of tertiary hospitals, regional hospitals, district hospitals and community health centres, with the latter two comprising the primary healthcare system. South Africa has the fifth greatest number of hospital beds per 1000 people and sixth highest number of physicians per 1000 people in Africa *(4)*.

Large inequality exists between the public and private healthcare system in South Africa. The public healthcare system supports 85% of the population (2005), yet only spends 47.7% (2011) of the overall health expenditure *(5,6)*. Disparities also exist in the distribution of hospitals between provinces and rural settings with a disproportionately high concentration of healthcare workers being employed in the private sector.

Primary healthcare is offered at no charge to the population, and all health services are free for pregnant women and children under six years of age *(5)*. Healthcare expenditures, which contributed to 8.5% of GDP, or US$ 689, in 2011, are funded through three major sources: (i) the government (47.7%), (ii) private insurance (42.4%), and (iii) out-of-pocket expenditures (7.2%)*(6)*. External resources and donations contribute to only 2.1% of healthcare expenditures *(6)*.

The South African healthcare system is currently undergoing reform with the National Health Act 2004, which aims to reduce healthcare inequality *(7)*. Specifically, this policy mandates the creation of National Health Insurance with the goal that universal healthcare will improve access. The National Health Act also outlined a "10 point plan" to address other national health priorities *(7,8)*.

6.3 Medical device industrial landscape and medical device market

Major industries in South Africa include mining, manufacturing, oil and gas, chemicals, agriculture and tourism *(9)*.

In 2008, South Africa imported US$ 670.1 million (US$ 13.7 per capita) and exported US$ 111.5 million of medical equipment and supplies – the greatest amount of imports and exports in Africa *(4)*. The import and export of medical devices has continued to increase with a CAGR of 10.8% and 0.8%, respectively *(4)*. The leading suppliers of imported medical equipment to South Africa are Germany, the United Kingdom and the United States of America *(4)*.

6.4 Medical device regulation

Table 8 displays the organizations responsible for medical devices in South Africa.

***Table 8** Key organizations in the South African national governance of medical devices*

Regulatory Organization	Key Role
National Department of Health	• Formulates national legislation for regulation of medical devices
Medicines Control Council	• Regulates manufacturing, import or export, and/or distribution of medical devices • Administers license to approve medical devices
Directorate of Radiation Control	• Administers license to approve electromagnetic or radiation-emitting medical devices
South African Health Products Regulatory Authority	• The new regulatory body responsible for medical devices (proposed in 2014), created through the Medicines and Related Substances Amendment Act 72 of 2008
South African Bureau of Standards	• Develops technical and regulatory standards

The Medicines and Related Substances Control Act 101 of 1965 is an overarching policy that provides a basic definition and licensing requirement for medical devices *(12)*.

In response to the need for stricter regulation, the Medicines and Related Substances Amendment Act 72 of 2008 was passed. The Act outlines the creation of a South African Health Products Regulatory Authority *(10)*. This body will provide a comprehensive set of regulations for medical devices, including the South African Bureau of Standards' development of a set of standard regulations for medical devices.

The South African Medical Device Industry Association (SAMED), a non-profit organization, also developed an informal marketing code and business practices for the medical device industry *(11)*.

Under the policy created by the Medicines and Related Substances Control Act 101 of 1965, a license must be obtained to manufacture, import or export, and/or distribute a medical device *(12)*. The Medicines Control Council grants licenses based on an evaluation of quality assurance, often validated through the preferred CE (Conformité Européene) Mark, but also through Food and Drug Administration (FDA) approval, good manufacturing and distribution practices, and an administrative fee. Ultimately, licenses are approved

at the discretion of the Council. A more rigorous licensing procedure is required for electromagnetic and radiation-emitting devices (e.g. ultrasound, magnetic resonance imaging, chest radiograph), and includes registering with the Directorate of Radiation Control of the National Department of Health, a more rigorous clinical assessment and a CE Mark certification. Donated medical equipment is regulated following WHO's Guidelines for Health Care Equipment Donations.

6.5 Innovation environment

South Africa ranks 39 out of 183 countries according to the World Bank's *Doing Business 2013* report. Notably, South Africa ranked in the top 10 under the categories of "getting credit" and "protecting investors," but scored poorly on "getting electricity" and "trading across borders"*(13)*. In the Global Innovation Index, South Africa was also ranked the second highest country in Africa, behind Mauritius, and 58 in the world *(14)*.

South Africa has established institutions for biomedical/clinical engineering education and research as well as training programmes for medical device technicians. According to the WHO Global Survey of Teaching Units and Associations, biomedical/clinical engineering training exists at the following universities: Tshwane University of Technology, University of Cape Town, University de Stellanbosch, and Witwatersrand University *(15)*. The Clinical Engineering Association of South Africa also provides training to medical device technicians *(16)*.

A diverse range of incentives exists for both domestic and foreign investors to increase manufacturing, entrepreneurship and general development in South Africa *(17)*. The Trade and Investment South Africa (TISA) programme, operated under the Department of Trade and Industry (DTI), provides primarily nontax-based incentives *(17,18)*. Specifically in the medical device industry, incentives exist for technology development, exporting goods and developing small- and medium-sized enterprises. South Africa offers a series of grants depending on the industry and services generated to encourage infrastructure development and job creation, among others. Notable incentives include the Industrial Development Zones designated to attract foreign direct investment for export-oriented manufacturing production; Overseas Private Investment Corporation programmes that use investment to aid development in sub-Saharan Africa, and the Manufacturing Investment Programme, Additionally, foreign investments are not heavily controlled by the government *(19,20)*. Further information on incentives and investments in South Africa can be found in the Department of Trade and Industry's *South Africa: Investor's Handbook 2014/15 (20)*.

A number of organizations and programmes specific to technical innovation and medical devices that facilitate research and development, and commercialization also exist in South Africa. These organizations include, but are not limited to, the Medical Device Manufacturers Association of South Africa, the South African Department of Science and Technology's Technology Innovation Agency and SAMED *(11,21,22)*.

6.6 Intellectual property

Patent protection. The Patents Acts 57 of 1978, henceforth referred to as "the Act," governs patent protection in South Africa. The Act established a Patent Office (Companies and Intellectual Property Commission) to administer all matters related to patents *(23)*.

The patent application process requires an in-country address where all notices and communications may be sent *(24)*. The applicant can claim priority to an earlier filing of a patent in any of the Paris Convention contracting states *(25)*.

A patentable invention is a novel inventive step that is non-obvious to someone who is skilled in the art and is not subject-matter that is excluded *(26)*. The registrar examines every application as to its completeness regarding specifications and compliance with formalities *(27)*. This examination process indicates that the Patent Office does not provide substantive examination and that the burden of proof is on the applicant in terms of patent validity. Once the registrar accepts an application with a complete specification, the applicant receives a written notice to this effect. The application is published for public inspection and is deemed sealed and granted as of the date of publication *(28)*. An opposition can be filed within two months from the date of advertisement in the journal *(29)*. The Act further sets out the procedure for the national phase of the Patent Cooperation Treaty *(30)*. Patent protection is initially granted for 20 years from the date of application subject to payment of renewal fees *(31)*.

The Act governs licensing provisions and sets out the conditions for licensing patents. A patent holder may endorse their patent allowing for any person to obtain a license to use the invention *(32)*. Any endorsement shall be recorded in the register and advertised in the Journal *(32)*. The Act provides for compulsory licensing for 'nonworking' and 'nonworking to an adequate degree', for refusing to grant licenses on reasonable terms, for patent interdependence in relation to nonworking and for products and processes of vital importance in the public interest *(33)*.

Design protection. The Designs Act 1993 governs design protection in South Africa. The Companies Intellectual Property Registration Office is the administrative office for design registration. A registration application may be made through an agent authorized by the registrar *(34)*. A classification system is outlined in the annex of the Design Act. A design registration application can be made in relation to aesthetics or function and should contain a definitive explanatory statement relating to the design *(35)*.

Once a design is received and the registrar has examined the design with no objections, and the design complies with the prescribed requirements, the design is registered *(36)*. The registrar issues a notification of registration to the applicant and the applicant is responsible for advertising such notices in the journal within three months *(37)*.

Trademarks. The Trademark and Services Act 1993 governs trademark acquisition in South Africa. The International Classification of marks is the basis for registering goods and services *(27)*. An applicant can claim priority for a trademark originating from a Paris Convention contracting state *(28)*. The Act sets out requirements for registration (distinctiveness) and subject matters prohibited from registration *(38)*.

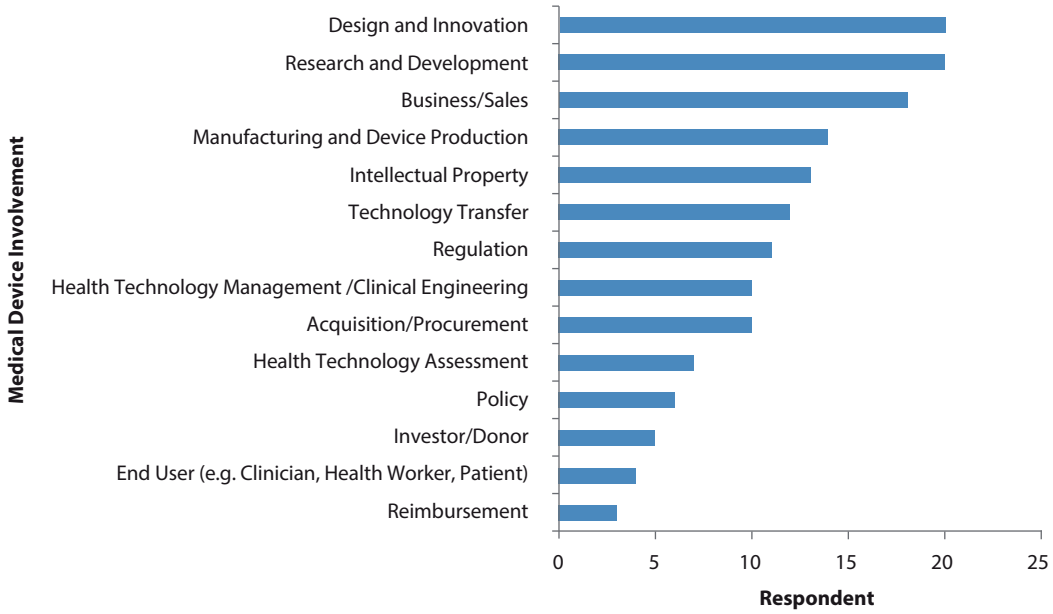
Once an application is received, the registrar shall advise on the acceptance or refusal of the trademark in conformity to the Act *(39)*. Once an application for a trademark has been accepted, the trademark is advertised in a manner prescribed by the registrar and any interested party may file an opposition within three months from the date of advertisement *(40)*. If there is no opposition within the prescribed period, the registrar will issue a registration certificate to the applicant *(41)*.

The initial registration period lasts for 10 years with a possible 10-year extension subject to fees and conditions for renewal as set out in the Act *(42)*. A trademark assignment (license) should be made in writing and signed, and is subject to registration *(43)*.

6.7 Results of the 2013 phase II survey on access to medical devices: South Africa

Of the 30 respondents from South Africa, 20 were involved in design and innovation as well as research and development; and 18 were involved in business and sales of medical devices (Figure 23). Many South African respondents reported involvement in multiple areas related to medical devices.

***Figure 23** South African respondents' involvement in medical devices*



n=30 respondents

Of the 29 respondents who answered a question regarding involvement in medical device development, 14 were associated with commercialized devices and 12 with medical devices "under development".

In response to a question regarding barriers to product development, 77% of 22 respondents reported limited financial resources for growth as a barrier to developing their product. All other factors were reported by less than 28% of respondents.

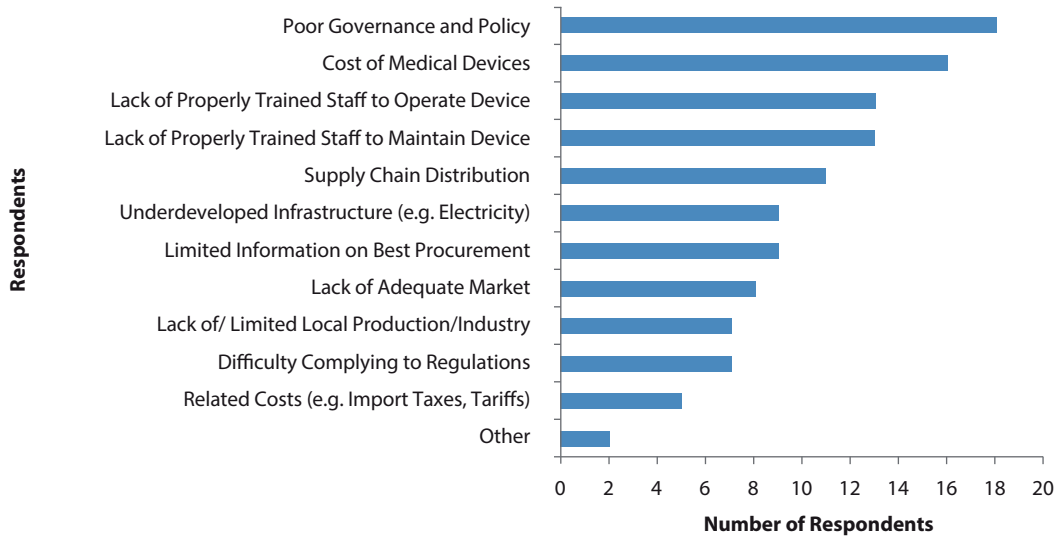
During the product development process, more than half of the 22 respondents consulted biomedical engineers (59%), regulatory experts (68%) and intellectual property experts (55%). However, none of the respondents consulted a manufacturing and product development expert.

Nineteen respondents cited the most common barrier to product development as **commercializing/selling** their medical device products, including products not listed for public procurement (47%), lack of seed funds (47%), limited local manufacturing capabilities (26%) and lack of business expertise (26%).

Based on seven responses, price (100%), compliance with technical specification requirement (86%), quality and safety (86%), and availability of local distributors (57%) were the key criteria in their medical device procurement decision.

Thirty respondents reported that the biggest barriers to access to medical devices in low-resource settings were poor governance and policy (60%), cost of medical devices (53%), lack of properly trained staff to maintain devices (43%), lack of properly trained staff to operate devices (43%) and underdeveloped infrastructure (30%) (Figure 24).

***Figure 24** South African barriers to access to medical devices*



n=30 respondents

6.8 Application of feasibility tool to South African candidate devices

Administration of the feasibility tool. The feasibility tool was sent to the in-country project coordinator, Mr Mladen Poluta from the University of Cape Town. Mr Poluta recruited four groups, each of which had been active in medical device development, and organized a meeting in 2013 to administer the feasibility tool to the participants and submit a survey response.

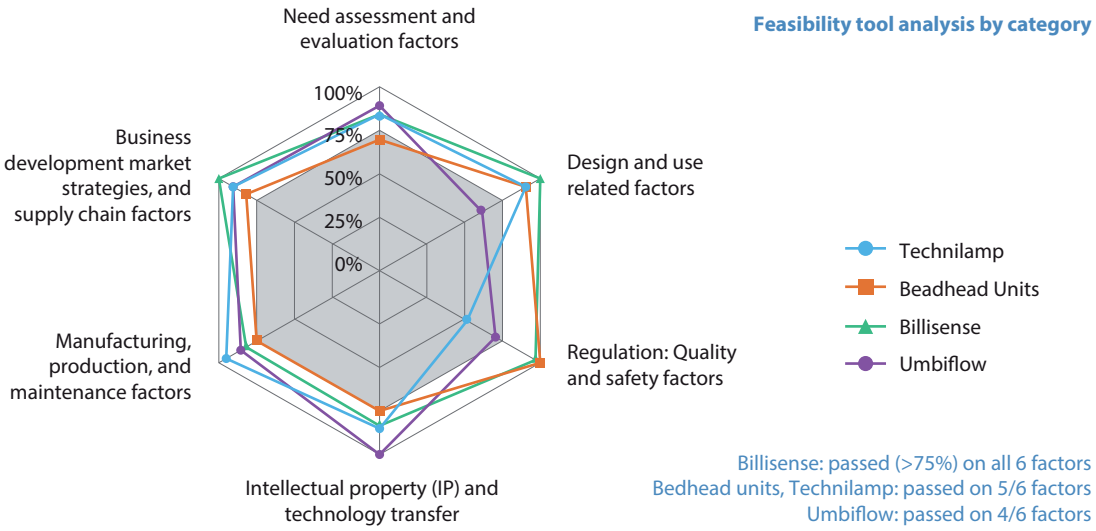
Candidate devices. Each of the four groups chose to use the feasibility tool to evaluate a device they had been developing for commercialization. The four devices were: (i) bedhead units; (ii) Billisense; (iii) Technilamp; and (iv) Umbiflow.

Feasibility Index and Response Rate scores. Across the set of submissions, the overall scores for the Feasibility Index and Response Rate were high. All submissions received an overall score greater than 75% for the Feasibility Index; the average score was 86% (range 83%–92%). The average score for the Response Rate was 88% (range 77%–99%).

The ratings on each of the individual sections of the feasibility tool may provide further insight. For each submission, the scores for the individual devices for each of the sections are given in Figure 25.

Device classification and identification of obstacles. Of the four submissions, Billisense was categorized as 'feasible', bedhead units and Technilamp were categorized as 'single obstacle', and Umbiflow was categorized as having 'multiple obstacles' (Figure 25). Note that the category identified as an obstacle for bedhead units was 'Need Assessment and Evaluation Factors' and the score for that category (72%) was just below the threshold of 75%. The single obstacle category for Technilamp was 'Regulation: Quality and safety factors'. The results for Umbiflow also indicated obstacles in the 'Regulation' as well as the 'Design and use-related factors' category.

Figure 25 Feasibility tool analysis by category



Note: Scores less than 75% (inside of shaded area) for a given category were interpreted as an 'obstacle' for that category.

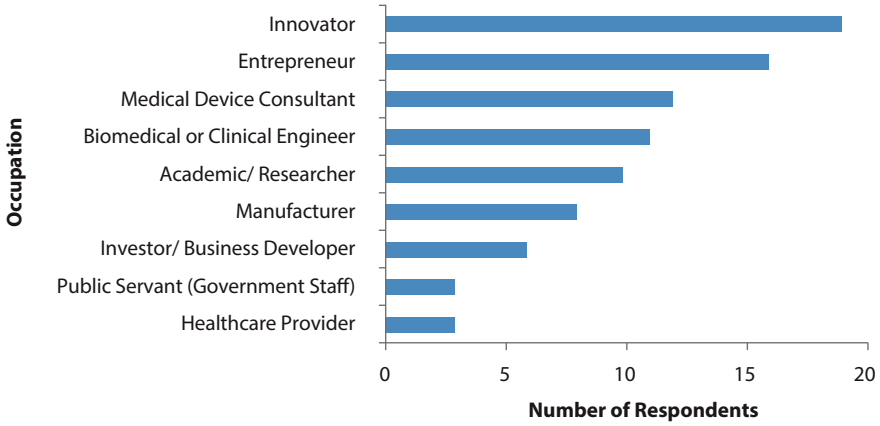
6.9 Workshop summary

Introduction. The LPTTMD Workshop in South Africa was held in Johannesburg at the Birchwood Hotel & Conference Centre on 24–25 November 2014. Attendees included representatives from the Department of Health, NAFDAC, other government agencies, several academic institutions and hospitals, the WHO country office, and WHO headquarters. A complete list of participants and a summary of their affiliations is provided in Annex VI.

Dr Habib Somanje (representing Dr Sara Barber, WHO) opened the meeting and expressed the importance of increasing access to affordable, safe and good quality medical devices. Dr Joey Gouws, from the Department of Health, spoke on the importance of discussing the new proposed regulations for medical devices and government goals in health service delivery with all stakeholders.

Occupations of workshop participants. Figure 26 illustrates the occupational distribution of the participants of the South African workshop. Note that multiple South African workshop respondents reported working in more than one field related to medical devices.

Figure 26 Occupations of South African workshop attendees



n=29 respondents

LPTTMD workshop outcomes: needs, barriers and action plans. The agenda, list of participants and access to all the presentations are available in Annex VI.

The workshop concluded with an action plan that included the following items:

WHAT	WHO?
Capacity building for health technology /medical devices innovation	**Academia**
Triple Helix Forum/Alliance (with core team) to follow up on issues and act; involve health professionals as stakeholders	Department of Science and Technology (DST)
Consider sector designation for medical devices	Department of Trade and Industry (DTI)
Innovation advocacy. National Health Service Innovations Model, Groote Schuur Hospital Innovations)	
Internationally accredited national capability for ISO 13485 accreditation	South African National Accreditation System (SANAS)/South African Bureau of Standards
Programme to support technology transfer (e.g. laboratory policy)	DTI
Identifying 'customer' (who are *they?*) unmet needs across the care continuum at all levels of delivery (including community/home-based) and how to verify/validate	**All**
Greater collaboration with external/global funders and projects (WHO can assist)	Electronic community network and WHO Listservs
Explore possibility of WHO prequalification or other processes for regulatory approval for Priority Medical Devices for African Region (link to In Vitro Diagnostics Regulatory process), with expense to innovator	WHO
Identify/characterize niche/neglected markets	All
Align initiatives with champions in other sectors (mHealth with cellphone providers)	Innovators
Advocate local uptake of local innovations	
Innovative incentives for off-shore manufacturers to partner with local manufacturers	

WHAT	WHO?
Capacity building for health technology/medical devices life-cycle management	**Department of Health**
Identify priority medical devices for different levels of care	Department of Health
Technical specifications for priority medical devices (for centralized, standardized procurement) – extend to provinces	WHO/NT
Greater alignment between national, provincial, district and local decision-making and management related to medical devices/health technology	Department of Health
Medical devices/health technology related information system/s (including needs assessment, asset management)	Department of Health
Improved distribution efficiencies (i.e. drugs model)	Department of Health
User and maintainer training (problems with high turnover of staff) – opportunity for innovation in the maintenance programme	Clinical Engineering Department
In-service training as part of continuing professional development	Ind/DoH
Re-instate province management teams + capacitate them – align with Health Technology System (FHP/HT Strategy)	
Implement HT Strategy + Stakeholder Forum for each pillar – seamless implementation – consider new/better systems, processes and structures; cost-effective regulation	
Develop national resources (including mailing lists, Listservs, workshops, etc.)	DoH/All
Identify and focus on key performance indicators (use WHO SARA and other tools, Best Care Always model)	All
Align with other stakeholders, e.g. NCD Alliance	
Follow-up with high-level stakeholders. Forum/workshop to be initiated by the government.	
Optimize procurement of medical devices/health technologies	DoH

Summary and conclusions.

The workshop in South Africa was held four months later than the workshops in other countries due to a new regulatory process for medical devices being proposed. This workshop gave the opportunity to share and disseminate national strategies and policies with professors from academia, standards organizations and the South African medical devices industry (who were producing medical devices organized under a trade association). The four areas of medical devices were in a very good stage of development with innovation, regulation, assessment and health technology management in place.

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7. Tanzania

7.1 Country indicators

DEMOGRAPHICS AND DISEASE BURDEN

ECONOMIC CLASSIFICATION	LOW INCOME COUNTRY
POPULATION (2015)	52.3 MILLION *(1)*
NATIONAL LANGUAGES	SWAHILI (OFFICIAL), ENGLISH (OFFICIAL), ARABIC, MANY LOCAL LANGUAGES
GNI PER CAPITA (US$, 2014)	630 *(2)*
HEALTH EXPENDITURES PER CAPITA (US$, 2011)	126 *(1)*
HUMAN DEVELOPMENT INDEX (2014)	0.488 *(3)*
LIFE EXPECTANCY (2012)	63 *(1)*

7.2 Healthcare environment

According to the Health Management Information Systems data 2009–2012, the leading causes of death in Tanzania were malaria, HIV/AIDS, cardiovascular diseases, acute respiratory infections, anaemia, TB, chronic respiratory diseases, cancers and diarrhoeal diseases *(4)*.

Since 2009, Tanzania has implemented the Third Health Sector Strategic Plan (HSSP3) (July 2009–June 2015), which will end in 2015. A mid-term review was conducted in 2014 and the development process for the fourth Health Strategic Plan is underway. The HSSP3 provides an overview of the priority strategic directions across the sectors which are guided by the National Health Policy, Vision 2025, the National Programme for Economic Growth and Poverty Reduction (MKUKUTA in Kiswahili) and the MDGs *(5)*. The Ministry of Health and Social Welfare (MoHSW) revised the 1990 National Health Policy in accordance with the National Health Policy of 2007. The Policy outlines achievements of and challenges to the health sector. The Policy also outlines the government's vision to have a healthy society with improved social wellbeing that will contribute effectively to personal and national development. The Policy mission is to provide basic health services in accordance to geographical conditions, which are of acceptable standards, affordable and sustainable. The health services will focus on the most at-risk populations and will satisfy the needs of the citizens to increase the lifespan of all Tanzanians *(6)*.

Tanzania is a union between Tanganika and Zanzibar, and both sides of the union are implementing health sector reforms with very similar goals. Tanzanian healthcare administration is divided into three health services levels: (i) national, (ii) regional and (iii) district *(7)*. This multi-tiered, decentralized system works as a referral pyramid, starting from dispensaries up to more specialized national hospitals.

At the national level, the MoHSW administers and supervises the national hospitals, consultant referral hospitals, special hospitals, training institutions, executive agencies and regulatory authorities. The MoHSW is responsible for policy formulation, health legislation, regulation and control, and manages the support of all level III hospitals including national, referral and special hospitals *(8)*.

At the regional level, the Regional Health Administration, with technical guidance from the Regional Health Management Team, is responsible for providing health services through mobilizing resources and translating policies into actions. The Regional Health Administration serves as a liaison between the districts and the Central Ministry of Health in matters pertaining to standards and quality of both public and private healthcare. Furthermore, the Regional Health Administration is responsible for providing technical support to the districts and supporting supervision and inspection of district health services *(8)*.

Finally, district council authorities, health service boards, facility committees and health management teams manage and administer health services at the district level *(8)*.

Disparities exist in the distribution of hospitals between districts and rural settings. In 2014, the MoHSW counted 692 health centres and 308 hospitals in the country with the majority of hospitals located in urban settings where only 25% of Tanzania's population lives.

Though total healthcare expenditures have increased over the past five years, government expenditures on health have not. Healthcare was funded through three major sources – (i) the government contributed 39.5%, (ii) donations accounted for 24.9%, and (iii) out-of-pocket expenditures accounted for 31.7% *(7)*. Private insurance contributed less than 1% of healthcare expenditure *(7)*. Healthcare services in Tanzania were only available to those who pay the required fees. Hospital beds increased from 49 544 in 2010 to 50 862 in 2014, providing a rate of 0.50 beds per 100 000 individuals; but with a physician rate of only 0.05 physicians per 1000 patients *(4)*.

The government is currently working with Global Health Initiatives (GHI) to reform their healthcare system to improve the health of all Tanzanians, especially the health of the most vulnerable groups (women, girls, newborns and children under five years of age). GHI is contributing to two of Tanzania's MDGs – the substantive reduction of deaths among children below five years of age and reduced maternal mortality by 2015. A 'Tanzania – Global Health Initiative Strategy (2010–2015)' has been developed to improve healthcare outcomes *(7)*.

7.3 Medical device industrial landscape and medical device market

Major industries in Tanzania include agricultural products, cigarettes, textiles, vegetable oil, cement and fertilizer *(29)*.

In 2008, Tanzania imported US$ 29 million and exported US$ 392 000 of medical equipment and supplies. The import and export of medical devices continues to increase with a CAGR of 20.0% and 173.6%, respectively. The leading suppliers of imported medical equipment are China, Germany and the United States of America *(4)*.

Medical device imports are controlled. Imported products either need to be registered or given authorization before they can enter the country. An invoice must be submitted, fee paid and product inspected at the port of entry. In some cases, sampling and testing is done before the product is released *(24)*.

All imports must have an import license. Only post-shipment inspection is done once a consignment has arrived at the port of entry. In case of discrepancies, the consignment can be detained pending destruction *(24)*.

There is no national medical device manufacturing industry *(24)*. Nonmedical commodities are produced locally by seven major manufacturers, of which six are not GMP certified. The lack of GMP certified manufacturers creates a challenge because the Medical Stores Department (MSD) can only purchase products from manufacturers with GMP certification *(24)*.

There is no national essential medical devices list for public procurement/reimbursement *(24)*. The MSD manages the procurement, storage and distribution of medicines and medical devices to zonal storage units and health facilities. The MSD is semi-autonomous and not funded by the government. The procurement process generally takes six to nine months. Staffing and operations of the MSD could be paid for by mark-up on products, but the government determines the price that will be paid for medicines and medical devices, presenting a cost-recovery challenge. However, donors and vertical programmes that purchase commodities independently channel these technologies through the MSD. The MSD faces the following challenges to procurement, storage and distribution of medicines as well as medical devices *(25)*.

- Government disbursements to buy medicines often fall short of predictions, sometimes by as much as 30%–40%. These payments are often delayed, causing stock shortages. A "basket fund" mechanism was created to support procurement. The six-to-eight month tender process is not ideal for delivering life-saving commodities that may be needed quickly.
- The MSD stores and distributes commodities to zonal storage units, and finally, directly to health facilities. The large number of facilities and infrastructure and transport problems sometimes leads to stock-outs *(25)*.

7.4 Medical device regulation

The Tanzania Food and Drugs Authority (TFDA) oversees the country's medical device regulation. TFDA is a semi-autonomous body under the MoHSW, and is responsible for controlling the quality, safety, and effectiveness of food, drugs, herbal drugs, cosmetics and medical devices. The Directorate of Inspection and Surveillance within the TFDA evaluates and registers all medical devices before approving them for distribution and marketing in the country. This Directorate ensures that medical devices are safe and meet their pre-established country quality and efficacy requirements. This Directorate is also responsible for inspecting manufacturers, wholesalers and retailers, clinical trial sites and devices at the port of entry to ensure that standard requirements are met.

The medical device registration system includes general requirements, device details, a technical summary, documentation, labelling requirements and an essential requirements checklist. Registration takes about six to 12 months; there is no fast track for registration. Limitations on device registration include inadequate human resources and inadequate funding to build capacity *(24)*.

The TFDA has assembled a list of registered medical devices that have met the requirements, a list of withdrawn medical devices, and a list of medical devices that have recently been

approved by the TFDA. However, there is no national list of medical devices for different types of healthcare facilities; nor a list of devices for specific procedures *(10)*. Assessments conducted by other agencies cannot be used to facilitate local registration of medical devices *(24)*.

The MoHSW and TFDA do not have any guidelines or regulations on donated medical devices.

The TFDA has established guidelines on: (i) submission of registration documentation for medical devices; (ii) permit applications regarding medical devices business; and (iii) good medical devices distribution practices *(11)*. The Directorate of Inspection and Surveillance oversees that medical device manufacturers, businessmen and other in-country representatives meet these requirements and guidelines. The TFDA has established fees and charges for nearly all in-country activities and application processes involving the TFDA *(12)* (clinical trial enrolment fees, medical devices registration fees, dealers' permits, etc.), and requires that individuals or businesses hoping to import medical devices and supplies submit an application for evaluation and approval *(13)*. The TFDA also oversees the import and export of medical devices, post-marketing product risk analysis, as well as laboratory analysis for quality, safety and effectiveness. Products are selected through the Medical Device Post-market Surveillance Plan and tested annually. Manufacturers, importers and health providers may record quality complaints through 'adverse events forms' *(24)*.

Medical device regulation challenges include the presence of counterfeit products in the Tanzanian market, inadequate technical capacity of staff to identify counterfeit products, inadequate numbers of staff and inadequate funds to carry out regulatory activities *(24)*.

7.5 Innovation environment

Tanzania ranks 145 out of 183 countries according to the World Bank's *Doing Business 2013* report. The report cites lack of electricity and access to finance as the main obstacles to doing business *(26)*.

Tanzania has established institutions for biomedical/clinical engineering education and research. However, there are currently no established training programmes for medical device technicians. Currently, the Dar es Salaam Institute of Technology and the College of Engineering and Technology offer degrees in clinical and biomedical engineering and carry out basic engineering research. A need still remains for trained individuals in biomedical engineering to maintain and repair medical equipment in hospitals, as well as to develop new medical devices that are needed throughout the country.

The Tanzania Investment Centre (TIC) is the first point of call for potential inventors in Tanzania. Through the TIC, investors may apply for a Certificate of Incentives, which provides investors with a number of incentives including the right to transfer 100% of earned foreign exchange profits and accumulated capital outside the country. Other incentives include 0% import duty for unprocessed products and 10% import duty for semi-processed products *(8,9)*. Additionally, no restrictions exist for enterprises entering technology transfer agreements. Manufacturing and other export-oriented sectors are considered priority areas *(8)*.

7.6 Intellectual property

Patents. The Patents (Registration) Act 1995, henceforth referred to as, "the Act," specifies the African Intellectual Property Office (ARIPO) as its Patent Office. A patent granted through ARIPO would have the same effect as a patent granted under the Patents Act in Tanzania. The patent application process requires a designated agent if the applicant is neither a resident nor has a place of business either within the country or one of the ARIPO contracting states. The applicant can claim priority to an earlier filing of a patent in any of the Paris Convention contracting states *(14)*. The application will be subject to examination as to form and unity of invention including an international type search report if warranted by the subject matter *(15)*. A substantive technical examination relating to the field of the invention may be carried out by ARIPO.

A granted patent would be registered and published in the Patent Office register. An opposition (appeal) procedure is outlined under the Act. The ARIPO specifies fees for patent filing, designation of protection in other regional member states, and annual fees. Patent protection is initially granted for 10 years with a five-year extension subject to conditions such as "working" of the invention *(16)*. The scope of the protection is determined largely by the terms of the claims.

The Act governs licensing provisions and sets out the conditions for patent licensing to licensees and third parties. Licensing contracts must be in writing and signed by the parties and shall be registered on the Patent register at ARIPO. The Act also prohibits a number of terms in licensing contracts, which in effect would amount to unfair contract terms.

The Act provides for compulsory licensing for 'nonworking' patents, for interdependence of patents in relation to 'nonworking' patents and for products and processes of vital importance (i.e. public health, defence and the economy) *(17)*.

Utility certificates. Utility certificates protect minor inventions under the Act. Novelty and industrial applicability form the grounds for utility protection. The term of protection is seven years with no possibility of renewal. Utility certificates are recorded in a separate register at the Patent Office. This kind of intellectual property protection might be appropriate for some medical devices for low-resource settings.

Design protection. The Act incorporates the United Kingdom Designs (Protection) Act and extends the Act to Tanzania. In essence, a Certificate of Registration of design protection in the United Kingdom would give the same protection in Tanzania. ARIPO offers design protection for all contracting states.

Trademarks. The Trademark and Services Act 1996 governs the acquiring trademarks in Tanzania. The International Classification *(18)* of marks forms the basis for registering goods and services. An applicant can claim priority for a trademark originating from a Nice Convention contracting state *(19)*. The requirements for registration (distinctiveness) are set out and matters prohibited from registration are also set out under the Act *(20)*. Once an application is received, an initial examination as to conformity and registrability is made *(21)*.

Once a trademark is examined and there are no such existing marks, the trademark is published in The Trade and Service Marks journals for 60 days in Tanzania. If there is no

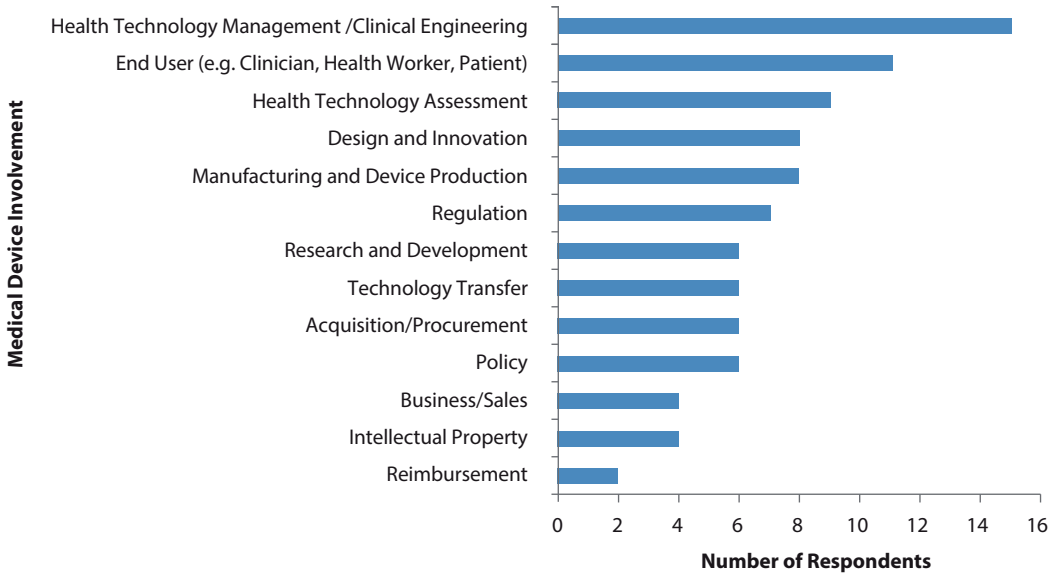
opposition, the patent can then be registered and fees paid. An initial period of registration is set out for seven years with an extension of 10 years subject to conditions for renewal set out in the Act *(22)*.

A licensing agreement for a trademark should be signed and the proprietor should ensure the quality of goods and services the mark would protect. The licensing agreement should also be entered into the trademarks register *(23)*. There is currently no verifiable data for medical device patents in Tanzania. There is an extensive legal framework for the protection of intellectual property, whether it is through ARIPO or the Patent Cooperation Treaty, at the international level.

7.7 Results of the 2013 phase II survey on access to medical devices: Tanzania

Of the 34 respondents to a question regarding involvement in medical devices, 15 reported involvement in health technology and clinical engineering, while 11 were end-users and nine were involved in health technology assessment (see Figure 27). There were no investors/donors among the respondents; however, multiple Tanzanian respondents reported involvement in numerous areas related to medical devices.

***Figure 27** Tanzanian respondents' involvement in medical devices*



n=34 respondents

Of the 14 respondents involved in medical device development at any stage, five were involved with commercialized products. The two most widely cited barriers to product development were limited financial resources for development (seven of eight respondents) and inadequate local facilities and tools (six of eight respondents).

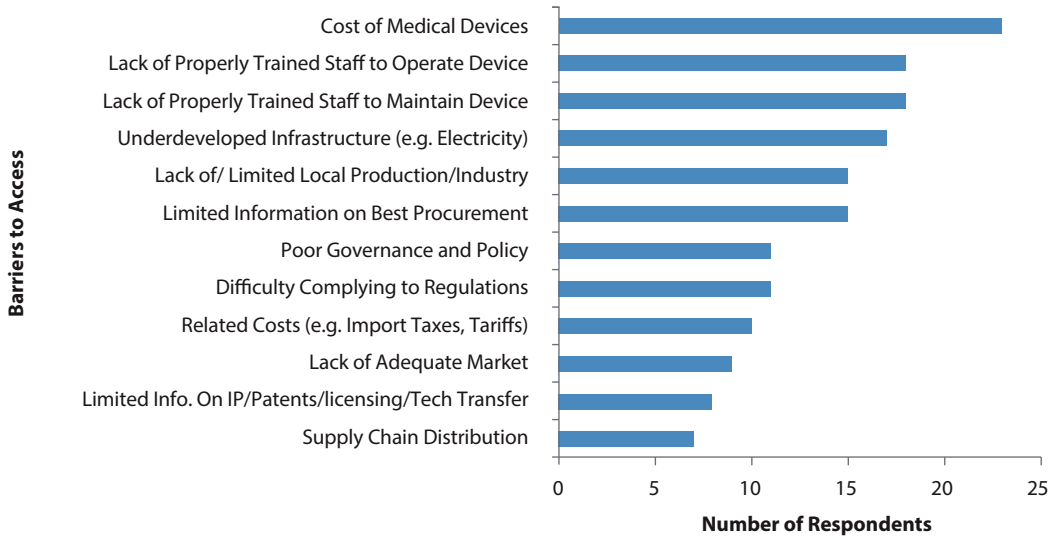
In response to a question regarding the use of consultants, respondents indicated they most frequently referred to clinicians (four of 10 respondents). None of the respondents consulted experts in manufacturing and product development, intellectual property, patients/patient groups, business development or reimbursement.

The most frequently cited barriers and obstacles that the eight respondents felt Tanzanian product developers faced were in **commercializing/selling** their medical device product due to the lack of seed funds (63%), limited local manufacturing capabilities (63%) and limited manufacturing infrastructure (63%).

Based on nine responses, 67% of respondents preferred using imported medical devices to local medical devices.

The greatest barriers to access to medical devices included cost of medical devices, lack of properly trained staff to maintain devices and lack of properly trained staff to operate devices (see Figure 28). Numerous respondents reported several barriers to access to medical devices.

***Figure 28** Tanzanian barriers to access to medical devices*



n=34 respondents

7.8 Application of feasibility tool to Tanzanian candidate devices

Administration of the feasibility tool. The feasibility tool was sent to the in-country consultant, Mr Godfrey Katabaro, who coordinated all aspects of administering the tool to local stakeholders in 2013. Mr Katabaro recruited 16 participants (the feasibility tool was administered later by others under instructions from Mr Katabaro). Some key features of the participant group were that nearly half of participants were engineers or technicians, one-quarter were clinicians, nearly half had education at the graduate or post-graduate level and more than half had positions that were based at a hospital. The expertise of the group was strongest (more than 75% of participants) in the areas of 'Medical device design and user analysis', 'Manufacturing and production', and 'Business development and market analysis'. Participant expertise was least strong (50% or fewer of participants) in the areas of 'Regulatory and standards evaluation' and 'Intellectual property and technology transfer'.

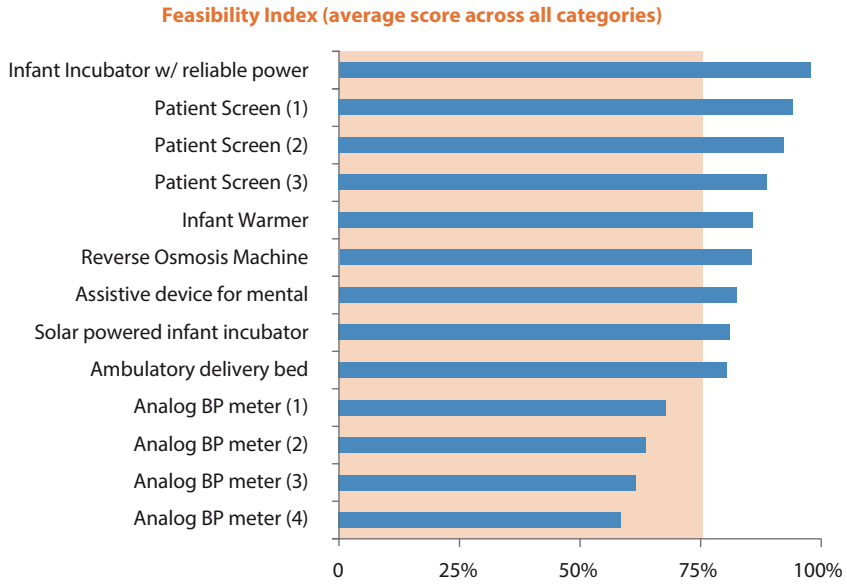
Candidate devices. Participants used the feasibility tool to select devices for evaluation. Some devices were selected based on factors including perceived need, initial assessment of production feasibility production, and prior interest in developing the device as a product. The full list of 13 submissions assessed eight different devices; some of the devices were

evaluated in two or more submissions. Of the 13 submissions, one person each evaluated 11 separate submissions, a group of two people evaluated one submission, and a group of three people evaluated one submission.

Feasibility Index and Response Rate scores. Across the set of submissions, the overall scores (Figure 29) for the Feasibility Index ranged from 59% to 98%, with an average score of 80%. Nine of the 13 submissions indicated a Feasibility Index greater than 80% and four submissions received a score of less than 75%. The average score for the Response Rate was 94% (range 74% to 100%), with only one submission scoring a Response Rate below 75%.

While the total score for a given submission can give an overall sense of feasibility, the ratings on each of the individual sections of the feasibility tool may provide further insights. The scores for the individual devices for each submission and each of the five sections are given in Figures 29.

Figure 29 Feasibility Index scores, average across all categories

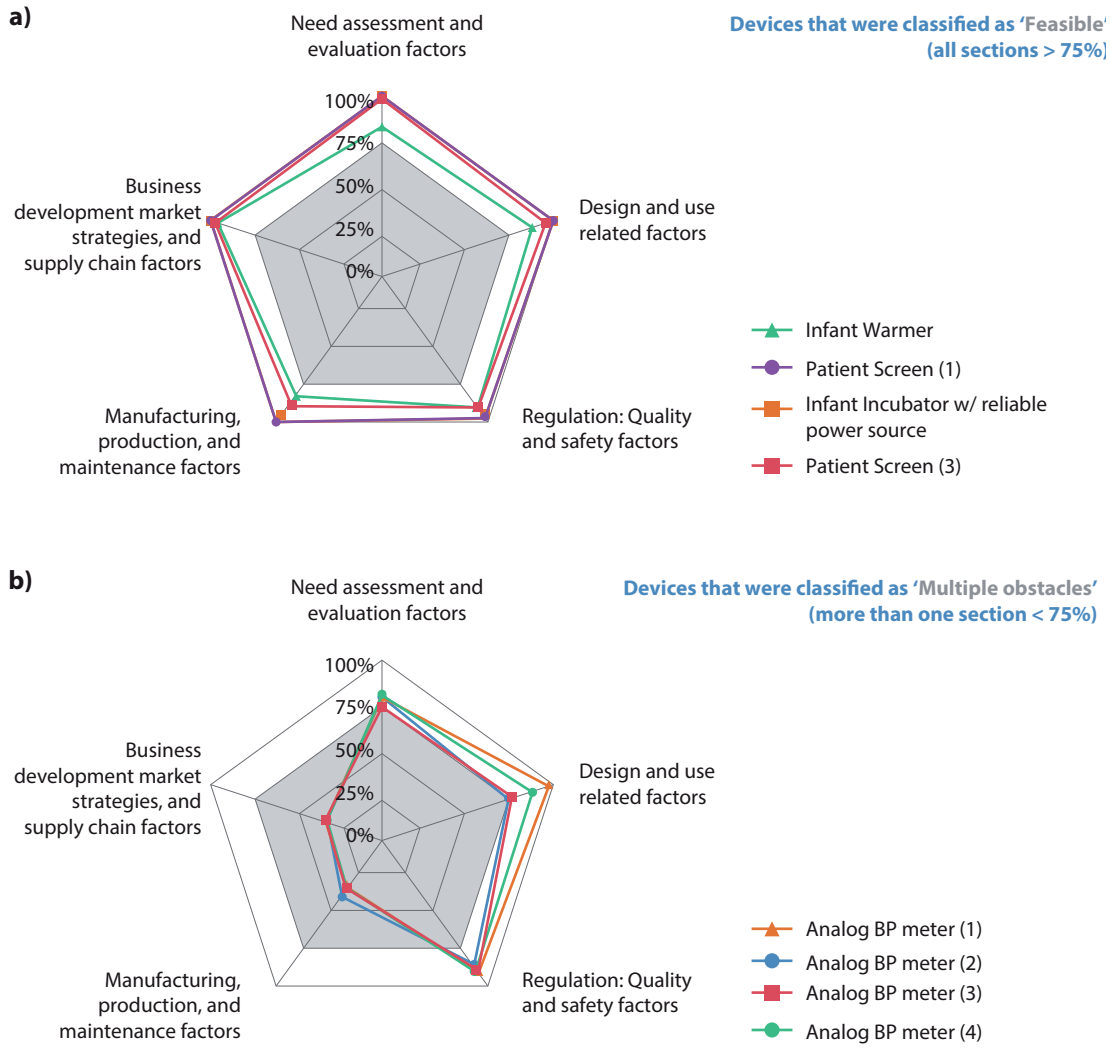


Note: Scores greater than 75% (outside of shaded area) were interpreted as 'feasible' when using the overall score. Numbers after the device name are used to indicate multiple instances of a device evaluation from this group.

Device classification and identification of obstacles. Of the 13 submissions, four were categorized as 'feasible' (Figure 30a), and four were categorized as having 'multiple obstacles' (Figure 30b). The four submissions that resulted in a 'feasible' classification included two submissions that assessed the feasibility of producing a patient screen; one for an infant warmer and one for an incubator. Of the five devices that were classified as having a 'single obstacle', four had low scores on 'Business development, market strategies and supply chain factors' and one had a low score on 'Design and use related factors'. Of the four submissions that were classified as having 'multiple obstacles', all assessed the feasibility of local production of an analog blood pressure monitor. Each of these submissions had low scores in the areas of 'Business development, market strategies and supply chain factors' and 'Manufacturing, production and maintenance factors', while one of the submissions also had a low score on 'Design and use related factors'.

Across the entire set of 13 submissions, more than half indicated 'Business development, market strategies and supply chain factors' as an obstacle to local production. The second most commonly cited obstacle was in the area of 'Manufacturing, production and maintenance factors', while the 'Needs assessment and evaluation factors' and 'Regulation' factors were not perceived as obstacles in any of the submissions.

Figure 30 Feasibility tool analysis by category



Note: Scores less than 75% (inside of shaded area) for a given category were interpreted as an 'obstacle' for that category.

Discussion of results. The feasibility tool submissions from this group of participants indicated a general sense of caution for local production in Tanzania. The devices that were classified as 'feasible' were all relatively simple to fabricate and most would not require regulatory approval. Given that one of the most commonly identified obstacles to local production was the set of 'Business development, market strategies and supply chain factors', this may indicate an opportunity for policy makers, investors and industrialists to institute changes that could have a broad impact on the capacity for supporting local production in Tanzania.

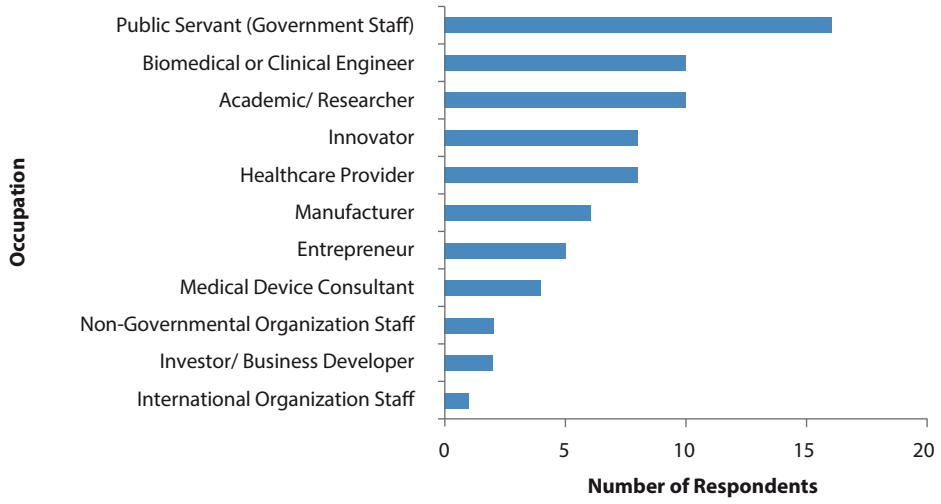
7.9 Workshop summary

Introduction. The LPTTMD Workshop in Tanzania was held at the New Africa Hotel in Dar es Salaam on 21–22 July 2014. Attendees included representatives from the MoHSW, several academic institutions and hospitals, the WHO country office and WHO headquarters. The list of participants and their affiliations is provided in Annex VI. Figure 31 illustrates the occupational distribution of the participants of the Tanzanian workshop.

The meeting was officially opened by Dr Donan Mmbando, Chief Medical Officer, Ministry of Health. Dr Mmbando emphasized the need to consider the evaluation, management and safe use phases of medical devices in addition to strengthening regulatory processes to ensure high quality medical products. Though Dr Mmbando noted that Tanzania faces immense challenges to locally produce medical devices, he also recognized the collaborative potential of bringing together stakeholders from different sectors, ranging from policy makers to academics and biomedical engineers, at the workshop. By bringing together various stakeholders, Dr Mmbando envisioned impactful work towards increasing access to medical devices and ultimately improving the quality of life, quality of health care provision and good health outcomes for the Tanzanian population.

Occupations of workshop attendees. Multiple workshop respondents reported working in more than one field related to medical devices.

Figure 31 Occupations of Tanzanian workshop attendees



n=34 respondents

LPTTMD workshop outcomes: needs, barriers and action plans. Action plans were developed in small group discussions and then a list of action items was established and consolidated in a full group discussion. Participants from the first session produced an action plan to increase access to medical devices (Table 9). Participants from the second session created a list of devices that addressed important needs and had local production potential (Table 10) while participants from the third session developed a roadmap for creating an environment that could be conducive to local production (Table 11).

The action plan for increasing access to medical devices strongly emphasizes improved utilization of key strategies for health technology management, from identifying needs through equipment decommissioning. Other key items identified in the action plan were

enhancing human workforce capacity for all aspects of health technology development, management and use.

Workshop attendees identified and discussed a number of devices that could be suitable for local production and identified key obstacles that must be overcome to achieve this goal. The group formed a consensus that the most productive strategy would be to first pursue developing devices that would be very simple to manufacture. These devices could include hospital furniture items or infrastructure as well as mechanical tools or assistive devices. This strategy would allow the medical device industry to overcome some of the primary hurdles to local production. As the industry matures, local entrepreneurs could gradually introduce items that would require more sophisticated manufacturing, testing and market strategies to be competitive with imported products.

The roadmap for creating a strong environment for local production emphasized creating opportunities and improving communication. Ideas for new opportunities included creating programmes to provide direct financial support to entrepreneurs, policies to provide financial incentives and policies to facilitate business creation. Ideas for improved communication included creating a forum for continued interaction across sectors and programmes to raise awareness amongst the general public about locally produced devices and amongst entrepreneurs about government programmes that support business creation and growth.

***Table 9** Recommended actions to increase access to medical devices*

WHAT	WHO	WHEN
1. Develop an essential list of medical devices for each level of health care facility	MoHSW with health facilities	1 year
2. Provide training to users and technical personnel at the regional level to ensure proper use of medical equipment	MoHSW	2 years
3. Plan preventive maintenance at different levels, train local personnel to improve knowledge of how to make medical devices available, review medical devices status	MoHSW, manufacturers, hospitals	3 months to strengthen
4. Review and update health technology policies	MoHSW and stakeholders	June 2015
5. Develop an integrated budget for medical equipment management (include maintenance, training, new procurement costs, etc.)	MoHSW, donors and other stakeholders	June 2015
6. Develop a knowledge base of devices to enable informed procurement	MoHSW, biomedical engineers	Ongoing
7. Provide knowledge of how to use new or donated equipment during installation	MoHSW, biomedical engineers, users, distributors	Ongoing
8. Establish procurement and management units that include biomedical engineers and users to aid in procurement, installation, maintenance, and upkeep of service manuals	MoHSW policy	Next budget
9. Develop a budget and procedures for maintenance and repair	MoHSW, healthcare facilities, biomedical engineers and users	June 2015

WHAT	WHO	WHEN
10. Establish policies to improve the number and quality of trained personnel	MoHSW, academia, institutions with biomedical engineers	To be reviewed in 2015
11. Finalize and disseminate guideline for reporting adverse events with medical devices	TFDA	2015

Table 10 Priority medical devices for local production

WHAT
Medical devices
Infant incubator for premature babies
Infant warmer
Phototherapy device
Assistive devices
Wheelchair
Walking crutches
Hospital equipment/infrastructure
Incinerator
Steam or UV sterilizer
Dry heat sterilizer
Hospital/clinic furniture
Hospital bed
Delivery bed
Operating table
Drip stand
Bed side lockers
Medication trolley
Patient screen
Soap dispensers
Other
Mosquito landing

Table 11 Recommendations to create an enabling environment for local production

WHAT	WHO?
1. Expand existing funding opportunities for research and development (e.g. The Commission for Science and Technology (COSTEC), Grand Challenges Canada, Bill & Melinda Gates Foundation˝)	Academics and innovators
2. Raise awareness of local production and technology transfer opportunities by organizing other workshops and meetings with more stakeholders (e.g. other ministries, trade, industry, Small Industries Development Organization, professional organizations)	MoH, with WHO support
3. Integrate efforts for local medical device production with efforts to locally produce pharmaceuticals	WHO, MoH, TFDA
4. Encourage Tanzania Investment Centre (TIC) to promote investment in local medical device production	MoH, TFDA
5. Develop a clear roadmap and guidelines to assist entrepreneurs in translating an idea to a marketed device in Tanzania	MoH, WHO, TFDA, COSTEC
6. Develop policies to support local production of medical devices (regulations, registration, tariffs, taxes, etc.)	MoH
7. Establish a local forum to continue information sharing	MoH
8. Raise awareness amongst the population about local production efforts and opportunities through news and television	MoH
9. Invest in research and development	Research institutions, academia, MoH, COSTEC
10. Increase financial support to local companies/idea innovators. (e.g. tax reduction, incentives, COSTEC, additional funds from other donors similar to Gulf Cooperation Council)	MoH, research institutes
11. Develop certification policies for locally produced products and strategies to promote the product (e.g. at local fairs and international trade fairs or events organized by MoH or other institutes)	MoH, research institutes
12. Develop guidance documents to assist innovators in the product development process	TFDA, MoH, research institutes

Summary and conclusions. The workshop provided an active forum for discussion among participants from a variety of sectors. A number of ideas were put forth, each of which could play an important role in improving the capacity for local production of medical devices. Across all sectors, participants had great interest and enthusiasm in local production, and identified significant barriers to be addressed. The roadmap provides a way forward for various actors to contribute towards successful efforts to locally produce medical devices. Key recommendations focused on creating new programmes to support business creation and growth, and developing programmes that would promote communication across government agencies, academia and industry.

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8. Conclusions and the way forward

This report aims to find strategies that improve access to selected medical devices through better policies, increased awareness, needs assessment, stakeholders participation and facilitation of local production of basic health technologies where and when possible. This report utilizes the findings from phase I with respect to the barriers and challenges to access and applies the feasibility tool results to enable the strategic selection of a device of high public health importance that could potentially be produced locally. Phase II specifically focused on devices needed to both decrease child and maternal mortality and address other primary health care needs within sub-Saharan Africa.

A detailed analysis of medical devices policies from four selected countries in Africa (Ethiopia, Nigeria, South Africa and Tanzania) was done to identify opportunities for the development of local medical devices. The country survey on access to medical devices used in phase I, was applied to local stakeholders to obtain specific local information on barriers and challenges to access including aspects surrounding regulation, taxation, tariffs, technical specification as well as lists of approved medical devices for reimbursement and procurement and finally installation, maintenance and users training issues. The survey and workshops demonstrated limited local manufacturing capacity and design mechanisms to incentivize manufacturers to engage in the production of priority medical devices. There was also lack of funds for research and development and support to bring products into the market and to final users that could be of high public health value.

In-country workshops were very helpful in discussing findings from the local survey and the feasibility tool results. The workshops were also helpful in creating an action plan along with government institutions, health sector providers, academia and industry applied to the different devices being developed locally as a public health priority.

The following specific activities are described in this report.

1. Undertaking an analysis of the Interagency List of Essential Medical Devices for Reproductive, Maternal and New Born Care, along with the list of the United Nations Commission of Life Saving Commodities with the aim to identify those medical devices products which still lack access but can be promising from the point of view of their local production in low- and middle-income countries.
2. Applying the phase I survey on access to medical devices for stakeholders in the four identified countries to allow better knowledge of specific local barriers and challenges.
3. Applying the feasibility tool developed during phase I to further identify and select the products that could be manufactured locally.
4. Determining the devices to be produced and searching for potential producers with information gained from the feasibility tool and the survey,.
5. Identifying products based on the following criteria.
   a. Is it related to the United Nations Commission on Life Saving Commodities?
   b. Is it one of the priority medical devices?
   c. Does it have a relatively simple manufacturing process?
   d. Is it compliant with technical and quality specifications?
   e. Does it have a high potential for local procurement, uptake and safe use?

6. Conducting discussions and technical support activities in medical devices manufacturing, regulations, selection, management and safe use. These will involve policy makers, regulators, academia, local manufacturers, local distributors, biomedical engineers, clinical engineers and other concerned stakeholders in local national workshops held in participating countries.

Target groups primarily included local manufacturers and staff in health technology or biomedical engineering units in the ministries of health and national regulatory authorities. This report would be of interest to policy makers, manufacturers, importers, distributors, academics, donors, NGOs and other stakeholders associated with local production or increasing access to appropriate medical devices in low- and middle-income countries.

Way forward

The phase II study on local production and technology transfer to increase access to medical devices focusing on Ethiopia, Nigeria, South Africa and Tanzania, expanded the knowledge base of the medical devices sector in these four countries. Results from this study can help other countries to analyse their progress in increasing access to medical devices. Moreover, the lessons and action plans from these four countries can be utilized by similar economies.

From the results of the survey and workshops, the following issues need to be addressed and advanced by WHO to provide concrete guidance to low- and middle-income countries.

Regulatory frameworks for medical devices. All countries had started to regulate medical devices, though to a very limited extent. In three of the four countries, regulation activities resulted in registration of very few devices indicating that much more is needed in this sector. Of the four countries reviewed, Tanzania advanced vigorously on regulation of medical devices while the other three countries were making steady progress. Regulatory agencies included biomedical engineering staff in Ethiopia and Tanzania, but none yet had been established in Nigeria or South Africa.

Most of the low- and middle-income countries lack a regulatory process for medical devices. Because of this, even if products were locally manufactured, they neither complied with any local approval nor marketed with the approval that these were safe and of good quality.

Thus, WHO is requested to provide more guidance on the regulation of medical devices, the process, the reliance, approach to a model regulatory framework as well as the human resources and competencies required.

Biomedical engineering or similar staff in government and procurement. The selection and procurement process of medical devices is critical to guarantee that the devices purchased are of good quality and affordable, and ensure that these are delivered to the healthcare facilities where they are needed. Healthcare facilities must also be able to maintain them in good operating condition, train the users on safe use and decommission appropriately.

These aspects were developed in the four countries in the past 10 years. Biomedical engineers and other technical staff were now in central offices in the ministries of health, central medical stores, procurement agencies and maintenance units. The ministries of health, professional local organizations and funding agencies requested further development, recognition, training and support for the staff. In addition, there was a high need for technical specifications for procurement for all case study countries. Ethiopia however had a very robust process and system that included biomedical engineering expertise among procurement officials.

Country case study results showed that all four countries had a biomedical engineer focal point person either within the ministry or department of health, or in a government institution dealing with medical equipment or health technology management.

It is important that biomedical engineers are appropriately trained and knowledgeable not only in matters related to technical specifications and performance, but on how to evaluate products and manufacturers to be in compliance with regulatory standards and processes (e.g. manufacture, process, marketing, post-market surveillance).

While there was no local industry for medical devices in Nigeria and Ethiopia, the opportunities to jumpstart the industry were available. Tanzania had very limited production while South Africa developed and exported medical devices. South African medical devices were mostly consumed beyond the local market, which means that opportunities to increase local consumptioncould be a priority.

Medical devices manufacturers lacked access to international standards that could guide them in the development of local products of good quality and governments were starting to incentivize local manufacturing of health products that were most needed in the provision of basic health services in all four countries.

The role of the government is very important in ensuring support for local production, but equally important is the role of academia to train biomedical engineers and other professionals capable of translating local needs into action and finding appropriate local solutions based on international best practices. The government should also make the regulatory requirements and framework both easily accessible and clear to manufacturers, importers and distributors.

Phase II lasted for two years, from inception and planning to finalization. During this time, several meetings and local workshops were conducted. Results indicated the need to develop solutions to: foster local production of high quality products, where and when possible; appropriately regulate, select and procure devices; distribute to healthcare facilities; and use all medical devices safely and effectively. All stakeholders were required to pursue these tasks together. The participants acknowledged that it would take years until best practices are realized. However, inviting all stakeholders from each focus country to meet together in the same workshops in 2014 was seen as a positive exercise. This helped them to become aware of their country's situation, and know who were responsible for regulating, selecting and producing medical devices. This knowledge is a first step to ensuring that the process from inception to planning can move more efficiently and effectively so that appropriate medical devices can be placed in every setting as needed. This in turn would provide better healthcare to the local population with locally produced, high quality, affordable and appropriate medical devices to respond to population needs.

While there is still a long way to go, the recognition that medical devices are necessary for health care delivery and that regulation, assessment and management, including logistics delivery and on-site training are indispensable processes, to have better access to the appropriate medical devices is a step forward.

After the project ends the actions plans will be followed up by WHO and the Member States to ensure that the work continues. Even if it seems complicated it is necessary that the United Nations, governments, manufacturers, healthcare professionals, funding agencies and civil society work together in collaboration to increase the well-being of the population, specially where resources are scarce and healthcare technology needs are high.

WHO encourages every stakeholder to find innovative ways to increase access of these technologies, and increase funds for research and development of appropriate affordable health technologies, so that diagnostics are done early, treatment is appropriate and the monitoring of patients is conducted in a better way. There is a shortage of specialized human resources for health in low- and middle-income countries for which WHO proposes to have appropriate technologies to empower these health workers, especially in primary healthcare settings. Therefore, all stakeholders could together join in to design smart, clean, safe, appropriate, acceptable, accessible health technologies to ensure a better and healthier life.

This project has ended but more work needs to done in these four countries and others by using information from this study and expanding and adapting, locally as needed.

Annex I: 2013 survey on development of appropriate, affordable, quality medical devices for low-resource settings questionnaire and survey respondents

The Survey may be accessed at https://extranet.who.int/datacol/survey.asp?survey_id=2448.

Survey Questionnaire

World Health Organization

Powered by WHO Extranet DataCol

2013 Survey on Development of Appropriate, Affordable, Quality Medical Devices for Low-Resource Settings

This survey is intended to inform a World Health Organization (WHO) report on local production and technology transfer to increase access to medical devices in low-resource settings. It will consolidate information from various stakeholders on the current situation of access to medical devices in low-resources settings, with a particular focus at the global level on research and development, innovative technologies and local production. The information garnered as a result of previous WHO surveys, WHO publications, expert consultation, literature reviews, and this specific survey will lead to a series of recommendations to improve access to quality medical devices that respond to population needs.

This is the second survey of its type. The results of the 2012 survey are published in Local Production and Technology Transfer to Increase Access to Medical Devices.

The survey includes numerous sections on different topics and it is not expected that everyone will need to answer every question. The survey is written in a way to guide you to questions relevant to your area of expertise and we estimate it would take approximately 30 to 60 minutes to complete. All information you provide here is strictly confidential and will be used for statistical and evaluation purposes. However, comments you provide may be reproduced with your permission only.

The survey consists of the following sections:
1. Personal Information (mandatory)
2. Introduction
3. WHO Innovation Projects
4. Product Development
5. Policy and Partnerships
6. Intellectual Property (IP)
7. Regulation
8. Academia
9. Technology Transfer
10. Acquisition/Procurement/Reimbursement
12. Biomedical/Clinical Engineering
13. Investor/Donor/NGO
14. Industry
15. End Users
16. General

We are extremely grateful for the time you take to answer the questions and provide us with valuable feedback garnered from your experience so that WHO can better serve the global health needs of its Member States. Please submit your completed survey no later than **31 July 2013**. Note: those submitting responses may be chosen to attend a capacity building workshop organized by WHO focusing on regulations, assessment, management and production of medical devices.

Note 1: Medical devices include single-use devices, assistive devices, implantables, surgical instruments, medical equipment, and eHealth solutions.

Note 2: Low-resource settings include low-income countries or any place/area/region where resources are limited or scarce. This includes limited or inability to access potable water, stable electricity, specialized health care professionals, and/or technical support.

Note 3: Local production is defined for the purposes of this survey as "domestic production of medical devices by international or national industries to solve a local public health need".

Instructions: Questions marked with * are mandatory. You may save your answers and continue completion of the survey at any time. To do so please click on the 'save partially completed form' button at the end of the survey; to continue completion, log on again. **When you have completed the survey, please click on the 'Submit the form' button at the end of the survey!** If you have any questions or need further assistance please contact Jimmy Abbas at abbasj@who.int or Jennifer Barragan at barraganj@who.int.

1) PERSONAL INFORMATION

1.1) First name (Given name): *

1.2) Last name (Family name): *

1.3) Profession: *

1.4) If other, please specify your profession.

1.5) Title or Rank: *

1.6) Organization: *

1.7) Country: *

1.8) Email address: *

The e-mail format is "xxxx@yyyy.zzz"

1.9) Website:

http://

The URL format is "http://xxxxx".

1.10) Do you grant WHO permission to publicly reproduce your comments? *

- ○ Yes
- ○ No

1.11) Have you worked on projects or as a consultant in Sub-Saharan Africa? *

- ○ Yes
- ○ No

2) INTRODUCTION

2.1) In what way are you involved with medical devices? Check all that apply. *

- ☐ Research and development
- ☐ Design and innovation
- ☐ Intellectual property
- ☐ Technology transfer
- ☐ Manufacturing and device production
- ☐ Policy
- ☐ Health technology assessment
- ☐ Regulation
- ☐ Acquisition/procurement
- ☐ Business/sales
- ☐ Reimbursement
- ☐ Health technology management/clinical engineering
- ☐ End User (e.g. clinician, health care worker, patient)

- [ ] Investor/donor

2.2) In which sector(s) are you working in or have primarily worked in? Check all that apply. *

- [ ] Government
- [ ] Academia
- [ ] Medical device industry
- [ ] Public health care provision/health care sector
- [ ] Private health care provision/health care sector
- [ ] International non-governmental organization (INGO)
- [ ] Local non-governmental organization (NGO)
- [ ] Intergovernmental organization (e.g. UN agencies)
- [ ] Law (Intellectual property, legal policy, etc.)
- [ ] Investment/business

2.3) Which of the following describes you the best (you may check multiple options or leave blank if no description is suitable):

- [ ] Innovator
- [ ] Entrepreneur
- [ ] Academic/researcher
- [ ] Investor/business developer
- [ ] Manufacturer
- [ ] Public servant (government staff)
- [ ] Non-governmental organization staff
- [ ] International organization staff
- [ ] Healthcare provider
- [ ] Biomedical (or clinical) engineer
- [ ] Medical device consultant
- [ ] Lawyer

3) WHO INNOVATION PROJECTS

The WHO Call for Innovative Technologies (2010), the *Compendium of new and emerging health technologies* (2011), and *Medical devices and eHealth solutions* (2012) [collectively referred to as WHO Innovative Technology Projects] were initiated and developed by WHO to encourage the dialogue between stakeholders and stimulate further development and technology dissemination. They serve as a neutral platform to introduce health technologies that have the potential to improve current health outcomes or to offer a solution to an unmet medical need in under-resourced regions and countries.

In 2012, WHO also released a report on *Local Production and Technology Transfer to Improve Access to Medical Devices* with the aim to analyse the main challenges and barriers to local production of and access to medical devices, and provide a set of recommendations to overcome those barriers.

For more information please see:
WHO Call for Innovative Technologies 2010
Compendium of new and emerging health technologies

Medical devices and eHealth solutions
Local Production and Technology Transfer to Improve Access to Medical Devices

3.1) Are you aware of any of the WHO Innovative Technology Projects or the Local Production Report? *

- ○ Yes
- ○ No, proceed to 4. PRODUCT DEVELOPMENT

3.2) Do you have a product(s) that was/were published in one of the following? Check all that apply.

- ☐ WHO Call for Innovative Technologies that Address Global Health Concerns 2010
- ☐ Compendium of new and emerging health technologies 2011
- ☐ Medical devices and eHealth solutions, Compendium of innovative health technologies for low-resource settings 2012
- ☐ Local Production and Technology Transfer to Improve Access to Medical Devices
- ☐ No, proceed to Question 3.7

3.3) Based on existing evidence, did involvement in the WHO Innovative Technology Projects have an impact on your product(s) in terms of (check all that apply):

- ☐ New investment
- ☐ Entrance into new markets
- ☐ Commercialization of the product
- ☐ Increased sales
- ☐ Increased use of the product in the field
- ☐ Increased partnerships/collaborations
- ☐ Design improvements
- ☐ Government/Ministries of Health interest

3.4) One of the main objectives of the WHO Innovative Technology Projects is to encourage dialogue between ministries of health, procurement officers, donors, technology developers, manufacturers, clinicians, academics and general public. Do you think this has been achieved?

- ○ Yes
- ○ No

3.5) Please explain why or why not. (max 50 words)

3.6) What were the positive and/or negative aspects of the WHO Innovative Technology Projects? (max 300 words)

3.7) Where did you first hear or find out about the WHO Innovative Technology Projects?

- ○ Searching or browsing the internet
- ○ In a print or online publication
- ○ At a conference or official meeting

- ○ Via notification from a colleague or friend
- ○ Via email invitation
- ○ Other

3.8) If other, please specify. (max 50 words)

3.9) Where would you recommend the WHO promote its next WHO Innovative Technology Project? Please list. (max 50 words)

4) PRODUCT DEVELOPMENT

4.1) Have you been involved with development of a medical device(s) for low-resource settings that is (are): (check all that apply)

- ☐ Never left concept/prototype stage
- ☐ Under development
- ☐ In clinical trials (or clinical validation)
- ☐ Underwent clinical trial, not commercialized
- ☐ Commercialized
- ☐ Not involved in development, proceed to Question 4.31

4.2) If the device did not leave concept/prototype or the clinical trial stage, please explain why. (max 100 words)

4.3) What method(s) have you used to identify and validate the need for the product(s) and appropriateness to the target market? Check all that apply.

- ☐ Personal observation of the need, knowledge of the target market
- ☐ Literature search
- ☐ Interview and/or focus group with the potential end users and stakeholders
- ☐ Interview and/or focus group with those with prior knowledge of the target market
- ☐ Clinical study or investigation
- ☐ Input from partner team or collaborator in target market
- ☐ Other

4.4) Please expand upon your choice. (max 100 words)

4.5) What barriers/obstacles have you faced thus far in DEVELOPING your product(s)? Check all that apply.

- [ ] Limited information on what already exists (e.g. existing devices, issued patents)
- [ ] Limited information on the health care issue that is going to be addressed
- [ ] Lack of technical engineering expertise
- [ ] Lack of technical medical expertise
- [ ] Inadequate local facilities and tools
- [ ] Limited financial resources for development
- [ ] Insufficient market information
- [ ] Lack of financial incentive/market appeal/or potential for return on investment
- [ ] Limited ability to obtain necessary partnerships (e.g. for clinical validation)
- [ ] Limited information on regulatory needs and approval process
- [ ] Inability to meet regulatory requirements or standards
- [ ] Other

4.6) If other, please list those barriers/obstacles. (max 50 words)

4.7) Did your firm/organization collaborate with any of the following, during the development of your product(s)? Check all that apply.

- [ ] Public institution (e.g. governmental agencies, ministries of health)
- [ ] Private institution
- [ ] Academic institution
- [ ] Medical device industry
- [ ] Non-governmental organization (NGO)
- [ ] Intergovernmental agency (e.g. UN agencies)
- [ ] Foundation
- [ ] Other
- [ ] None

4.8) If other, please list the type of organization(s). (max 50 words)

4.9) What other stakeholders have you involved (or consulted) in the development process? Check all that apply.

- [ ] Investors
- [ ] Business development experts
- [ ] Intellectual property experts
- [ ] Manufacturing and product development experts
- [ ] Regulatory experts
- [ ] Reimbursement experts
- [ ] Buyer (e.g. government agency, hospital, etc.)
- [ ] Frontline health providers (e.g. community health workers)

- [ ] Clinicians
- [ ] Patients/patient groups
- [ ] Biomedical (or clinical) engineers
- [ ] Other engineers
- [ ] Other

4.10) If other, please list those stakeholders. (max 50 words)

4.11) Was it difficult to measure the effectiveness of your device(s) in low-resource settings (e.g. perform clinical trials, gather evidence)?

- ○ Yes
- ○ No
- ○ Product did not reach this stage, proceed to Question 4.13

4.12) Please explain why or why not, and please explain how effectiveness was measured, financially supported, and evaluated. (max 300 words)

4.13) Have you considered the role of Intellectual Property (IP) rights during your research/design or target market identification?

- ○ Yes
- ○ No

4.14) Please explain why or why not. (max 300 words)

4.15) Have you ever transferred the intellectual property rights of your innovative technology to any industry or organization for implementation in low-resource areas?

- ○ Yes
- ○ No

4.16) Please explain why or why not. And if yes, please explain how the technology was transferred and to whom. (max 300 words)

4.17) What barriers and obstacles have you faced thus far in COMMERCIALIZING/SELLING your medical device product(s)? Check all that apply.

- [ ] IP issues (e.g. filing patents or trademarks)
- [ ] Licensing
- [ ] Lack of seed funds (financing)

- [ ] Lack of business expertise
- [ ] Unknown market size
- [ ] Regulatory clearance (device did not meet quality standards)
- [ ] Limited manufacturing infrastructure
- [ ] Limited local manufacturing capabilities
- [ ] Product not appropriate to the intended setting
- [ ] Product not affordable for intended users
- [ ] Product not listed for public procurement
- [ ] Product does not meet technical specifications for public procurement
- [ ] Unaffordable tariffs and taxes
- [ ] Limited supply chain
- [ ] Other

4.18) Please explain how and why these were barriers/obstacles. (max 300 words)

4.19) Has/Have your product(s) reached the intended user?

- ○ Yes
- ○ No

4.20) If not, please elaborate on reasons that you believe hinder/prevent your device(s) from reaching the intended user? (max 100 words)

4.21) Has/Have your product(s) been approved for sale (i.e. passed regulatory requirements of the country of origin, target countries, or organization)?

- ○ Yes, proceed to Question 4.24
- ○ No

4.22) Which of the following, if any, do you believe prevented sale of your product(s) into your desired target market? Check all that apply.

- [ ] Not yet approved in suppliers catalog
- [ ] Price
- [ ] Preference for international brand name devices
- [ ] Significant competition by alternative solutions
- [ ] Similar product(s) are donated not sold
- [ ] End users preferred products they were familiar with or were simpler to use
- [ ] Corruption

- [ ] Lack of technical experts for maintenance, repairs
- [ ] Lack of technical experts for user training
- [ ] Other
- [ ] No issues that prevented sale

4.23) Please expand upon the issues that prevented sale. (max 100 words)

4.24) In which countries has/have the product(s) been approved for sale? Check all that apply.

All countries
Afghanistan
Albania
Algeria
Andorra

To make multiple selections, press the "Ctrl key" and click on the items to choose.
Click to Select / unselect all

4.25) Is/Are your product(s) available for procurement through any of the following? Check all that apply.

- [ ] Authorized national distributors/agents
- [ ] International distributors
- [ ] UN agencies such as UNICEF, UNFPA, etc.
- [ ] Non-governmental organizations (NGOs)
- [ ] Donation
- [ ] Other

4.26) If other, please list. (max 50 words)

4.27) Is/Are your product(s) one of the following? Check all that apply.

- [ ] Locally manufactured. Sold only in local market.
- [ ] Locally manufactured. Sold in local market and exported to other countries.
- [ ] Partially manufactured or assembled locally
- [ ] Manufactured in different country than intended country

4.28) If product is locally manufactured and sold only in local market, have you considered manufacturing in other countries to increase sales?

- ○ Yes
- ○ No
- ○ Not applicable

4.29) Please explain why or why not. (max 300 words)

4.30) If product(s) is (are) manufactured in a different country than the intended target market, please expand upon barriers preventing local production. (max 300 words)

4.31) Do you have an idea for an appropriate and affordable medical device for use in low-resource settings that you have been UNABLE to develop? *

- ○ Yes
- ○ No, proceed to 5. POLICY AND PARTNERSHIPS

4.32) If yes, what kept you from developing it? Check all that apply.

- ☐ Limited information on what already exists (e.g. existing devices, issued patents)
- ☐ Limited information on the health care issue that is going to be addressed
- ☐ Lack of technical engineering expertise
- ☐ Lack of technical medical expertise
- ☐ Inadequate local facilities and tools
- ☐ Limited financial resources for development
- ☐ Insufficient market information
- ☐ Lack of financial incentive/market appeal/or potential for return on investment
- ☐ Limited ability to obtain necessary partnerships (e.g. for clinical validation)
- ☐ Limited information on regulatory needs and approval process
- ☐ Inability to meet regulatory requirements or standards
- ☐ Other

4.33) If other, please explain what kept you from developing the product. (max 50 words)

5) POLICY AND PARTNERSHIPS

5.1) Are there any policies/incentives to actively support the local development, local manufacturing, and/or technology transfer of medical devices in your country? *

- ○ Yes
- ○ No
- ○ Do not know

5.2) If yes, please provide details. (max 300 words)

5.3) Is there an approved list of medical devices for procurement and reimbursement in your country? *

- ○ Yes, both

- ○ Yes, procurement only
- ○ Yes, reimbursement only
- ○ No, proceed to Question 5.5
- ○ Do not know, proceed to Question 5.5

5.4) Are locally produced medical devices included in the list for procurement or reimbursement in your country?

- ○ Yes, both
- ○ Yes, procurement only
- ○ Yes, reimbursement only
- ○ No
- ○ Do not know

5.5) Are there any Centres of Excellence, Industry/Academia collaborations, Product Development Partnerships (PDP's) or other such collaborations focusing on medical device innovation and access that currently exist in your country? *

- ○ Yes
- ○ No, proceed to question 5.14
- ○ Do not know, proceed to 6. INTELLECTUAL PROPERTY

5.6) If yes, please provide details. (max 300 words)

5.7) Are you a member of any of these type of collaborations and how did you become involved?

- ○ Not part of a partnership or collaboration
- ○ Initiated the partnership/collaboration
- ○ Sought out involvement in the partnership/collaboration
- ○ Was contacted directly by members of the partnership/collaboration
- ○ Got involved incidentally during the process

5.8) What is the main driving force behind these partnerships? Check all that apply.

- ☐ Local public health needs and local demand
- ☐ Market demand and profit
- ☐ Other

5.9) If other, please specify. (max 300 words)

5.10) In what ways are/were these partnerships effective? Check all that apply.

- ☐ Facilitating early stage product development
- ☐ Facilitating clinical trial and validation

- [ ] Facilitating technology transfer
- [ ] Facilitating local manufacturing
- [ ] Creating a product market
- [ ] Facilitating distribution
- [ ] Improving access to medical devices
- [ ] Other

5.11) If other, please explain how they are effective. (max 300 words)

5.12) What, if anything, impedes the ability of such collaborations to increase access to medical devices? Check all that apply.

- [ ] Limited market demand
- [ ] Limited incentives
- [ ] Limited information on public health needs
- [ ] Limited political will
- [ ] Other

5.13) If other, please list any other limitations. (max 100 words)

5.14) What would encourage the creation of such partnerships? (max 300 words)

6) INTELLECTUAL PROPERTY (IP)

6.1) To what extent are you familiar with IP rights? *

- ○ Familiar
- ○ Not familiar, proceed to 7. REGULATION

6.2) Does your country offer PATENT PROTECTION?

- ○ Yes
- ○ No, proceed to Question 6.6

6.3) Are patent registries accessible electronically?

- ○ Yes

○ No

6.4) Is the information in the patent registries up to date?

○ Yes

○ No

6.5) If available, please provide linkto registry:

http://

The URL format is "http://xxxxx".

6.6) Does your country offer TRADEMARK PROTECTION?

○ Yes

○ No, proceed to Question 6.10

6.7) Are trademark registries accessible electronically?

○ Yes

○ No

6.8) Is the information in the trademark registries up to date?

○ Yes

○ No

6.9) If available, please provide linkto registry:

http://

The URL format is "http://xxxxx".

6.10) Does your country offer DESIGN PROTECTION?

○ Yes

○ No, proceed to Question 6.14

6.11) Are design registries accessible electronically?

○ Yes

○ No

6.12) Is the information in the design registries up to date?

○ Yes

○ No

6.13) If available, please provide linkto registry:

http://

The URL format is "http://xxxxx".

6.14) Do you or does your organization file globally for PATENT PROTECTION using the World Intellectual Property Organization (WIPO) Patent Cooperation Treaty (PCT)?

○ Yes

○ No

6.15) Do you or does your organization file for INTERNATIONAL TRADEMEARKS using the World Intellectual Property Organization (WIPO) Madrid System for Trademarks?

○ Yes

○ No

6.16) If you work in or with African countries, do you file for REGIONAL PATENTS through the African Regional Intellectual Property Organization (ARIPO) and/or the Organisation Africaine de la Propriété Intellectuelle (OAPI/AIP)?

- ○ Yes
- ○ No

6.17) If you work in or with African countries, do you file for REGIONAL TRADEMARKS through the African Regional Intellectual Property Organization (ARIPO) and/or the Organisation Africaine de la Propriété Intellectuelle (OAPI/AIP)??

- ○ Yes
- ○ No

6.18) If you work in or with African countries, do you file for DESIGN PROTECTION through the African Regional Intellectual Property Organization (ARIPO) and/or the Organisation Africaine de la Propriété Intellectuelle (OAPI/AIP)??

- ○ Yes
- ○ No

6.19) What effect do patents and licensing have on local manufacturing of medical devices?

- ○ Encourage local manufacturing
- ○ Discourage potential for local manufacturing
- ○ No effect

6.20) Please explain why you believe this is the case. (max 300 words)

6.21) What changes to the current IP system in your country (or desired sales market) could be made in order to encourage local innovation and manufacturing of medical devices? (max 300 words)

7) REGULATION

7.1) To what extent are you familiar with regulation of medical devices? *

- ○ Familiar
- ○ Not familiar, proceed to 8. ACADEMIA SECTION

7.2) Has the government/national regulatory authority (NRA) in your country (or desired target market) attempted any of the following? Check all that apply.

- ☐ Drafted and ratified regulations to control the import, distribution, and sale of medical devices
- ☐ Implemented medical device regulations
- ☐ Actively enforced industry compliance to medical device regulations
- ☐ None of the above, proceed to Question 7.10

7.3) Which activities are included in the regulation? Check all that apply.

- ☐ Product registration
- ☐ Risk classification or other medical device classification system
- ☐ Establishment registration (manufacturer, importer, distributor)
- ☐ Authorization for sale of medical devices
- ☐ Premarket evaluation of safety, effectiveness, & quality
- ☐ Site inspections (manufacturer, importer, distributor)
- ☐ Post-market surveillance
- ☐ Technovigilance including adverse event reporting
- ☐ None of the above
- ☐ Do not know

7.4) Are regulations applied equally to domestic manufacturers and foreign manufacturers?

- ○ Yes
- ○ No
- ○ Do not know

7.5) If no, what aspects of regulation differ? (max 300 words)

7.6) For product developers, did any of the following play a role in the selection of your target market?

- ☐ Existence of harmonized regulatory processes
- ☐ Simplicity and transparency of the regulatory process
- ☐ Lack of regulations
- ☐ Your knowledge of the local regulatory environment

7.7) Which of the following harmonization initiatives does the national government/NRA in your country (or desired target market) currently participate in? Check all that apply.

- ☐ Global Harmonization Task Force (GHTF)
- ☐ International Medical Device Regulators Forum (IMDRF)
- ☐ Asia Pacific Economic Cooperation (APEC)
- ☐ Association of Southeast Asian Nations (ASEAN)
- ☐ Asian Harmonization Working Party (AHWP)
- ☐ East African Community (EAC)
- ☐ Mercosur
- ☐ Latin American medical device regulators network
- ☐ Other
- ☐ None

☐ Do not know

7.8) If other, please list the harmonization initiative(s). (max 50 words)

7.9) What barriers/obstacles, if any, do regulations create for local development, manufacturing, distribution, sale (either by a domestic or foreign firm), and technology transfer of medical devices in your country (or desired sales market)? (max 300 words)

7.10) What changes to the current regulatory system could be made in order to encourage technology transfer and local manufacturing of medical devices? (max 300 words)

8) ACADEMIA

8.1) Are you involved in medical device research, design, and development at the university level? *

○ Yes

○ No, proceed to 9. TECHNOLOGY TRANSFER

8.2) Is there a biomedical engineering unit/department at your university?

○ Yes

○ No

8.3) At your institution, is there a focus on researching and/or developing medical devices that address global health priorities?

○ Yes

○ No

8.4) If yes, please provide details on the work being done. (max 300 words)

8.5) As a researcher/student/professordo you receive incentives (promotion, payment, recognition) for:

☐ Research and development

☐ Publishing papers

☐ Filing patents

☐ Technology commercialization

☐ Other

8.6) If other, please list. (max 50 words)

8.7) Does the government provide special funding for research & development of medical devices at your institution?

- ○ Yes
- ○ No

8.8) If yes, please provide additional information on the special funding. (max 300 words)

8.9) Do you pursue commercialization of your innovation?

- ○ Yes
- ○ No, proceed to Question 8.11

8.10) When do you begin to think about commercializing your innovation?

- ○ Before the design process starts
- ○ When it is clear the design shows potential
- ○ When design is complete
- ○ When design has been validated

8.11) What difficulties, if any, have you faced in bringing your innovation from the lab to use in the field? (max 300 words)

8.12) Does your institution have an IP and Tech transfer office that will help in the commercialization of your innovation?

- ○ Yes
- ○ No, proceed to 9. TECHNOLOGY TRANSFER

8.13) To what extent is this office involved in assisting inventors in obtaining IP rights and proceeding with technology transfer? Check all that apply.

- ☐ They only provide advice
- ☐ They will (non-financially) assist in obtaining IP rights
- ☐ They will fund patent applications
- ☐ They will negotiate the transfer of technology to an established company or organization
- ☐ Do not know

8.14) Does the institution you work for intend to obtain any IP (patents, utility models, and design or trademark) rights in relation to medical device inventions?

- ○ Yes
- ○ No
- ○ Do not know

8.15) Does your institution currently have (or have they filed in the past) for any IP rights in

relation to medical devices?

- ○ Yes
- ○ No
- ○ Do not know

8.16) Does your institution have a business incubator that facilitates technology transfer (e.g. establishing spin offs, negotiating with industry, etc.)

- ○ Yes
- ○ No
- ○ Do not know

8.17) Do you as an individual intend to obtain any IP (patents, utility models, and design or trademark) rights in relation to medical device inventions?

- ○ Yes
- ○ No

8.18) Do you currently have (or have you filed in the past) for any IP rights in relation to medical devices?

- ○ Yes
- ○ No

9) TECHNOLOGY TRANSFER

9.1) Do you have a background or experience in technology transfer of medical devices? *

- ○ Yes
- ○ No, proceed to 10. ACQUISITION/PROCUREMENT/REIMBURSEMENT

9.2) Are you aware of successful technology transfer leading to local production of a medical device(s) in low-resource settings?

- ○ Yes
- ○ No

9.3) If yes, please provide example(s). (max 300 words)

9.4) Are you aware of any investment funds available to facilitate potential technology transfer and manufacturing of appropriate or affordable medical devices?

- ○ Yes
- ○ No

9.5) If yes, please provide example(s). (max 300 words)

9.6) Are you aware of public-private partnerships to increase availability of medical devices in low-resource settings?

- ○ Yes
- ○ No

9.7) Are you aware of public-private partnerships to support technology transfer to further increase access to medical devices?

- ○ Yes
- ○ No

9.8) If yes to either 9.6 or 9.7, please provide example(s). (max 300 words)

10) ACQUISITION/PROCUREMENT/REIMBURSEMENT

10.1) How involved are you in procurement decisions? *

- ○ Make or assist in procurement decisions
- ○ Have a good working knowledge of the procurement process but not involved in decision-making, proceed to Question 10.8
- ○ No involvement, proceed to 12. BIOMEDICAL/CLINICAL ENGINEERING

10.2) At which level of authority do you make or assist in procurement decisions?

- ○ National
- ○ Regional (state)
- ○ Local (municipality/village)
- ○ Health facility
- ○ Non-governmental organization (NGO)
- ○ Other

10.3) If other, please list. (max 50 words)

10.4) If you are involved in reimbursement, at which level of authority do you make or assist in reimbursement decisions?

- ○ National
- ○ Regional (state)
- ○ Local (municipality/village)
- ○ Health facility
- ○ Non-governmental organization (NGO)
- ○ Other

10.5) If other, please list. (max 50 words)

10.6) How do you procure medical devices? Check all that apply.

- [ ] International tender
- [ ] National tender
- [ ] Donations
- [ ] Direct purchase from agent/supplier
- [ ] Other

10.7) If other, please list. (max 50 words)

10.8) Are you aware of any national policies in place for acquiring donated medical devices?

- ○ Yes
- ○ No

10.9) If yes, please attach policy if available.

Seleccionar archivo Ningún archivo seleccionado
File size is limited to 10MB.

10.10) Do you or your organization follow any policy for the donation of medical devices?

- ○ International policy
- ○ National policy
- ○ Both international and national
- ○ Other
- ○ None

10.11) If you use a donation policy, please provide the name and link to the policy if possible.

10.12) What are the most important criteria in your medical device procurement decisions? Check up to a maximum of 4 responses.

- [ ] Quality and safety
- [ ] Price
- [ ] Compliance with technical specifications required
- [ ] Cultural acceptability
- [ ] Innovation
- [ ] Product is locally manufactured
- [ ] Product is internationally manufactured
- [ ] Compliance with norms and standards
- [ ] Availability of local distributors

☐ Other

10.13) Please explain your choices and rank their relative importance. (max 100 words)

10.14) What factors prevent procurement of an innovative technology designed specifically with the developing world in mind? Check all that apply.

☐ Prefer proven products from well-known manufacturers

☐ Lack of information on these types of "innovative" products (e.g. safety, effectiveness, etc.)

☐ Not aware of what devices are available

☐ Inability to purchase (e.g. no agents in-country selling the product)

☐ National or local decision makers do not elect procurement of such devices

☐ The bidding process

☐ Lack of available technical specifications

☐ Lack of customer support (e.g. maintenance, spare parts, etc.)

☐ We procure innovative products whenever possible

☐ Other

10.15) If other, please list. (max 50 words)

11.16)
What percentage of devices that you procure are in the following categories?

	% (total should add up to 100)
Specifically designed for low-income settings:	
Not designed but significantly modified for low-income settings:	
Not designed or modified for low-income settings, but appropriate:	
Inappropriate for low-income settings, but no alternative:	

12) BIOMEDICAL/CLINICAL ENGINEERING (NATIONAL OR LOCAL LEVEL)

12.1) Are you a biomedical engineer, clinical engineer, or a biomedical technician? *

○ Yes

○ No, proceed to 13. INVESTOR/DONOR/NGO

12.2) What's your highest level of education?

○ Technician level (2 years post-secondary)

○ Bachelors level (4 years university/college degree)

○ Masters post-graduate degree (2 years after Bachelors)

- ○ PhD, post-graduate degree (4 or more years after Bachelors)

12.3) Where do you work?

- ○ National government
- ○ Regional (state) government
- ○ Local (municipality/village) government
- ○ Public health care facility
- ○ Private health care facility
- ○ Medical device industry
- ○ Academia
- ○ Other

12.4) If other, please explain. (max 50 words)

12.5) Are you aware of local innovations/products to solve local needs in rural and low resources settings? Check all that apply.

- ☐ Not aware
- ☐ Aware of products for hospitals
- ☐ Aware of products for rural health centers
- ☐ Aware of products for health post/community worker use
- ☐ Aware of home health/eHealth/telemedicine products

12.6) If yes, please provide example(s). (max 300 words)

12.7) Is there a catalog of national medical device or equipment suppliers?

- ○ Yes
- ○ No
- ○ Do not know

12.8) If yes, please provide more details on where the catalog can be obtained. (max 50 words)

12.9) Do you have technical specifications for medical devices?

- ○ Yes
- ○ No

12.10) If yes, are the specifications applicable for both locally produced and imported (or donated) devices? (max 300 words)

- ○ Yes
- ○ No
- ○ Do not know

12.11) If not applicable to both, please explain the difference. (max300 words)

12.12) Are you responsible for managing, maintaining and repairing equipment?

- ○ Yes
- ○ No, proceed to 13. INVESTOR/DONOR/NGO

12.13) What is the catchment population you are responsible for?

- ○ less than 10,000
- ○ between 10,000 and 50,000
- ○ between 50,000 and 150,000
- ○ between 150,000 and 500,000
- ○ between 500,000 and 1,000,000
- ○ greater than 1,000,000
- ○ Do not know

12.14) For which facilities are you responsible for the equipment management, maintenance and repair? Check all that apply.

- ☐ Health post/clinic
- ☐ Health center
- ☐ District/provincial hospital
- ☐ Regional hospital
- ☐ Specialized hospital

12.15) If known, please provide the number of each type of facility you are responsible for.

12.16) If known, please provide the number of other engineers or technicians working in the same capacity to cover the same area?

12.17) What percentage of equipment in your inventory would you estimate is currently not operational?

- ○ Less than 5%
- ○ 5-25%
- ○ 25-50%
- ○ 50-75%
- ○ Greater than 75%
- ○ Do not know

12.18) What percentage of equipment in your inventory would you estimate is donated?

- ○ Less than 5%
- ○ 5-25%

- ○ 25-50%
- ○ 50-75%
- ○ Greater than 75%
- ○ Do not know

12.19) What percentage of donated equipment in your inventory would you estimate is not operational?

- ○ Less than 5%
- ○ 5-25%
- ○ 25-50%
- ○ 50-75%
- ○ Greater than 75%
- ○ Do not know

12.20) How much of your inventory is manufactured nationally versus internationally?

- ○ Less than 5%
- ○ 5-25%
- ○ 25-50%
- ○ 50-75%
- ○ Greater than 75%
- ○ Do not know

12.21) On average, who provides better delivery, maintenance and training services?

- ○ Local manufacturers and service providers
- ○ International manufacturers and service providers
- ○ Same quality from both

12.22) Please explain your choice and provide examples. (max 300 words)

12.23) Are there any continuous training courses to further update the training of biomedical engineers, clinical engineers or biomedical technicians in your country?

- ○ Yes
- ○ No

12.24) If yes, please describe. (max 100 words)

13) INVESTOR/DONOR/NGO

13.1) Are you an investor, donor, or NGO providing financial resources to developing countries with regards to medical devices? *

- ○ Yes
- ○ No, proceed to 14. INDUSTRY

13.2) What do you typically provide financial resources for? Check all that apply.

- ☐ Product development
- ☐ Device production
- ☐ Clinical validation/trials
- ☐ Regulations compliance
- ☐ Marketing/distribution
- ☐ Procurement of medical devices
- ☐ Procurement of device related accessories and/or consumables
- ☐ Training on use of medical devices
- ☐ Training on maintenance of medical devices
- ☐ Maintenance of medical devices

13.3) What do you consider before providing financial resources for the DEVELOPMENT of innovative medical devices? Check all that apply.

- ☐ Need for the medical device
- ☐ Cost of developing the concept
- ☐ Cost of manufacturing the device
- ☐ Number of lives that could potentially benefit
- ☐ Ease of distribution and sale of the product
- ☐ Return on investment
- ☐ Do not provide financial resources for product development

13.4) What, if anything, makes you hesitant to provide financial resources for the DEVELOPMENT of innovative medical devices? Check all that apply.

- ☐ Cost of investment as compared to potential benefit
- ☐ Other public health priorities
- ☐ Other
- ☐ Not hesitant, I provide financial resources for innovation

13.5) If other, please specify. (max 50 words)

13.6) What do you consider before providing financial resources to an institution (government or NGO) to PROCURE medical devices? Check all that apply.

- ☐ That the medical device(s) is(are) needed
- ☐ That the medical device(s) is(are) appropriate to the setting
- ☐ That procurement comes with proper training
- ☐ That there are resources available to maintain the device (e.g. trained technicians, accessories,

consumables available)

- [ ] The recipient decides the best use of the financial resources
- [ ] Do not provide financial resources for procurement

13.7) What, if anything, makes you hesitant to provide financial resources for the PROCUREMENT of innovative medical devices? Check all that apply.

- [ ] Difficulty in ensuring that equipment will actually be used
- [ ] Likelihood of mismanagement, misuse, and/or short potential life span of device
- [ ] Other public health priorities
- [ ] Low likelihood of financial viability
- [ ] Other
- [ ] Not hesitant, I provide financial resources for procurement of innovative medical devices

13.8) If other, please specify. (max 50 words)

13.9) Do you invest in or provide resources to increase capacity for local production of medical devices?

- ○ Yes
- ○ No

13.10) If yes, please explain the initiatives you have invested in. (max 300 words)

13.11) What are the main barriers to investing or providing financial resources to develop local capacity for the production of medical devices? (max 300 words)

14) INDUSTRY

14.1) Do you work within or are you associated with the medical device industry? *

- ○ Yes
- ○ No, proceed to 15. END USERS

14.2) Is the company you work with (or are associated with) an:

- ○ International enterprise
- ○ Local enterprise

14.3) Are your devices available for sale, distribution, or donation on the:

- ○ Local market only (country of production is the target market)
- ○ International market only (country of production is different from target market)
- ○ Both of the above

14.4) Do products manufactured in the target market benefit from any tax exemption/reduction or other advantages compared to imported medical devices?

- ○ Yes
- ○ No
- ○ Do not know

14.5) If yes, please provide the details of such advantages. (max 300 words)

14.6) What are the main barriers, if any, in manufacturing medical devices locally?

- ☐ High overall cost and financing barriers
- ☐ Expensive startup cost
- ☐ Limited availability of required materials or parts
- ☐ Limited trained staff and/or necessary skills
- ☐ Limited legal/legislative support
- ☐ Lack of trust in products manufactured locally
- ☐ Bureaucratic procedures to setup local manufacturing
- ☐ International competition
- ☐ Other
- ☐ No barriers

14.7) Please explain your answer. (max300 words)

14.8) What are the main barriers to selling locally manufactured products? Check all that apply.

- ☐ Product price
- ☐ Product quality
- ☐ Warranty quality/length
- ☐ Foreign competition
- ☐ Public perception/trust
- ☐ Other

14.9) If other, please specify the barriers. (max 50 words)

14.10) Is there any national association or union for locally produced medical devices in your country?

- ○ Yes

- ○ No
- ○ Do not know

14.11) If yes, please provide contact details if possible. (max 50 words)

14.12) What kind of regulatory approval is needed for medical devices sold in the country (whether manufactured locally or imported)?

- ○ Local regulatory approval only
- ○ International regulatory approval only
- ○ Both local or international regulatory approval
- ○ Either local or international regulatory approval

14.13) Please list the names of institutions that regulatory approval can be obtained from. (max 300 words)

14.14) What conditions would stimulate the manufacture of your product(s) in a limited resource setting? (max 300 words)

15) END USERS

15.1) In what capacity are you a user of a medical device? *

- ○ Clinician
- ○ Community health worker
- ○ Patient
- ○ Other
- ○ I am not an end user, proceed to 16. GENERAL

15.2) If other, please explain. (max 50 words)

15.3) Do you have a preference for using local or imported medical devices?

- ○ Local
- ○ Imported
- ○ No preference

15.4) If there is a preference, please explain your choice. (max 300 words)

15.5) Do you trust that locally manufactured medical devices are safe to use?

- ○ Yes
- ○ No

15.6) Please explain why or why not. (max 300 words)

15.7) Do you trust that locally manufactured medical devices are effective?

- ○ Yes
- ○ No

15.8) Please explain why or why not. (max 300 words)

15.9) Do you receive training on operation and/or maintenance of:

- ○ Locally produced medical devices
- ○ Imported medical devices
- ○ Both
- ○ Neither

15.10) What are the major barriers to effectively and safely use a medical device as the end user? Check all that apply.

- ☐ Not knowing how to best use the device
- ☐ No training on best use
- ☐ No instructions in the local language
- ☐ No trust in using the device because of frequent failure
- ☐ Low quality device
- ☐ Very old equipment
- ☐ No consumables available
- ☐ No spare parts available for repair
- ☐ Other

15.11) If other, please explain. (max 100 words)

15.12) What would you propose to increase the uptake of medical technology locally? (max 300 words)

15.13) What would you propose to increase the uptake of medical technology on a national level? (max 300 words)

16) GENERAL

16.1) Which do you believe are the biggest barriers to access to medical devices in low-resource settings (choose up to 3)? *

- ☐ Poor governance and policy
- ☐ Difficulty in complying to regulations
- ☐ Limited information regarding what device to best procure for the setting
- ☐ Cost of medical devices
- ☐ Related costs (e.g. import taxes, tarifs, etc.)
- ☐ Supply chain distribution
- ☐ Lack of properly trained staff to operate device
- ☐ Lack of properly trained staff to maintain device
- ☐ Underdeveloped infrastructure (e.g. electricity)
- ☐ Lack of or limited local production/industry
- ☐ Limited information on IP, patents, licensing, and technology transfer
- ☐ Lack of adequate market
- ☐ Other

16.2) If other, please describe the barrier. (max 50 words)

16.3) In your experience, does local production of medical devices have a role to play in increasing access to medical devices?

- ○ Yes
- ○ No
- ○ Do not know

16.4) Please explain. (max 300 words)

16.5) Please enter any additional comments or suggestions you may have with regards to access to medical devices in limited resource settings, relevant barriers, or opportunities. You may also you use this space to provide any information to support your answers above. (max 300 words)

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Respondents

The 2013 Survey on development of appropriate, affordable, quality medical devices for low-resource settings was completed by:

Argentina: Mr Diego Kadur

Australia: Mr Michael Flood, Mr Bruce Morrison and Mr Meseret Teferra

Bangladesh: Dr Aminul Hasan and Dr K Siddique-e Rabbani

Belgium: Dr Jos Vander Sloten

Botswana: Ms Bonang Sylvia Tlhomelang

Brazil: Dr Saide Calil, Mr Jose Carlos Lapenna, Mr Joao Leandro, Mr Cleber Santos, Dr Alexandre Ferreli Souza, Mr Ryan Pinto Ferreira

Cameroon: Mr Vincent Ngaleu Toko

Canada: Dr Jan Andrysek, Dr Mark Ansermino, Ms Joanne Lim, Mr Barry Pask and Mr Howard Weinstein

China: Dr Li Tao and Ms Xuedan Yuan

Colombia: Ms Tatiana Molina

Comoros: Dr Said Ahamada

Costa Rica: Mr Mario Vega

Côte d'Ivoire: Mr Kouakou Kouame

Dominican Republic: Mr Diogenes Hernandez

Ethiopia: Mr Gebru Ayehubzu Alamrew, Mr Yewoinhared Bayeh, Mr Demeru Desta, Mr Habtamu Dobamo, Mr Dawit Elias, Dr Dawit Getahun, Mr Ashenafi Hussein, Mr Dawit Demeke Kassaye, Mr Gizeaddis Lamesgin, Mr Wondafrash Million, Ms Helen Mulugeta, Mekdes Seyoum and Mr Gizachew Anteneh Wolde

Gabon: Dr Ikechukwu Anosike

Gambia: Mr Andrew Demba

Germany: Mr Markus Kraemer, Dr Jens Waldmann and Mr John Zienaa

India: Mr Jai Ganesh, Mr Einstein Albert Kesi, Dr Niranjan Khambete, Mr Clint Geo Mathew, Dr Anantha Naik, Dr Vijayaraghavan Srinivasan and Mr Sashikumar Valiyaveetil

Japan: Mr Mitsuro Tokugawa

Jordan: Dr Anan Abu Hassan

Kenya: Ms Salome Mwaura

Kiribati: Dr André E Reiffer and Dr Patrick Timeon

Kygyzstan: Mrs Ainura Abalieva

Lao People's Democratic Republic: Mr Thanom Insal and Mr Laurent Mangenot

Malawi: Dr Elizabeth Molyneux

Malaysia: Dr Sivalal Sadasivan

Mexico: Ms Lorena Arriaga, Mr Roberto Ayala Perdomo, Ms Verónica Gallegos and Mr Luis Martinez

Namibia: Ms Belinda Wolbling

The Netherlands: Prof Henry Banta

Niger: Ms Mariama Sambo

Nigeria: Menyanga Abu, Ms Mary Aki, Ms Christine Arodiogbu, Dr Oluyombo Awojobi, Dr Adaeze Ayuk, Mr James Inuwa Balami, Mr Brendan Bright Nnaji, Mr Temitope Bombata, Ms Chinyere Chike-Ozobia, Mr Williams Eigege, Ms Joy Elugbe, Mr Bukola Emannuel Esan, Obehi Iyamah, Mr Yakubu James Sumi, Dr Nathaniel Jiyah Joseph, Mrs Oladunni Ladipo, Mr Julius Odion, Dr Olatunde Odusote, Ms Agatha Ifechidelu Ogwogwo, Dr Ngozi Ojinnaka, Dr Beauty Okologo, Mr Donald Onekutu, Mr Boniface Pius, Mr Gbolahan Sokunbi, Dr Ogori Taylor, Unyime Udofia and Ekong Umoh

Pakistan: Dr Arshad Altaf, Ms Tazeen Saeed Bukhari and Mr Ali Habib

Republic of Korea: Mr Jun Hwan Lee

Russian Federation: Dr Denis Sharikadze

Rwanda: Mr Didier Mukama

South Africa: Mr Howard Ball, Mr Mark Banfield, Dr Gbemisola Boyede, Mr Mark Brand, Dr Anthony Bunn, Mr Marion Burgess, Ms Mariette Conning, Mr Hylton Cowie, Mr Matthys Cronje, Mr Lindsay John Curran, Mr Chris de Villiers, Mr Leon Du Toit, Mr Brian Goemans, Mr Dean Hodgkiss, Mr Julian Hutz, Dr Baset Khalaf, Mr Michael Melvill, Mr Trevor Milton, Mr Anele Mlungu, Mr Hans Pietersen, Mrs Jane Rogers, Dr Cornie Scheffer, Ms Carrie Strauss, Mr Andre ten Napel, Mr Riaan van der Watt, Mr Jeremy Wallis, Dr David Walwyn, Dr David Woods and Mr Nkosinathi Zondo

Sweden: Ms Johanna Staxäng

Switzerland: Mr Rainer Voelksen and Mr Claudio Zaugg

Thailand: Mr Andy Barraclough and Dr Yot Teerawattananon

Turkey: Dr Nese Kalaycioglu Akalin

Uganda: Mrs Philippa Makobore, Dr Paget Stanfield, Mr Sam Steve Balayo Wanda and Dr Alexander Yule

United Kingdom of Great Britain and Northern Ireland: Dr Julian Duncan, Mr Andrew Gammie, Dr Julien Reboud, Dr Steven Reid, Dr David Swann and Mr Ben Williams

United Republic of Tanzania: Dr Muzdalifat Abeid, Ms Marry Alfred, Mr RAmadhan Baruti, Dr Goodluch Gotora, Mr Jaison Jacob, Dastan Kanza, Mr Godfrey Katabaro, Mr Francis Lumumba, Prof Samwel Manyele, Mathna Marine, Kulu Maswanya, Ms Jane Mazigo, Mr Expedito Milyaso, Finias Mlinga, Mr Kondo Mohamoud, Mr James Moyo, Mr Gasper Msabika, Mr Emmanuel Msalika, Ms Halima Msengi, Ms Idrisa Mukama, Shaharusadu Musa, Mr Valentino Mvanga, Dr Helga Naburi, Mr Fidelis Ndano, Dr Faiton Ndesanjo, Mr Thandaiah Prabu, Ms Abella Richard Rwiguza, Mr Ricky Thomson Sambo, Ms Vivian Saria, Ms Lekshmi Sudha, Dr Rogers Temu, Mr Denis Vedasto and Mr Bowden Visso

United States of America: Ms Aya Caldwell, Prof Alexander Capron, Ms Robyn Frick, Dr Jessica Haberer, Mr Tom Judd, Dr Ashok Kumar, Dr Jacqueline Linnes, Dr Robert Malkin, Ms Kelley Maynard, Mr Ibrahim Mohedas, Mr Keith Neroutsos, Mr Gabriel Rangel, Dr Amir Sabet Sarvestani, Dr Andreas Seiter and Dr Mark Siedner

Uruguay: Mr Jorge Omar Morales Mello and Dr Ana Perez; from

Yemen: Mr Faisal Mujamal

Zambia: Mr Tsibu J Bbuku and Dr Bruce Chikasa Bvulani.

Annex II: Feasibility Tool

Feasibility Tool Questions (Section I)

I. Preliminary screening: (if the answer is yes to ALL of the following questions, move to section II). Considering the selected medical device and the target setting's characteristics, please answer the following questions (yes, or no):

If the answer is yes to ALL of the following questions, proceed to section II

1. Is there a **need for this medical device** (as a tool for diagnosis, prevention, treatment, or rehabilitation, or a support tool for other medical devices) to address a pressing local health problem or a priority disease? Need can be based on statements by healthcare workers, data presented in literature, through observations, interviews, focus groups, etc.
2. Does the medical device have a **significant value added** compared to currently existing solutions or the current standard of care (e.g. increased quality of life, lower care delivery time, lower cost, etc.)?
3. If applicable, given the medical device's development stage, does the medical device **meet regulatory requirements** of the country where the medical device is intended for use?
4. Does the medical device **meet the technical requirements** necessary to be clinically effective in the intended region of use?
5. Is the medical device **suited for use in the intended low-resource setting** (e.g. low reliance on maintenance/consumables, limited training required, functions within limited infrastructure, culturally appropriate, etc.)?

General Comments:

Feasibility Tool Questions (Section II)

Answer to each question: "Yes", "No", "Not Applicable", or "Don't Know"

II.A Need assessment and evaluation factors

A1 Is the medical device filling a need in the region of interest because no similar competitive medical device is available?

A2 Is the medical device needed in more than one health care setting type (e.g., health care centre, district hospital, referral hospital)

A3 Answer the following questions considering the medical device design in comparison to the current standard of care (alternative solutions) in the region's market, or alternative solutions:

- A3.1 Is the medical device **more effective** (increased quality of outcome)?
- A3.2 Is the medical device **easier to use** (i.e. is it less complicated to use and/or requires reduced training time)?
- A3.3 Is the medical device **easier to maintain** by locally available workforce?
- A3.4 Does the medical device **facilitate task-shifting** (can a less-trained health provider perform the task)?
- A3.5 Does the medical device **provide safer outcomes** for patients?

A3.6 Does the medical device **pose less risk** to care providers (users)?

A3.7 Does the medical device design **provide increased social or cultural acceptability**?

A3.8 Does the medical device **require fewer resources** (e.g., less electricity, less clean water supply, fewer consumables) for operation?

A3.9 Does the medical device **provide better long-term value** (cost to own) considering upfront (initial) and operational costs?

A3.10 Is the medical device **more affordable**?

A3.11 Is the medical device **more durable**?

A4 Are there relevant human resources (e.g., physicians nurses, or community health workers) available, overall in the region, that would **require minimal to no training to use** or handle the device?

A5 Are there relevant human resources (e.g. engineers, technicians or users) available, overall in the region, that **require minimal to no training to maintain the device** if applicable?

A6 Is the medical device design **resistant against** electrical surges, dust, drastic temperature changes, extreme heat and/or humidity, or other **adverse conditions**, as found in the target region?

A7 Does the medical device design allow for **easy installation**, given the available local infrastructure?

A8 Is the medical device listed as **essential** (priority/necessary) by the Ministry of Health?

A9 Is the medical device **endorsed or pre-qualified** by any UN affiliated organization?

A10 Is the medical device **classified as essential** in any guideline of WHO, UNICEF, or UNFPA?

A11 Is the medical device **endorsed** by any well-reputed NGO or global health organization?

A12 Has the medical device **been acknowledged** by any prestigious award (e.g., for innovation, or for focus on low-resource setting appropriateness)?

A13 Is the medical device type **on a donor list** (e.g., Oxfam, USAID, MSF)?

II. B Design and use related factors

B1 Can the medical device be **used safely and effectively** without extensive training (e.g., more than a day) by the intended users (physicians, nurses, community health workers, patients)?

B2 Answer the following questions considering the target region's available resources, and users' training:

B2.1 Is the medical device **appropriate for** use for **home care** purposes?

B2.2 Is the medical device **appropriate for** use by a **mobile health unit**?

B2.3 Is the medical device **appropriate for use** within a **telemedicine** care system?

B2.4 Can the medical device be **used in a health post and/or health centre** (i.e. primary level facility)?

B2.5 Can the medical device be **used in a district hospital** (e.g., offers primary care, such as obstetrics-gynaecology, surgery, paediatric)

B2.6 Can the medical device be **used in a regional hospital** (4 or more specialties)?

B2.7 Can the medical device be **used in a specialized hospital** (e.g., teaching hospital)?

B2.8 Can the medical device be **safely reused**? (i.e. after disinfecting, sterilizing, or cleaning the device, can it be reused without posing any additional risk to user (patient))?

B2.9 Does the medical device design allow its use without any scarce resources (e.g. electricity, gas, water, etc.)?

B2.10 Is the medical device **easy to transport** (consider settings where there is a limited transportation infrastructure)?

B2.11 Is the medical device **easy to install** (e.g., consider number of hours required to install or required trained human resource to install)?

B3 Can the medical device use be explained by pictorial manual?

B4 Is disposal of medical device (or any consumables, or spare parts), if applicable, risk-free for workers and environment?

B5 Can the medical device (or any consumables, or spare parts) be disposed without any special machinery or tools, or if there is a need for special machinery or tools, are they available?

B6 Is availability of consumables in the region highly likely?

B7 Is availability of spare parts in the region highly likely?

B8 If the medical device requires built-in software, is it (software) available in an open-source format?

B9 Has ease of cleaning, sterilization, or sanitation of the medical device been taken into account in the design?

B10 Does the design of the medical device account for the potential lack of availability and high cost of consumables?

B11 In the case of disposing the device, is it safe to recycle parts of the device?

B12 Does the medical device comply with any international standards or technical specifications, issued by UN organizations or Ministry of Health for medical devices?

B13 Do healthcare providers accept (confidence in quality assumption and brand) locally produced medical devices in the target regions of the device?

B14 Do healthcare providers prefer (confidence in quality assumption and brand) locally produced medical devices in the target regions of the device?

II.C Regulation: Quality and safety factors

Regulatory factors

C1 If applicable, have you obtained regulatory approval so the medical device can be legally produced and sold in the country?

C2 Do the medical device production, sale, and use comply with civil (ethical) and/or labour laws in the country?

C3 Do the medical device production, sale, and use comply with environmental laws (if any) of the country?

C4 Has any type of approval to market from a regulatory agency (e.g., CE, FDA, SFDA, TFDA, etc.) been obtained?

C5 If yes, does that approval meet the regulatory requirements of the country where the medical device is intended for use?

C5.1 Is there any reporting mechanism in place locally to report any adverse events of usage of the medical device?

C6 Does the target country's regulatory body require any post-market surveillance?

Safety factors

C7 Has the medical device been **tested for safety**, and are its **outcomes proven** causing no harm in the setting for which it is intended?

C8 Can the medical device be used safely without regular **safety checks**?

C9 If the medical device requires regular safety checks, is the routine safety check-up available?

C10 Can the medical device be used safely without regular **calibration checks**?

C11 If the medical device requires regular calibration, is the routine calibration available?

C12 Are there any institutional review boards (IRBs) locally available to review and approve clinical trials using the device, if needed and appropriate?

C13 Are there organizations or institutions locally available to conduct a human subject trial (clinical trial) with the device, if needed and appropriate?

C14 Are there organizations or institutions locally available to conduct long-term human subject trials (clinical trials) with the device, if needed and appropriate?

C15 Is the risk level for the patient, user, or healthcare provider as low as possible because the medical device **works without radiation**, or if there is a need for radiation, is the risk managed safely?

C16 Is the risk level for the environment as low as possible because the medical device works without radiation, or if there is a need for radiation, is the risk managed safely?

C17 Is the risk level for the patient, user, or healthcare provider as low as possible because the medical device works without sharps, or if there is a need for sharps, is the risk managed safely?

C18 Is the risk level for the environment as low as possible because the medical device works without sharps, or if there is a need for sharps, is the risk managed safely?

C19 Is the risk level for the patient, user, or healthcare provider as low as possible because the medical device works without any hazardous chemicals (like mercury), or if there is a need for chemicals, is the risk managed safely?

C20 Is the risk level for the environment as low as possible because the medical device works without any hazardous chemicals (like mercury), or if there is a need for chemicals, is the risk managed safely?

C21 Is the risk level for the patient, user, or healthcare provider as low as possible because the medical device works without any toxic or inflammable gas, or if there is a need for any gas, is the risk managed safely?

C22 Is the risk level for the environment as low as possible because the medical device works without any toxic or inflammable gas, or if there is a need for any gas, is the risk managed safely?

C23 When using the device, is the risk level due to contamination (e.g., infection, etc.) for the patient, user, or healthcare provider as low as possible?

C24 When using the device, is the risk level due to contamination for the environment as low as possible?

C25 Is the risk level for the patient, or user, healthcare provider as low as possible because the medical device works without any implantable components, or if there is a need for any implantable components, is the risk managed safely?

C26 Is the risk level for the environment as low as possible because the medical device works without any implantable components, or if there is a need for any implantable components, is the risk managed safely?

C27 Is the risk level during manufacturing for the user (operator) as low as possible because the medical device is produced without moving parts in machinery, or if there is a need for moving parts, is the risk managed safely?

C28 Is the risk level during manufacturing for the user (operator) as low as possible because the medical device is produced without high-voltage access or if there is a need for any high-voltage, is the risk managed safely?

C29 Is the risk level during manufacturing for the user (operator) as low as possible because the medical device is produced without toxic fumes or if there are any toxic fumes produced, is the risk managed safely?

C30 Is the risk level during installation of the medical device minimized (i.e. can the medical device be installed without causing any harm)?

C31 Is the device environmentally friendly in that it works without water pollution?

C32 Is the device environmentally friendly in that it works without air pollution?

II.D Intellectual property (IP) and technology transfer

Intellectual property factors

D1 Does the country's legal framework and policies provide patent rights (i.e. can you file for a patent to protect an invention)?

D2 If this medical device you are evaluating is the subject matter of a patent (i.e. there is a valid, unexpired patent), do you have (or can you obtain) a license (permission) to produce or manufacture the device?

D3 If you are the technology developer and the medical device is in the development phase, have you considered filing for patent protection for the device?

D4 If you are an inventor or manufacturer, do you hold the intellectual property rights necessary to produce and sell this medical device?

D5 Does the country's legal framework and policies provide design rights (i.e. can you register industrial designs to protect your invention)?

D6 Does the country's legal framework and policies provide trademark rights (i.e. can you file for a trademark to protect goods and services)?

Technology transfer factors

D7 In general, are there any **public-private partnership initiatives** available locally to support the technology transfer of medical devices?

D8 Do you have access to a **technology transfer office** or licensing officer within your organization?

II. E Manufacturing, production and maintenance factors

Manufacturing factors

E1 Are the **components** required to make the medical device simple to produce in the region of interest?

E2 Can the medical device components be produced in the region of interest **without heavy machinery**?

E3 Can the medical device components be produced in the region of interest **without high precision measurement** instrumentation?

E4 If the medical device components cannot be produced in the region, can they be **easily imported** to the region?

E5 Does the available manufacturing capacity in the region allow for integration of electrical components in the device?

E6 Does the available manufacturing capacity in the region allow for integration of biological components (technology) in the device?

E7 Does the available manufacturing capacity in the region allow for integration of chemical components in the device?

E8 Does the available manufacturing capacity in the region allow for integration of mechanical components in the device?

E9 Can the medical device be produced using a **production line already in place** for other devices/products?

E10 Can the medical device be **assembled without requiring specialized tools**?

E11 Can the medical device be **assembled without requiring highly trained experts?**

E12 Can the medical device be **assembled without requiring high precision measurement tools?**

E13 Can the medical device be **assembled without requiring access to complex infrastructures** (e.g., clean room, etc.)?

E14 If applicable, has **refurbishment process** for the medical device been considered as part of the production operation?

Maintenance Factors

E15 Can a **user** with limited training **perform preventive maintenance** services for the device?

E16 Can a **user** with limited training **perform corrective maintenance** services for the device?

E17 Is there locally trained staff available to perform preventive and/or corrective maintenance service for the device?

Infrastructure and resources

E18 Is the level of engineering, production, or quality control required skills available to manufacture the medical device in the region of interest (country/region)?

E19 Is the level of required skill for preventive and/or corrective maintenance services aligned with existing training of technicians practicing in the region's health care settings?

E20 Is the machinery required to manufacture the medical device available in the region, or if not, is it easy to import?

E21 Are the tools required to manufacture the medical device available in the region, or if not, are they easy to import?

E22 Are the required energy resources (e.g., electricity, water, etc.) to manufacture the medical device available in the region?

E23 Are there suppliers available in the region of interest to provide raw materials to produce the medical device in the intended region of use?

E24 Can the device be manufactured in the region without a need for accreditation/ certification of manufacturing facility?

II. F Business development, market strategies, and supply chain factors

Business development factors

F1 Does the country's legal framework and policies provide financial incentives for building a medical device production business?

F2 Does the country's legal framework and policies provide protective measures for a local production business of the medical device against imported alternative products?

F3 Is setting up (registering) a business in the region with the government straightforward (i.e., reasonable required time and cost to do business)?

F4 Does the bureaucratic administrative system support the establishment and maintenance of a business in the region?

F5 Are there any business incubators (i.e. environments facilitating the growth and advancement of small (or medium), new businesses by providing professional support) available in the region?

F6 Is there any credit financing available to facilitate medical device production and sale in the country?

F7 Is there an investment network (e.g., private equity and venture capital funds, public support funds, etc.) available in the region to support medical device production and sale in the country?

F8 Have you performed any **competitive price analysis**?

F9 Have you performed any **market testing** (e.g., pilot market, customer/end-user interview, etc.) in the region, and have they indicated that here is a demand for the device?

F10 Are there any **local professional associations or groups** available that potentially can partner (e.g., to support and promote the medical device use, etc.) with this medical device business?

F11 Does the medical device have the **potential to be deployed** in a large number of regions (e.g., neighbouring countries) with similar needs?

F12 Has the **return on investment** (ROI) and the payback time for investment in setting up production of this medical device been considered with a financially sustainable outcome?

F13 Has a **comprehensive business plan** (e.g. operations, manufacturing, supply chain, financial projections) for the production of this medical device been developed?

Cost (affordability) factors

F14 Is the device's final cost, if produced in the region of interest, **competitive** (lower or almost similar) in comparison to currently existing solutions?

F15 Can the medical device be produced and sold in the region of interest at a **lower cost** than currently imported ones?

F16 If there is a need for **consumables or spare parts**, are their costs competitive (lower or almost similar) in comparison to currently existing solutions?

F17 Are the **costs of operation** (e.g., service, maintenance, consumables) competitive (lower or almost similar) in comparison to currently existing solutions?

F18 If applicable, is the cost of imports, considering tariffs, fees, and import taxes of consumables, or spare parts, or accessories, affordable (i.e., is the final cost of the medical device still competitive in comparison to existing solutions)?

F19 Will use of the medical device **lower the cost of the current (clinical) procedure** (or intervention, etc.)?

F20 Will (or is) the device (type) on the major insurances' reimbursement list?

Supply chain, distribution, and operations factors

F21 To facilitate the production of the device, are the required consumables, or spare parts, or accessories **locally available** within an accepted and pre-determined time frame?

F22 Does the **local infrastructure** allow for easy distribution of the medical device in a reasonable time frame?

F23 If the required distribution network is unavailable, can one be developed (e.g. partnering with another distributor etc.), to distribute the medical device widely in the region?

F24 Are there any well-integrated organizations available that potentially can partner to assist in the distribution of the device?

Annex III: Meeting Plan for Phase II

a. Meeting Summary

Meeting Objectives

- To inform country representatives and team consultants and advisers about the major objectives, deliverables and timeline of Phase II of the LPDTT project and develop a comprehensive work plan.
- To review the "feasibility tool", which will be evaluated and implemented in each country during this phase, and collect feedback from participants to further refine the tool.
- To review the "survey on medical devices", which will be implemented in-country during this phase of the project to provide a clear baseline of the current status of medical devices and biomedical engineering field in-country.

Expected outcomes

- A developed work plan based on each country's needs and capacities for Phase II
- Feedback from participants to update the feasibility tool
- Feedback from participants to update survey on medical devices
- A developed work plan for country's capacity building workshops

Appointments

Co-Chairs:

April 29, 2013: Ms Adriana Velazquez Berumen and Dr Heike Hufnagel

April 30, 2013: Mr Kamel Abudl Rahim

May 1, 2013: Dr Heike Hufnagel and Dr Amir Sabet Sarvestani

Rapporteurs

Dr James Abbas, Dr Amir Sabet Sarvestani, Ms Lisa Stroux

Organization

The meeting took place over three days (April 29/30, May 1, 2013) at the World Health Organization, Geneva.

b. Agenda

Monday, 29 April 2013	
09:00	Welcome and objectives of the meeting *Ms Adriana Velazquez Berumen*
09:10	Introduction of participants Selection of the Chair and Rapporteur
09:30	Setting the scene: Increasing access to health products through innovation and technology transfer *Mr Robert Terry*
09:45	Background: Overview of the report of the "local production and technology transfer" (Phase I) *Ms Adriana Velazquez Berumen*
10:30	Presentations of the results of the survey on access to medical devices (phase I), and the tool to assess feasibility of technology transfer and local production *Dr Heike Hufnagel*
10:45	Discussion and Q/A
11:15	Open discussion: Optimization of feasibility tool – all 1: Need assessment strategies (e.g., national burden of disease, immediate and long term needs and impact, end-users identification and involvement, market analysis, etc.)
13:45	2: Design innovation strategies (e.g., concept generation and selection, stakeholder involvement, rapid prototyping, private and public investment, legal and IP, clinical trial strategy, etc.)
14:45	3: Regulatory, quality evaluation, and procurement strategies (e.g., country approval process, inclusion in the national list of procurement, import laws, etc.)
15:45	4: Manufacturing, production, and supply chain strategies (e.g., outsourcing, local production, etc.)
16:45	5: Business development and market strategies (e.g., for-profit vs. low-profit vs. non-profit, reimbursement and financing, role of IP, etc.)
17:45	Summary of the day's activities, review of the outcomes and agenda for the next day *Ms Adriana Velazquez Berumen*
18:00	Adjourn
Tuesday, 30 April	
09:00	Welcome and objectives of the day. Joint meeting on local production and technical specifications, all participants *Ms Adriana Velazquez Berumen*
09:10	Introduction of participants Selection of Chair and Rapporteur
09:30	Presentation of work done in WHO medical devices unit Introduction, projects and publications *Ms Adriana Velazquez*
	Global atlas – baseline country survey *Dr Ricardo Martinez*
	Local production and technology transfer to increase access to medical devices *Ms Adriana Velazquez Berumen*
	Survey on barriers to access to medical devices *Dr Heike Hufnagel*

	Compendium of innovative health technologies for low-resource settings *Dr Heike Hufnagel and Dr Amir Sabet Sarvestani*
	H4+ interagency list of essential medical devices for maternal and newborn health *Ms Alejandra Velez Ruiz Gaitan*
	Medical devices for noncommunicable diseases *Dr Yukiko Nakatani*
	Global challenges on medical devices *Ms Adriana Velazquez Berumen*
10:20	Panel on the work done with other UN organizations
	Declaration on Non communicable diseases, WHO *Dr Andreas Ullrich, Dr Ludo Scherling (via Skype from UNICEF Copenhagen), Dr Wilma Doedens, UNFPA, Ms Adriana Velazquez Berumen, UN Commission on Life Saving Commodities*
	Country presentations: The current status and the issue of priority medical devices (needs, challenges, best practices, and lessons learned in the country)
10:45	Ethiopia *Mr Mulugeta Mideksa*
11:00	India *Dr Jitendra Kumar Sharma and Dr Niranjan Khambete*
11:30	Tanzania *Mr Godfrey Katabaro*
11:45	South Africa *Mr Mladen Poluta*
12:00	Discussion
13:45	Collaborating centres
	Jordan, Biomedical Engineering Directorate *Dr Firas Mustafa Abu-Dalou*
	Mexico, CENETEC *Mr Roberto Ayala Perdomo*
14:15	Technical advisory panel *Mr Dan Fitzpatrick, Mr Andrew Gammie, Ms Linga Kalinde, Dr Nicolas Pallikarakis and Mr Didier Vallens*
15:00	Discussion
16:00	Activity: Prioritization of medical devices and the challenges
17:30	Summary of the day's activities, review of the outcomes and agenda for the next day Announcement of the Second Global Forum of Medical Devices: Ms Adriana Velazquez Berumen
18:00	Group photo
	Adjourn
Wednesday, 1 May	
09:00	Wrapping up: Expected deliverables and outcomes of the Local Production and Technology Transfer project (AFRO) – Overview *Ms Adriana Velazquez Berumen*
	Group work
09:30	Specific next steps, strategies and actions for the country survey (phase II): (i.e., who is going to do what, how, when and where? Setting a timeline, deliverable list, etc.)
	Group work

10:30	Specific next steps, strategies and actions for the use of the revised feasibility tool (phase II): (i.e., who is going to do what, how, when and where? Setting a timeline, deliverable list, etc.) Group work
14:00	Specific next steps, strategies and actions to determine priority medical devices for (phase II): (i.e., who is going to do what, how, when and where? Setting a timeline, deliverable list, etc.) Group work
15:30	Specific next steps, strategies and actions for the capacity building task (phase II): (i.e., who is going to do what, how, when and where? Setting a timeline, deliverable list, etc.) Group work
16:15	Discussion to facilitated awareness meeting and reporting strategies
16:45	Overview of final outcomes and conclusions
17:00	Closure of the meeting

Day 1 (April 29, 2013)

Welcoming remarks

Ms Adriana Velazquez Berumen, Coordinator of the WHO Medical Devices Unit, opened the meeting by greeting the participants and outlining the objectives of the meeting.

Medical Devices Unit (WHO)

Ms Velazquez Berumen presented an overview of the Medical Devices Unit within the WHO. The Unit is part of the Health Systems and Innovation cluster and works in collaboration with UN departments, NGOs, governments and stakeholders, including those in industry, to reduce access gaps to medical devices. The Unit publishes a variety of reports on medical devices (general information), research and development, and regulation and assessment. Key documents include the *Baseline country survey of medical devices, Managing the mismatch: an outcome of the priority medical devices project*, the *Compendium of new and emerging technologies* and medical devices technical series.

Local production in support of access to medical technologies

Mr Robert Terry presented an overview of the 'local production in support of access to medical technologies' project, which began in 2008 and was funded and supported by the European Union. The project initially focused on pharmaceuticals and vaccines, but expanded to include in vitro diagnostics, blood and blood products, and medical devices. Infrastructure-related topics (e.g., hospital buildings, healthcare infrastructure) were excluded. Mr Terry articulated the importance of medical devices within the current system and the need to consider intellectual property, regulatory mechanisms and other relevant factors. Mr Terry emphasized that Phase II should aim to address lessons learned from Phase I.

Phase I report summary

Ms Velazquez Berumen presented key findings from the Phase I project outlined in a recent report entitled, *Local production and technology transfer to increase access to medical devices*.

This report established a baseline evaluation of the global medical devices landscape, research and development in the field, existing regulatory pathways, health technology management and assessment. Five country profiles (Brazil, China, Ethiopia, India and Jordan) were featured in order to assess these topics with country-specific analyses, including corresponding case examples. Success stories of locally produced medical devices in low-resource regions were also included. In order to determine the potential of a specific medical device for local production in a low-resource setting, a feasibility tool was developed and presented.

A landmark global survey was conducted to assess access to medical devices and document challenges to key stakeholders. For example, the survey documented that local manufacturers approached intellectual property in three main ways: (i) a lack of general understanding surrounding the process and merits of intellectual property; (ii) an appreciation for intellectual property with deliberate steps to guard it; and (iii) an understanding of intellectual property and treatment of intellectual property as a moral good (i.e. free sharing, "open software"). Significant barriers to local production were documented and included underdeveloped or absent regulatory pathways, high cost and financing for local development and production and issues of trust between all parties, ranging from national and local government levels to health providers, innovators, academicians, manufacturers, NGOs and international organizations.

Survey on barriers to local production

Dr Heike Hufnagel presented the results of the country survey on access to medical devices. The country survey focused questions to identify barriers to local production under four major categories, with subgroups in each category (see Table A3–1).

Table A3–1 Barriers to local production targeted in country survey

Category	Subgroup
Access to medical devices	Cost
	Governance
	Trained staff
Local development and production of medical devices	Lack of market information
Sale and commercialization of medical devices	Financing
	Regulatory clearance
Commercialization of locally manufactured medical devices	Foreign competition
	Trust

Feasibility tool to evaluate the potential for local production

Dr Hufnagel then discussed the feasibility tool, which was developed to provide a checklist of items to review when considering whether or not a medical device should be produced locally. This checklist assesses four categories – need, technical factors, regional infrastructure and market-related factors – through a series of questions that result in a final numeric score to answer the question, "is medical device 'X' suitable for local production, by either creating or expanding upon existing infrastructure of a successful business, in low-resource region 'Y'?" This tool was developed based upon a literature review, existing

practice, results of the survey for access to medical devices, and consultations with medical devices experts (e.g. industry, academia, etc.). Dr Hufnagel emphasized that the tool is continuously refined, with special attention given to issues of weighting different question types, as all questions are currently treated with equal weight.

General discussion on local production

Meeting attendees discussed the value of local production and recommended including additional factors to improve the rigors of assessment. One stated concern was that the current WHO list of core health technologies does not include the cost of logistics and delivery (e.g. freight). For example, bed nets produced in Tanzania appear to be more expensive than those produced in China, but this is not the case due to costs of distribution. Attendants also discussed the effect of NGOs on local production and operations. Since NGOs often have established networks, their distribution/operations cost is likely lower than other institutions. Hence, local manufacturers could potentially leverage established resources by partnering with NGOs, which may prove advantageous for local production. However, without a partnership NGOs could also pose competition that would compromise country operations and market size for local producers, manufacturers and distributors. Furthermore, if NGOs donate or heavily subsidize similar devices, this could also significantly hinder local production. Members suggested further identifying and using in-country success examples from organizations that facilitate or support the local production process to elucidate similar challenges and solutions.

General discussion on the feasibility tool

Members discussed the versatility of the feasibility tool and the potential for applying this tool towards improving education, communication and feasibility studies surrounding evaluating new devices for manufacturing or exploring new market opportunities for existing devices. This tool can be applied as an informational exercise to enrich academic programmes and increase capacity building with biomedical technicians, investors and other members focused on design and development of devices for low-resource settings. Additionally, the tool may be used as a communication method to coordinate efforts between the industry, NGOs and international organizations as well as to improve discussion between local and national governments. Finally, the feasibility exercise can improve understanding of a larger system (rather than a device alone), including the feasibility of producing consumables, or key parts of a larger system (e.g. producing tubes for an X-ray machine).

For maximal efficacy of the feasibility tool, members agreed upon the importance of defining clear and specific objectives, expected outcomes and a target set of respondents. With a strongly defined target user (e.g. early-stage research and development, beginning of scale-up), the questions within the tool can be optimized for specificity. Alternatively, the tool can be modular and customizable based upon the user (e.g. physician, engineer, investor) and stage of development or serve as a checklist to guide the commercialization process.

To further refine the feasibility tool, suggested improvements included assessing user qualifications to improve the accuracy of reported data. Participants suggested improved quality control mechanisms such as including a section for the respondent to assess his/her confidence in specific questions or adding a "don't know" option, with a decision-making

algorithm to subsequently tailor questions to his/her expertise. These discussions aim to address whether the respondent is the optimal person to answer these questions. These measures were also recommended for the country survey.

In order to improve clarity and ease-of-use of the tool itself, members discussed the perspective in which the needs assessment should be framed. The two main suggestions were either a disease-oriented approach where the leading questions surround major health problems of a country or a device-oriented approach that explores the current competing devices and how the health challenge is currently being addressed. Increased examination of competitors was also suggested to ensure viable commercial potential. Additional comments advocated for increased precision in wording (e.g., change "superiority" to "competitive advantage"). Implementing an online feasibility tool was also suggested to improve accessibility and ease of score reporting for the user.

Ultimately, the importance of the tool for low-resource settings was articulated as its practicality in identifying what devices are needed and which can be produced locally. In a country like Ethiopia, where 50% of medical devices are out-of-commission due to lack of spare parts, the feasibility tool can aid local production that has the potential to both improve access to new medical technologies, and also operationalize already existing devices available in-country.

Day 2 (April 30, 2013)

Country presentations

During the second day of the meeting, country representatives, consultants and WHO staff gave individual presentations. These talks spanned the topics of biomedical engineering, country-specific health information, regulatory processes, successful examples of local production and medical devices for low-resource settings. The featured country representatives were either from nations involved in the local production and technology transfer of medical devices project (phase II), or from nations that were chosen as successful and relevant examples in developing and implementing medical devices in developing regions. An overview of the presentations is provided below, arranged in the order of presentations.

Table A3–2 Individual presenters and summary points

Name	Country/ Affiliation	Summary Points	Further Resources
Dr Niranjan Khambete	India; Sree Chitra Tirunal Institute for Medical Sciences and Technology	Provided examples of relevant commercialized medical technologies and discussed challenges to local production	Sree Chitra Tirunal Institute example technologies
Mr Andrew Gammie	On India	Discussed development of new technical specifications for devices in India and the difficulties of government involvement	N/A

Name	Country/ Affiliation	Summary Points	Further Resources
Mr Peter Laser	On India	Outlined developing a training programme with MoH to improve medical device procurement Emphasized importance of human resource training	N/A
Mr Mulugeta Mideksa	Ethiopia; Ethiopian Biomedical Engineering Association	Discussed the landscape of medical devices in Ethiopia, including the current state of biomedical engineering Highlighted success stories in Ethiopia, including the development of medical device guidelines	Guidelines for Medical Device Donation in Ethiopia
Mr Godfrey Katabaro	Tanzania	Addressed the status of biomedical engineering and local production in Tanzania, and challenges associated with local production	N/A
Dr Oluyombo Awojobi	Nigeria	Invited participant but Unavailable to contact him via phone due to connection problems	N/A
Mr Mladen Poluta	South Africa; University of Cape Town, South Africa	Discussed disease burden in South Africa, and the country's accomplishments in biomedical engineering (e.g. Umbiflow, a lost-cost ultrasound system), education, and international collaboration Spoke about challenges in administration, budget, and corruption	Umbiflow University of Cape Town & Northwestern Collaboration
Mr Roberto Ayala	Mèxico; CENETEC	Outlined medical device landscape in Mexico Identified need for greater visibility and importance of biomedical engineering in healthcare system and key challenges in biomedical engineering sector	N/A
Dr Firas Abu-Dalou	Jordan; Directorate of Biomedical Engineering (DBE), Ministry of Health	Explained main duties of DBE, and the major achievements, challenges, and future plans surrounding medical technology	N/A
Mr Didier Vallens	France; On Berundi	Discussed EU-funded project to develop local policy for medical equipment and the associated challenges with project implementation	N/A
Dr Nicolas Pallikarakis	Greece; University of Patras, Biomedical Technology Unit	Gave overview of the biomedical engineering landscape in Europe and discussed a study demonstrating increasing medical device recalls due to software issues	N/A

Name	Country/ Affiliation	Summary Points	Further Resources
Mr Dan Fitzpatrick	East Meets West Foundation	Outlined organization's focus on R&D for neonatal medical equipment, and explained the lessons learned while working with local manufacturers	East Meets West
Ms Linga Kalinde	WHO's Medical Devices Unit	Discussed her focus on intellectual property within the local production and technology transfer of medical devices project Overviewed licensing and technology transfer agreements procedures	N/A
Mr Andrew Gammie	UK	Spoke about organizing an appropriate medical technology conference (broadcasted live globally through webcast) for September 2014 Overviewed prior work on technical specifications in India and Nepal	The 7th International Conference on Appropriate Healthcare Technologies
Ms Aya Caldwell	Consortium for Affordable Medical Technologies	Explained Consortium's current global partnerships and programmes that provide innovative grant awards for affordable medical technologies and foster interdisciplinary collaborations	Consortium for Affordable Medical Technologies
Mr Amir Sabet Sarvestani	WHO Medical Devices Unit, University of Michigan	Explained Appropedia: a wiki-based, open-source, compendium of medical devices featuring technologies designed to address top 10 causes of death and maternal and infant mortality	Appropedia
Mr Kamel Abudl Rahim	Former WHO staff – Iraq country office	Discussed his experience within the medical device department in the Iraqi MoH, focused on device maintenance and associated challenges	N/A

Day 3 (May 1, 2013)

On the final day, participants developed country specific plans-of-action based on pre-determined objectives and deliverables of the local production and technology transfer of medical devices project (Phase II). The meeting separated into small groups in order to facilitate the design of each country's methods and strategies, identification of essential people, and creation of an appropriate timeline for each of the deliverables.

In conclusion, participants articulated their excitement and commitment towards improving technology transfer and local production of essential priority medical devices in low-resource settings to improve the healthcare delivered in these regions.

c. Participants

GOVERNMENT

Dr Firas Mustafa Abu-Dalou
Directorate of Biomedical Engineering, Ministry of Health
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Explained main duties of the Directorate, and the major achievements, challenges and future plans surrounding medical technology.

Mr Godfrey Katabaro
Tanga Regional Referral Hospital
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gkatabaro@gmail.com
Addressed the status of biomedical engineering and local production in Tanzania, and challenges associated with local production.

Dr Niranjan Khambete
Sree Chitra Tirunal Institute for Medical Sciences and Technology
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Provided examples of relevant commercialized medical technologies and discussed challenges to local production.

Mr Kamel Abdul Rahim
Directorate of Biomedical Engineering, Ministry of Health
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Discussed his experience within the medical device department in the Iraqi MoH, focused on device maintenance and associated challenges.

ACADEMIA

Ms Clara Aranda
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Mr Mulugeta Mideksa
Johns Hopkins Technical Support for the Ethiopian HIV/AIDS Initiative
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Discussed the landscape of medical devices in Ethiopia, including the current state of biomedical engineering, and highlighted success stories in Ethiopia including the development of medical device guidelines.

Dr Nicolas Pallikarakis
University of Patras, Biomedical Technology Unit
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Presented an overview of the biomedical engineering landscape in Europe and discussed a study demonstrating increasing medical device recalls due to software issues.

Mr Mladen Poluta
University of Cape Town
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Discussed disease burden in South Africa, and the country's accomplishments in biomedical engineering (e.g. Umbiflow, a lost-cost ultrasound system), education and international collaboration; also spoke about challenges in administration, budget and corruption.

Ms Lisa Stroux
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PRIVATE SECTOR

Mr Andrew Gammie
Fishtail Consulting Ltd
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Discussed development of new technical specifications for devices in India and the difficulties of government involvement.

WHO SECRETARIAT

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Ms Jennifer Barragan
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Dr Heike Hufnagel
Technical Officer, Diagnostic Imaging and Medical Devices, WHO
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Ms Linga Kalinde
Consultant, WHO
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Discussed her focus on intellectual property within the local production and technology transfer of medical devices project; also overviewed licensing and technology transfer agreement procedures.

Dr Yukiko Nakatani
Technical Officer, Diagnostic Imaging and Medical Devices, WHO
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Dr Amir Sabet Sarvestani
Technical Officer, Diagnostic Imaging and Medical Devices, WHO
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Explained Appropedia: a wiki-based, open-source, compendium of medical devices featuring technologies designed to address top 10 causes of death and maternal and infant mortality.

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Mr Roberto Ayala Perdomo
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Outlined medical device landscape in Mexico; also identified the need for greater visibility and importance of biomedical engineering in healthcare system and key challenges in the biomedical engineering sector.

Mr Didier Vallens
Independent Consultant
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Discussed EU-funded project to develop local policy for medical equipment and the associated challenges with project implementation.

Mr Dan Fitzpatrick
East Meets West Foundation
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dan.fitzpatrick@eastmeetswest.org
Outlined the Foundation's focus on R&D for neonatal medical equipment, and explained the lessons learned while working with local manufacturers.

Ms Aya Caldwell
Consortium for Affordable Medical Technologies
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Explained the Consortium's current global partnerships and programmes that provide innovative grant awards for affordable medical technologies and foster interdisciplinary collaborations.

Mr Peter Laser
Representative of Trade Association of Medical Devices
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Outlined the developing of a training programme with MoH to improve medical device procurement, and emphasized the importance of human resource training.

Annex IV: Ethiopia In-Country Workshop

a. Agenda

'Increase Access to Quality Affordable Medical Devices, the Role of Local Production and Technology Transfer Workshop' 17 to 18 July 2014, Addis Ababa, Ethiopia

Programme of work

Day 1	**Thursday, 17 July 2014**
08:30	Registration
09:00	Welcome Message Dr Pierre Mpele Kilebou, WHO Representative to Ethiopia
09:15	Key Note Message Mr Yehulu Denekew, Director General, Ethiopian Food, Medicine and Health Care Administration and Control Authority (FMHACA)
09:30	Introduction of Participants
09:40	Objectives of the Workshop Ms Adriana Velazquez Berumen
09:50	Group photograph
10:00	Background, Public Health and Innovation Dr Zafar Mirza
12:00	Discussion
10:20	Overview of medical device activities at WHO (including Regional perspective on health technologies) Description of Local Production and Technology Transfer Project UN Commission on Life-Saving Commodities Ms Adriana Velazquez Berumen
10:50	Discussion
11:30	2013 Country Activities and Survey and Innovations Workshop Review of Country Profile (handout) Mr Mulugeta Mideksa Results of Access to Medical Devices Survey (handout) Global results vs. Ethiopian results Mr Mladen Poluta
12:20	Discussion- All participants
13:40	Inventor Presentations
15:00	Discussion and questions for presenters
15:40	Feasibility Assessment General Concepts Ethiopian innovators' results Dr James Abbas

16:20	Discussion- All Participants
16:40	Open Discussion for new ideas for medical devices to be presented on Day 2 All participants
17:00	Conclusions and Closing Remarks Session Chairs

Day 2 Friday, 18 July 2014

08:30	Welcome Back & Debriefing of Day 1 Activities Ms Adriana Velazquez Berumen
09:00	Module 1: Needs Assessment Health professionals (Medical Doctor and Nurse from Tulu Bolo District Hospital) Health extension worker from Tulu Bolo Health Post
09:20	Discussion – All participants
09:40	Module 2: Design and Use Innovation Health technology assessment Donations Procurement Maintenance Ms Adriana Velazquez Berumen, WHO Mr Ashenafi Hussein, Pharmaceutical Fund and Supply Agency and FMoH
10:10	Discussion – All participants
10:50	Module 3: Regulatory and Safety Ms Adriana Velazquez Berumen FMHACA presentation
11:10	Discussion – All participants
11:30	Module 4: Intellectual Property and Technology Transfer Module 5: Manufacturing Module 6: Business Development Ms Adriana Velazquez Berumen Ms Chloé Coves and Ms Mary Kathleen Quinn, ANDI Local participants

12:10	Discussion – All participants
13:30	New device ideas presentations Ten participants give 3–5 minute informal presentations on ideas for potential or existing devices that could have a large impact on healthcare in Ethiopia (selected on Day 1)
14:20	Questions and discussion on presentations- All participants
15:00	Develop an action plan for key stakeholders to increase access to medical devices
15:40	Define priority medical device technologies/ideas Select a set of five *(5)* devices or ideas from the previous presentations that Ethiopia could most benefit from
16:20	Next steps for local production Based on action plan and priority devices/ideas, develop a roadmap and recommendations for turning these needs into reality
17:00	Conclusions and closing remarks Mr Mekonnen Engida, FMoH

b. Photo

c. Participants

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Ms Adriana Velazquez Berumen
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d. Ethiopian workshop attendees by occupation

Innovator	5
Entrepreneur	6
Academic/researcher	5
Investor/business developer	2
Manufacturer	3
Public servant (government staff)	4
Nongovernmental organization staff	3
International organization staff	3
Healthcare provider	5
Biomedical (or clinical) engineer	10
Medical device consultant	1
Lawyer	2

e. Ethiopian workshop evaluation

	Not Applicable	Strongly disagree				Strongly agree
The workshop material was clearly presented			1	2	2	14
The workshop facilitators were knowledgeable and well-prepared				1	6	12
This workshop provided opportunities to network with professionals who have expertise in different areas				3	4	12
This workshop provided me with opportunities to learn about topics that are important to me				1	3	15
I will be able to use what I learned in these workshops				2	8	9
After attending this workshop I am now more likely to pursue opportunities for local production of medical devices.				3	6	10
I would be interested in attending follow-up workshops on Local Production and Technology Transfer						19
I would be interested in attending a workshop on other aspects of medical devices				1	2	17

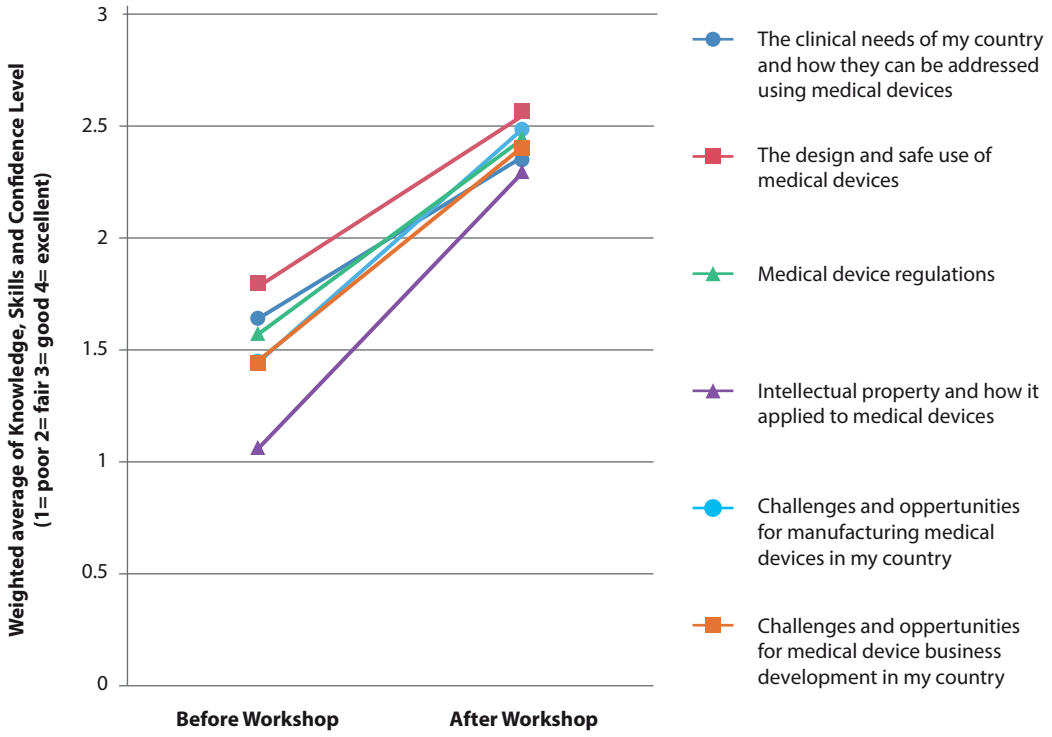
f. Ethiopian workshop attendee knowledge, skills and confidence pre- and post- workshop

	Poor	Fair	Good	Excellent
The **clinical needs** of my country and how they can be addressed using medical devices				
before	4	6	7	1
after		3	7	8
The **design and safe use** of medical devices				
before	4	4	8	2
after		2	9	8
Medical device **regulations**				
before	4	8	5	1
after	1	2	12	5
Intellectual property and how it applied to medical devices				
before	3	2	5	1
after	1	2	8	7

	Poor	Fair	Good	Excellent
Challenges and opportunities for **manufacturing** medical devices in my country				
before	7	6	3	2
after		2	10	7
Challenges and opportunities for medical device **business development** in my country				
before	5	10	1	2
after		1	10	7

Workshop evaluation. The knowledge, skill and confidence levels of participants before and after participating in the workshop were collected in a survey for which the data can be found in section e and f of the present annex.

***Figure A4-1** Overall increase in knowledge, skills and confidence felt by Ethiopian attendees pre- and post-workshop*



Annex V: Nigeria In-Country Workshop

a. Agenda

Local Production and Technology Transfer Workshop, 14 to 15 July 2014, Abuja, Nigeria

Day 1	Monday, 14 July
08:30	Registration
09:00	Opening Prayer
09:05	Welcome Address Director Food and Drug Services
09:15	Welcome message *Dr Rui Vaz*
09:30	Introduction of participants
09:40	Objectives of the workshop *Dr Beauty Onajite Okologo*
09:50	Address on behalf of the Ministry of Health
10:00	Group Photograph
11:00	Regional perspectives of health technologies
11:30	Background Overview of medical device activities at WHO Description of Local Production and Technology Transfer Project (Phase I and II) UN Commission on Life-Saving Commodities *Ms Adriana Velazquez Berumen*
12:00	Discussion
12:20	2013 Country Activities Review of Country Profiles *Dr Ogori Taylor*
12:40	Results of Access to Medical Devices Survey (handout) Global results vs. Nigeria results *Mr Mladen Poluta*
13:10	Discussion – All participants
14:15	Inventor Presentations Medical device inventors give 3–5 minute presentations about the development status of their devices
15:15	Questions and discussion on inventor presentations – All participants
15:40	Feasibility Assessment General concepts
	Innovators' results
	Dr James Abbas

16:20	Discussion- All participants
16:40	Open discussion for new ideas for medical devices to be presented on Day 2
	All participants
17:00	Conclusions and Closing Remarks
	NAFDAC

Day 2	**Tuesday, 15 July, 2014**
08:30	Welcome Back & Debriefing of Day 1 Activities
	Director Hospital Services
09:00	Module 1: Needs Assessment
	Clinicians, nurses, community health workers
	Department of Hospital Services
	Department of Public Health
	Department of Family Health
	National primary health care
	(All users express which medical devices they most need)
09:30	Discussion– All participants
09:50	Module 2: Design and Use
	Innovation
	Health technology assessment
	Donations
	Procurement
	Maintenance
	Ms Adriana Velazquez Berumen, WHO – global guidance, general perspectives
	Engr. Bukola Esan, Department of Hospital Services, FMoH – procurement process, maintenance issues in Nigeria
	Ministry of Science and Technology, Project Development Institute
10:10	Discussion – All participants
10:50	Module 3: Regulatory and Safety
	Ms Adriana Velazquez Berumen, WHO
	NAFDAC
11:10	Discussion– All participants
11:30	Module 4: Intellectual Property and Technology Transfer
	Patent Office, Ministry of Commerce
	Module 5: Manufacturing
	Ministry of Science and Technology
	Module 6: Business Development
	Ministry of Science and Technology

12:00	Discussion– All participants
13:20	New device ideas presentations Five (5) participants give 3–5 minute informal presentations on ideas for potential or existing devices that could have a large impact on healthcare in Nigeria
14:20	Questions and discussion on presentations- All participants
15:00	Develop an action plan for key stakeholders to increase access to medical devices
15:40	Define priority medical device technologies/ideas Select a set of five (5) devices or ideas from the previous presentations that Nigeria could most benefit from
16:20	Next steps for local production Based on action plan and priority devices/ideas, develop a roadmap and recommendations for turning these needs into reality
17:00	Conclusions and closing remarks *Ms Monica Eimunjeze*, Director Food and Drugs Services

b. Photo

c. Invited to participate

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d. Occupation of Nigerian workshop attendees

Innovator	6
Entrepreneur	4
Academic/researcher	2
Investor/business developer	2
Manufacturer	1
Public servant (government staff)	6
Nongovernmental organization staff	
International organization staff	
Healthcare provider	7
Biomedical (or clinical) engineer	5
Medical device consultant	
Lawyer	

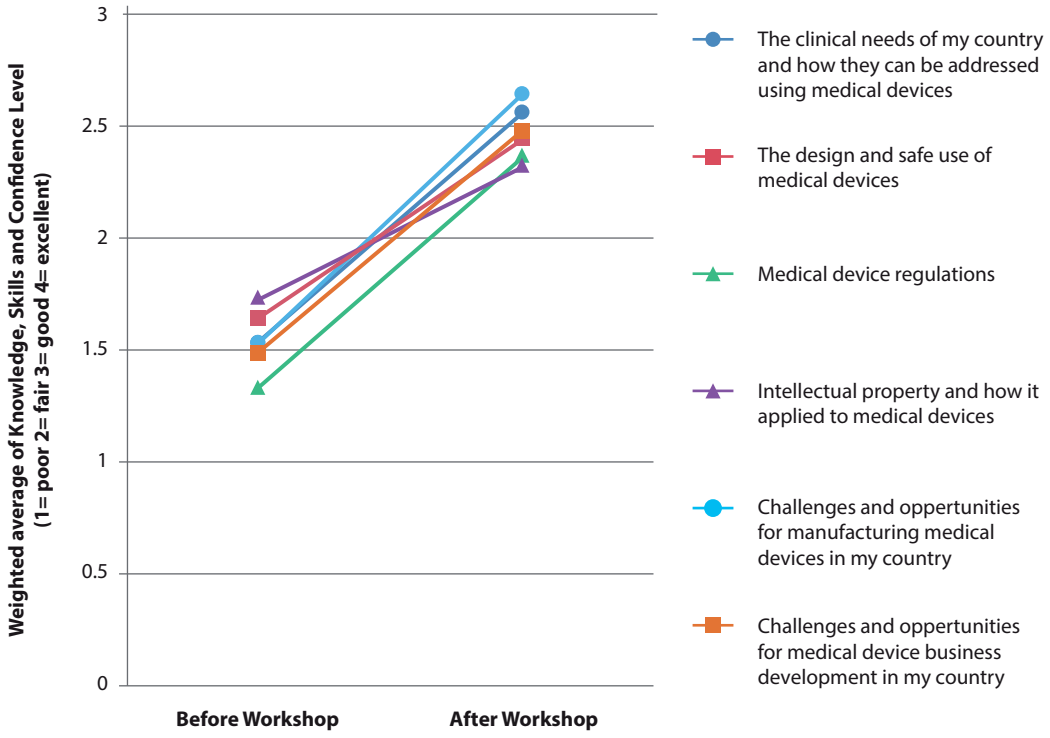
e. Nigerian workshop evaluation

	Not Applicable	Strongly disagree				Strongly agree
The workshop material was clearly presented				2	5	15
The workshop facilitators were knowledgeable and well-prepared					3	20
This workshop provided opportunities to network with professionals who have expertise in different areas			1	2	2	18
This workshop provided me with opportunities to learn about topics that are important to me				2	8	12
I will be able to use what I learned in these workshops				1	8	13
After attending this workshop I am now more likely to pursue opportunities for local production of medical devices.	5			3	4	11
I would be interested in attending follow-up workshops on Local Production and Technology Transfer	1				3	19
I would be interested in attending a workshop on other aspects of medical devices					2	21

f. Nigerian workshop attendee knowledge, skills and confidence pre- and post-workshop

	Poor	Fair	Good	Excellent
The **clinical needs** of my country and how they can be addressed using medical devices				
before	7	11	3	
after		3	14	4
The **design and safe use** of medical devices				
before	5	12	4	
after		4	15	2
Medical device **regulations**				
before	7	7	4	
after		5	11	4
Intellectual property and how it applied to medical devices				
before	5	14	2	1
after	1	4	15	1
Challenges and opportunities for **manufacturing** medical devices in my country				
before	9	8	3	1
after		4	14	4
Challenges and opportunities for medical device **business development** in my country				
before	7	12	2	
after		5	12	4

***Figure A5-1** Overall increase in knowledge, skills and confidence felt by Nigerian attendees pre- and post- workshop*



Annex VI: South Africa In-Country Workshop

a. Agenda

Increased access to quality, affordable and safe medical devices: The Role of Local Production and Technology Transfer: WHO Workshop 24 and 25 November 2014 – Johannesburg, South Africa

Day 1	**Monday, 24 November 2014**
08:15	Registration
09:00	Welcome message *Ms Joey Gouws*
09:15	WHO Statement and objectives *Dr Habib Somanje*
09:30	Introduction of participants
10:00	Overview of medical device activities at WHO *Ms Adriana Velazquez Berumen*
10:20	Discussion
11:00	Report: 2013 Country overview on medical devices *Mr Sam Setlhare Bakhane*
11:20	Discussion
11:40	Results of 2013 South Africa workshops and survey *Mr Mladen Poluta*
12:00	Feasibility tool of innovative technologies and modules description *Dr James Abbas*
12:20	Discussion
13:30	Module 1: Needs assessment (breakaway session) What priority medical device-related innovations are needed in South Africa? Community health workers/district and regional hospital health professionals with other stakeholders- breakaway group session
14:30	Discussion
15:00	Inventor presentations Medical device inventors give 3 minute presentations about their devices and related challenges and development status (as examples of local innovation)
15:40	Module 2: Health technology management: planning, specification, selection, procurement and utilisation of medical devices Overview of WHO resources relating to life-cycle management of medical devices *Ms Adriana Velazquez Berumen*
16:00	Implementation of health technology management practices in South African public sector *Mr Sam Setlhare Bakhane*
16:20	Discussion – All participants
17:00	Adjourn

Day 2	Tuesday, 25 November, 2014
08:30	Module 3L: Local manufacture and related standards
	Medical device standards and inspections
	Dr Elsabe Steyn
	Mr Lucas Monyai
09:00	Discussion – All participants
09:15	Module 4: Regulatory process: quality and safety
	Current medical device regulations
	Mr Leon du Toit
	Proposed regulatory oversight on medical devices
	Ms Joey Gouws
10:00	Discussion
10:30	Module 5: Recent study on South African medical devices sector
	Mr Andre Kudlinski
10:50	Discussion – All participants
11:00	Module 6: Business development and local production
	Dr Malan de Villiers
11:20	Shareholder panel to provide a brief overview of their contribution to, and perspective of, medical device innovation
	DTI: trade and related imperatives – *Mr Andre Kudlinski*
	DST: research support and related capacity building – *Dr Glaudina Loots*
	TIA: business development support – *Mr Timothy K Newman*
	SAMED: *Ms Tanya Vogt*
13:30	Define roadmap to enable innovation and local production and technology transfer of priority medical devices
	All participants
15:00	Develop an action plan for key stakeholders to increase access to safe and quality appropriate medical devices
	All participants
15:45	Conclusions and closing remarks
	Dr Sara L Barber
17:00	Adjourn

b. Photo

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d. South African workshop evaluation

	Not Applicable	Strongly disagree				Strongly agree
The workshop material was clearly presented			1	2	9	
The workshop facilitators were knowledgeable and well-prepared			2	1	5	3
This workshop provided opportunities to network with professionals who have expertise in different areas		1		2	4	5
This workshop provided me with opportunities to learn about topics that are important to me			2	2	3	4
I will be able to use what I learned in these workshops		1		3	4	4
After attending this workshop I am now more likely to pursue opportunities for local production of medical devices.	2	1	1	3	2	3
I would be interested in attending follow-up workshops on Local Production and Technology Transfer	2		1		1	8
I would be interested in attending a workshop on other aspects of medical devices				2	2	8

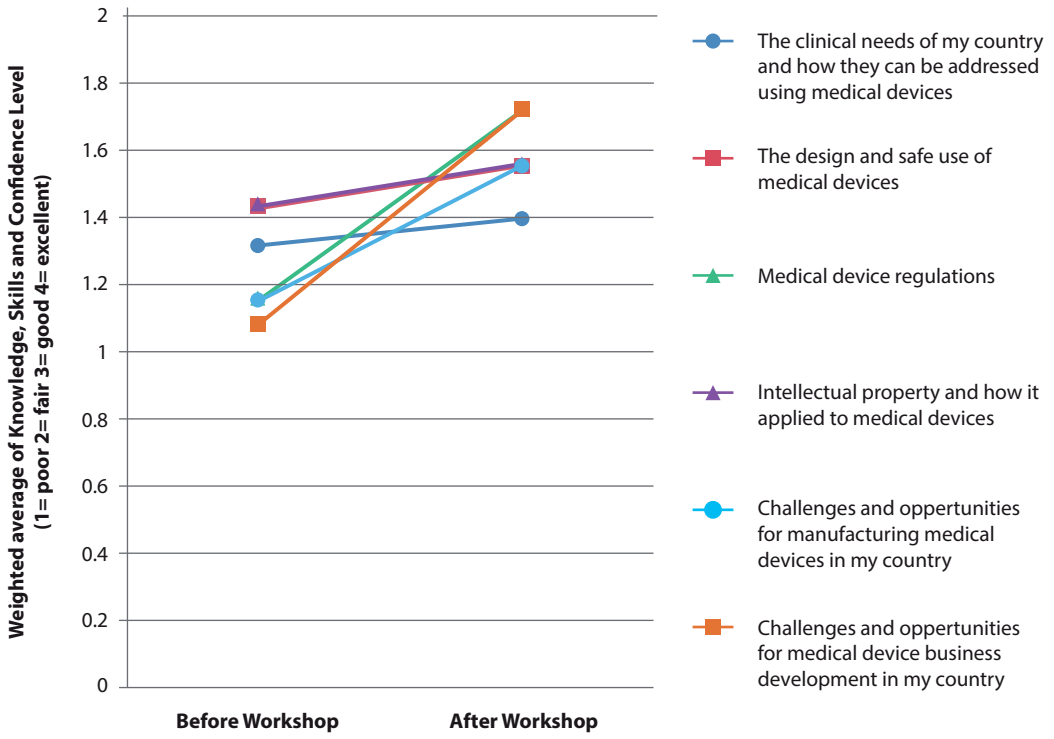
e. Nigerian workshop attendee knowledge, skills and confidence pre- and post- workshop

Workshop evaluations. The knowledge, skill and confidence levels of participants before and after their participation in the workshop were collected in a survey (see Annex V). The overall increase in South African Workshop participants' knowledge, skills and confidence levels is presented below.

	Poor	Fair	Good	Excellent
The **clinical needs** of my country and how they can be addressed using medical devices				
before		5	5	2
after		5	7	1
The **design and safe use** of medical devices				
before		3	6	3
after		2	6	4
Medical device **regulations**				
before	2	3	4	4
after	1	2	6	4

	Poor	Fair	Good	Excellent
Intellectual property and how it applied to medical devices				
before	2	3	4	4
after	1	2	6	4
Challenges and opportunities for **manufacturing** medical devices in my country				
before	1	7	2	2
after		3	7	3
Challenges and opportunities for medical device **business development** in my country				
before	3	4	4	1
after		2	9	3

***Figure A6-1** Overall increase in knowledge, skills and confidence felt by South African attendees pre- and post- workshop*



Annex VII: Tanzania In-Country Workshop

a. Agenda

Local Production and Technology Transfer Workshop, 21 to 22 July 2014, Dar es Salaam, Tanzania

Day 1	Monday, 21 July 2014
08:30	Registration
09:00	Welcome Introduction of participants
09:15	WHO welcoming remarks
09:30	Opening of the workshop *Dr Donan Mmbando*
9:40	Objectives of the workshop and regional perspective of health technologies
10:10	Overview of medical devices Description of Local Production and Technology Transfer Project (Phase 1 and II) UN Commission on Life-Saving Commodities *Ms Adriana Velazquez Berumen*
10:40	Discussion
11:20	2013 Country activities Review of country profiles (hand-outs) *Dr James Abbas* Results of access to medical devices survey (hand-outs) Global results vs Tanzania results *Mr Mladen Poluta*
12:20	Discussion – All participants
13:40	Inventor presentations Medical device inventors give 3–5 minute presentations about the development status of their devices *Mr Godfrey Katabaro, Dr Fredros Okumu, Mr Dickson Wilson Lwetoijera, Mr Johnson Kyeba Swai, Prof Samwel Manyere, Mr Emmanuel Bukuku*
15:00	Questions and discussion on inventor presentations – All participants
15:40	Feasibility assessment General concepts Tanzanian innovators' results *Dr James Abbas*
16:20	Discussion – All participants
16:40	Open discussion for new ideas for medical devices to be presented on Day 2 All participants
17:00	Conclusions and closing remarks *MoH/Ms Adriana Velazquez Berumen*

DAY 2	TUESDAY, 22 JULY 2014
08:30	Welcome back
	Debriefing of Day 1 activities
	Ms Adriana Velazquez Berumen
09:00	Module 1: Needs assessment
	Needs and the essential medical devices for a hospital setting
	Dr Faiton Ndesanjo Mandari and Ms Jane Mazigo
09:15	Integrated results of the proposals of clinical needs by participants
	Dr James Abbas
09:20	Discussion – All participants
09:30	Module 2: Design and use
	Innovation, health technology assessment, donations, procurement, maintenance
	Ms Adriana Velazquez Berumen
09:35	Challenges in maintenance of medical devices
	Mr Valentino Mvanga
09:50	Discussion – All participants
10:00	Module 3: Regulatory and safety
	Ms Adriana Velazquez Berumen
10:05	Medical devices regulations and requirements for innovators
	Mr Hiiti Sillo
	Need for adhering to standards for medical devices
	Mr Geofrey Thomas
10:20	Discussion – All participants
11:00	Module 4: Intellectual property and technology transfer
	Module 5: Manufacturing
	Module 6: Business development
	Mr Mladen Poluta
11:20	Discussion – All participants
11:30	New device ideas presentations
	Ten participants give 3–5 minute informal presentations on ideas for potential or existing devices that could have a large impact on healthcare in the country (selected on Day 1)
12:10	Questions and discussion on presentations – All participants
13:30	Develop an action plan for key stakeholders to increase access to medical devices
14:30	Define priority medical device technologies/ideas
	Select a set of five devices or ideas from the previous presentations that the country could most benefit from
15:45	Next steps for local production
	Based on action plan and priority devices/ideas, develop a roadmap and recommendations for turning these needs into reality

16:45	Conclusions and closing remarks *MOH/Ms Adriana Velazquez Berumen*
17:00	Adjourn

b. Photo

c. Participants

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d. Occupation of Tanzanian workshop attendees

Innovator	5
Entrepreneur	3
Academic/researcher	4
Investor/business developer	
Manufacturer	2
Public servant (government staff)	4
Nongovernmental organization staff	2
International organization staff	
Healthcare provider	3
Biomedical (or clinical) engineer	6
Medical device consultant	2
Lawyer	

e. Tanzanian workshop evaluation

	Not Applicable	Strongly disagree				Strongly agree
The workshop material was clearly presented			1		2	10
The workshop facilitators were knowledgeable and well-prepared						12
This workshop provided opportunities to network with professionals who have expertise in different areas				1	2	9
This workshop provided me with opportunities to learn about topics that are important to me				1	2	9
I will be able to use what I learned in these workshops					4	8
After attending this workshop I am now more likely to pursue opportunities for local production of medical devices.				1	3	9
I would be interested in attending follow-up workshops on Local Production and Technology Transfer						13
I would be interested in attending a workshop on other aspects of medical devices						13

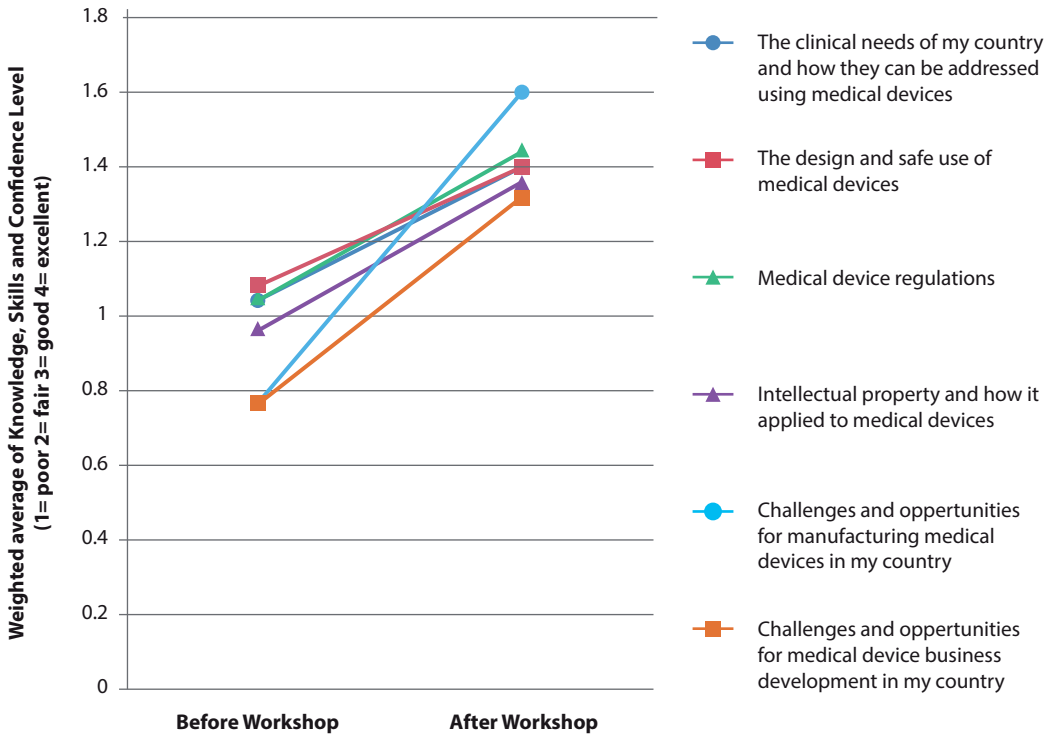
f. Tanzanian workshop attendee knowledge, skills and confidence pre- and post-workshop

Workshop evaluations. The knowledge, skill and confidence levels of participants were collected in a survey before and after their participation in the workshop.

	Poor	Fair	Good	Excellent
The **clinical needs** of my country and how they can be addressed using medical devices				
before	2	6	4	
after		1	7	3
The **design and safe use** of medical devices				
before	2	6	3	1
after		1	7	3
Medical device **regulations**				
before	3	4	5	
after		1	6	4

	Poor	Fair	Good	Excellent
Intellectual property and how it applied to medical devices				
before	3	6	3	
after		1	8	2
Challenges and opportunities for **manufacturing** medical devices in my country				
before	5	4	2	
after			8	4
Challenges and opportunities for medical device **business development** in my country				
before	5	4	2	
after		1	9	1

Figure A7-1 Overall increase in knowledge, skills and confidence felt by Tanzanian attendees pre- and post-workshop



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