Needs for Appropriate, Affordable, and Safe Medical Devices"

Adriana Velazquez Berumen
Coordinator of Medical Devices
Essential Medicines and Health Products Department
Health Systems and Innovations Cluster
Medical devices are indispensable for health care

XXI C. still many have no access to essentials!

We all can help, what will you do?
Overview

1. General framework on medical device
2. Innovative medical devices and eHealth solutions for low-resource settings
3. Local production and technology transfer to increase access to medical devices
4. Discussion
Medical device

- An article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose.

- Typically the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means. Reference to GHTF, 2005.

- Examples: syringes, intraocular lenses, ophthalmoscopes, pacemakers, hip replacements, defibrillators, anesthesia machine, scalpel, stents, iv lines, hearing aid, ultrasound, PET scanners…
WHA 60.29 Requests WHO

To develop guidelines and tools, norms and standards…

To provide support to member states to assess national needs of medical devices…

To develop methodological tools … for medical devices needs..

To provide technical guidance to implement policies…

To work with other UN organizations and professional bodies to support MS

To establish a database, ….clearing house…

To provide support to identify and put in place appropriate medical devices to facilitate access to primary health care.
To ensure improved access of safe, quality medical devices.

**Research and development**

- Regulations: Medical devices
  - Registration and premarket approval

**Assessment**

- Health Technology Assessment

**Management**

- Needs Assessments/Selection
- Installation, Inventories; CMMS, Maintenance
- User training and clinical effectiveness
- Decommissioning, Replacement

Post market surveillance and Adverse event reporting

DMD, need for affordable, appropriate medical devices. April, 2013
National health policy and plan

Medical devices: Policies and strategies

- Safety
- Quality
- Equity
- Universal coverage

Research and development
Regulation
Management
Assessment

Population needs
Medical devices technical series

- to ensure improved access, quality and use of medical devices:
  - Policies
  - Innovations R&D
  - Regulations
    - HTR
  - Assessment
    - HTA
  - Management:
    Clinical engineering

DMD, need for affordable, appropriate medical devices. April, 2013
Searching for affordable technologies…..

Call and compendium of innovative technologies for low resource settings.
Call for innovative technologies and report on local production and tech transfer
Call and compendium of innovative technologies for low resource settings

- **Idea:** Collect information about safe, effective, innovative appropriate technologies: medical devices and e-health

- **Objectives:**
  - Raise awareness of the pressing need for appropriate design solutions in low-resource settings.
  - Encourage dialogue between ministries of health, procurement officers, donors, technology developers, health care professionals.
  - Share best practices, challenges and lessons learned
Health topics addressed

including:

- Prematurity and low birth weight
- Birth asphyxia and birth trauma
- Neonatal infections
- Deficient maternal health
- Diarrheal diseases
- HIV/AIDS
- Tuberculosis
- Malaria
- Pneumonia
- Cancer
- Vascular diseases
- Diabetes mellitus
- Ischemic heart disease
- Lower respiratory infections
- Hearing loss
- Conditions related to aging
Criteria for selection: Does the technology improve health outcome in low-resource settings?

- The technology is better suited to address a health problem than existing solutions available.

or

- The technology provides an appropriate solution to a health problem not yet addressed by any other technology.
2010 call for innovative technologies that address global health concerns: outcomes

3.5.5 Reusable neonatal suction system

The purpose of this system is to remove obstructive mucus from the air passages of newborn infants, to reduce the risk of asphyxia, and support neonatal resuscitation. The device is claimed to be made of silicone and therefore reusable (capable of being boiled between users). The device also requires no electricity.

3.5.10 Single use assistive vaginal delivery system

The purpose of the system is to assist fetal extraction, in cases of prolonged second stage labour, without having to use forceps, a vacuum extractor, or to resort to caesarean sectioning. The lack of rigid instruments in the system is claimed to reduce the risk of injury to both mother and child.
Compendium 2011

44 technologies, classified in two sections:

1. Technologies under development
2. Commercialized technologies

<table>
<thead>
<tr>
<th>Technology</th>
<th>Country of origin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-powered pulse oximeter</td>
<td>United Kingdom</td>
</tr>
</tbody>
</table>

**Health problem addressed**

10.8m children die every year. 99% of these deaths are in developing countries and 2.7m are due to congestive diseases that result in hypoxemia. Early detection of hypoxemia is essential in reducing mortality and morbidity. $S_O_2$ monitoring facilitates this. $S_O_2$ monitoring is also essential during anesthesia. It is called the 5th vital sign.

**Product description**

Our pulse oximeter is a portable, easy to use monitor that measures blood oxygen saturation levels and the pulse rate. It is designed for use in low resource settings and is rugged, reliable and has its own on board human powered energy source.

**Product functionality**

The oximeter offers the highest quality pulse oximetry on the market. It analyses the entire graphic wave form, locating the onset of a pulse and resulting in extreme pulse detection. It has excellent low perfusion and motion-compensating performance, warning the user and preventing inaccurate readings.

**Developer’s claims of product benefits**

This a monitor specifically designed for use in low resource settings or where electricity supply is a problem. The $S_O_2$ monitor is rugged and reliable and has its own on-board power generator. Human energy is converted into electricity and saved in rechargeable batteries. The monitor gives 10-15 minutes of monitoring per minute of winding. The monitor may also be recharged using grid power when available. The pulse oximeter is designed to be compatible with a wide
**Compendium 2012**

- Only commercialized technologies
- 27 medical devices
- 22 eHealth solutions

Printed and in PDF

Example: non invasive hyperthermia indicator
# eHealth solutions – 2012 entries

## Country of origin
- United States of America
- Canada
- India
- Argentina
- Netherlands
- Tanzania
- Australia
- Malawi
- Burkina Faso
- Belgium
- Switzerland
- Ukraine

## Solutions being used in
- United States of America
- Australia
- Canada
- India
- Argentina
- Zambia
- Burkina Faso
- South Africa
- The Gambia
- Botswana
- Ghana
- Kenya
- Lesotho
- Mali
- Bangladesh
- Botswana
- Madagascar
- Nigeria
- Rwanda
- Sierra Leone
- Tanzania
- Togo
- Uganda
- Colombia
- Ecuador
- Mozambique
- Malawi
- Afghanistan
- Mexico
- Nicaragua
- Benin
- Mauritania
- Senegal
- Cameroon
- Chad
- Ukraine
- Liberia
Local production and technology transfer to increase access to medical devices

Local production for access to medical products
Developing a framework to improve public health

This set of materials provides an overview of activities undertaken by WHO and its partners during the first phase of a project on the local production of medical products for improved access in developing and least developed countries. The aim is to provide a framework that brings together and guides policy-makers and others from all relevant fields.

Reports
About this project
Medical devices market and patent application

World medical markets by sector, 2010
*Based on The World Medical Markets Fact Book 2011, which provides estimates based on the 66 countries for which sufficient data are available.


- Patent applications in the field of medical technology by country, 2005-2009

United States of America, 42.0%
Japan, 15.8%
Others, 11.3%
China, 4.1%
Germany, 7.5%
France, 2.5%
Italy, 1.0%
United Kingdom, 2.8%
Republic of Korea, 2.7%
Netherlands, 1.5%
Russia, 1.3%
Sweden, 1.4%
Switzerland, 3.5%
Canada, 1.3%
Australia, 1.1%
East Europe 4%
Middle East/Asia 3%
West Europe 27%
Asia 21%
Americas 45%
Survey on access to medical devices in low-resource settings

Stakeholders Participants with backgrounds and expertise in 46 different countries.
Survey respondents' fields of expertise

- Research and development
- Design and innovation
- Intellectual property
- Technology transfer
- Policy
- Health technology assessment
- Regulation
- Acquisition/procurement
- Business/sales
- Reimbursement
- Health technology management/clinical engineering
- Clinician/health professional/final user
- Investor/donor
- Patient
Main barriers to access to medical devices in low-resource settings

- Poor governance and policy
- Difficulty in complying to regulations
- Lack of information regarding what device to best procure for the setting
- Cost of medical devices themselves
- Related costs (e.g. import taxes, tariffs, etc.)
- Supply chain distribution
- Lack of properly trained staff to operate equipment
- Lack of properly trained staff to maintain equipment
- Gaps in infrastructure (e.g. electricity)
- Lack of local production/industry
- Lack of information on IP, patents, licensing, and technology transfer
Scoping study on local production of medical devices

- Overview of the medical device production in low-resource settings.
  - Global medical devices market, Innovation of medical devices, Research and development for medical devices, Technology transfer and intellectual property, Governance and regulation, etc.

- Country case studies phase I: 2012
  - Brazil, Americas Region
  - China, Western Pacific Region
  - Ethiopia, Africa Region
  - India, South-East Asia Region
  - Jordan, Eastern Mediterranean Region

- Country cases phase II: 2013
  - Ethiopia, Nigeria, South Africa, Tanzania
### success stories

<table>
<thead>
<tr>
<th>Device Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neonatal intensive care</td>
<td>Devices offered through the Breath of Life Programme in eight countries in South and South-East Asia.</td>
</tr>
<tr>
<td>equipment</td>
<td></td>
</tr>
<tr>
<td>Life Straw</td>
<td>A point-of-use water filtration device.</td>
</tr>
<tr>
<td>Mechanical heart valve</td>
<td>Award-winning valves produced in India and exported to neighboring countries.</td>
</tr>
<tr>
<td>Jaipur Foot</td>
<td>Leg and knee prosthetics made of locally sourced materials. The prosthetics are offered without cost to amputees. <a href="http://www.youtube.com/watch?v=T2XhHxvE-Es">http://www.youtube.com/watch?v=T2XhHxvE-Es</a>. Page 55 report</td>
</tr>
<tr>
<td>Intraocular lenses</td>
<td>Lenses developed at less than one eighth of the price of comparable imports.</td>
</tr>
<tr>
<td>Non-pneumatic anti-shock</td>
<td>Device controls the impact of post-partum haemorrhage.</td>
</tr>
<tr>
<td>garments</td>
<td></td>
</tr>
<tr>
<td>Odon device</td>
<td>Assisted vaginal delivery device.</td>
</tr>
<tr>
<td>Solar Ear</td>
<td>A solar powered hearing aid.</td>
</tr>
</tbody>
</table>
Jaipur foot, rubber and wood

Solar ear, deaf people develop solar chargers

http://downloads.eastmeetswest.org/docs/EMW_WHO2min.wmv

Odon device to help birthing

Phototherapy equipment in Vietnam
Figure 1 Sections and subsections of the Feasibility Tool

- Feasibility to produce a medical device
  - Needs assessment
    - Need
    - Assessment
  - Technical factors
    - Recommendations
    - Use-related factors
      - Safety
    - Operational factors
    - Transport/installation
  - Context of use
    - Procurement
    - Regulatory
      - Setting/distribution
    - Infrastructure
  - Market-related factors
    - Cost
    - Use
      - Local setting
Barriers faced in commercializing/selling medical devices

- IP issues (e.g. obtaining patents)
- Licensing
- Financing
- Regulatory clearance
- Production/manufacturing
- Device did not meet quality standards
- Complex procurement processes
- Tariffs and taxes
- Supply chain
- Other

DMD, need for affordable, appropriate medical devices. April, 2013
Conclusions

- We have to design, develop, manufacture and provide solutions that meet the needs of the populations.

- Not impose technology, but listen to the needs.

- Consider social, economical, organizational, production, human resources available in the setting.

- Be open minded, have empathy, do networking!

- Remember: Safe, Effective, Affordable, Appropriate, Accessible, Acceptable!!!

- Always consider the end user: patient or health worker !!!

- Search for good health outcomes!
http://www.who.int/medical_devices/en/

WHO Medical Devices Reports (2008-2011)

Country Publications

WHO Regions

Global initiative on Health Technologies

DMD, need for affordable, appropriate medical devices. April, 2013