Assessing feasibility of local production of medical devices in Sub-Saharan Africa to improve access to quality medical care using the WHO Feasibility Tool

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Background

• Health Technologies Resolution in 2007 (WHA 60.29)
  • WHO was tasked to establish the baseline of access to medical devices

• Local Production (in low-resource settings) and Technology Transfer
  • Phase I:
    • global survey + selected country / case studies
  • Phase II:
    • focus on Africa: Ethiopia, Nigeria, South Africa, Tanzania
Context: WHO and Local Production

Local Production for Access to Medical Products: Developing a Framework to Improve Public Health

Increasing Access to Diagnostics Through Technology Transfer and Local Production

Local Production and Technology Transfer to Increase Access to Medical Devices
Addressing the barriers and challenges in low- and middle-income countries

Policy Brief
Local Production for Access to Medical Products
Developing a Framework to Improve Public Health

This briefing paper 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 (LDCs). This is an action of the European Union. The project is in the context of the Global Strategy and Plan of Action on Public Intellectual Property. The aim of phase 1 was to develop a framework and shared goals that could bring together partners and others from the fields of public health, trade, industrial policy and other relevant sectors.
Potential impacts of local production:

Summary of published evidence:

- Potential cost savings
- Reliability of supply
- Improved quality standards
- Foreign import savings
- Increased local innovation capacity
- Development of export capacity
- Development of human capital

Phase II Objectives

- establish baseline evaluation of country access to medical devices through a survey
- develop, revise, and evaluate a Feasibility Tool to assess the likelihood of success of local production of medical devices
- apply the tool to gauge feasibility of local production of medical devices in four target countries and
Participating countries and local contacts

Ethiopia:
Mr. Mulugeta Mideksa, Addis Ababa University

Federal Republic of Nigeria:
Dr. Ogori Taylor, WHO Country Office

United Republic of Tanzania:
Mr. Godfrey Katabaro, Tanga Regional Hospital

Republic of South Africa:
Mr. Mladen Poluta, University of Cape Town & University of Pretoria
Feasibility Tool

to assess likelihood of success in locally producing and implementing a medical device

for whom?

Aspiring entrepreneurs: a checklist

Investors: re-assurances

Policy-makers: identify needs
Phase II LP Feasibility Tool: Conceptual Framework

Section I
(must pass to proceed to Section II)

Preliminary screening

Section II

Categorical analysis

A. Need assessment
B. Design and user-related factors
C. Regulation and safety
D. IP and tech transfer
E. Manufacturing, production, maintenance
F. Business, market, and supply chain
Feasibility tool analysis by category

Tanzania

- Baby Warmer
- Solar powered infant incubator
- ReSoP - Baby Incubator
- Analog BP meter
- Reverse Osmosis
- Patient Screen
- Ambulatory delivery bed

- Need assessment and evaluation factors
- Design and use related factors
- Regulation: Quality and safety factors
- Manufacturing, production, and maintenance factors
- Business development, market strategies, and supply chain factors
Feasibility tool analysis by category

Devices that ‘passed’ all categories (> 75%)

- Baby Warmer
- Patient Screen
- ReSoP - Baby Incubator
- Reverse Osmosis
- Patient Screen

Tanzania
Feasibility tool analysis by category

Tanzania

Devices that ‘failed’ one category

- Solar powered infant incubator
- Patient Screen
- Assistive device for mental disabilities
- Ambulatory delivery bed
Feasibility tool analysis by category

Devices that ‘failed’ >1 category

- BP meter
- BP meter (mechanical)
- Analog BP meter (mechanical)
- Analog BP Meter
- Analog BP Meter

Tanzania

Need assessment and evaluation factors
Design and use related factors
Business development, market strategies, and supply chain factors
Manufacturing, production, and maintenance factors
Regulation: Quality and safety factors
Feasibility tool analysis by category

Ethiopia
Feasibility tool analysis by category

- Business development, market strategies, and supply chain factors
- Manufacturing, production, and maintenance factors
- Need assessment and evaluation factors
- Design and use related factors
- Regulation: Quality and safety factors

Ethiopia

- ECG
- Vein Viewer & UV-Light
- Autoclave
- Height–Weight machine with NIBP
- Ultra Sound
- Infant incubator
- Mobile Phone Microscope
- NIBP and stethoscope
Feasibility tool analysis by category

Device categories:
- Need assessment and evaluation factors
- Business development, market strategies, and supply chain factors
- Manufacturing, production, and maintenance factors
- Design and use related factors
- Regulation: Quality and safety factors

Devices that ‘failed’ one category:
- Mobile phone-Microscope
- Neonate incubator
- Infant incubator
- Suction
- ECG
- Patient monitor
- Suction, NIBP & Stethoscope
- Vein Viewer and Phototherapy

Ethiopia
Interpreting results

Points to remember:

• opinions/perceptions
• small sample size
• variability in expertise, knowledge and experience
• scoring system based on assumptions
Observations:

- examples of devices or device categories that were perceived to be ‘feasible’
- examples of trends that indicate shortcomings in specific categories
- information may be useful to innovators, investors, policy-makers, stake-holders
Next Steps

Considering the role of WHO as an enabler and facilitator for increasing access to medical devices:

• Next steps for WHO?

• FT as a checklist and/or a decision-support tool …
  • can it be useful for:
    • medical device innovators?
    • stakeholders in facilitating the innovation/commercialization process?
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