Market Dynamics: Supporting Country Decision-Making on Medical Devices

Ray Cummings, MS, MBA
Director, Market Dynamics
PATH
rcummings@path.org

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PATH’s global impact

Work in more than 70 countries
150 million people reached each year (average)

6 billion vaccine vial monitors ensuring that vaccines are potent when given

6.3 million people reached with rice fortified with critical micronutrients

6.2 million lives saved with PATH-pioneered approaches to malaria control
PATH: Accelerating global health innovation

Expertise in 5 platforms

Serving women and children

70 countries
Average of 150 million people served per year

From R&D to scale-up:
Focusing on “middle of the value chain” where greatest challenges lie

WWW.PATH.ORG

TECHNOLOGIES

40 years of experience
81 products in the pipeline
Market dynamics

- Market dynamics involves studying how diverse elements or forces in a market function and interact, identifying areas of dysfunction and their root causes, and developing strategies for addressing those issues to strengthen markets. In the global health field, market forces can include the actions of manufacturers, distributors, procurement agencies, regulators, donors, healthcare providers, and individual users.

- Market “health” - An effectively-functioning market for healthcare products is characterized by at least five attributes:
  1. Affordability
  2. Availability
  3. Assured quality
  4. Appropriate design
  5. Awareness

Photo: PATH/Ngo Thi Than Thuy
PATH is well-positioned to foster healthy markets

- 40-year history in developing appropriately-designed health products for low- and middle-income country needs.
- Extensive collaborations with innovators, manufacturers, regulatory bodies, and procurement agencies.
- Market dynamics specialists work in close collaboration with PATH product development, public health, and country program teams.
- Country program staff in nearly 20 countries, with strong working relationships with ministries of health, disease control programs, and other health agencies.
Market dynamics: creating healthy markets from the beginning and strengthening existing markets

**Inform**
- Market sizing, demand forecasts
- Impact modeling
- Manufacturer engagement
- Cost of goods (COGS) modeling
- Procurement, distribution analysis

**Strengthen**
- Supply, demand, access measures
- Sustainability of quality-assured supply
- Procurement, distribution practices and pricing
- Intervention design & modeling

**Product value chain**

**Research / Design** ➔ **Develop / Validate** ➔ **Approve / Recommend** ➔ **Introduce / Optimize** ➔ **Scale up / Apply**

**Ensure**
- Product introduction strategy
- Quality of supply
- Supply forecasting
- Cost-effectiveness
- Engagement with health ministries and national and global procurers
Oxygen delivery devices and pulse oximeters are mature markets:
- Technologies first commercialized over 30 years ago
- Numerous suppliers with active sales
- Considerable price reductions attained

However, access remains limited in many low-resource settings.

PATH is assessing potential market shaping activities to improve and sustain access to these essential devices.
Global access to oxygen project

PATH conducted local market assessments in **four** focus countries to understand the factors that contribute to poor availability of oxygen delivery devices and pulse oximeters.

<table>
<thead>
<tr>
<th>STAKEHOLDERS CONSULTED</th>
<th>PROJECT ACTIVITIES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GLOBAL</strong></td>
<td><strong>IN-COUNTRY</strong></td>
</tr>
<tr>
<td>• Manufacturing industry</td>
<td>• Programmatic</td>
</tr>
<tr>
<td>• Global distribution companies</td>
<td>• Policy makers</td>
</tr>
<tr>
<td>• Global health partners</td>
<td>• Medical device regulation</td>
</tr>
<tr>
<td>• Financiers</td>
<td>• Procurement</td>
</tr>
<tr>
<td></td>
<td>• Biomedical engineers</td>
</tr>
<tr>
<td></td>
<td>• Local distributors</td>
</tr>
<tr>
<td></td>
<td>• Local NGOs*</td>
</tr>
<tr>
<td></td>
<td>• Professional organizations</td>
</tr>
<tr>
<td></td>
<td>• Healthcare workers</td>
</tr>
</tbody>
</table>

* Non-governmental organizations

- **Financing** allocations and **budget** practices for medical devices
- Current & potential future **demand**
- Existing device **manufacturers** and local **distributors**
- Prevailing market **prices** and past **purchases**
- The process and costs associated with device **regulation**
- **Procurement** processes, **ownership** models and **aftersales services** in the public and private health sectors
- **Applicability** to similar country archetypes
Identified barriers to safe oxygen delivery

<table>
<thead>
<tr>
<th>BARRIERS TO SAFE OXYGEN DELIVERY</th>
<th>TOOLS TO ADDRESS BARRIERS</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Reliable oxygen sources are unavailable in many low- and middle-income countries</td>
<td>• Methods to assess and strengthen the market for oxygen delivery devices and pulse oximetry</td>
</tr>
<tr>
<td>• When available, oxygen is often delivered without pulse oximetry</td>
<td>• Approaches for conducting a <strong>medical device census</strong> to determine gaps</td>
</tr>
<tr>
<td>• Lack of alignment across global normative guidance and national policies</td>
<td>• <strong>Ownership and maintenance models</strong> to improve device uptime</td>
</tr>
<tr>
<td>• Limited supply chain infrastructure</td>
<td>• Tools for <strong>assessing the suitability</strong> of available pulse oximeters to inform procurement</td>
</tr>
<tr>
<td>• Inadequate maintenance capacity</td>
<td>• <strong>Policy advocacy to increase access to oxygen therapy devices</strong></td>
</tr>
</tbody>
</table>
**Much more on oxygen markets tomorrow!**

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thu. 11:00-12:30</td>
<td>Health service delivery: Oxygen supply systems (round-table)</td>
</tr>
<tr>
<td></td>
<td><strong>Session Chair:</strong> Dr Shamin Qazi, WHO, Switzerland</td>
</tr>
<tr>
<td></td>
<td><strong>Session Co-Chair:</strong> Dr Dino Rech, Bill and Melinda Gates Foundation, United States of America</td>
</tr>
<tr>
<td></td>
<td>Availability and oxygen use in small hospitals</td>
</tr>
<tr>
<td></td>
<td>Dr. Wilson Were, WHO, Switzerland</td>
</tr>
<tr>
<td>A194</td>
<td>Methods for strengthening the market for safe oxygen delivery</td>
</tr>
<tr>
<td></td>
<td>Ms. Lisa Smith, PATH, United States of America</td>
</tr>
<tr>
<td>R140</td>
<td>Medical device ownership models and maintenance contracting approaches</td>
</tr>
<tr>
<td></td>
<td>Ms. Lisa Smith, Michael Ruffo, PATH, United States of America</td>
</tr>
<tr>
<td>R574</td>
<td>Quantifying gaps in access using medical device census information</td>
</tr>
<tr>
<td></td>
<td>Mr. Michael Ruffo, Lisa Smith, PATH, United States of America; Prabhat, Anjaney, National Health System Resource Center, India</td>
</tr>
<tr>
<td>A195</td>
<td>Multi-country suitability assessment for available pulse oximeters</td>
</tr>
<tr>
<td></td>
<td>Mr. Michael Ruffo, Ben Creelman, Gene Saxon, Lisa Smith, PATH, United States of America</td>
</tr>
<tr>
<td>R307</td>
<td>Strengthening policy advocacy for medical devices</td>
</tr>
<tr>
<td></td>
<td>Ms. Jaclyn Delarosa, PATH, United States of America</td>
</tr>
<tr>
<td>R595</td>
<td>Oxygen system technologies</td>
</tr>
<tr>
<td></td>
<td>Mr. Kristoffer Gandrup-Marino, UNICEF, Denmark</td>
</tr>
</tbody>
</table>
Example 2: Diagnostic testing for G6PD deficiency

- A hereditary condition called G6PD (glucose-6-phosphate dehydrogenase) deficiency complicates treatment of *P. vivax* malaria.

- For people with G6PD deficiency, treatment with certain drugs against *P. vivax* malaria can be dangerous—causing potentially fatal hemolytic anemia.

- Diagnosis of G6PD status is key to safely using drugs for radical cure of *P. vivax* malaria.

- New G6PD diagnostic tests are in development.

- *A key question: how many diagnostic devices are needed to support radical cure treatment of *P. vivax* malaria, and where should they be located?*
Due to the way diagnosis for G6PD deficiency and radical cure treatment for malaria will take place, it’s crucial for the model to consider the level of each health facility in the health system.
G6PD device forecasting using GeoDx tool

Goal:
To forecast the number of G6PD diagnostic devices and testing commodities needed in a country or region of a country

3 data sources
1. National Ministries of Health
   • Facility locations and tiers
   • Malaria prevalence maps
3. National Aeronautic and Space Administration (NASA)
   • Population density maps

Step 1: Map health facility locations
Step 2: Map malaria prevalence
Step 3: Map population density
Step 4: Calculate modeled number of *P. vivax* cases per facility
Step 5: Calculate number of G6PD devices and test commodities needed per facility

<table>
<thead>
<tr>
<th></th>
<th>Devices</th>
<th>Tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td></td>
<td>78</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td>33</td>
</tr>
<tr>
<td>10</td>
<td></td>
<td>136</td>
</tr>
</tbody>
</table>

Data sources:
1. National Ministries of Health
   • Facility locations and tiers
   • Malaria prevalence maps
3. National Aeronautic and Space Administration (NASA)
   • Population density maps
G6PD device modeling using GeoDx

Map of selected country and *P. vivax* prevalence

**Adjustable model inputs:**
- Country
- Test sensitivity
- Test costs
- Uptake curves
- Level of facility with diagnostic device

**Model outputs:**
- Demand forecasts
- Excel sheet of number of devices and tests needed at each facility
G6PD diagnostic summary

- Modeling tools allow geospatial data on disease prevalence, health facility locations, and population density to be overlaid.

- Ministries of health and national malaria control programs can examine different sets of assumptions about locations of diagnostic devices by facility level.

- The model allows assessment of product deployment strategies to achieve desired coverage while controlling costs.

- Demand estimates conducted together with national agencies can provide useful information to manufacturers and to larger international procurers such as the Global Fund.
Case Study: Access and use of cervical pre-cancer treatment devices in low- and middle-income countries
Cervical cancer is the 4th most common cancer in women

Over 3 million women will die in the next 10 years unless prevention is scaled up. Effective and affordable methods for screening and treatment are available, but fewer than 10% of eligible women have been screened and even fewer get treatment.

Source: GLOBOCAN 2012
Three-year project, focused on increasing access to ablative cervical pre-cancer treatment

Project overview

Country level demand

Improved access to and use of cervical pre-cancer treatment in low and middle income countries

Costs
(Procurement / Financing)

Regulatory

Objectives of country level demand work

- Develop country level models to inform strategic decision making
- Provide specific recommendations in 2 focus countries (Ghana and Uganda)
- Make models and tools available for other countries

Project goal

Catalyze the market for cervical pre-cancer treatment in Ghana and Uganda with the aim that other LMICs will take action based on the improvements seen in these two countries
Cryotherapy devices for ablative treatment*

Cryotherapy freezes the pre-cancerous lesions of the cervix


Image credit: PATH/Denise Njema-Meya

* Focused on technologies appropriate for LMICs
Thermal coagulation devices for ablative treatment*

Thermal coagulation cauterizes the precancerous lesions of the cervix

Photo sources: Manufacturers’ websites (http://www.thermo-coagulation.com/c3-mobile-coagulator/ (left) ; http://curemedicalglobal.com/product/thermocoagulator/ (right)

* Focused on technologies appropriate for LMICs
Stakeholder interviews in two focus countries to inform modeling and strategy

Approach

Conducted qualitative interviews to understand the current state of Ghana and Uganda’s cervical cancer treatment program(s), confirm key model inputs, and provide on-the-ground insights to inform each country’s options for device deployment.

Stakeholder interviews

- 46 interviews were conducted in total across both countries
- Interviews conducted across 4 stakeholder groups*
  - Policy influencers (MOH and regulatory bodies)
  - Health facilities (providers/end users & facility “managers”)
  - NGOs
  - Supply chain agencies
- Policy influencers, health facilities, and NGOs interviewees were shown product concept cards and asked to provide information on device preferences

*PATH attempted to interview bilateral and multi-lateral donors in both countries but none of the identified donors were supporting cervical pre-cancer treatment activities
Market landscaping and interview findings

<table>
<thead>
<tr>
<th>Key Features</th>
<th>Cryotherapy</th>
<th>Thermal Coagulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mechanism / Administration</td>
<td>Freezing</td>
<td>Cauterizing</td>
</tr>
<tr>
<td>Time to administer each treatment</td>
<td>10-15 minutes</td>
<td>&lt; 1 minute</td>
</tr>
<tr>
<td>Electricity (power grid) / Battery available</td>
<td>No / No need</td>
<td>Yes / Yes</td>
</tr>
<tr>
<td>Consumable parts (Y/N)</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Regulatory status</td>
<td>FDA approved</td>
<td>Depends on the manufacturer</td>
</tr>
<tr>
<td>Estimated cost of device (USD) *</td>
<td>$1,700-$2,000</td>
<td>$1,500-$2,500</td>
</tr>
<tr>
<td>Compressed gas tank required w/ adaptor (Y/N)</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Easily portable (Y/N)</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Appropriate for non-physician provider (Y/N)</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**Key learnings from interviews**

- End users/providers at the health facilities preferred devices that had faster treatment times and were easier to handle.
- Since thermal coagulation is not as commonly used in LMICs currently, many providers were concerned about hurting the patient during treatment.
- NGOs or policy influencers paid more attention to the costs (both initial equipment cost and ongoing gas tank purchases) and how easily it could be deployed for mobile outreach.

* Focused on technologies appropriate for LMIC; estimated costs are for most commonly used cryotherapy devices; additional tips cost approximately $200/each.
Planning tools developed for country decision-makers for cervical pre-cancer equipment

Model purpose

- To understand optimal deployment of cervical pre-cancer treatment devices by evaluating tradeoffs between the following:
  - Number of women treated
  - Number of units of equipment needed
  - Associated high level costs*

Model approach

- Scenario based Excel and Tableau tools are being generated for use by country stakeholders to inform decision making
  - Tools will be shared in Q2 2017 for feedback and refinement
  - Uganda, Ghana and Zimbabwe models have been generated using country specific data inputs
  - Blank data entry sheet has been created to allow countries to add in their own data to generate results

*Current model includes start-up costs for equipment and training
Estimating the number of women needing treatment

- American Society of Clinical Oncology (ASCO) guidelines recommend 30-49 years of age for “basic settings” and “limited settings”

- UNAIDS data (females aged 15-49)

- UNAIDS coverage of ART data used as a proxy for diagnosis rate (females aged 15+)

- Calculated

- World Health Organization (WHO) guidelines for screening and treatment of precancerous lesions for cervical cancer prevention

- Country strategic plans for cervical cancer

- Pink Ribbon Red Ribbon targets

- Calculated

- Country specific estimates are used for cervical pre-cancer positivity rates (Pink Ribbon Red Ribbon suggests 4x to 5x multiplier for HIV+ women)*

- WHO Prevention of Cervical Cancer Through Screening Using Visual Inspection With Acetic Acid (VIA) and Treatment With Cryotherapy (2012)

- Varies by five equipment deployment scenarios

- Calculated

*HIV-positive women are 4-5 times more likely to develop cervical cancer than women who are HIV-negative
Five scenarios for Uganda that consider trade-offs between access and equipment utilization

**Scenario 1:** Single-visit screen and treat (Tx)
- National modeling
- Screening and Tx at all health center (HC) III and above (health posts excluded)

**Scenario 2:** Hospital treatment
- National modeling
- Screening at HC III+; Tx at all hospitals (HC IV+)

**Scenario 3:** District optimization
- District-level modeling & mapping
- Screening at HC III+; Tx at hospital, minimum 1 device per district, additional based on estimated demand

**Scenario 4:** Clustering districts
- District-level modeling & mapping
- Screening at HC III+; Tx at hospital, but districts clustered according to estimated demand

**Scenario 5:** Hybrid static-mobile
- District-level modeling & mapping
- Screening at HC III+; Tx at hospital (majority) & delivered by mobile unit from hospital to screening site

Equipment at more facilities; assume higher Tx rates
Equipment at fewer facilities; assume lower Tx rates
Equipment units limited but some are mobile; moderate Tx rates
Uganda’s intermediate HIV prevalence and lower urbanization rate are key considerations for expanding access to treatment.
Data visualization to enhance model utility
Tools highlight key trade-offs across scenarios for Uganda

<table>
<thead>
<tr>
<th></th>
<th>Scenario 1</th>
<th>Scenario 2</th>
<th>Scenario 3</th>
<th>Scenario 4</th>
<th>Scenario 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of women treated</td>
<td>55,867</td>
<td>43,452</td>
<td>37,244</td>
<td>31,037</td>
<td>49,659</td>
</tr>
<tr>
<td>Number of devices (total)</td>
<td>1,624</td>
<td>345</td>
<td>115</td>
<td>80</td>
<td>60</td>
</tr>
<tr>
<td></td>
<td>1,363 (NG)</td>
<td>289 (NG)</td>
<td>96 (NG)</td>
<td>67 (NG)</td>
<td>50 (NG)</td>
</tr>
<tr>
<td></td>
<td>261 (G)</td>
<td>56 (G)</td>
<td>19 (G)</td>
<td>13 (G)</td>
<td>10 (G)</td>
</tr>
<tr>
<td>Treatments/device/year; % utilization</td>
<td>34 3%</td>
<td>126 12%</td>
<td>324 31%</td>
<td>388 37%</td>
<td>832 80%</td>
</tr>
<tr>
<td>Start-up costs*</td>
<td>$3,173,179</td>
<td>$606,296</td>
<td>$185,249</td>
<td>$128,869</td>
<td>$96,147</td>
</tr>
</tbody>
</table>

NG: Non-gas thermal coagulation devices

G: Gas devices

*Current model includes start-up costs for equipment and training
Ghana’s higher urbanization rate and large number of districts are key considerations for expanding access to treatment.
Zimbabwe’s high HIV prevalence is a key consideration for expanding access to treatment.
### Interim findings: Ghana vs. Uganda. vs. Zimbabwe

Key differences across these three countries’ inputs can influence potential scale-up of cervical pre-cancer treatment.

<table>
<thead>
<tr>
<th>Model inputs</th>
<th>Ghana (Population 24.7M)</th>
<th>Uganda (Population 34.6M)</th>
<th>Zimbabwe (Population 13.3M)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of districts</td>
<td>216</td>
<td>112</td>
<td>91</td>
</tr>
</tbody>
</table>

*Number of districts is very high in Ghana relative to the population. Under utilization is a concern for scenario 3.*

<table>
<thead>
<tr>
<th>Urbanization rate</th>
<th>Ghana</th>
<th>Uganda</th>
<th>Zimbabwe</th>
</tr>
</thead>
<tbody>
<tr>
<td>54%</td>
<td>16%</td>
<td>32%</td>
<td></td>
</tr>
</tbody>
</table>

*Non-gas technologies may be very important in Uganda and Zimbabwe with low urbanization rates.*

<table>
<thead>
<tr>
<th>HIV Prevalence</th>
<th>Ghana</th>
<th>Uganda</th>
<th>Zimbabwe</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.0%</td>
<td>8.3%</td>
<td>17.2%</td>
<td></td>
</tr>
</tbody>
</table>

*High HIV prevalence in Zimbabwe results in nearly half of treated women being HIV positive.*

<table>
<thead>
<tr>
<th>Current estimate of gas cryo devices</th>
<th>Ghana</th>
<th>Uganda</th>
<th>Zimbabwe</th>
</tr>
</thead>
<tbody>
<tr>
<td>LEEP may be common*</td>
<td>35 units</td>
<td>73 units</td>
<td></td>
</tr>
</tbody>
</table>

Countries are using different approaches to treat cervical pre-cancer and are currently at different stages of equipment scale-up.
Model timeline

- Collected data in Ghana and Uganda
- Developed model for Uganda and presented findings at the 2016 World Cancer Congress
- Developed models for Ghana and Zimbabwe and built in HIV capability
- Presented model in Zimbabwe to aid in discussions on the strategic plan
- Tools are planned to be available to the public in Q4 2017 after additional feedback is obtained from country-level stakeholders.
- Test model in focus countries and deploy

Where we are to date
Summary

- Market dynamics can provide qualitative and quantitative information on products and on the national and global markets for those products to support procurement and product deployment decision-making by national and subnational health agencies.

- Tools can include global pricing data, product suitability guides, financing strategies, and models to assess the quantity of product need and to guide product selection and deployment strategies.

- Geospatial modeling provides a powerful tool for modeling product placement and utilization to determine how to balance access/coverage and procurement costs.
Disclosure, acknowledgments

- Source of funding: The Bill & Melinda Gates Foundation.
- Conflicts of interest: None.
- Acknowledgements; contacts:
  - G6PD: Nick Luter, nluter@path.org
  - Oxygen: Lisa Smith, lsmith@path.org
  - Cervical pre-cancer treatment:
    Bhavya Gowda, bgowda@path.org
    Tara Herrick, therrick@path.org
Thank you

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PATH/Eric Becker