Global Market Shaping (Rec 1): Phase I Review
Global Market Shaping strategies are currently employed to address a few key marketplace issues with a range of potential interventions.

### R4D Global Market Shaping Toolkit for the UN Commission:

<table>
<thead>
<tr>
<th>Marketplace issue</th>
<th>Possible solutions / interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Supply and demand</strong></td>
<td><strong>High price / low volume trap</strong>&lt;br&gt;Low volumes keep prices high; high prices prevent demand growth</td>
</tr>
<tr>
<td><strong>Demand</strong></td>
<td><strong>Limited demand visibility, which can render suppliers unable to plan capacity and respond to demand increases</strong>&lt;br&gt;<strong>Demand fragmentation, which can lead to suboptimal patient outcomes, supply risks, and/or higher costs</strong></td>
</tr>
<tr>
<td><strong>Supply</strong></td>
<td><strong>Limited supply base, which can lead to high prices, poor service or quality, and/or availability issues</strong>&lt;br&gt;<strong>Suboptimal product design / innovation, due to inadequate incentives for suppliers</strong></td>
</tr>
</tbody>
</table>
At a high level, a few key parameters indicate the potential utility of these interventions in specific product markets

1. **Are optimal formulations currently being manufactured?**
   - Yes
   - No → Defer to Innovators or Regulators

2. **Can or could this product be manufactured at the global level?**
   - Yes
   - No → Defer to Local Manufacturers

3. **Are any of the following major barriers to access: High prices, limited demand visibility, fragmented procurement, limited supply?**
   - Yes
   - No → Defer to Others; Continue Monitoring

4. **Are major purchasers known and amenable to market shaping interventions?**
In order to prioritize commodities for near-term global market shaping intervention, CHAI collected information in-country and at the global-level

4 country assessments completed, 2 ongoing

- Comprehensively diagnosed in-country bottlenecks for all 13 commodities to guide recommendations and strategic approach
- Collected procurement, pricing, and registration data in CHAI focal countries

Global commodity assessments

- Collected and analyzed data at the global-level to characterize the supplier and pricing landscape for prioritized commodities (Indian Export Database, IMS, etc.)
- Identified issues and opportunities for each commodity at the global level, in conjunction with commodity TRTs
- Engaged manufacturers to assess interest in global market shaping interventions
- Worked with other TRTs to ensure collaborative approach to defining global market shaping priorities and strategies

Identified priority UNCoLSC commodity markets that could benefit from Global Market Shaping interventions in the near-term
Near-term Global Market Shaping (Rec 1) prioritization based on Phase I assessments

<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Implants</td>
<td>Resuscitation eq.</td>
<td>Amoxicillin DT</td>
</tr>
<tr>
<td>Oxytocin</td>
<td></td>
<td>Magnesium Sulfate</td>
</tr>
<tr>
<td>Misoprostol</td>
<td></td>
<td>Chlorhexidine</td>
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<tr>
<td></td>
<td></td>
<td>Corticosteroids</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Zinc/ORS</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EC</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Female Condoms</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Injectable Antibiotics</td>
</tr>
</tbody>
</table>
Implants
Based on the initial Global Market Shaping assessment, contraceptive implants were the top priority for the Rec 1 TRT and partners in Phase I.

1. **Are optimal formulations currently being manufactured?**
   - **Yes,** Jadelle & Implanon are SRA-approved & demand has grown substantially.

2. **Can or could this product be manufactured at the global level?**
   - **Yes,** the two SRA-approved products are supplied by Bayer & Merck.

3. **Are any of the following major barriers to access: high prices, limited demand visibility, fragmented procurement, limited supply?**
   - **Yes,** high prices, low volumes, & limited demand visibility are key barriers.

4. **Are major purchasers known and amenable to market shaping interventions?**
   - **Yes,** largest purchasers are UNFPA, USAID, & Social Marketing Organizations.

**Donor-assisted implant demand and pricing**

In Sub-Saharan Africa (SSA)

Pricing historically declined only modestly as demand grew, and suppliers noted limited visibility into demand.
As reviewed in recent market dynamics publications, a volume guarantee is particularly well-suited to address the key barriers to implant access.

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Market Imperfections Addressed</th>
<th>Examples</th>
<th>Benefits</th>
<th>Risks/Challenges</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume Guarantee</td>
<td>• Demand is highly uncertain</td>
<td>• Rotavirus vaccine</td>
<td>• Lower prices</td>
<td>• Global donors’ hesitation to take on risks</td>
</tr>
<tr>
<td></td>
<td>• Low market size</td>
<td>• Jadelle Implant</td>
<td>• Higher supply security</td>
<td>• Could create barriers to entry for new manufacturers</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Lowers lead-times</td>
<td>• Requires good demand forecasts</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Perceived as choice limiting</td>
</tr>
</tbody>
</table>

Certain market characteristics enable successful implementation of a VG, and the implant market satisfied all of them.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Implant market</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Centralized buying agency that aggregates demand</td>
<td>✔️</td>
<td>UNFPA, USAID/DELIVER, SMOs</td>
</tr>
<tr>
<td>Pooled funding of purchases</td>
<td>✔️</td>
<td>UNFPA, USAID/DELIVER</td>
</tr>
<tr>
<td>High forecasted volume/value</td>
<td>✔️</td>
<td>Annual demand projected to increase roughly 100% from 2012 to 2020</td>
</tr>
<tr>
<td>Supplier willingness to discount based on supply security &amp; volume</td>
<td>✔️</td>
<td>Bayer &amp; Merck both amenable to price reductions &amp; other access efforts</td>
</tr>
</tbody>
</table>
Key risks associated with using a volume guarantee for the implant market were mitigated by the partners involved in the newly formed Implant Access Program.

<table>
<thead>
<tr>
<th>Key Risks</th>
<th>Mitigating Factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>VG prevents new low-cost, high-quality suppliers from entering the market</td>
<td>Allow for re-structuring of contract terms if a lower-cost, quality-assured supplier enters the market</td>
</tr>
<tr>
<td>Forecasted demand may not materialize (financial risk for guarantors)</td>
<td>Vet forecast outputs &amp; methodology with various stakeholders, only guarantee a portion of forecasted volume</td>
</tr>
<tr>
<td>Growth in procurement volumes is not complemented by capacity building investments at country-level</td>
<td>BMGF, NORAD, CHAI, MoHs and others to secure funding &amp; programming for capacity building activities in-country</td>
</tr>
</tbody>
</table>
Consequently, we worked with the implants TRT, donors, and other stakeholders to secure price reductions of both WHO pre-qualified implantable contraceptive products.

Highlights of the recent contraceptive implant announcements:

1. Discussions were pursued with both PQ-approved suppliers
2. Bayer has provided a > 50% price reduction on Jadelle
3. Merck has provided a ~50% price reduction on Implanon & NXT
4. All 69 countries prioritized by the FP2020 Summit are eligible
5. Estimated lives saved over 6 years > 300,000; $ savings > $300M
Oxytocin
Oxytocin is one of the more accessible maternal health drugs; however, major quality and heat stability issues often preclude effective use in LMICs

### Cross Cutting Findings

**Registration:** Oxytocin is typically registered for the prevention and treatment of PPH.

**Procurement and Availability:** Oxytocin is better stocked than many other commodities; however, due to poor inventory management, forecasting, and supply chain failures, it is still often unavailable in facilities.

**Administration:** Oxytocin requires an IV or IM injection. Midwives, community health workers, and many primary practitioners are not permitted or do not have the skills to deliver the drug.

**Quality:** While not studied in CHAI focal countries, quality concerns exist. A 2013 study in Ghana indicated that 97.5% of samples failed sterility tests, lacked sufficient API or both.* WHO’s quality survey reflected similar results.

**Heat Stability:** Oxytocin requires cold storage, particularly in environments above 30 degrees Celsius. However, many countries do not have proper refrigeration at the primary health care level. This leads to degradation of the product.

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### Heat Map of Oxytocin in CHAI Focal Countries

<table>
<thead>
<tr>
<th>Country</th>
<th>Registered</th>
<th>Procured Centrally</th>
<th>Stocked in Facility</th>
<th>Optimally Used</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Primary</td>
</tr>
<tr>
<td>Kenya</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Malawi</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nigeria</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tanzania</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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*This table reflects the availability and use of Oxytocin in CHAI focal countries as of the 2012 report. Further updates may be necessary for accurate representation.
The oxytocin supplier landscape is fragmented, with 10IU/1ml and 5IU/1ml formulations being the most common.

**Supplier Overview**

- An estimated 100+ manufacturers produce oxytocin globally, none are PQ’ed
- Novartis is the innovator selling the Syntocinon product, 5IU or 10IU, in a 1ml vial*

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### Number of Unique Oxytocin Suppliers Identified in 4 Target Countries**

- **Nigeria**: 12
- **Kenya**: 6
- **Malawi**: 5
- **Tanzania**: 2

### Number of 5 IU/1ml and 10 IU/1ml Oxytocin Registrations in 4 Target Countries**

- **Nigeria**: 10 IU/ml (1), 5 IU/ml (1)
- **Kenya**: 10 IU/ml (3), 5 IU/ml (4)
- **Malawi**: 10 IU/ml (4), 5 IU/ml (2)
- **Tanzania**: 10 IU/ml (1), 5 IU/ml (1)

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*DELIVER, Oxytocin Landscape  
**Drug Registers in Nigeria, Kenya, Malawi, Tanzania  
Note: Some manufacturers supply more than one oxytocin formulation in certain countries

Novartis is registered for the 10IU/1ml formulation in Malawi and Nigeria, as well as the 5IU/1ml in Malawi, Nigeria and Kenya.
While oxytocin is eligible for the WHO prequalification program, no manufacturers have qualified to date and few are SRA approved.

### FDA-Approved Manufacturers of 10IU/1ml Oxytocin*

<table>
<thead>
<tr>
<th>Company</th>
<th>Drug Name</th>
<th>Year Approved</th>
<th>Marketing Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Novartis</td>
<td>Syntocinon</td>
<td>1980</td>
<td>Discontinued</td>
</tr>
<tr>
<td>Pfizer</td>
<td>Pitocin</td>
<td>1980</td>
<td>Prescription</td>
</tr>
<tr>
<td>Baxter Healthcare</td>
<td>Oxytocin</td>
<td>1980</td>
<td>Prescription</td>
</tr>
<tr>
<td>Fresenius-Kabi</td>
<td>Oxytocin</td>
<td>1980</td>
<td>Prescription</td>
</tr>
<tr>
<td>Teva</td>
<td>Oxytocin</td>
<td>2008</td>
<td>Discontinued</td>
</tr>
<tr>
<td>Hikma</td>
<td>Oxytocin</td>
<td>2013</td>
<td>Prescription</td>
</tr>
</tbody>
</table>

The Concept Foundation and Jhpiego will be providing technical assistance to manufacturers with the aim of helping them obtain ERP Category 1 or 2 status and WHO prequalification. They will be working on applying unified standards and evaluating products with respect to quality, safety, and efficacy.
IMS data shows that volume leaders do not necessarily correspond to sales leaders in higher-income markets, as pricing is variable across countries.

Snapshot of 10IU/1ml volumes and sales by manufacturer to select markets. Not representative of entire market

10IU/1ml Manufacturers by Total Volume – June ‘12-13
Total – 102m vials*

- Shanghai Harvest Pharma 19%
- Furen Huaiqingtang Pharma 14%
- Fengyuan Maanshan Pharma 11%
- Pfizer 7%
- Nanjing Xinbai Pharma 11%
- Other 38%

10IU/1ml Manufacturers by Total Sales – June ‘12-13
Total: 40m USD*

- Novartis 24%
- Nanjing Xinbai Pharma 15%
- Fresenius 15%
- Pfizer 6%
- Alliance Pharma 5%
- Other 35%

Avg FOB price of Top 5 Manufacturers by Sales: $0.82
Avg FOB price of Remainder: $0.20

*IMS Data
However, in low-income countries, pricing is relatively similar across data points and is not reported as a major barrier to access.

Price Points for the 10IU/1ml and 5IU/1ml formulation across data sources*

*See Appendix for definitions of each pricing source

Often private sector and higher income purchasers, leading to higher pricing.
Indian Export Data also shows limited price variability of the 10IU/1ml formulation to LMICs, regardless of volume.

**2012 India Export Volumes and Prices of 10IU/1ml Oxytocin to LMICs***

*Total Volume – 8.6m vials*

Exports to LMICs out of India averaged $0.07. This is far lower than the IMS average of $0.25 to LMICs, due to higher prices charged by western companies.

*Indian Import/Export DB
**Pricing is the landed price – product price and shipping costs to port of destination (do not include customs and country duties)*
Raw material pricing has not fluctuated over the past few years; however, API pricing decreases substantially with volume.

**Average API pricing out of India for Aug-Oct of ‘07, ‘11, ‘12, ’13**

- **SRA purchasers**
- **Non-SRA purchasers**

- **SRA**
  - Total volume in grams: 6,199
  - Avg price per gram: $102
- **Non-SRA**
  - Total volume in grams: 11,589
  - Avg price per gram: $45**

**API Pricing vs Grams Purchased out of India – Aug-Oct of ‘12**

- **SRA purchasers**
- **Non-SRA purchasers**
- **Linear (SRA purchasers)**
- **Linear (Non-SRA purchasers)**

*Amount of API in a 10IU/1ml vial varies between 20-25 mcg. 1 gram of API equates to 40-50k vials*

*Infodrive India. Export Database

**2007 prices significantly lower due to higher volumes. This drives the average lower than if 2011-13 were solely used*
Global Market Shaping interventions should aggregate demand around quality-assured, affordably-priced oxytocin formulations, while simultaneously promoting the development of heat-stable, easier-to-administer oxytocin formulations in the longer-term.

### Key Bottlenecks

Low quality of oxytocin formulations, with a majority of samples across several studies failing in assay content and sterility*

IV requirements and heat stability issues limit distribution, particularly to the PHC and community levels

### Next Steps

Work with regional blocks (e.g. EAC) to aggregate demand to ensure oxytocin is being procured from quality-assured, affordably-priced suppliers (as products receive ERP recommendations or WHO PQ approvals)

Supplier engagement to develop non-injectable, heat-stable formulations of oxytocin (powder, inhaler, nasal spray)

### Shelf Life of Oxytocin**

<table>
<thead>
<tr>
<th>Temperature</th>
<th>Shelf Life</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-8°C</td>
<td>3 years</td>
</tr>
<tr>
<td>&lt;21°C</td>
<td>2 years</td>
</tr>
<tr>
<td>25°C</td>
<td>1 year</td>
</tr>
<tr>
<td>30°C</td>
<td>6 months</td>
</tr>
<tr>
<td>40°C</td>
<td>1 week</td>
</tr>
</tbody>
</table>

*PATH and USP Studies in Ghana, India and Indonesia

**IDA Foundation. Simulation study stability Oxytocics. Michiel de Goeje. Stability data simulation study based on study performed in collaboration with WHO WHO/DAP/93.6. Available at: http://www.pphprevention.org/files/Simulationstudyoxytocics_000.ppt
Misoprostol
The key barriers to access for misoprostol include political stigma due to its use in medical abortion and quality issues with the formulations available in LMICs.

**Cross Cutting Findings**

**Registration:** Misoprostol is generally registered for the management of PPH, but its use often actively discouraged by government.

**Procurement and Availability:** Misoprostol is not procured centrally in Kenya and Malawi, and it is rarely available in health facilities across all four countries. The drug is controversial due to its use for abortion and is primarily available on the private market.

**Administration:** In countries where it is not procured centrally, there is a lack of knowledge on how to use the product.

**Quality:** Content and purity studies across 11 low-income countries indicated numerous quality concerns. 34 of the 74 samples had less than 90% content and 8 had less than 20%.* Additionally, a large recall was identified in Tanzania through Sigma Aldrich, causing significant stock outs that lasted over a year.

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*Concept Foundation.
20+ countries have registered misoprostol for the management of PPH, but many countries have registered the drug solely for treatment of gastric ulcers.

Global Misoprostol Registration by Indication*

*Venture Strategies International
There are numerous suppliers of the 200mcg formulation, most originating in India

Supplier Overview
• 60 suppliers identified in total, 1 of which was PQ’ed in early 2014
• 32 originate from India, and the remainder are based in 15+ countries around the globe
• India is the only identified manufacturing base of packs of 1 x 200mg tablet of mifepristone + 4 x 200mcg tablets of misoprostol (9 brands have been identified)

Number of Identified Suppliers of 200mcg Misoprostol in Sample Countries

Note: Misoprostol use is discouraged by government, indicating large private sector use of the drug
While misoprostol is eligible for the WHO prequalification program, only one manufacturer has qualified to date and few products are SRA approved.

<table>
<thead>
<tr>
<th>Company</th>
<th>Drug Name</th>
<th>API</th>
<th>Year Approved</th>
<th>Marketing Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Linepharma</td>
<td>Hemoprostol</td>
<td>Misoprostol</td>
<td>2014</td>
<td>WHO – PQ (Prescription)</td>
</tr>
<tr>
<td>GD Searle - Pfizer</td>
<td>Arthrotec</td>
<td>Diclofenac + Miso</td>
<td>1997</td>
<td>Prescription</td>
</tr>
<tr>
<td>Sandoz</td>
<td>Diclofenac + Miso</td>
<td>Diclofenac + Miso</td>
<td>2013</td>
<td>Prescription</td>
</tr>
<tr>
<td>Watson Labs</td>
<td>Diclofenac + Miso</td>
<td>Diclofenac + Miso</td>
<td>2012</td>
<td>Prescription</td>
</tr>
<tr>
<td>GD Searle - Pfizer</td>
<td>Cytotec</td>
<td>Misoprostol</td>
<td>1988</td>
<td>Prescription</td>
</tr>
<tr>
<td>IVAX (Teva)</td>
<td>Misoprostol</td>
<td>Misoprostol</td>
<td>2002</td>
<td>Prescription</td>
</tr>
<tr>
<td>Novel Labs</td>
<td>Misoprostol</td>
<td>Misoprostol</td>
<td>2012</td>
<td>Prescription</td>
</tr>
<tr>
<td>Corcept Therap.</td>
<td>Korlym</td>
<td>Mifepristone</td>
<td>2012</td>
<td>Prescription</td>
</tr>
<tr>
<td>Danco Labs</td>
<td>Mifeprex</td>
<td>Mifepristone</td>
<td>2000</td>
<td>Prescription</td>
</tr>
</tbody>
</table>

The Concept Foundation is providing technical assistance to manufacturers with the aim of helping them obtain WHO prequalification and ERP recommendations. They will be working on applying unified standards and evaluating products on quality, safety, and efficacy.
Quality issues have been identified, indicating poor manufacturing of the API and/or final formulation

Samples were collected from Argentina, Bangladesh, Cambodia, Egypt, Kenya, India, Mexico, Nigeria, Pakistan, Peru and Vietnam, identifying poor assay content and sterility. 74 samples analyzed for content, and 58 for impurities. Of the 74 samples analyzed, 35 had content less than 90% and 8 had less than 20%. 31 samples tested positive for impurities.*

Large Recalls**
Identified a recall in Tanzania, where Sigma Aldrich experienced significant quality issues, causing a recall and stock-outs of misoprostol that lasted nearly a year

QA and QC Testing
MSI and other institutional buyers have resorted to conducting their own quality-assurance and quality-control testing to determine which suppliers to purchase from

*Concept Foundation  
**Tanzania CHAI Team
Limited public procurement of misoprostol has been identified, but large volumes have been captured from donors and import/export data

Demand Overview
• While misoprostol may be registered to treat PPH, it is often not procured publicly but is procured through non-governmental sources (92% of women of childbearing age in Africa live in countries with restrictive abortion laws*)
• This could be changing in the coming months, as Pathfinder countries under the UN Commission will be increasing focus on the availability of misoprostol
• Nigeria and Liberia are working on ensuring access to the product for community health workers
• Ethiopia and Malawi will be looking at increasing the supply of misoprostol through supply chain interventions

Identified Procurement

<table>
<thead>
<tr>
<th>Drug</th>
<th>East Africa</th>
<th>Wholesaler</th>
<th>Donors</th>
<th>India Exports</th>
</tr>
</thead>
<tbody>
<tr>
<td>Misoprostol, 200 mcg</td>
<td>120,000</td>
<td>1,323,170</td>
<td>530,000</td>
<td>4,979,020</td>
</tr>
<tr>
<td>Mifepristone 200mg + Misoprostol 200mcg x 4</td>
<td>0</td>
<td>45,120</td>
<td>0</td>
<td>TBD</td>
</tr>
</tbody>
</table>

Pricing for the 200mcg misoprostol formulation varies depending on the source cited

Many groups report large variability in end-user pricing, given the range of distributor mark-ups (upwards of $2.32 a tablet in Kenya). This is especially true in countries where there is a large private sector presence or where misoprostol is being sold in a grey or black market.
There is low correlation between price and volume for 200mcg misoprostol to LMICs out of India; however, price variability between countries does exist.

2012 India Export Volumes and Prices of 200mcg Misoprostol Tablets to LMICs*

*Indian Import/Export DB

**Pricing is the landed price – product price and shipping costs to port of destination (do not include customs and country duties)
Primary misoprostol bottlenecks and next steps

**Key Bottlenecks**

- Low quality of misoprostol formulations, with many products failing in assay content and sterility
- Policy concern in some countries about potential for misoprostol misuse
- Anecdotal evidence of high prices in the private sector

**Potential Solutions**

- Work with regional blocks (EAC) and Pathfinder countries to aggregate demand to ensure misoprostol is being procured from manufacturers with SRA/WHO PQ approvals
- Assist MoHs as appropriate to develop and implement community-level availability and use strategies
- Investigate distributor margins and retail prices as levers to lower costs to consumer
Neonatal Resuscitation Equipment
Resuscitation equipment is not procured centrally and there is little awareness on how to effectively use the products, particularly at the primary facility level.

**Heat Map of Neonatal Resuscitation Equipment in CHAI Focal Countries**

<table>
<thead>
<tr>
<th>Country</th>
<th>Registered</th>
<th>Procured Centrally</th>
<th>Stocked in Facility</th>
<th>Optimally Used</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Primary</td>
</tr>
<tr>
<td>Kenya</td>
<td>Green</td>
<td>Red</td>
<td>Yellow</td>
<td>Yellow</td>
</tr>
<tr>
<td>Malawi</td>
<td>Green</td>
<td>Red</td>
<td>Yellow</td>
<td>Yellow</td>
</tr>
<tr>
<td>Nigeria</td>
<td>Green</td>
<td>Red</td>
<td>Yellow</td>
<td>Yellow</td>
</tr>
<tr>
<td>Tanzania</td>
<td>Green</td>
<td>Red</td>
<td>Yellow</td>
<td>Yellow</td>
</tr>
</tbody>
</table>

**Cross Cutting Findings**

**Registration:** Neonatal resuscitation equipment is included in each of the country’s guidelines for the management of neonatal asphyxia.

**Procurement and Availability:** Resuscitation equipment is not procured centrally in any of the four focus countries, with procurement taking place through facilities or donors. Availability is extremely poor in each country, with slightly improved availability in Tanzania and Malawi due to the presence of large HBB programs.

**Administration:** Extremely poor awareness across all countries on how to effectively use neonatal resuscitation equipment. Global evidence suggests that high degrees of skills atrophy exist post-training, yet continued mentoring and/or supervision is often not provided.
Numerous manufacturers have been identified; however, it is hypothesized that Laerdal has the largest market share in LMICs

**Supplier Overview**

- **Bag and Mask** - An estimated 100+ manufacturers manufacturing and/or distributing bag and mask resuscitators. Originating from regional concentrations in China/Taiwan, India, the UK, other European countries and the United States.*

- **Suction Bulb** - Little transparency in suction bulb market. PATH led most comprehensive evaluation; a total of 34 devices labeled for infant use were procured, and a total of 20 devices were evaluated.** Unbranded products also exist in the form of improvised suction devices; however, the number of suppliers in this market has never been assessed.

- **Mannequins** – Little known about manufacturing base. Major manufacturers include Laerdal, Gaumard Scientific, Nasco, and Ambu.

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*Laerdal is the assumed market leader of bag and mask resuscitators, suction bulbs and mannequins in LMICs given that they are affordable, have high brand recognition, produce a high-quality product, and are the preferred manufacturer by HBB and clinicians in low-resource settings.*

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Pricing varies substantially depending on the manufacturer, source of supply, and sophistication of the product.

**Pricing Overview**
- **Bag and Mask** - A blend of prices has been observed through the supply chain in various African countries, with resuscitators ranging from $10-225.* Several high-quality resuscitators have been identified in the $10-15 range. Laerdal offers its resuscitator for $15 (priced at ~$259 in high-income markets).

Pricing Overview

• **Suction Bulb** – Pricing ranges from $0.50-$0.85 for unbranded versions and $0.75-$10.00 for branded models. Laerdal offers the Penguin Suction bulb, the superior product on the market, for $3 (normally $22 for high-income markets).

• **Mannequins** – Pricing ranges from $35-$1,645 for neonatal CPR and resuscitation mannequins and varies greatly based on the sophistication of the device. On the lower end, the bulk of the products are oriented towards basic CPR and first aid, while more expensive products enable IV therapy, umbilical catheterization, positive-pressure ventilation, airway management, intraosseous infusion, etc. Laerdal offers a simulator for $50-$70 depending on the package selected. It is considered the highest quality model in this price range.
Only a small proportion of demand in LMICs has been identified, almost all of which is donor-funded

**Demand Overview**

- In CHAI focal countries – Malawi, Nigeria, Tanzania, Kenya, Ethiopia, Liberia – no centralized procurements of neonatal resuscitation devices have been identified
- Procurements have been identified at the facility/district level, through private wholesalers and distributors
- Procurement is largely donor driven. From 2010 to present, 120,000 bag and mask resuscitators, 150,000 penguin suction devices, and 50,000 NeoNatalie simulators have been procured through HBB

**Identified Procurement of Resuscitation Equipment by Country (2010-2014)**

Volumes collected from Jhpiego, LDS Charities, UNFPA, URC and CHAI Ethiopia – 5,752 mannequins, 13,989 suction bulbs, 14,633 B&Ms

Includes 38 countries

*UNFPA, Jhpiego, URC, LDS*
The availability of bag and mask resuscitators and suction bulbs is quite low across low-resource settings.

Availability of Bag and Mask Resuscitators in 16 countries at PHCs*

Availability of Suction Bulbs in Africa, Asia and Latin America at varying facility levels**

Low availability is compounded by poor HCW awareness and low retention of proper resuscitation techniques.

### Primary neonatal resuscitation bottlenecks and next steps [scoping phase]

<table>
<thead>
<tr>
<th>Key Bottlenecks</th>
<th>Potential Solutions</th>
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</thead>
<tbody>
<tr>
<td>Lack of HCW training and mentorship on equipment use, maintenance, and ordering processes</td>
<td>Train and mentor HCWs in proper equipment use, ordering, and maintenance</td>
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<tr>
<td>Low availability and limited government procurement of NNR equipment due to high prices and lack of transparency in supply landscape – current reliance on external partners</td>
<td>Work across countries to increase transparency in pricing and relative product specifications and to encourage governments to take ownership of NNR scale-up</td>
</tr>
<tr>
<td>The high prices of high-quality suction bulbs, resuscitators, and mannequins from manufacturers and private distributors discourage use</td>
<td>Engage manufacturers to explore potential reductions in FOB pricing; Investigate local manufacturing opportunities to reduce pricing and decrease lead times</td>
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</table>
Commodities De-prioritized in Near-term
<table>
<thead>
<tr>
<th>Commodity</th>
<th>Reasons for Near-term De-Prioritization</th>
</tr>
</thead>
</table>
| Reproductive Health| Female Condoms • Demand is low and volatile year-over-year
                | • Global Market Shaping interventions should be considered once demand shows consistent growth       |
|                    | EC • Pricing/supply not reported as key barriers to access
                | • Purchasing base is extremely fragmented, so increasing visibility into demand and/or aggregating demand at global-level are unlikely in the near-term |
| Maternal Health    | Magnesium Sulfate • Pricing and supply not cited as major barriers to access; supply base is highly fragmented
                | • Key barrier to access is training and awareness of HCWs – should be addressed at country-level       |
| Child Health       | Zinc/ORS • Fragmented, local manufacturing base unlikely to benefit from global or regional demand aggregation
                | • Barrier to use is primarily uptake & awareness driven                                              |
|                    | Amoxicillin DT • Amoxicillin DT has yet to be integrated in many country guidelines and/or procured in large volumes
<pre><code>            | • Opportunity to be revisited once multiple suppliers receive WHO PQ or ERP category 1/2/3 ratings    |
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<table>
<thead>
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</tr>
</thead>
</table>
| Injectable Antibiotics    | • New WHO guidelines on optimal sepsis treatment have yet to be finalized  
                           | • Low pricing, fragmented supply base, and few quality issues identified for currently recommended products  
                           | • Inconsistent availability due primarily to supply chain and forecasting challenges |
| Chlorhexidine             | • Low pricing and fragmented, local manufacturing base unlikely to benefit from global or regional demand consolidation  
                           | • Key issues are low awareness of HCWs and lack of inclusion in national guidelines |
| Corticosteroids           | • Fragmented supply base, low pricing, and few quality issues identified  
                           | • Barriers to use are primarily awareness-oriented, particularly at the PHC level |