Neonatal Resuscitation Devices: Market & Supply Update
August 2014

1. Summary

- From 2008 to 2013, UNICEF’s procurement of neonatal resuscitation devices and training models tripled, reaching ~$1.4 million. The targeted efforts to improve emergency neonatal (newborn) care through the UN Commission on Life-Saving Commodities for Women and Children (the UN Commission) and the Helping Babies Breathe® (HBB) training programme have driven the increase, albeit modest in overall magnitude of procurement.
- UNICEF and WHO, together with other neonatal resuscitation partners, have developed an Every Newborn Action Plan (ENAP) endorsed by the World Health Assembly (WHA) in May 2014. The plan includes the scale-up, availability and use of resuscitation devices to reduce neonatal mortality.
- Currently, only one manufacturer globally offers newborn resuscitation products “at cost” to low-income countries through 2015 through UNICEF and other partners. UNICEF encourages all manufacturers to offer products at improved affordable pricing.
- UNICEF believes that a healthy neonatal resuscitation market should include multiple, competitive manufacturers (e.g., minimum 3) able to provide affordable and high-quality devices appropriate for use in low-resource settings. It should also offer the opportunity for all manufacturers to compete for partnerships that increase their capacity to develop, test and supply products in low-resource settings. These principles will help guide UNICEF’s forthcoming procurement strategy.

2. Background

Birth asphyxia is the failure to initiate and sustain breathing at birth. It accounts for approximately 760,000 neonatal deaths a year, representing up to one quarter of neonatal deaths globally in addition to an unknown number of misclassified stillbirths. Neonatal resuscitation is required to treat birth asphyxia. When trained skilled birth attendants (SBAs) using quality devices administer the intervention, mortality can decrease by up to 30%. The UN Commission identified neonatal resuscitation as one of 13 key strategic, cost-effective interventions that can prevent and reduce child mortality and has supported activities to improve both global and facility-level availability of resuscitation devices.

Neonatal resuscitation is part of a broader platform of essential basic neonatal care, which includes thermal and umbilical cord care, early and exclusive breastfeeding for every newborn, as well as the

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identification and management of infections and low birth weight. Basic neonatal resuscitation requires the use of a resuscitator and suction device and is to be performed by a SBA that has undergone competency-based training using a training model.

Resuscitators are hand-operated devices that provide positive pressure ventilation (PPV) to patients that require assistance to breathe. The ‘bag and mask’ design is the most commonly used product, and is the model recommended, where available, by WHO as the first choice for neonatal resuscitation. Most bag and mask models have additional functionality to enable increased concentrations of oxygen during PPV at higher-level health facilities. UNICEF offers resuscitators in three sizes for neonatal, infant/child and adult patients with several different sized facemasks. The following table presents the products required for neonatal resuscitation and training (Table 1):

Table 1 Standard Clinical and Training Resuscitation Products

<table>
<thead>
<tr>
<th>Product</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neonatal bag and mask resuscitator</td>
<td>A self-inflating bag and mask used to cover the baby’s nasal and buccal airway passages to support the provision of positive pressure ventilation.</td>
</tr>
<tr>
<td>Suction device&lt;sup&gt;8&lt;/sup&gt;</td>
<td>A simple handheld squeezable device to provide suction under negative pressure and clear the nasal and buccal airway passages to facilitate breathing.</td>
</tr>
<tr>
<td>Training model</td>
<td>A model used to provide skilled birth attendants with competency-based training, practice and refreshment training.</td>
</tr>
</tbody>
</table>

Source: Every Woman Every Child.

Despite the availability of affordable devices and training, SBAs in resource-limited settings often lack the training and equipment necessary to offer appropriate intervention. A number of initiatives support and address key challenges to promote and facilitate the access and availability of appropriate resuscitation devices and training.

UNICEF, in collaboration with WHO, UNFPA, UN Women, the World Bank and UNAIDS, established the H4+ partnership to harmonize and accelerate actions to improve maternal and child health. The forthcoming H4+ interagency list<sup>10</sup> of essential medical devices for Reproductive, Maternal, Neonatal and Child Health (RMNCH) will detail an up-to-date compendium of essential interventions and medical devices that support neonatal care. The list will facilitate government and partner resuscitator commodity planning and procurement and is due for publication in 2014.

Many national SBA training programmes lack the facilities to offer competency-based practical training on interventions such as neonatal resuscitation. The Helping Babies Breathe (HBB®) initiative, launched in 2010 by the American Academy of Pediatrics (AAP), USAID and other partners, includes a basic neonatal resuscitation training package for use in resource-limited settings. Neonatal resuscitators, suction devices and training models complement the HBB curriculum. The HBB products are sole-sourced and sold at cost from Laerdal Global Health.

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<sup>8</sup> Suction devices are not included in the scope of this update.


<sup>10</sup> The link to the H4+ interagency list provides information on the work in progress.
Separately, the UN Commission’s neonatal resuscitation technical reference team (TRT),\(^\text{11}\) of which UNICEF is a member, supports the scale-up, access and availability of neonatal resuscitation devices. UNICEF procures resuscitators and training devices in three separate commodity groups (Table 2).

Table 2 UNICEF Neonatal Resuscitation Devices and Training Models Commodity Groups

<table>
<thead>
<tr>
<th>Commodity Group</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resuscitators</td>
<td>Resuscitator sets for clinical use, including neonate, infant/newborn and adult models.</td>
</tr>
<tr>
<td>HBB Training Package®</td>
<td>HBB training package that includes neonatal resuscitators; suction bulbs; training models and learning materials.</td>
</tr>
<tr>
<td>Other Training Models</td>
<td>Neonatal CPR and advanced care simulators and trainers; childbirth simulators; babies and other miscellaneous anatomical components.</td>
</tr>
</tbody>
</table>

Source: UNICEF Supply Division.

3. Current Market Situation

3.1. Demand and Forecast

UNICEF neonatal resuscitation device procurement increased over the past decade to reach 18,000 units a year on average from a previous 3,600 units annually (Figure 1). The HBB training package introduced in 2010 contributed substantially to the increase, accounting for 50% of the volume. UNICEF Country Offices (COs) often buy in bulk and stock in their warehouses for distribution over several years. The 2014 forecast is based on a past 3-year average annual procurement (2011-2013), plus 10% growth.

Figure 1 UNICEF Neonatal Resuscitation Devices 2004-2013 Procurement and 2014 Forecast

UNICEF has supplied neonatal resuscitation devices to 55 countries during 2011 - 2013. Ten countries accounted for 85% of the procurement volume. Tanzania and Ethiopia were the two largest receiving countries (Figure 2).

Figure 2 Top Ten Countries Procuring Resuscitators through UNICEF 2011-2013


Figure 3 UNICEF Resuscitator Procurement (Volume) 2004-2013

Figure 4 UNICEF Resuscitator Procurement (Value) 2004-2013

From 2010 to 2013, UNICEF procured 34,400 HBB resuscitators, in addition to learning materials, suction bulbs and training models included in the HBB training package (Figures 5, 6). The procurement accounted for approximately one-third of all HBB resuscitators supplied during this period (through all procurement agents and supply channels).

12 The data is based on shipments Ex UNICEF Copenhagen warehouse and procurement orders.
Countries also procure other training models in support of their own national training programmes. These other training models accounted for 10% of all models procured in 2013 (Figures 7, 8).

3.2. Supply

The HBB training package includes a neonatal resuscitator, a suction device, a newborn training model and learning materials and complements the HBB curriculum. UNICEF currently procures 18 individual HBB products, including training models and learning materials in English and Spanish.

UNICEF also procures other training models called ‘patient simulators’, ‘mannequins’ or ‘anatomical models’ for use in health training programmes. Training models mimic a patient’s response to clinical intervention and are an important part of competency-based training for birth attendants and health workers. UNICEF currently procures 15 different training models for various RMNCH interventions, including basic and advanced life support and childbirth.
UNICEF has several supply arrangements in place for quality neonatal resuscitators and training models. Five manufacturers hold Long Term Arrangements (LTAs) with UNICEF (Table 3):

Table 3 UNICEF Resuscitator and Training Model Manufacturer LTAs

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ambu A/S</td>
<td>Neonatal resuscitators</td>
</tr>
<tr>
<td>VBM Medizintechnik GmbH</td>
<td>Neonatal resuscitators</td>
</tr>
<tr>
<td>Laerdal Medical AS&lt;sup&gt;14&lt;/sup&gt;</td>
<td>Neonatal resuscitators and training models (HBB programme)</td>
</tr>
<tr>
<td>3B Scientific</td>
<td>Training models</td>
</tr>
<tr>
<td>Gaumard</td>
<td>Training models</td>
</tr>
</tbody>
</table>

Source: UNICEF Supply Division.

Prices from manufacturers vary considerably depending on the models, components and items procured. Laerdal Global Health<sup>15</sup> offers its products to low-income countries at cost through UNICEF and other global partners through 2015.<sup>16</sup> Their neonatal resuscitators, training models and other products included in the HBB programme have a substantial price differential compared to other manufacturers (Table 4). UNICEF encourages all manufacturers to offer their products at improved affordable pricing, and is interested in soliciting ideas of how improved overall pricing can be achieved. UNICEF believes that any opportunity for donors’ financial (or other) support to manufacturers should be encouraged to continue to further develop the market, and that it be done on an equal-opportunity basis.

Table 4 Neonatal Resuscitator Comparative Price Ranges and Differences

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Other Manufacturers</td>
<td>Laerdal Global Health</td>
<td>Other Manufacturers</td>
</tr>
<tr>
<td>Lowest price</td>
<td>$65.05</td>
<td>$31.74*</td>
<td>$60.65</td>
</tr>
<tr>
<td>Average price</td>
<td>$66.97</td>
<td>$15.40</td>
<td>$61.23</td>
</tr>
<tr>
<td>Highest price</td>
<td>$70.82</td>
<td>$65.56</td>
<td>$63.81</td>
</tr>
</tbody>
</table>

Source: UNICEF Supply Division.

* Note: The 2012 $31.74 low neonatal resuscitator price was as a result of large local purchase from China.

Table 5 Neonatal Resuscitator and Training Models Estimated Delivery Lead Times

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Estimated lead times for delivery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laerdal</td>
<td>2-36 weeks depending on volume and product</td>
</tr>
<tr>
<td>Ambu</td>
<td>3-5 weeks</td>
</tr>
<tr>
<td>Gaumard</td>
<td>4-6 weeks</td>
</tr>
<tr>
<td>VBM</td>
<td>7-9 weeks</td>
</tr>
<tr>
<td>3BScientific</td>
<td>14 weeks</td>
</tr>
</tbody>
</table>

Source: UNICEF Supply Division.

<sup>14</sup> Note: UNICEF procures Laerdal resuscitators through a HBB supply arrangement.

<sup>15</sup> Laerdal Global Health is a not-for-profit sister company of Laerdal Medical AS.

In March 2014, UNICEF surveyed suppliers to assess the market and assess its capability to supply quality products. The majority of suppliers (19) who replied to the survey can supply all resuscitator models (neonatal, infant/child and adult) to UNICEF product specifications and quality requirements. Just under half of the suppliers have local distributors in low-income countries, most can supply internationally, and several are based in middle-income countries. Further analyses from these surveys will inform UNICEF’s forthcoming procurement strategy, programme needs and details on suppliers’ ability to deliver. In particular, UNICEF will be constructing an approach to achieve the following:

- Assure multiple affordable manufacturers remain engaged in the market, despite currently modest procurement, by leveraging the UN Commission’s activities to increase local demand of resuscitator products.
- Achieve improved longer-term price visibility for resuscitators products, in particularly for the post-2015 period.
- Increased transparency of quality requirements for resuscitators to encourage improved compliance with appropriate standards.
- If possible, promotion of potential supplier base’s expansion to include domestic, quality suppliers in programme countries.

4. Issues, Challenges and Quality Considerations

- Laerdal Global Health’s provision of low-cost products through HBB ensures accessible and affordable products that can lead to increased neonatal resuscitator use and coverage. UNICEF looks forward to continued commitment to attractive pricing, and believes that other manufacturers should also offer products at improved, affordable cost. UNICEF believes that having multiple, competitive manufacturers (e.g., minimum 3) providing affordable and high quality will support sustainable planning and budgeting.
- Sample testing of resuscitators has identified relatively frequent device failures due to low quality materials, mechanical valve failure and substandard finishing which often results in leaking valves, fittings and dust particles within the device. Rigorous quality assurance and control is essential for resuscitators and manufacturers which must conform to ISO 10651-4:2009 Lung ventilators, Part 4: Particular requirements for operator-powered resuscitators and ISO 13485:2003 Medical devices, Quality management systems, Requirements for regulatory purposes as well as the EU Medical Device Directive 93/42/EEC and CE marking requirements.

Other issues and challenges that affect the neonatal resuscitator market identified by UNICEF COs and the Program for Appropriate Technology in Health (PATH) are summarised below (Table 6).17

<table>
<thead>
<tr>
<th>Challenges</th>
<th>Description</th>
<th>Consideration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Availability and supply</td>
<td>More than 100 neonatal resuscitators from 68 different manufacturers were identified in a global inventory. Whereas the majority were the ‘bag and mask’ type in both disposable and reusable formats, with prices ranging from less than $10 to more than $200, few were affordable, appropriately designed or of sufficient quality to be used in resource-limited settings. Industry reference standards, quality and features were not harmonised.</td>
<td>A healthy, sustainable and diverse manufacturer supplier base of at least 3-4 manufacturers is required to ensure the supply of affordable, high quality resuscitation devices that adhere to a quality standard.</td>
</tr>
</tbody>
</table>

Regulatory approval

Lack of in-country regulatory capacity for medical devices is a significant challenge in many low-income countries. Neonatal resuscitators are often not subject to any regulatory approval, which affect the quality of devices available on the local market.

Different regulatory product approval processes and wide ranging product standards, description, features, components and pricing structures make it difficult to ensure consistent procurement standards across countries.

Medical device regulatory authority capacity and local technical knowledge needs to be encouraged and strengthened in order to contribute to a healthy local quality device markets.

End-user challenges

While reusable models are more cost-effective than single-use (disposable) types, improper cleaning and sterilisation practices can reduce the quality and lifespan of the devices.

In many instances, high cost, insufficient training, low prioritisation and gaps in supply decrease access to available devices in resource-limited settings. Devices are often not available at primary health facilities.

UNICEF COs reported training (69%), availability (62%), quality (46%), and disinfection and cleaning (46%) as the main challenges faced by neonatal resuscitator end-users. COs have identified general durability and a lack of local language user manuals as key challenges reported by health workers using resuscitators.

National training institutions and curricula for SBAs and other health workers working on RMNCH need to be further developed and strengthened.

5. Steps Forward

- UNICEF will continue to monitor the market and will encourage partners and manufacturers to share pricing visibility beyond 2015, as well as encourage opportunities for all manufacturers to compete for product inclusion in training programmes and partnerships. UNICEF is developing a procurement strategy for resuscitators, due for completion by end-3Q 2014 and will use partner and supplier inputs to guide its construction.
- UNICEF Supply Division will review its current product portfolio and update it prior to the next tender exercise. This review will ensure that supply arrangements for non-HBB training models are maintained despite the relatively low demand in order to preserve access to these products for competency-based training in national curricula.
- UNICEF will also review and update its product range to ensure access to essential RMNCH devices in-line with the recommendations of the forthcoming H4+ interagency list, which includes neonatal resuscitators within the spectrum of basic essential newborn care interventions.
- UNICEF COs are encouraged to support the development and strengthening of national training institutions and curricula for SBAs and other health workers working on RMNCH.
- UNICEF will work with TRT members to discuss the key findings from its own consultations with UNICEF COs, the supplier survey, in addition to other work to be completed by other partners such as an “Adequacy of Supply” study being conducted by PATH and in-country availability studies by other TRT members.
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