

A PATH update

Shaping the market for neonatal resuscitation equipment

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I. Introduction

PATH has more than three decades of experience working with partners around the globe to develop and introduce innovative interventions into a wide range of markets. When new interventions (i.e., new technologies, products, and systems) are moving through the typical value chain from research to scale, distinct sets of activities at each phase must be properly performed and bottlenecks have to be identified and addressed in a timely manner. This report describes how PATH, in collaboration with partners, undertakes distinct activities at each phase in order to shape the global market and accelerate introduction and scale-up of basic neonatal resuscitation equipment (reusable bag and mask newborn resuscitator, reusable manual bulb suction device and resuscitation training mannequin) for developing countries (Appendix 1), as well as some potential risks and mitigation plans going forward.

II. Shaping the market to accelerate scale-up of resuscitation devices for developing countries

PATH began supporting the development and supply of appropriate technologies to address birth asphyxia, a major cause of neonatal mortality, in the mid-2000s, through the HealthTech program funded by the US Agency for International Development (USAID). The following section describes the five main activities that PATH has undertaken in order to shape the market for resuscitation devices.

Global landscape analysis to understand availability and accessibility of neonatal resuscitators in the global market

Our original premise was that the high cost of bag-and-mask newborn resuscitator devices was resulting in lack of availability and accessibility of resuscitators in the public sector in developing countries. To confirm this, PATH performed a global landscape analysis of resuscitation devices to inventory neonatal resuscitators in the market. The landscape analysis confirmed that, while more than 100 companies were producing and/or distributing neonatal resuscitators in high- and middle-income countries, few were priced for low-resource countries. The landscape analysis identified two additional challenges: many of the resuscitation devices were of low quality and most were not appropriately designed for low-resource countries.

Market assessment to articulate market dynamics

Following the global landscape analysis, PATH led a more in-depth assessment of the market dynamics present in two regions of sub-Saharan Africa in order to ascertain available devices, pricing, suppliers, and procurement mechanisms for these devices, and to estimate their market size in the public sector. The

first assessment was conducted in the Southern African Development Community (SADC) region in 2008; the second assessment was conducted in the Economic Community Of West African States (ECOWAS) region in 2010. Results from these studies demonstrated the following:

- There is a strong need for high-quality and affordable, reusable neonatal resuscitation devices in SADC and ECOWAS countries.
- Distribution channels are not well established and vary across the region. The United Nations Children's Fund was identified as playing a critical role in the supply of medical devices to SADC countries. However, many manufacturers distribute their products to end users primarily using their own distributor.
- There are no consistent purchasing standards across the region as a whole. Providing guidance to low-resource countries is necessary for better procurement decisions.
 - A wide range of devices that have different product descriptions, features, and price points (US\$10 to \$225) are available in the SADC region.
 - In the Republic of South Africa, devices that are no longer recommended for use are still being used at some facilities.
- Pursuing local manufacturing of neonatal resuscitator devices is not the most efficient way to increase availability. Because there are already a number of manufacturers of neonatal resuscitation devices, it will be more cost and time efficient to work with existing manufacturers rather than investing in the development of local production capacity.
 - Among existing manufacturers, devices manufactured by Laerdal Medical AS (Stavanger, Norway) are considered to be very high quality by providers.

Initiating a public-private partnership to develop high-quality, low-cost resuscitation devices

Our market assessments indicated that, although there are many available, Laerdal products consistently enjoyed excellent brand recognition and trust among providers. Beginning in 2010, PATH worked with Laerdal Medical to share our market research data and understand how distributors priced their products. In response to learning that their products are consistently priced at the high end of the pricing continuum, Laerdal Medical began considering how they might increase availability to lower end users while still building and maintaining brand recognition in developing countries.

Developing and providing guidance for low-resource countries for their procurement decisions

In 2005, PATH conducted a bench and user assessment of the performance and functionality, safety during use and reuse, ease of assembly and disassembly, and construction of many devices. Particular

attention was given to reusable, silicone bag-and-mask devices costing less than US\$30 each. The features and performance of the devices were compared in order to guide procurement decisions, with the expectation that demand from developing countries could be driven to high-quality and affordable devices. Results of the evaluations were compiled in Practical Selection of Neonatal Resuscitators, Version 3: A Field Guide (see: <http://www.path.org/publications/detail.php?i=1565>). The electronic version of this guide was distributed widely via implementing-partner organizations and through the PATH website. Around the same time, PATH conducted a web-based survey of neonatal experts to determine practices and preferences related to neonatal resuscitators in developing countries (see: [Coffey, Kelly, and Tsu, 2007](#)).

In 2008, PATH conducted a participatory evaluation of various resuscitation devices among providers in the KwaZulu Natal Department of Health (see: <http://www.path.org/publications/detail.php?i=1775>). At the completion of this study and at the request of the government in South Africa, PATH compiled a region-specific version of the field guide noted above (see: <http://www.path.org/publications/detail.php?i=2023>). Bag-and-mask as well as two tube-and-mask designs were included. This guide presents the criteria used during the device evaluation, evaluation results for each device, and suggestions on how to choose a resuscitator.

Additionally, in 2012 to 2013, PATH participated in the World Health Organization (WHO) consultation for technical specifications for procurement and the regulatory pathway of medical devices determined by the UN Commission on Life-Saving Commodities for Women and Children and advocated for and provided technical support to include resuscitation equipment in the WHO and Interagency List of Essential Medical Devices.

Building demand through Helping Babies Breathe

The Helping Babies Breathe (HBB) Global Development Alliance (GDA) was created in 2010 to train birth attendants in developing countries in the essential skills of newborn resuscitation, with the goal of having at least one person who is skilled in neonatal resuscitation at the birth of every baby. HBB is an evidence-based educational program to teach basic neonatal resuscitation techniques in resource-limited areas. The HBB GDA, a public-private partnership, originally consisted of the American Academy of Pediatrics, USAID, the US National Institute of Child Health and Human Development, Save the Children, Laerdal Global Health, and USAID implementing partners (which included PATH). HBB partners implemented the basic resuscitation training curriculum, which contributed to increasing demand for low-cost, high-quality neonatal resuscitation devices. In response, Laerdal Global Health developed low-cost, high-quality resuscitation devices for resource-limited settings in consultation with HBB members. This suite of equipment is available at a guaranteed at-cost price through 2015 to public-sector procurers (see: <http://www.laerdalglobalhealth.com/doc/2472/NeoNatalie>). In preparation for the HBB rollout, PATH was asked to work with the partners to identify technical and potential programmatic issues. PATH's recommendations were disseminated in the document: Procurement and Logistics Issues

Related to the Implementation of Helping Babies Breathe® (see: http://www.helpingbabiesbreathe.org/docs/PATH_HBB%20Procurement-Logistics%20Report_June2011.pdf). Further, PATH and the Maternal & Child Health Integrated Program designed and implemented the scale of HBB in the Latin America Caribbean region and also co-authored the HBB implementation guide and its translation into Spanish.

III. Potential risks and mitigation plan for future market sustainability

Risks and benefits of sole-sourcing

Today, in practice, Laerdal Global supplies much of the HBB efforts. As the demand for low-cost, high-quality resuscitation devices is likely to continue to increase in the future, there have been discussions regarding the potential risks and benefits if the HBB GDA continues to rely on only one supplier. The potential risks and benefits identified are outlined in the following table.

	Single supplier	Multiple suppliers
Potential risks	<ul style="list-style-type: none"> • May not be able to meet future global demand. • Supply sustainability is dependent on that one supplier. • May not lead to product improvements or price reduction, which is often achieved through competition. • Provides limited product choices for procurers. 	<ul style="list-style-type: none"> • Might demotivate the one supplier if other manufacturers are included. • Might fragment the market. <ul style="list-style-type: none"> - The market size for each supplier might not be sufficient in order for it to invest in further product improvements or cost reduction. • Difficult to negotiate prices if a procurement quantity from each manufacturer becomes small. • Difficult for procurers to select appropriate devices without clear guidance.
Potential benefits	<ul style="list-style-type: none"> • Can have a sizable market, which may provide incentives to a single supplier to continue investments in product improvements and/or cost reduction. • Able to facilitate negotiations and price reduction through procuring a large quantity from a single supplier. 	<ul style="list-style-type: none"> • Likely to meet the future global demand. • Easier to achieve supply sustainability by having alternative suppliers. • Can lead to product improvements and/or price reduction through competition. • Can provide a wider array of choices to procurers.

Risk mitigation plans

Weighing the potential risks and benefits of having a single supplier, PATH and USAID reached a consensus in 2013 to discontinue active engagement with other resuscitator manufacturers. The major reasons are:

- Laerdal Global Health has shown strong commitment to reduce neonatal mortality by providing high-quality, low-cost devices to developing countries. They have invested in product development and improvement, and it is likely that their commitment will remain the same for the foreseeable future.
- It is unlikely that Laerdal Global Health will be unable to meet the global demand in the near future. PATH's estimate of the potential total market size for the eight pathfinder countries targeting reproductive, maternal, neonatal, and child health (including heavily populated countries such as Nigeria), is 400,000 bag-and-mask resuscitators and the same number for multi-use suction bulbs. Laerdal has indicated that it can supply at least one million devices per year and so should not have any problem in meeting this level of global demand.
- Although the market will grow due to continued efforts by the HBB GDA, the immediate demand for resuscitation devices will not increase dramatically given the innate challenges of scaling this kind of intervention in countries.
- Soliciting active participation by additional suppliers in the HBB GDA will likely fragment the already small initial market and will not contribute to increasing accessibility or availability of affordable, high-quality devices. Additionally, no supplier other than Laerdal has given any indication of interest and/or ability to support the public-sector market in low-resource settings with affordable and appropriate equipment. It is, therefore, critical that stakeholders continue to support Laerdal in its efforts to supply affordable, high-quality equipment in the near term.
- The HBB GDA should continue to inform countries about the variety of affordable, high-quality devices available from multiple manufacturers and reiterate that countries are free to make their final purchasing decisions as they wish; the PATH purchasing guide is being used for this purpose.

Based on conversations with USAID on how to further mitigate the risks of potential supply and high price, PATH is currently estimating the adequacy of the production capacity of select suppliers of resuscitation commodities to meet the future estimated market size. PATH has also developed a simple, easy-to-use market forecasting tool to support countries in estimating their demand for resuscitation devices.

Appendix
 Shaping the market for neonatal resuscitation equipment

