WORKING PAPER

Prepared for the United Nations Commission on Life-Saving Commodities for Women and Children

March 2012

CASE STUDY

Newborn Resuscitation Devices

Prepared for the United Nations Commission on Life-Saving Commodities for Women and Children

February 2012

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Acknowledgements

The authors would like to thank the following individuals for their contributions: Olaolu Aderinola, Patrick Aliganyira, Norma Aly, Asma Badar, Sherri Bucher, Anna Chinombo, Elizabeth Dangaiso, Maria Isabel Degrandez, Todd Dickens, Ivonne Gómez, Abra Greene, Jorge Hermida, Jud Heugel, Miguel Hinojosa-Sandoval, Jessica Hulse, Nnenna Ihebuzor, William Keenan, Etleva Kadilli, Peter Kaimenyi, Pancho Kaslam, Diana Khonje, Sam Kompheak, Norma Aly Leitzelar, Goldy Mazia, Bernarda Méndez, G. Mhlanga, Kanté Modibo, Helene Moller, Georgina Msemo, Erna Mulati, Sirgut Mulatu, Guillermina Nadal, Iv Ek Navapol, Ida Neuman, Bridget Okoeguale, Dipo Otolorin, Bertha Pooley, Mercedes Portillo, Patricia Quinteros, Mirwais Rahimzai, Olga Arroyo Reyes, Rina Rohsiswarmo, Sayed Rubayet, Janet Saulsbury, Ludo Scheerlinck, Jill Sherman-Konkle, Gretchen Shively, Elizabeth Silva, Monique Supiot, Chea Meng Tieng, Nani Walandouw, Abimbola Williams, and Judy Wong.

PATH's contribution to this case study was made possible by the generous support of the American people through the United States Agency for International Development (USAID) under the terms of the HealthTech Cooperative Agreement # AID-OAA-A-11-00051. The contents provided by PATH are the responsibility of PATH and do not necessarily reflect the views of USAID or the US Government.

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Photo 1: A mother in Nepal lies with her baby. © 2008 Suaahara/JHUCCP; courtesy of Photoshare.

Photo 2: A baby in Djoliba, Mali. © 2000 Hannah Koenker; courtesy of Photoshare.

Photo 3: A newborn child sleeps next to his mother at the Tinh Gia District Health Center in Vietnam. © 2004 Philippe Blanc; courtesy of Photoshare.

Acronyms

AAP	American Academy of Pediatrics
DOH	Department of Health
GDA	Global Development Alliance
HBB	Helping Babies Breathe
MCHIP	Maternal and Newborn Health Integrated Project
MDG	Millennium Development Goal
MOH	Ministry of Health
NGO	Non-governmental organization
SADC	Southern African Development Community
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
WHO	World Health Organization

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Executive Summary

Almost half of all newborn deaths are in the first 24 hours after birth, the majority resulting from intrapartum hypoxia, also known as birth asphyxia. This condition, manifesting as the failure of the newborn to establish breathing after birth, kills 814,000 newborns every year, accounting for almost a quarter of newborn deaths.[1] Additionally, there are an estimated 1.02 million intrapartum stillbirths every year, an unknown number of them may be live born but misclassified as fresh stillbirth when no resuscitation has been provided.[2] Many of these deaths could be easily prevented with basic neonatal resuscitation which requires tactile stimulation, a neonatal bag and mask, suction device, and a resuscitation training mannequin. For many babies born in low-resource settings, however, this basic intervention is not available. Ensuring universal access to newborn resuscitation is an essential and necessary challenge in the effort to reduce neonatal mortality.

Although there is a large supplier base supporting this category of medical devices in both developed and developing countries, resuscitation equipment is more likely to be available in tertiary and district hospitals than in lower-level health facilities and is almost nonexistent in home deliveries where a large proportion of births take place. A major barrier is the poor resuscitation skill of health providers at all levels of health care delivery in low-resource settings. In addition, saving the lives of newborns requires more than having access to appropriate neonatal resuscitation equipment. An appropriate environment, as well as appropriately trained users of the products should be available at all times. Global-level donor procurement of bag and mask resuscitators, suction devices, and training mannequins has been revitalized since the launch of the Helping Babies Breath Global Development Alliance. Since June 2010, the program and products have been introduced in 34 countries with national scale-up being planned in 10 of them. With increased national-level attention being paid to newborn health and the advent of donor-supported initiatives to program essential newborn care, procurement of bag and mask resuscitators, suction devices, and training mannequins and their corollary training programs are the single most important and strategic investment on the part of countries that are interested in reducing neonatal mortality due to birth asphyxia. The challenges outlined in this report are being mitigated by the success of recent global efforts and can be further addressed by the following set of ten interrelated actions:

1. Prioritize publication of the World Health Organization Essential Medical Devices List for priority interventions for maternal, newborn, and child health. Use this list, which includes neonatal resuscitators (bag and mask) and suction devices, as a reference for device lists at the country level.
2. Ensure access to information about high-quality, affordable resuscitation products to international and national purchasing agents by updating and disseminating the international purchasing guide on sources, prices and quality.[3]

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[1]Black R, Cousens S, Johnson HL, et al. Global, regional, and national causes of child mortality in 2008: a systematic analysis. *Lancet*. June 2010;375(9730):1969–1987.
[2]Lawn J, Shibuya K, Stein C. No cry at birth: global estimates of intrapartum stillbirths and intrapartum related neonatal death. *Bulletin of the World Health Organization*. 2005;409–417.
[3] PATH. *Practical Selection of Neonatal Resuscitators: A Field Guide (Version 3)*. Seattle, WA: PATH; 2010. Available at: http://www.path.org /publications/detail.php?i=1565. Accessed February 1, 2012.

3. Promote the use of skilled birth attendants and, where necessary, address policies that impede access to resuscitation in home births.
4. Increase funding for scaling up newborn resuscitation program efforts that create demand as well as purchase of critical resuscitation equipment and skills. The Helping Babies Breath Global Development Alliance, one example of a global initiative to strengthen demand, provides an opportunity for a rapid increase in coverage of a quality resuscitation program since it is already established, has a widespread global footprint, and has begun to increase product demand in some countries. Position Helping Babies Breath activities as a critical component of national integrated essential newborn care and/or emergency obstetric care and newborn resuscitation programming at all levels of health delivery.
5. Build on the public-private partnership model, bringing together donors, governments, non-governmental organizations, manufacturers, and suppliers to work toward a common goal of scaling up focused high-impact interventions.
6. Extend the same or parallel model across more countries and/or diverse priority commodities for newborn and maternal health such as prevention of postpartum hemorrhage with uterotonics.
7. At the country level, advocate to include newborn resuscitation equipment in country essential device lists; fund the national roll out of resuscitation; establish a coordinating body at the central level for planning, budgeting, and supervision; and strengthen systems for scaling up resuscitation—pre-service and in-service education and training. In addition, provide mentoring and supervision; monitoring; tracking information on services, supplies, and outcomes; improve quality; and ensure availability of supplies.
8. Undertake periodic independent reviews by an objective body to ensure quality of design until national regulatory agencies have built capacity.
9. Negotiate tariff reductions to streamline procurement and delivery of affordable, high-quality resuscitation equipment manufactured by global and regional producers.
10. Fund further evaluation and research of resuscitation technology and program impact.

1. Introduction

The United Nations Commission on Life-Saving Commodities for Women and Children aims to build consensus around priority actions for increasing the availability, affordability, accessibility, and rational use of selected commodities for women's and children's health. The purpose of this case study is to describe the global burden and need for quality newborn resuscitation devices; current availability, access, and use of such devices; barriers that impede increased use; innovative technologies; strategies to expand use; and to provide recommendations for addressing barriers and scaling up innovations.

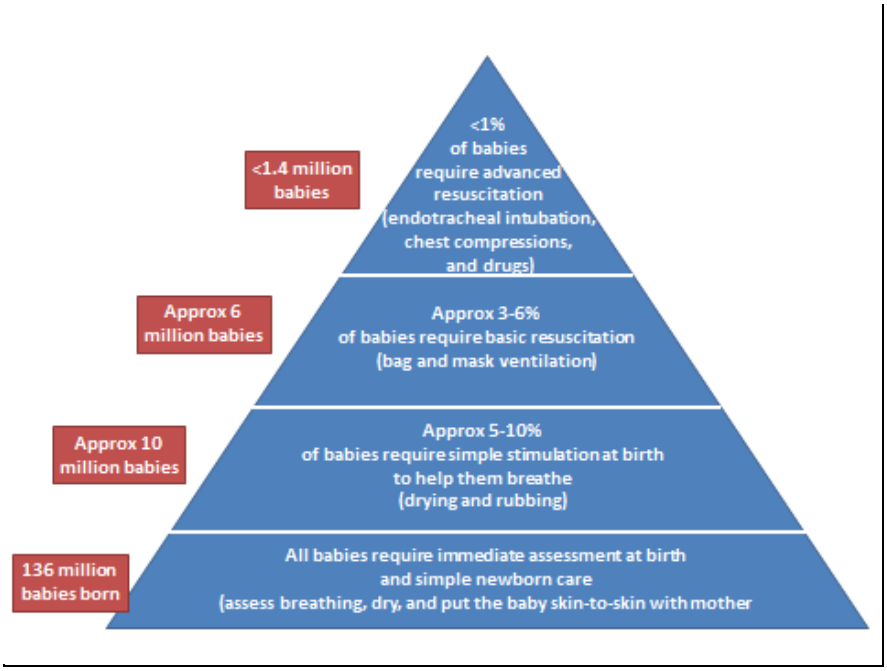
Global burden

Over the last decade, the number of newborn deaths has declined from 3.9 to 3.1 million and the mortality rate from 33 to 23 per 1,000 live births. However, the average annual rate of decline has been slower for neonatal mortality (1.7 percent) than for under age five mortality (2.2 percent) and maternal mortality (2.3 percent). As a result of the uneven pace of decline, the proportion of newborn mortality among children under age five has increased (37 percent to 41 percent).[4]

Almost half of all newborn deaths are in the first 24 hours after birth, the majority resulting from intrapartum hypoxia, also known as birth asphyxia. This condition, manifesting as the failure of the newborn to establish breathing after birth, kills 814,000 newborns every year, accounting for almost a quarter of newborn deaths.[5] Additionally, there are an estimated 1.02 million intrapartum stillbirths every year, an unknown number of whom may be live born but misclassified as fresh stillbirth when no resuscitation has been provided.[6] As shown in Figure 1 below, an estimated 5 percent to 10 percent of newborns (~10 million) need the initial steps of resuscitation such as tactile stimulation, airway clearing, or positioning. About 3 percent to 6 percent of all newborns (~6 million) need these initial steps as well as assisted ventilation with bag and mask. Less than 1 percent of births (~1.4 million) need advanced resuscitation with endotracheal intubation, chest compression, and drugs.[7]

[4]United Nations Children's Fund. Levels and Trends in Child Mortality. New York: United Nations: 2011.
[5]Black R, Cousens S, Johnson HL, et al. Global, regional, and national causes of child mortality in 2008: a systematic analysis. *Lancet*. June 2010;375(9730):1969–1987.
[6]Lawn J, Shibuya K, Stein C. No cry at birth: global estimates of intrapartum stillbirths and intrapartum related neonatal death. *Bulletin of the World Health Organization*. 2005;409–417.
[7]Wall S, Lee ACC, Niermeyer S, et al. Neonatal resuscitation in low-resource settings: What, who, and how to overcome challenges to scale-up? *International Journal of Gynecology and Obstetrics.*2009;107:S47–S64.

Figure 1: Estimates of global numbers of babies in need of resuscitation at birth.



Source: Wall S, Lee ACC, Niermeyer S, et al. Neonatal resuscitation in low-resource settings: What, who, and how to overcome challenges to scale up? *International Journal of Gynecology and Obstetrics.*2009;107:S47–S64.

In general, a minimum of equipment is needed for newborn resuscitation. Availability and proper use of a dry towel, bag and mask resuscitator, and a suction device, should be promoted for all births, even at the lower health facility levels and in the community.[8] With this basic equipment and effective pre- and in-service training, successful newborn resuscitation successful newborn resuscitation can be accomplished in about 30 percent of cases that otherwise would end in death among full term babies and 5 to 10 percent among preterm births.

2. Global Policy

2.1 World Health Organization Guidelines

In June 2011, the World Health Organization (WHO) led a technical consultation to update the evidence and recommendations on newborn resuscitation based on the Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) approach. These recommendations were conditionally approved by the WHO Guidelines Review Committee in December 2011.[9] It needs to be published urgently. Relevant recommendations regarding the bag and mask and suction bulb are below:

- ***Self-Inflating Bag and Mask*:** For newborns requiring positive pressure ventilation [resuscitation], ventilation should be provided using a self-inflating bag and mask. In an emergency situation where a

[8] Newton O, English M. Newborn resuscitation: defining best practice for low-income settings. *Transactions of the Royal Society of Tropical Medicine and Hygiene*. 2006;100:899–908.
[9] World Health Organization (WHO). *Draft Guidelines on Basic Newborn Resuscitation*. Geneva: WHO; December 2011.

self-inflating bag is not functional, mouth to tube and mask or mouth to mask can be used for providing positive pressure ventilation.

- ***Suction Bulb*:** For newborns requiring suction to clear the airway, a device with a mechanical source of negative pressure [such as an electric or a foot-operated vacuum pump] is recommended. In settings where a device with a mechanical source of negative pressure is not available, suction by a single-use or easy-to-clean bulb syringe is preferable to a mucous extractor with a trap for newly born babies who require suction to clear the airway [because of lower risk of infection with the former devices]. The expert group also recommended that only single-use bulb syringe or mucous extractor should be used; if this is not possible, only those devices that can be easily and thoroughly cleaned should be used.

2.2 The World Health Organization Essential Medical Devices List

WHO is currently developing a draft Essential Medical Devices List for priority interventions for maternal, newborn, and child health. This list includes neonatal resuscitators (bag and mask), suction devices, and resuscitation training mannequins.

3. Current Resuscitation Technologies

3.1 Neonatal resuscitators

Current resuscitation technology is a self-inflating bag and mask device (see Figure 2), which is specified by international policy guidelines as the standard, evidence-based technology for newborn resuscitation. Despite advances in features and materials, the bag and mask technology is not new. The first manual resuscitation device with a self-inflating bag was developed in 1954. However, for decades the equipment remained too costly for low-resource settings. Only recently have affordable, quality devices become available. Tube and mask devices (Figure 2), which require the user to blow into the tube, were previously developed as a low-cost alternative to bag and mask devices and may be useful in environments where self-inflating bags are not available, affordable, or functional.[10] However, manufacture of tube and mask devices is severely limited, making them a less feasible option for low-resource settings.

[10] Wall S, Lee ACC, Niermeyer S, et al. Neonatal resuscitation in low-resource settings: What, who, and how to overcome challenges to scale up? *International Journal of Gynecology and Obstetrics.*2009;107:S47–S64.

Figure 2. Examples of tube and mask and self-inflating bag and mask resuscitators.

PATH/Patrick Mckern

In 2006, PATH conducted an evaluation of select neonatal resuscitation devices that were available in developing countries and found a high safety profile for bag and mask devices, including evidence that bag and mask devices were sufficient to reliably achieve resuscitation by appropriately-trained providers. Prices ranged from US$8 to over US$100.[11] Below are features of bag and mask resuscitators:

- ***Mask*:** Proper resuscitation depends on a good seal between the mask and the neonate's face, hence neonatal masks for resuscitators generally come in two sizes to fit low- and normal-birth-weight babies. An important safety feature is the pressure-relief valve which is designed to limit the pressure that the resuscitator can deliver to prevent lung damage to the newborn. Additional features augment ease of use such as ridged surfaces on parts that facilitate assembly and disassembly with wet hands and color-coded parts that distinguish different components.
- ***Bag*:** A resuscitator bag (usually 240 ml or 500 ml size volume) specifically designed for providing appropriate tidal volumes (volume of air between normal inspiration and expiration) for neonates can help reduce errors during use and simplify training.

[11] PATH. *Practical Selection of Neonatal Resuscitators: A Field Guide (Version 3)*. Seattle, WA: PATH; 2010. Available at: http://www.path.org /publications/detail.php?i=1565. Accessed February 1, 2012.

3.2 Suction Devices

Neonatal suction devices are used to clear the airway of the newborn to help facilitate breathing (see Figure 3). Suctioning of the mouth and nose of baby is not recommended as a routine intervention at birth but only when required. The method used to clear the airway depends on local availability and choices of devices. International guidelines recommend use of a mechanical source of negative pressure [such as an electric or foot-operated vacuum pump] and, in absence of such a device, bulb suction should be used. Vacuum suction pumps are composed of disposable single-use sterile suction tubes attached to a low-pressure suction machine (less than 100 mmHg or 130 cm of water). No industry reference standards are available for newborn bulb suction devices. Manual bulb suction device requirements include the following design parameters: (a) for use on neonates for mucus and amniotic fluid, (b) able to suction mouth and nose, (c) easy to use, (d) durable and reusable, (e) affordable, and (f) easily cleaned and disinfected.

Figure 3. Examples of neonatal suction devices.

Photo: PATH

In 2011, PATH evaluated a range of neonatal bulb suction devices.[12] A total of 34 devices were procured, all of which were labeled for use specifically with infants. A total of 20 representative devices were tested. Product prices ranged from US$2 to US$10 each. Two devices, Easy Grip Transparent Baby Nasal Aspirator and the Laerdal NeoNatalie Penguin suction device, were identified as being high-performing devices. Findings indicate that the single product in the group of large one-piece aspirators with a top that opens (Laerdal NeoNatalie Penguin device) performed similarly to the one-piece suction bulbs with the added advantage of offering multiple cleaning and disinfection options and excellent durability.

3.3 Resuscitation training mannequin and materials

[12] PATH. *Evaluation of Manual Neonatal Bulb Suction Devices for Use in Low-Resource Settings*. Seattle: PATH; 2011.

A training mannequin is a model of the baby permitting visualization of selected features of effective ventilation such as chest rise (see Figure 4). Although the mannequin is not required for resuscitation of babies, it is a *critical* component for programs as it is allows *competency-based* training of health workers before practicing on babies. It is also useful for subsequent follow-up practice and during supervisory visits to improve quality of care, especially in centers with fewer births where lack of exposure to adequate cases of resuscitation results in loss of skills. Various training materials are currently available that integrate use of this technology including the WHO Basic Newborn Resuscitation Guide, the American Academy of Pediatrics' (AAP) Neonatal Resuscitation Program and Helping Babies Breathe® (HBB) Program, and the UK Resuscitation Council Newborn Life Support.

Figure 4. Example of a neonatal resuscitator training mannequin.

Photo: Laerdal Global Health

In 2009, PATH comprehensively documented and categorized all available neonatal resuscitator training mannequins and assessed the need for refined and/or lower-cost training mannequins among potential users to contribute to an evidence-based decision on the value of pursuing development of a low-cost training mannequin.[13] PATH found that product prices ranged from US$50 to US$1,500 and that no commercially available mannequin possessed all the ideal features desired by key informants, thereby confirming the need for a low-cost mannequin for neonatal resuscitation training in low-resource settings. Difficulty procuring high-quality, affordable resuscitation equipment spawned a call to action for

[13] PATH. *Assessing the Need for a Low-Cost Manikin for Neonatal Resuscitation Training*. Seattle: PATH; 2009.

appropriate product designs for low-resource settings.[14] Appendix A illustrates one private company's response to this need.

4. Global and National Regulatory Policy

All imports of medical equipment and devices are subject to the approval of the government through a foods and drugs board or similar organization in each country. The device must be on the national essential medical equipment/devices list or a formal application made specifically for approval for the importation of the device. The WHO Interagency List of Essential Medical Devices is often used as a base document for national health authorities to create their individual essential medicine and equipment lists. In a recent multi-country survey of 20 countries, 79 percent had a medical supplies and equipment regulatory board. However, of the countries that had such a board, over a quarter (27 percent) did not regulate newborn resuscitation equipment.[15] National essential equipment lists were obtained from Liberia and Togo as indicators for both the anglophone and francophone settings in sub-Saharan Africa. The list for Liberia mentions resuscitators generally, whereas the list for Togo does not include the device.[16] Updated international purchasing guide on sources, prices and quality on high-quality, affordable resuscitation products are available to international and national purchasing agents.

5. Access and Use of Devices

5.1 Country-level data

Neonatal resuscitation with bag and mask by professional health workers for babies who do not breathe at birth is considered an essential evidence-based intervention to reduce newborn mortality at the primary and referral levels of care.[17] Countries often do not prioritize newborn resuscitation equipment needs among many other conflicting priorities. Availability of the necessary equipment to support this intervention is not often available. For example, in the seven countries that have conducted Maternal and Child Health Service Provision Assessment surveys in the past ten years, 59 percent of babies were born in facilities and only 11 percent of them had access to resuscitation (25 percent were born in facilities equipped with newborn resuscitation commodities and 11 percent were attended by health providers trained in resuscitation) (Figure 5).[18]

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[14] Wall S, Lee ACC, Niermeyer S, et al. Neonatal resuscitation in low-resource settings: What, who, and how to overcome challenges to scale up? *International Journal of Gynecology and Obstetrics.*2009;107:S47–S64.
[15] Helping Babies Breathe Global Development Alliance. *Multi-Country Rapid Newborn Resuscitation Assessment for the UN Commission on Life-Saving Commodities for Women and Children*. January 2012 (unpublished report).
[16] PATH. *Market Assessment of Neonatal Resuscitators, Training Mannequins, and Suction Devices in Countries Within the Economic Community of West African States (ECOWAS). A HealthTech Report*. Seattle: PATH; 2009.
[17] The Partnership for Reproductive, Maternal, Newborn & Child Health (RMNCH). *Global Review of the Key Interventions Related to Reproductive, Maternal, Newborn and Child Health*. Geneva: RMNCH; 2011.
[18] Survey sources: Ministry of Health and Population, El-Zanaty Associates, and ORC MACRO. *Egypt Service Provision Assessment Survey 2004*. Calverton; ORC MACRO: 2005.; Ghana Statistical Service, Health Research Unit, Ministry of Health, and ORC MACRO. *Ghana Service Provision Assessment Survey 2002.* Calverton: ORC MACRO: 2003.; National Coordinating Agency for Population and Development Kenya, Ministry of Medical Services, Kenya, Ministry of Public Health and Sanitation, the Kenya National Bureau of Statistics, and ICF Macro. *Kenya Service Provision Assessment Survey 2010.* Washington DC: ICF Macro International Inc.; 2011.; Ministry of Health and Social Services (MoHSS) [Namibia] and ICF Macro. 2010. *Namibia Health Facility Census 2009*. Windhoek: MoHSS and ICF Macro; 2010.; National Institute of Statistics [Rwanda], Ministry of Health, and Macro International Inc. *Rwanda Service Provision Assessment Survey 2007.* Calverton: Macro International Inc.; 2008.; National Bureau of Statistics [Tanzania] and Macro

Figure 5: Access to resuscitation among newborns in health facilities in Egypt, Ghana, Kenya, Namibia, Rwanda, Tanzania, and Uganda.

Source DHS 2006-2008. Service Provision Assessment: 2002-2010. MACRO International Inc.

Another survey conducted by the United States Agency for International Development (USAID) Maternal Child Health Integrated Program (MCHIP) in 597 hospitals and health centers in Ethiopia, Kenya, Madagascar, Rwanda, and Tanzania (including Zanzibar) assessed the availability of bag and mask (infant size) resuscitators, bulb suction devices, suction apparatuses for use with catheter, and resuscitation tables. It was found that, overall, 71 percent of health facilities had all three types of newborn resuscitation equipment (resuscitator, one type of suction device, and table). The overall average for specific resuscitation items were as follows: 71 percent—resuscitation table, 74 percent—bulb suction device, 73 percent—bag/mask/tube. Despite the high overall availability of resuscitation equipment there were substantial country disparities. The availability of the resuscitation items ranged from 48 percent to 90 percent: bag and mask ranged from 54 percent to 100 percent; bulb suction device ranged from 32 percent to 89 percent; suction apparatus from 56 percent to 100 percent; and resuscitation tables from 48 percent to 100 percent.

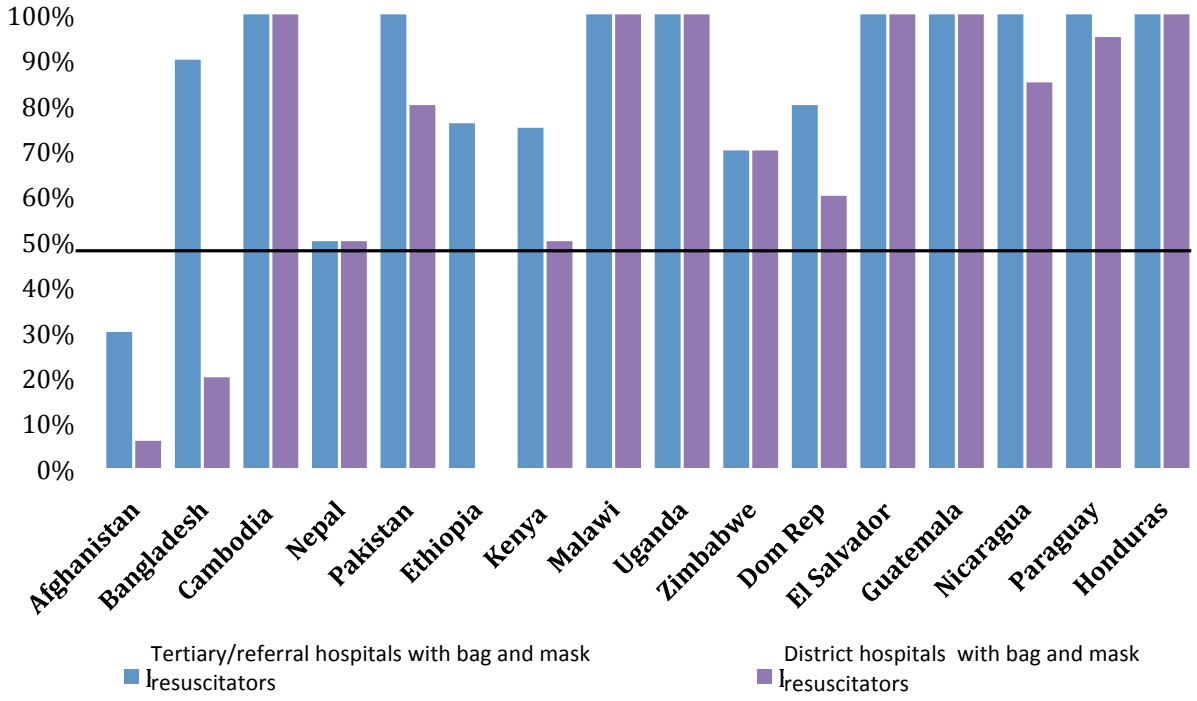
While a large percentage of facilities had resuscitation devices, a simulation test conducted in three of the five countries found that only about half (49 percent; range 42 percent to 52 percent) of health providers were able to ventilate newborns correctly. In the two countries where the resuscitation simulation was not

International Inc. T*anzania Service Provision Assessment Survey 2006*. Calverton: Macro International Inc., 2007.; Ministry of Health (MOH) and Macro International Inc. *Uganda Service Provision Assessment Survey 2007*. Kampala: MOH and Macro International Inc.; 2008.

conducted, health providers were asked to list the key steps in resuscitation. Only one-third (33 percent; range 30 percent to 35 percent) were able to list the correct steps for newborn resuscitation.[19]

Similar results were seen in the 2012 multi-country assessment[20] where stakeholders and implementers in 20 participating countries were asked to estimate the availability of bag and mask in their tertiary/referral hospitals, district hospitals, and primary/health centers (Figure 6). Although seven countries estimated to have 100 percent availability of bag and mask at referral and district hospitals, the other nine countries lack this essential piece of equipment at tertiary- and district-level hospitals.

Figure 6: Percentage of availability of bag and mask resuscitators in hospitals in 16 countries.

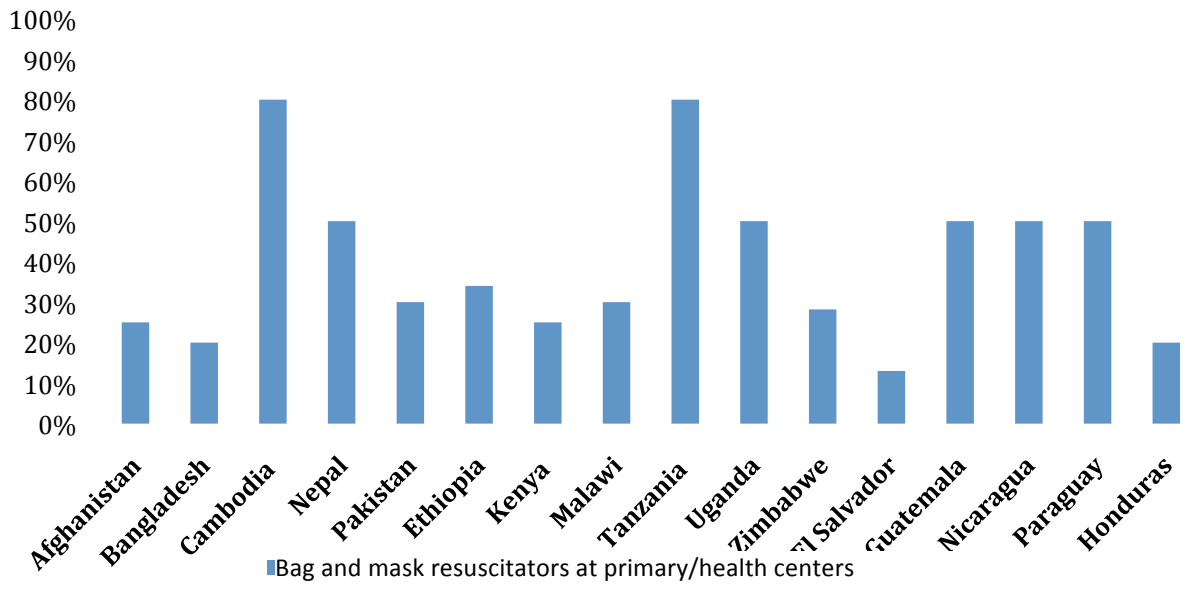


The following chart shows that a large percentage of primary health centers are not equipped with bag and masks ranging from 20 percent in Cambodia and Tanzania to as high as 87 percent in El Salvador (Figure 7).

Figure 7: Availability of bag and mask resuscitators in primary health centers in 16 countries.

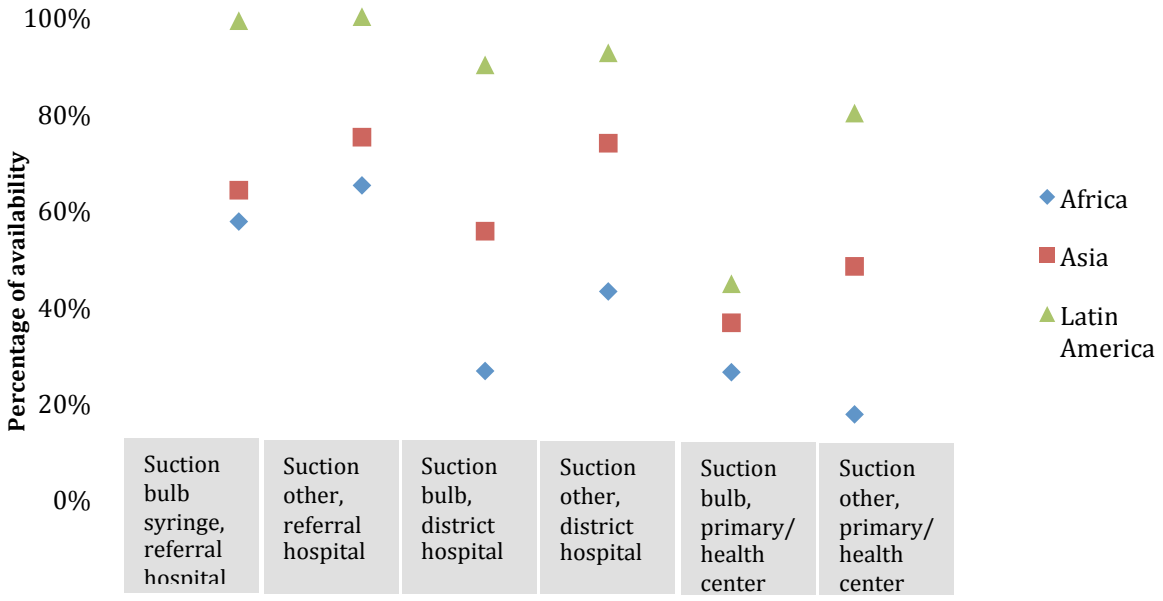
[19]Ricca J. Assessing the quality of care for prevention, identification, and management of maternal and newborn complications at the time of birth: Results from 5 country facility surveys. Presented at: MCHIP meeting with USAID, September 2011. Available at: http://www.mchip.net/sites/default/files/MCHIP%20Q0C%20panel%20presentation%20for%20APHA%20October%2028%20FINAL%20(2).pdf. Accessed February 15, 2012.

[20] Helping Babies Breathe (HBB) Global Development Alliance (GDA). *Multi-Country Rapid Newborn Resuscitation Assessment for the United Nations Commission on Life-Saving Commodities for Women and Children*. January 2012 (unpublished report).



The same availability pattern as for the bag and masks is demonstrated with suction devices; it is more common to find bulb suction and manual/electric suction pumps at hospitals compared to health centers (Figure 8). Most countries do not have adequate supplies of suction devices. There seems to be regional variation in terms of availability of suction in health facilities, with the biggest gap identified in Africa, followed by Asia, while Latin America maintains adequate availability overall.

Figure 8: Average availability of suction bulb syringes and other suction devices (manual/electric pump) at district-level hospitals and primary health centers by region in Africa, Asia, and Latin America.



An Ethiopian national emergency obstetric and newborn care assessment[21] was conducted at the end of 2008 among 797 facilities (751 of which provided services for childbirth). This assessment showed that health centers and hospitals were not ready to provide newborn resuscitation. As many as 20 percent of the hospitals where short of mucus extractors, and one-quarter did not have a resuscitation bag and newborn-sized mask. Although all health centers should be prepared to perform basic neonatal resuscitation, more than half of them did not have a mucus extractor (bulb syringe or similar), 68 percent lacked the correct size face masks, and 66 percent did not have a resuscitation bag and mask. When facilities were asked why they did not provide newborn resuscitation, the major reason given (66 percent) was the unavailability of bag and mask. In addition, significant numbers of health centers (40 percent) did not have trained health providers that could provide basic newborn resuscitation. The survey also revealed that over 75 percent of midwives and 50 percent of nurses in the surveyed health facilities had received some sort of newborn resuscitation training with using bag and mask, most of them as part of their pre-service training or in combination with in-service training. However, only seven health officers were found that had ever done newborn resuscitation training, which clearly indicates a gap in their pre-service education.

In a 2007 study of newborn care services in 11 districts of 10 states in India, availability of resuscitation equipment varied by level of care. All but two district hospitals had self-inflating bags (240 ml) with two face masks, and all had suction devices. The majority of the community health centers had at least one self-inflating bag with a reservoir primarily in the labor rooms and operation theaters. Most of the facilities did not have face masks in the operation theater although they were available in a substantial number of labor rooms. All community health centers had at least one suction device, and the majority had one to two available in the labor room and operation theater. Neither self-inflating bags with reservoirs nor suction devices were available in the majority of the primary health centers.[22]

As in the other studies noted earlier, while a large percentage of hospitals and health centers had resuscitation equipment, not all health providers were able to use it effectively. Approximately half of the 44 doctors and 21 staff nurses and about 40 percent of the 23 auxiliary nurse midwives included in the Indian study demonstrated satisfactory knowledge and skills related to resuscitation.

5.2 Increasing availability, access, and use of newborn resuscitation equipment and skills

In 2010, the AAP launched Helping Babies Breathe (HBB), a simplified evidence-based resuscitation training program to address lack of neonatal resuscitation skills in resource-limited areas. The curriculum was developed in response to the need for an evidence-based and harmonized training program in neonatal resuscitation designed to be easily incorporated along with other ongoing maternal and newborn care initiatives and strategies, such as the WHO programs, Essential Newborn

[21] Federal Ministry of Health (FMOH). *National Baseline Assessment for Emergency Obstetric and Newborn Care*. Addis Ababa: FMOH; 2008.

[22] United States Agency for International Development, Government of India, IndiaCLEN, National Rural Health Mission, PATH. *Rapid Assessment of Essential Newborn Care Services and Needs in National Rural Health Mission Priority States of India*. New Delhi: PATH; 2007.

Care and Integrated Management of Childhood Illness. The scientific basis of the HBB program is the evidence evaluation of the International Liaison Committee on Resuscitation, the evidence base also shared by the Neonatal Resuscitation Program of the AAP and the American Heart Association. The global curriculum is designed to be used by skilled birth attendants who may or may not have assistance from a second trained helper.

Once an appropriate training curriculum and associated equipment for low-resource settings were made available, a Global Development Alliance (GDA) was established to roll out the curriculum. Strategic resource partners of the alliance are USAID,[23] the Eunice Kennedy Shriver National Institute for Child Health and Human Development, AAP, Save the Children, Laerdal Global Health, Johnson and Johnson, and Latter Day Saints Charities. The objectives of the GDA are to increase attention on and mobilize resources for newborn resuscitation; improve availability of high-quality, appropriate, and affordable resuscitation devices and training materials; improve the resuscitation capabilities of birth attendants with an emphasis on skilled birth attendants; strengthen the supply chain logistics system for resuscitation devices; and evaluate the impact of resuscitation programs at scale.

6. Cultivating Demand From Caregivers

Newborn survival and development is often a national priority and with support from the Helping Babies Breath Global Development Alliance, national newborn resuscitation programs are being scaled up which has increased the coverage of a quality resuscitation program and the demand for newborn resuscitation devices in some countries. Since the launch in June 2010, the GDA has introduced HBB in 34 countries. Of these, national scale-up is planned in 10 countries. Almost 70,000 health providers were trained between June 2010 and December 2011. At least 45,000 bag/masks and suction bulbs were procured by these countries either through the United Nations Children's Fund (UNICEF) supplies office or directly from Laerdal Global Health. There are indications that other brands of resuscitators also became increasingly available as countries developed greater awareness and commitment to roll out resuscitation.

6.1 Provider barriers

Low levels of skilled birth attendants and adequate training in resuscitation skills

In Millennium Development Goal (MDG) countries, skilled birth attendants attend 54 percent of all births. The inadequate supply of skilled birth attendants and low coverage of facility delivery impedes the use of resuscitation equipment. Data from the multi-county assessment[24] of 20 countries indicate that 70

[23] The United States Agency for International Development's implementing partners include: Save the Children and Jhpeigo under the global Maternal and Newborn Health Integrated Project, University Research Corporation under the global Health Care Improvement, PATH under the global HealthTech IV/V projects, Management Sciences for Health under the regional African Strategies for Health Project (replacing Africa's Health in 2010), CORE Group, Africa Regional Center for Quality Health Care, East Central and Southern African Health Community, East Central Southern Africa College of Nursing, Reproductive Health Association of Cambodia, and the Reproductive and Child Health Alliance in Cambodia.

[24] HBB GDA. *Multi-Country Rapid Newborn Resuscitation Assessment for the United Nations Commission on Life-Saving Commodities for Women and Children*. January 2012 (unpublished report).

percent of the participating countries had categories of workers that are not permitted to perform neonatal resuscitation, as per national standards, even though they are assisting in deliveries. Most of these are community-level providers such as traditional birth attendants and community health workers (57 percent) while others such as ward attendants, assistant nurses, auxiliary nurses, health assistants, and medical students (24 percent) attend deliveries in health facilities.

Skilled birth attendants may not be adequately trained in newborn resuscitation since pre-service training for resuscitation is not always competency-based. Most pre-service institutions lack the necessary resuscitation equipment for hands-on training by the students. Limited or no time is allowed during service to practice or refresh skills that have been learned. Moreover, in-service training is often off-site, inadequate and irregular, and relies mostly on a limited number of costly training simulators. Finally, there is often no post-training system to support providers to maintain their skills after the off-site training.

Due to a lower case load, newborn asphyxia occurs relatively infrequently in small hospitals and peripheral health centers. This results in low exposure to asphyxia cases and inadequate use and retention of resuscitation skills by health workers, especially by those very infrequent users in peripheral centers. Supply of mannequins for practice and periodic refresher training is essential in this situation.

Recent studies of the HBB educational program conducted in Kenya and Pakistan evaluated the skills of 31 facilitators and 102 learners (pediatricians, obstetricians, medical officers, nurse midwives, nurses, community health workers). The studies indicate that HBB training results in significant improvement in resuscitation knowledge and skills. However, the studies also showed that developing competency skill in newborn resuscitation with bag and mask is complex and requires adequate time for instruction and possibly mentoring.[25] Because learning resuscitation skills is complex, providers can sometimes use resuscitation equipment inappropriately. This includes incompetent techniques such as poor or excessive ventilation with the bag and mask and high negative pressured suction being applied with some suction machines. The studies showed that increased practice time and regular retraining is necessary to keep bag and mask skills effective for neonatal resuscitation.

Finally, forecasting of supply requirements is often not done where it is most needed; as shown in the multi-country rapid assessment, forecasting is often done by the ministry of health (MOH)(48 percent, n=27) rather than directly at the facility level (30 percent).[26] The calculation of actual need therefore becomes a vague top-down exercise instead of basing the forecasting plan on an actual needs assessment. Even when forecasting is done at the facility level there is a failure to prioritize newborn equipment needs among many other conflicting priorities.

Selection and maintenance of equipment

Providers and facility procurement staff may possess inadequate knowledge about procurement of the

[25] Singhal N, Lockyer J, Fidler H. Helping Babies Breathe: Global neonatal resuscitation program development and formative educational evaluation. *Resuscitation*. 2012;83:90–96.
[26] HBB GDA. *Multi-Country Rapid Newborn Resuscitation Assessment for the United Nations Commission on Life-Saving Commodities for Women and Children*. January 2012 (unpublished report).

appropriate commodities for resuscitation of newborn babies. Examples include lack of awareness of the suitable sizes of the self-inflating bag and masks and appropriate negative pressures required with the use of suction machines.

Often when equipment is available it may not be readily accessible in the delivery room. Because of difficulties in procurement, the respirators and mannequins may be locked up, especially during the night shift. Providers sometimes exhibit poor motivation for maintaining quality of care including appropriate maintenance of resuscitation commodities. This includes cleaning of the devices at point of use as well as maintaining proper storage conditions. Inadequate cleaning and disinfection of the bag and mask and reuse of single-use items such as suction tubes and bulbs are likely to increase risk of infection. Only recently have affordable, multiple cleaning and disinfection options have become available.

7. Cultivating Demand From Consumers

Demand for newborn resuscitation equipment is best generated at the provider/health system level as the end-users are different types of providers in varying levels of the health system. It may be beneficial, however, to raise awareness and acceptability of the use of resuscitation equipment during birthing, especially in the community setting. Pregnant women and the community often lack awareness that asphyxiated babies could be saved by appropriate resuscitation equipment and skills. Having this awareness could empower pregnant women and communities to ask providers if they are equipped to resuscitate their babies should the need arise.

Over 50 percent of women give birth in a community setting, yet most countries have resuscitation equipment only in health facilities. Only a few countries, such as Bangladesh, Ethiopia, Indonesia, and Nepal actively promote use of resuscitators and suction devices at home and community health posts. However, even in these countries, the availability of bag and masks and suction bulbs is very low (estimated at 20 percent in Bangladesh and 50 percent in Nepal) according to the multi-country rapid assessment.[27]

8. Product Innovation

Innovation in the product category focuses on simplification of device design and parts so that infrequent users at peripheral health centers will be better able to use the technology. Currently, the only two promising innovations include:

1. ***Simplified resuscitator (price TBD)*:** This new simplified bag and mask design by Laerdal Global Health has fewer parts (eight) compared to the conventional newborn resuscitator that has ten parts. This makes it easier to disassemble and reassemble for appropriate cleaning and disinfection.
2. ***Self-inflating bag and mask designed as an upright resuscitator (price TBD)*:** This new bag and mask design by Laerdal Global Health is currently being evaluated by PATH and Save the Children. The new design makes using and cleaning the device easier so that it can expand access to and use by

[27] HBB GDA. *Multi-Country Rapid Newborn Resuscitation Assessment for the United Nations Commission on Life-Saving Commodities for Women and Children*. January 2012 (unpublished report).

health workers, especially those at peripheral centers and by community health workers who are not likely to see many asphyxia cases. The new design includes changes to the mask, fewer parts (six), bigger volume of the bag (300 ml) and a change in orientation of the bag in relation to the mask.

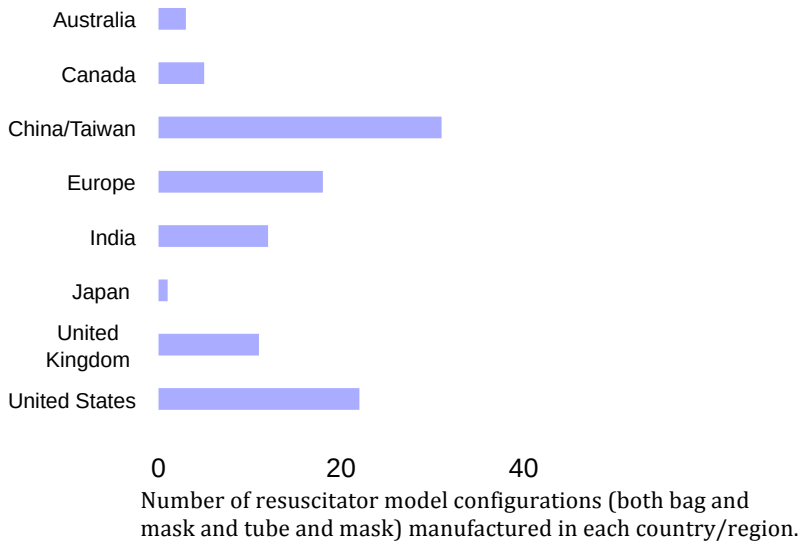
9. Manufacturing

9.1 The global resuscitation/suction device industry

In December 2011 and January 2012, PATH contacted the manufacturers and distributors identified in the 2006 neonatal resuscitator global inventory report to obtain updated manufacturer and product information. Findings from this update indicate that while a few manufacturers have discontinued producing neonatal resuscitators or dropped some neonatal resuscitators from their product line, the large majority of the 2006 global inventory[28] neonatal resuscitator manufacturers and distributors continue to provide the product, with some expanding their resuscitator product line. The 2012 global inventory update also found fewer manufacturers offering the tube and mask resuscitator configuration, due primarily to one manufacturer discontinuing production of resuscitators and a distributor of this configuration going out of business.

Resuscitators are manufactured in multiple locations worldwide with regional concentrations in China/Taiwan, India, the United Kingdom, other European countries, and the United States (see Figure 9). Most manufacturers indicate that they have worldwide distribution capabilities. However, very few could offer a precise list of the countries or regions they service.

Figure 9. Resuscitator model configurations available from manufacturers by country or region.

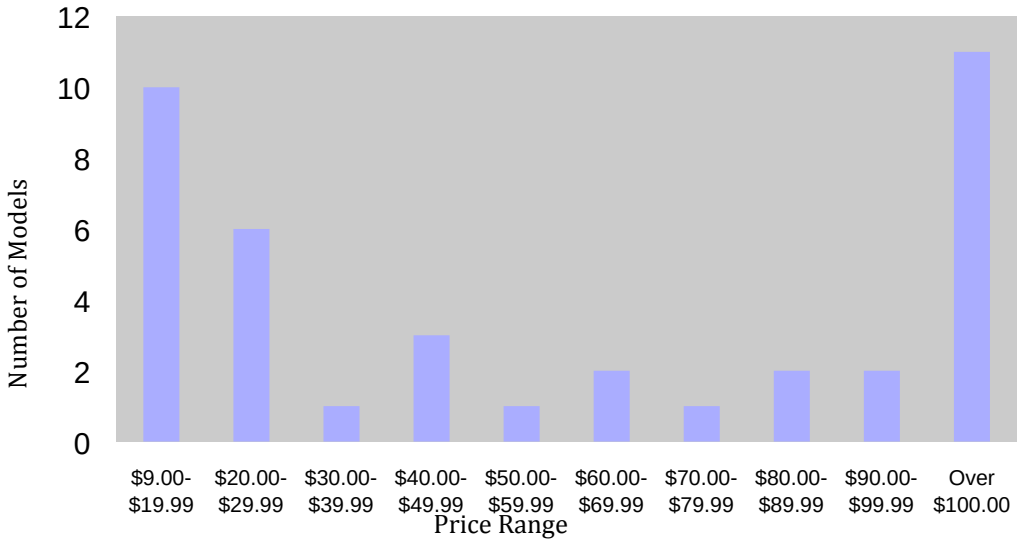


Reusable neonatal resuscitators fall into two distinct price groups—resuscitators costing more than and less than US$60 (Figure 10). Notwithstanding differences in configurations and accessories, the material

[28] PATH. *Global Inventory of Resuscitators. A HealthTech Report*. Seattle: PATH; June 2006.

composition of lower-cost reusable resuscitators is often different from the material composition of higher-cost resuscitators. Some reusable resuscitators are made of synthetic rubber or another material that can be sterilized but is less durable than silicone. Some silicone models are made of an inferior grade of silicone that can be just as effective as more expensive grades but less durable.

Figure 10. Reusable bag and mask resuscitators. Price range (US$) and number of models available within each price range.



Differences in production costs also affect price. Some manufacturers realize economies of scale by producing silicone resuscitators alongside other silicone-based products. Other manufacturers specialize in electronic respiratory products and/or cardiopulmonary resuscitation equipment and manufacture manual resuscitators to complement these devices. Better-known manufacturers typically charge higher prices than lesser-known ones. Even price-sensitive buyers are often willing to pay a premium for the assurance that comes with a globally recognized brand.

Availability of devices in regional markets

A survey conducted by PATH in the Southern African Development Community (SDAC)[29] in 2008, funded by USAID under the HealthTech program, found that most neonatal resuscitation devices used in SADC countries are silicone bag and mask-type manual resuscitation devices that are imported from China, India, and Japan, with secondary suppliers (manufacturers and distributors) in South Africa and the United States. Neonatal resuscitation devices available in SADC countries range in price from US$10 to US$225. Of the 23 South African facilities surveyed that deliver babies, all but two rural facilities had neonatal resuscitation devices available. The neonatal resuscitation devices most often found in South Africa facilities were the Adcock Ingram Samson SSR 0010 and Laerdal 0305 Silicon Reusable resuscitators.

[29] SDAC countries include: Botswana, Democratic Republic of Congo, Mauritius, Mozambique, South Africa, Swaziland, Tanzania, and Zambia.

Another survey conducted by the HealthTech program in the Economic Community of West African States countries in 2009 found that neonatal resuscitators were available in 42 percent of the surveyed facilities, with the highest presence at the tertiary level (82 percent) and lowest at the primary facilities (35 percent). Resuscitator training mannequins were available in one in ten health facilities. One-half of training mannequins are found in tertiary or secondary institutions in Burkina Faso, Gambia, Ghana, Niger, and Nigeria, while the rest were reported in primary-level facilities in Benin, Ghana, Guinea, Niger, Nigeria, and Sierra Leone.

Approximately 20 brands of suction devices, the majority of which were powered by electricity, were seen in the health care facilities. The unbranded rubber bulb syringe has very widespread usage as an improvised suction device across the subregion. This type of unbranded bulb syringe suction device was present in all countries at a cost between US$0.50 and US$0.85 per device. Also in use at the facilities were various other improvised devices for suction although no specifics on device design parameters were obtained.

The price range of US$105 to US$150 was reported in the study for manual resuscitators; source of supply for all three types of devices was well identified although data about specific manufacturers were not always available. The brands available in the 13 countries that provided data were not homogeneous. The Ambu bag brand was available in Niger and four English-speaking countries, (Ghana, Liberia, Nigeria—the largest market, and Sierra Leone). The most common bag size was 500 ml. Notable findings included the lack of any resuscitator brand loyalty among countries or facilities. The majority (62 percent) of the distributors operated within their respective countries with 15 out of the 42 operating outside their local markets. Neither UNICEF nor the public sector was mentioned in the context of procurement or distribution.

9.2 Supplier barriers

Although there is a large supplier base supporting this category of medical devices in both developed and developing countries, there are in practice a variety of considerations that complicate procurement decisions:

- Resuscitation with a bag and mask is integrally linked with the need to clear the airway first. Ideally, a minimum set of supplies for suction should be bundled with those needed in resuscitation.
- The selection of products is influenced by the settings in which they will be used and equally so the anticipated patient loads on which they will be used. Options exist for disposable and/or reusable devices. Selection is further complicated by the fact that there is neither standardization in sizes of the masks nor in the specifications nor in the nomenclature used to describe them.
- The past decade saw further development of hand-operated resuscitators in the design and mostly the materials used. Today’s flexible parts are mostly made of silicone, which is soft but durable, can be autoclaved while retaining its qualities, and is transparent allowing for monitoring of the airways during the procedure.

- Quality assurance and quality control of products is vital. Subcontracting the manufacturing of various parts of the devices is common, often resulting in some parts being CE marked and some not as manufacturing takes place in multiple manufacturing sites.
- Quality failures occur relatively frequently, most commonly due to the quality of material used; mechanical failure during operation, mostly of valves; substandard finishing lacking precision (leakage of valves and fittings); or dust particles inside the device. This situation makes product testing in addition to adherence to the International Organization for Standardization standards for this product category a key part of quality assurance.
- Price variations among seemingly similar products are enormous. While sourcing cheap products may be tempting, attention to the quality issues mentioned above is imperative.

Equipment is primarily manufactured by global or regional companies; in-country manufacture is limited. Hence, countries must rely on international or regional procurement. This poses challenges including long delays in delivery—as much as six months—and additional costs from customs duty. It takes on average two to three months for countries (n=16) to receive the equipment including time for the customs, with the custom clearance ranging from one month in Pakistan and Zimbabwe to six months in Cambodia, Ethiopia, and Malawi. Procurement of equipment may be facilitated by identifying local distributors and manufacturers; this has been instrumental in reducing equipment costs in Asia. Where local manufacturers are supplying the equipment, it is essential that the products meet international standards.

Variable policies regarding customs duty also affect supply. In some countries (e.g., Cambodia), resuscitation devices are exempt from importation fees. In Bangladesh, the government bears the cost of customs duty while stakeholders purchase the equipment. Less than half of the countries in the 2012 multi-country assessment (n=14) are exempt from customs duty or granted customs duty waivers when clearing newborn bag and mask and suction equipment.[30] In most cases, stakeholders and health facilities are responsible for procurement and importation costs. The fact that these devices are lifesaving should be a strong advocacy point in procuring exemption from customs duty.

Low-resource settings face a lack of appropriate companies, agents, and distributers to procure and supply the necessary commodities, institute repairs, replace spare parts, or get new equipment and supplies in a manner that ensures continuous supply. In parallel, very few countries have standard policies or guidelines for procuring, repairing, replacing, and maintaining standards of quality for resuscitation equipment through the government/health system infrastructure. Finally, a product can sometimes be warehoused for an excessive amount of time—sometimes years—before distribution can be completed. In some countries, access to resuscitation equipment is so limited that inferior equipment designed for single, disposable use is used instead.

9.3 Pros and cons of local versus centralized manufacturing

[30] HBB Global Development Alliance. *Multi-Country Rapid Newborn Resuscitation Assessment for the United Nations Commission on Life-Saving Commodities for Women and Children*. January 2012 (unpublished).

In Asia, several manufacturers with regional distribution systems are already in place in countries such as India and Taiwan. These manufacturers are supplying quality product[31] and include reputable companies such as Zeal Medical Pvt. Ltd.[32] and Besmed®.[33]

In sub-Saharan Africa, local manufacturing of resuscitation products might be possible in some select countries. In the SADC region, most country representatives felt that their country did not have manufacturing capacity, except in Zambia and South Africa where representatives indicated that they could probably manufacture locally. Only one device reported to be in use was manufactured locally—the Samson bag and mask device—manufactured by Adcock Ingram. As of 2012, however, Adcock Ingram was no longer offering resuscitator in their product line.

In contrast, many manufacturers based in Asian countries such as China (Taiwan), Europe, and the United States are operating sustainable businesses by selling resuscitators that are not necessarily affordable in low-resource settings. In most cases, these manufacturers do not offer the companion suction and training mannequin products nor do they target sales in low-resource settings.

The innovative product offering by Laerdal Global Health (based in Norway) offers an affordable option for low-resource settings. The NeoNatalie equipment is currently being produced in China to offset higher labor costs in Europe. Laerdal Global Health has committed to continuing to provide the NeoNatalie equipment to all 68 MDG countries on a not-for-profit basis through 2015.

10. Supply Chain Management

10.1 Supply chain considerations (shipping and shelf life)

For resuscitators and manual suction devices, product standards require performance testing after storage at -40˚C and +60˚C and up to 95% relative humidity. Medical devices are also required to be designed and packed so that their function is not adversely affected by storage or shipping. Cardboard packages may have shipping labels stating the shipping or storage environmental limits set by the manufacturers. There are no particular shelf-life requirements in the product standards for resuscitators and manual suction devices; however, there are labeling and risk management standards that apply. If the manufacturer sets a shelf life, the packaging should be labeled with the expiry date. Fortunately the more complicated supply chain problems such as expiry dates and cold chain do not apply to these products.

10.2 Existing distribution systems

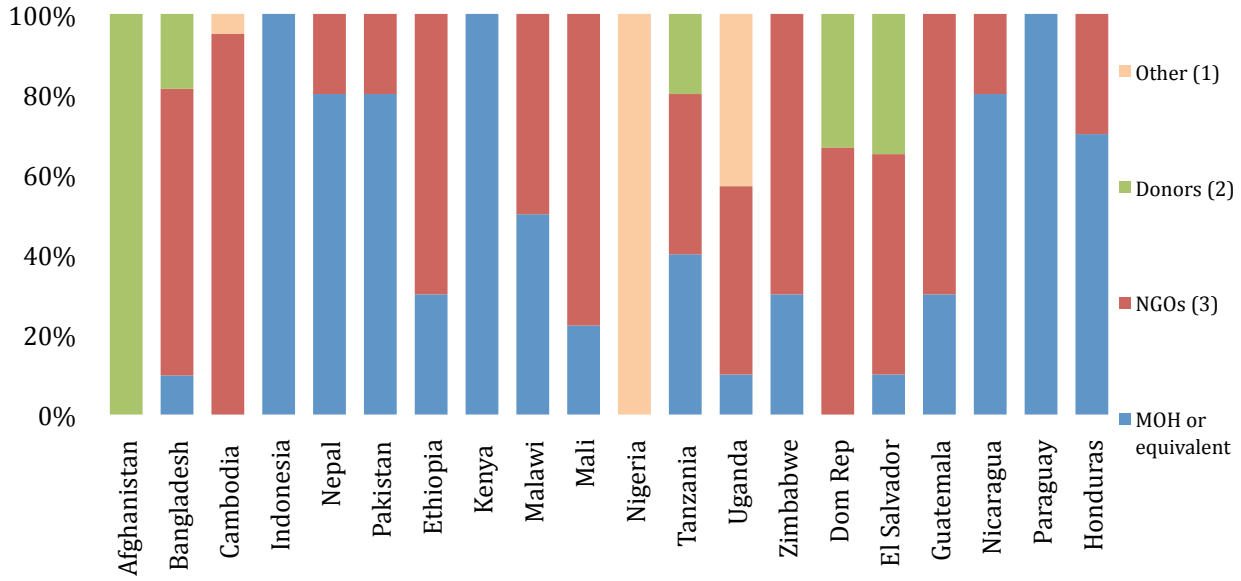
According to the HBB GDA rapid assessment, the most common way to procure neonatal bag and mask and suction devices is through importation using the MOH, national drug and supplies agencies, or large nongovernmental organizations (NGOs). This method is used in 14 out of 20 countries surveyed. Eight countries reported buying directly from retailers and seven countries reported importing products using

[31] PATH. *Practical Selection of Neonatal Resuscitators: A Field Guide (Version 3)*. Seattle, WA: PATH; 2010. Available at: http://www.path.org /publications/detail.php?i=1565. Accessed February 1, 2012.
[32] Zeal Medical Pvt. Ltd. website. Available at: www.zealmedical.com. Accessed February 15, 2012.
[33] Besmed® website. Available at: www.besmed.com. Accessed February 15, 2012.

local wholesalers/retailers. Almost half of the countries have a combination of two or more of the different ways to get the supplies in country to make the procurement process as efficient and fast as possible.[34] With countries relying on international and regional procurement, delays in delivers, custom clearance and additional tariffs and customs costs pose a challenge.

Currently, a number of countries receive these commodities through stakeholders that support resuscitation as a part of essential newborn care. Eighteen of twenty countries surveyed stated that they depend on financial support from NGOs and donors to purchase bag and mask and suction devices (Figure 11). In these cases, countries are dependent on external funding for initial purchases so sustainable supply is not ensured.

Figure 11. Percent of organizations financing procurement of bag and mask resuscitators and suction devices by country (n=20).



(1) Other: private for-profit and non-profit organizations. In Nigeria, the facilities themselves have to ensure funding for the procurement.
(2) Donors: USAID, World Bank, Swiss Aid, Australian Aid, United Nations Agencies, Laerdal Foundation.
(3) NGOs; Latter-Day Saint Charities, Management Sciences for Health, Plan, the Reproductive and Child Health Alliance, Save the Children, UNICEF, the United Nations Population Fund, University Research Co. LLC/Health Care Improvement Project, WHO.

The PATH survey of SADC countries found that **p**urchasers in SADC countries are at the national government level except for South Africa where purchasing is completely decentralized to the health care facility level. Most SADC countries use public sector tendering for neonatal resuscitation device procurement and require adherence to international and national standards. UNICEF was identified by all key informants as playing a critical role in the supply of medical devices to SADC countries. However,

[34] HBB Global Development Alliance. *Multi-Country Rapid Newborn Resuscitation Assessment for the United Nations Commission on Life-Saving Commodities for Women and Children*. January 2012 (unpublished).

UNICEF requires a minimum order of US$5,000, which could pose a challenge for making a low-cost device widely available through this channel.

Furthermore, exports and imports between SADC countries are more cumbersome than exports and imports from other countries. Distribution channels vary by country with international aid organizations (i.e., UNICEF and missionary organizations through their hospitals) playing an important role in all SADC countries except South Africa. The main distributor was reported to be the government, except in Zambia and South Africa.

Procurement of equipment is a key challenge, especially in countries where the equipment is not included on essential supply lists. Organizations implementing HBB programs have effectively ordered product from UNICEF or Laerdal Medical using both the online form and email with no issues. Because most HBB implementers are international NGOs that are supported by donors and coordinate directly with the local MOH, up-front payment in United States currency was not a problem. This could cause future issues, however, when countries begin procuring and quantities/total values are larger. Many countries have difficulty providing payment up front due to restrictive procurement policies, and buyers have to take additional steps to justify sole-source procurements.

Once the products are available in the country, they must be distributed to the end-users that attend births. All countries but Paraguay reported two or more ways to distribute newborn resuscitation bag and mask and suction bulbs, with 17 out of 19 countries using government distribution systems followed closely by using partners and NGOs (16 out of 19) or giving out the equipment during or after the training (16 out of 19). Other ways to undertake distribution include providing it directly to the facility during clinical mentoring (8 out of 19). Three countries are using private distributors: Bangladesh, Indonesia, and Nigeria. Although a combination of distribution methods is used to speed up the process to get the supplies to their final destination, there are still major barriers that delay the distribution. The most common are inadequate logistics coordination, planning, and budgeting—especially in large countries with remote health facilities, which can result in high transportation costs.

UNICEF product offerings

UNICEF country offices often act as a distribution channel by providing support for the supply of devices at the country level. These devices are sourced from their supply headquarters in Copenhagen, Denmark. The UNICEF Supply Catalogue offers a reusable bag and mask resuscitator that is used to ventilate neonates with a body weight below 7 kg. This product comes with two masks (one neonate and one infant size) and two Guedel airways (a medical device to maintain an open oral airway) at a cost of US$77 each. The procurement price of devices supplied via UNICEF varies between US$45 and US$84. In addition, the UNICEF Supply Catalogue offers a basic resuscitation kit to facilitate resuscitation in all types of environments, including emergency situations. The kit includes a foot-operated suction pump, adult and infant resuscitation devices, and Guedel airways at a cost of US$400.73 each.

11. Financing

11.1 Cost-effectiveness data

Costing analyses of newborn resuscitation programs are not easily comparable because of different training strategies and resuscitation devices used. Estimates ranged from US$42 to US$88 per life saved in Indonesia[35] and Brazil,[36] respectively. If resuscitation is integrated with routine maternal and newborn care, the cost was reduced to US$28 per neonatal death averted as shown in the study from Indonesia. As noted by Wall et al., the cost per life saved appears to be well below the currently accepted benchmarks for cost-effectiveness of one to three times the gross domestic product per capita.[37]

11.2 Potential for global-level/donor procurement

Global level/donor procurement of bag and mask resuscitators, suction devices and training mannequins has been revitalized since the launch of the HBB GDA. Since June 2010, the program and products have been placed in 34 countries with national scale-up being planned in 10 of them.

11.3 Potential for national-level/public procurement

With increased national-level attention being paid to newborn health and the advent of donor-supported initiatives to program essential newborn care, the procurement of resuscitators, suction devices, and training mannequins, as well as corollary training programs with suitable follow-up for quality assurance and monitoring and evaluation are the most important and strategic investments on the part of countries that are interested in reducing neonatal mortality due to birth asphyxia.

11.4 Potential for private sector user purchases

Private sector sales are often an important complement to public sector provision. Resuscitation equipment is already being purchased in the private sector. The push now is to enable access to this life-saving equipment in the public sector using the private sector as a sustainable base.

12. Monitoring and Evaluation

There are several different ways to monitor and evaluate the transition of resuscitators, suction devices, and training mannequins from being overlooked equipment to being treated as routine commodities. Suggested metrics are included in Table 1.

Table 1. Illustrative indicators for monitoring and evaluation

Supply Metrics	• Geographic reach of manufacturers. • Quality of manufactured products.
Demand Metrics	• Number of countries participating in HBB GDA activities. • Volume of public-sector orders for resuscitators, suction devices, and training mannequins. • Number and type of national integrated health management information systems that

[35] PATH. *Reducing Birth Asphyxia Through the Bidan di Desa Program in Cirebon, Indonesia: Final Report Submitted to Save the Children.* Jakarta: PATH; 2006.
[36] Vidal SA, Ronfani L, da Mota SS, et al. Comparison of two training strategies for essential newborn care in Brazil. *Bulletin of the World Health Organization*. 2001;79(11):1024–1031.
[37] Wall S, Lee ACC, Niermeyer S, et al. Neonatal resuscitation in low-resource settings: what, who, and how to overcome challenges to scale-up? *International Journal of Gynecology and Obstetrics*. 2009;107(1):S47–S64.

	identify health facilities that have functioning resuscitation equipment. • Percent of public and private facilities with functioning resuscitation equipment.
Correct Use Metrics	• Percent of caregivers who have access to resuscitation equipment. • Percent of caregivers that have attended initial or refresher training course in past three months.
Impact Metrics	• Neonatal mortality rate. • Neonatal mortality from birth asphyxia.

13. Recommendations

13.1 Market shaping

Global level

1. Prioritize the publication of the WHO Essential Medical Devices List for priority interventions for maternal, newborn, and child health. Use this list that includes neonatal resuscitators (bag and mask) and suction devices as a reference for device lists at the country level.
2. Ensure access to information about high-quality, affordable resuscitation products to international and national purchasing agents by updating and disseminating the international purchasing guide on sources, prices, and quality.[38]
3. Promote the use of skilled birth attendants and, where necessary, address policies that impede access to resuscitation in home births.
4. Increase funding for scaling up newborn resuscitation program efforts that create demand as well as purchase of critical resuscitation equipment and skills. The HBB GDA, one example of a global initiative to strengthen demand, provides an opportunity for rapid increase in coverage of a quality resuscitation program since it is already established, has a widespread global footprint, and has begun to increase product demand in some countries.
5. Build on the public-private partnership model, bringing together donors, governments, NGOs, manufacturers, and suppliers to work toward a common goal of scaling up focused high-impact interventions.
6. Extend the same or parallel mechanism across more countries and/or diverse priority commodities for newborn and maternal health such as prevention of postpartum hemorrhage with uterotonics.

Country level

1. Advocate with the government to include newborn resuscitation equipment in country essential medicines lists, fund the national roll out of resuscitation, and establish a coordinating body at the central level for planning, budgeting, and supervision.

[38] PATH. *Practical Selection of Neonatal Resuscitators: A Field Guide (Version 3)*. Seattle, WA: PATH; 2010. Available at: http://www.path.org /publications/detail.php?i=1565.Accessed February 1, 2012.

2. Develop costed national plans for scaling up newborn resuscitation and embed this plan within the broader national newborn strategy (if one exists). Make national and district budget allocations to procure newborn resuscitation equipment to ensure sustainability and availability in health facilities.
3. Develop/strengthen national information systems for tracking supplies, services, and outcomes: forecasting/quantification and procurement of equipment, tracking, and accountability mechanisms for equipment purchased; tracking the number of providers trained, facilities equipped, and newborns resuscitated.
4. Create demand among key stakeholders in a coordinated way by discussing key issues with a national-level group that includes representatives from the MOH; professional bodies; university teachers involved in pre-service education of medical, nursing, and midwifery students; and implementing organizations.
5. Increase awareness and use of standards to ensure availability and quality of resuscitation practice at the facility level. Institute quality improvement processes such as mentoring, supportive supervision, and regular practice in skills labs.
6. Establish policies to require pre- and post-service neonatal resuscitation education and training at the MOH level. Establish policy that newborn resuscitation equipment and space be made available for every delivery including adequate numbers of mannequins and space (a "newborn corner" for resuscitation and other special care for the baby as required).
7. Promote use of skilled birth attendants, and where necessary address policies that impede access to resuscitation in home births in situations with poor access to facilities as some countries have done (e.g., Nigeria's community health extension workers, Ethiopia's health extension workers, Nepal's female community health volunteers, and Bangladesh's community skilled birth attendants).

13.2 Regulatory environment

- Device regulation is in its infancy in many countries. In order to assure product quality and until national regulatory agencies have built capacity, undertake periodic independent reviews by an objective body to ensure quality of product design.
- Negotiate tariff reductions to streamline procurement and delivery of affordable, high-quality resuscitation equipment manufactured by global and regional producers.

13.3 Best practices and innovation

- Position HBB activities as a critical component of national integrated essential newborn care and/or emergency obstetric care and newborn resuscitation programming at all levels of health delivery. This should include plans for training, equipment, quality assurance of programs, and information systems.
- Fund further evaluation and research of resuscitation technology and program impact.

Appendix A

Response from a private company

The difficulty in procuring high-quality, affordable resuscitation equipment spawned a call to action for appropriate product designs for low-resource settings. To address this need, Laerdal Global Health created the NeoNatalie suite of neonatal resuscitation devices (Figures A and B) which the company has made available to all 68 Millennium Development Goal countries at a not-for-profit cost. These include (a) the NeoNatalie bag and mask unit priced at US$15 made of silicone and polysulphonate which can be boiled or autoclaved, is extremely durable, and comes with two mask sizes; (b) the NeoNatalie training mannequin, priced at US$50, can be used to train health workers at all levels and includes squeeze bulbs to simulate birth cries, chest rise to demonstrate breathing, and palpable umbilical pulse to demonstrate heart rate; and (c) the NeoNatalie suction device, priced at US$3, is made in one piece of silicone, can be boiled or autoclaved, and withstands hundreds of uses. The device is shaped like a penguin, with the beak being used for newborn oral and nasal suction, and the head can be opened for easy emptying and cleaning.

Figures A and B. The NeoNatalie suite of neonatal resuscitation devices.

A

B

Photos: Laerdal Global Health