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A Toolkit for Procuring Quality-Assured Basic Neonatal Resuscitation Commodities

Version 2

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Life Saving Commodities
Improving access, saving lives

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Contents

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Cover photo: PATH/Amy MacIver

Acronyms

AAP	American Academy of Pediatrics
CPR	cardiopulmonary resuscitation
ENAP	Every Newborn Action Plan
GDA	Global Development Alliance
GMP	good manufacturing practice
HTC	harmonized tariff code
HBB	Helping Babies Breathe
HBS	Helping Babies Survive
ICC	International Chamber of Commerce
IMDRF	International Medical Device Regulators Forum
ISO	International Organization for Standardization
LGH	Laerdal Global Health
LMIC	low- and middle-income countries
MEG	Medical Export Group
NGO	nongovernmental organization
NRP	Neonatal Resuscitation Program
RFQ	Request for Quotation
SRA	stringent regulatory authority
UN	United Nations
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
USFDA	United States Food and Drug Administration

Section I: Introduction

Target audience

A Toolkit for Procuring Quality-Assured Basic Neonatal Resuscitation Commodities is intended for program managers and procurement personnel as well as others involved in any level of the planning, procurement, quantification, supply, distribution, and use of basic neonatal resuscitation commodities for both clinical and training settings.

Purpose

This toolkit is intended to help with the quantification of commodity needs, development of effective procurement plans, and in writing specifications for national tenders. It provides information on where and how to procure quality-assured neonatal resuscitation commodities and addresses international shipping considerations. The purpose of the toolkit is to provide information to low- and middle-income countries (LMICs), particularly within ministries of health and collaborating nonprofits, to ensure placement of adequate amounts of high-quality basic neonatal resuscitation commodities in the appropriate levels of the health system. Although some countries rely heavily on donors to provide neonatal resuscitation commodities, there will be a time when governments will handle their own procurements, and the toolkit has been designed to aid with that process. Ultimately, appropriate procurement practices will contribute to the safety of newborns who are resuscitated in low-resource settings.

Background

Birth asphyxia, defined as the failure of the newborn to establish breathing immediately after birth, kills 662,000 newborns every year—almost a quarter of all newborn deaths.[1] In addition, an estimated 1.3 million intrapartum stillbirths occur every year, an unknown number of whom may be live-born but misclassified as fresh stillbirths when no resuscitation has been provided.[2,3] Neonatal resuscitation is an intervention to help babies breathe and help their heart beat after they are born when they do not begin breathing on their own.[4]

Each year, approximately 10 million babies do not breathe immediately at birth, and about 6 million require basic neonatal resuscitation.[5] One of the major burdens is in low-resource settings, where health system capacity to provide neonatal resuscitation is inadequate.

Rationale

The Helping Babies Breathe (HBB) curriculum was introduced in 2010 to train birth attendants in LMICs 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. This contributed to a rise in procurements of neonatal resuscitation commodities for LMICs. According to the United Nations Children's Fund (UNICEF) Supply Division's Neonatal Resuscitation Devices Market and Supply Update, published in August 2014, "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." As LMIC governments and major programs took on the responsibility of procuring neonatal devices, it became apparent that there were information gaps in determining the number and type of commodities procured at a reasonable cost while maintaining a high level of quality.

Basic neonatal resuscitation commodities

The five basic neonatal resuscitation commodities that should be included in a neonatal resuscitation procurement plan are resuscitation bags, resuscitation bag masks, manual suction devices, training manikins, and training materials. A brief description of the commodities is provided below, and more detailed specifications, including sizes and other important information, can be found in *Section III: Quality of Medical Devices.*

Self-inflating resuscitation bag with masks (reusable)

Examples of reusable resuscitation bags and masks. Photo: PATH/Jillian Zemanek

Many babies can begin breathing on their own after a few assisted breaths with the use of a bag-and-mask resuscitator. These devices consist of a mask that covers a baby's nose and mouth, attached to a self-inflating bag that pumps air when squeezed. Each bag should be equipped with two masks: size 0 for preterm babies and size 1 for full-term babies.

Manual suction device (reusable and single-use)

Small hand-held manual suction devices allow health workers to clean an infant's mouth and nose, often freeing these passageways for a baby's first breath. Use of a suction device should only occur in the instance that the baby's nose and mouth are full of secretions (not routine practice).[4] There are both reusable suction and single-use suction devices. Single-use suction devices (also known in the field as suction bulbs) must be discarded after use.

Example of a manual reusable suction device and examples of manual single-use suction devices. Photos: left: PATH/Fay Venegas; right: PATH/Patrick Mckern.

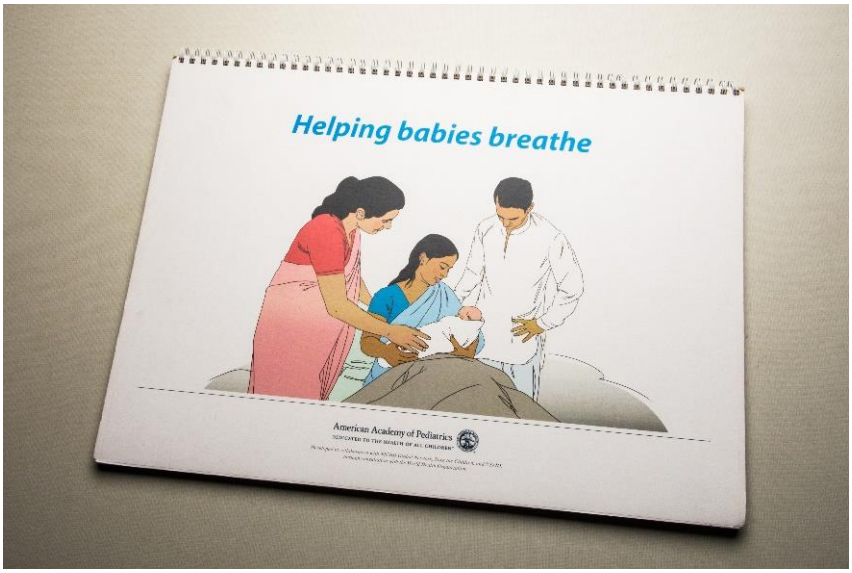
Training manikin

The training manikin is a specially constructed doll with simulated respiratory and cardiovascular functions designed to demonstrate and teach techniques for neonatal resuscitation. Health worker and student access to training manikins is essential in learning, practicing, and maintaining the necessary skills required for effective neonatal resuscitation. Along with the training manikin, a self-inflating bag with masks, suction device, and training materials need to be procured for a complete training set.

Example of a training manikin. Photo: PATH/Patrick Mckern

Training materials

Helping Babies Breathe (HBB) is a neonatal resuscitation curriculum developed for low-resource countries that contains a number of educational materials, including a flip chart, learner workbook, and a variety of posters. The materials are available in English, French, Spanish, and Swahili.



Example of training material. Photo: PATH/Patrick Mckern

Unique procurement needs for neonatal resuscitation commodities

Compared to other medical commodities, procurement of neonatal resuscitation commodities is unique in several ways:

- Resuscitation commodities should ideally be bundled together in a set of three commodities for clinical purposes (bag, masks, and suction device[s]) and five commodities for training pre- and in-service training purposes (bag, masks, suction device, manikin, and training materials), which may require procurement from different vendors.
- A country may or may not have special requirements or registration processes for medical devices. In either case, it is important to select manufacturers and devices that fit quality assurance needs and requirements.
- Many resuscitation commodities are reusable. This means that the quantity of commodities needed may differ, depending on the commodity, and may require that stock be replenished at different periods, depending on the level of the health care system they are being procured for, frequency of use, and storage and cleaning practices.
- These commodities are used for both clinical and training purposes and are often procured by different units of a country's ministry of health.
- Resuscitation commodities are quantified and procured by a variety of quantification methods—not only by number of births—but also by number of rooms, number of students, etc.
- A country may benefit from a customized transition plan if that country has previously benefited from donated single-use devices (such as single-use suction devices [known in the field as suction bulbs]).

Section II: Procurement and Program Planning Considerations

When introducing neonatal resuscitation commodities into a country, governments have a range of considerations to take into account in order to aid and facilitate procurement and the successful implementation of the program, such as the following:

- Policy
- Transition plan
- Import regulations
- Training requirements
- Budget
- Donor coordination
- Quantification of needs
- Safety stock
- Quality assurance
- Specifications
- Time frame
- Tender/request for quotation
- Storage and distribution
- Consumption data
- Reordering
- User feedback
- Donation guidelines

These considerations are outlined below, along with related key questions and actions required when introducing neonatal resuscitation commodities into a country. There are often a number of different units within a ministry of health (MOH) that need to be involved with procurement and program planning considerations, and personnel from each unit should ensure that there is a clear path of communication between the respective units. These questions and considerations are not exclusive, but are meant to be a starting point as governments begin to plan the procurement of neonatal resuscitation commodities.

Policy

Key questions

- Under the current national guidelines, which staff are expected to perform basic neonatal resuscitation (skilled birthing attendants, community health workers, etc.)?
- Are there national plans to train other staff currently not included in the existing national guidelines?

- What level of health facility will receive the commodities (hospitals, health centers, dispensaries, etc.)?
- Will the private sector be impacted?
- Are there other policy considerations?

The first stage of planning for the procurement of neonatal resuscitation commodities is to know what commodities are acceptable within the country. For example, the government of Tanzania currently only allows reusable suction devices in their public-sector health facilities, so it is unnecessary to quantify for single-use suction devices.

To quantify a country's neonatal commodity needs, it is important to know the country's policies and guidelines including health care staff allowed to use the product and where those personnel are posted. For example, midwives might only be posted in hospitals and larger health centers and not in lower-level health centers and dispensaries.

Transition plan

Key questions

- Is a transition plan needed? (For example, if switching to reusable suction devices, how and when will the single-use suction bulbs be collected?)
- How should single-use suction bulbs be destroyed?
- How will the private sector be involved (health facilities, pharmacies, local distributors, etc.)?

If a country decides to adopt a policy to purchase only reusable suction devices, a plan to collect and destroy the single-use suction devices needs to be developed. A time frame for such a transition also needs to be considered, as it is important for any new devices to be in the health facilities long enough for health care workers to use them and report any potential product or user issues.

If the private sector is also expected to transition to reusable suction devices, then private-sector health facilities will need to be notified and provided with a time frame in which the change is expected to occur.

If a country decides to change from single-use to reusable suction devices, it is also prudent to notify the local distributors and pharmacies, etc., who buy and sell these products and to provide details of the new products.

Import regulations

Key questions

- Are medical devices regulated?
  - If yes, what are the regulations?

  - How many manufacturers/products are registered in the country?
  - What is the process and time frame for registration?
  - How does this correspond with procurement regulation? (For example, if only one manufacturer is registered, is sole sourcing allowed?)
- Is an import waiver required?
  - If yes, what is the process and time frame?

For further discussion on import regulations see *Section III: Quality of Medical Devices.*

Training requirements

Key questions

- What materials and other resources are needed to train staff?

To quantify the amount of neonatal resuscitation commodities to procure, it is important to know that even when staff have received training, they need to continue practicing on a regular basis. Training manikins, along with neonatal resuscitation bags and masks, suction devices, and training materials, will need to be procured for both pre-service and in-service training. For further information on training materials, see Helping Babies Breathe, American Academy of Pediatrics, and Laerdal Global Health in *Section V: Organizations, Manufacturers, and Wholesalers Selling Neonatal Resuscitation Commodities and/or Training Materials.*

Budget

Key questions

- Who is paying for the products?
- Does the budget meet the need?

Budget is a standard consideration for all procurement planning. However, as shown in *Section VI: Detailed Commodity Information,* basic neonatal resuscitation commodities vary considerably in price. A training manikin, for example, can sell for less than US$100 or cost thousands of dollars, depending on the features that are required and the organization selling the product.

Donor coordination

Key questions

- Are other stakeholders procuring these commodities?
  - If yes, what are they procuring, how many, when, and for which facilities?

A number of different donors are procuring neonatal resuscitation commodities either directly or through nongovernmental organizations (NGOs) in various LMICs. Before a country begins to quantify their procurement needs, it would be beneficial to understand what has already been procured, when the commodities were procured, and where they are located. Coordination between donors, various NGOs, other stakeholders, and the government may be lacking in some countries.

Quantification of needs

Key questions

- How many of each product are needed?

Although the Quantification Tool provided in the Annex of this toolkit can assist with determining needs at the national, district, or health facility level, it is important to remember that it is up to the individual health facility to ensure that each room (delivery rooms, theaters, etc.) where a newborn may be located has the number of neonatal devices they need. For example, a regional hospital might quantify three neonatal resuscitation bags and masks and three reusable suction devices per room due to the larger number of babies being delivered in these hospitals. Once the devices arrive, however, hospital staff might put five devices into a busy labor room and two devices in two quieter rooms. Health facilities need to request enough devices to account for times when the equipment is being cleaned and is not ready for use, and for when equipment fails. For this reason, it is highly recommended that a MINIMUM of two resuscitation bags and masks and two reusable suction devices be placed in any room where a newborn may be located. For full information regarding quantification of the resuscitation bags and masks, suction devices, and manikins, see *Annex: Quantification Tool.*

Safety stock

Key questions

- How much safety stock should be maintained?
  - At the central level?
  - At the regional level?
  - At the district level?
  - At heath facilities?

Each neonatal resuscitation commodity should have an average lifespan, according to the manufacturer; however, it is difficult to determine an exact lifespan, as much will depend on how often the products are used, how they are handled and stored, and how they are cleaned. It is therefore suggested that while collecting consumption data on these commodities, a country maintain extra safety stock at the central level as well at the other appropriate levels of the supply chain.

Quality assurance

Key questions

- What quality assurance measures can be taken (strong specifications, international standards [ISO], stringent regulatory authority [SRA] approval, etc.)?

This consideration is discussed further in *Section III: Quality of Medical Devices.*

Specifications

Key questions

- What specifications will be used?
- Who will provide and/or check the specifications?

See *Section III: Quality of Medical Devices* for the key aspects of specifications developed by WHO and PATH.

Time frame

Key questions

- When are the commodities needed?
- What is the average manufacturer/distributor lead time?
- Where are the commodities shipping from?
- How will they be shipped (ocean or air)?

Knowing when commodities are needed, the standard lead times, and the shipping time frames is standard procurement planning practice. However, additional attention to this information may be required as the procurement of neonatal resuscitation commodities is new to many LMICs.

Tender/request for quotation

Key questions

- Who will receive a request for quotation or notification of a tender release (if applicable)?
- What key information should be included in a tender/request for quotation?
- What type of tender should be issued?

See *Section III: Quality of Medical Devices* for tender considerations*; Section IV: Basic Tender/Request for Quotation Requirements* for key document contents; and *Section V: Organizations, Manufacturers, and Wholesalers Selling Neonatal Resuscitation Commodities and/or Training Materials* for a sampling of organizations selling high-quality neonatal resuscitation commodities.

Storage and distribution

Key questions

- Is there enough storage space throughout the supply chain for one shipment, or do shipments need to be phased?

When importing a new commodity into a country it is important to know how much space will be required at each level (medical stores and health facilities). These commodities can be bulky, and if storage space is lacking, they may need to be shipped into the country more than once a year, even though they may be procured annually or every two years.

Consumption data

Key questions

- How can consumption data be collected for reusable commodities so that the average lifespan can be determined?
- How is feedback provided to the national level?
- Who at the national level provides an analysis of the data?
- What is the annual amount of loss and breakage?

Collecting consumption data for a reusable commodity can be challenging. It is, however, advisable for a country to consider how usage can be monitored. By paying attention to breakages and losses, future quantification efforts can be perfected and wastage rates can be included into the annual quantification.

It is important that information from all health facilities return to the central level for a national analysis of the usage patterns of these commodities.

Reordering

Key questions

- How long do the commodities last?
- How do care and maintenance practices affect the life of the commodity?
- How often should each commodity be reordered?

The lifespan of a commodity will depend on which commodity is procured and from whom, as well as how often the commodity is used, how it is handled and stored, and how it is cleaned. For example, a product sitting in a bleach solution overnight will not last as long as a product that is in the solution according to the manufacturer's cleaning guidelines.

For more information on cleaning guidelines, the *Reprocessing Guidelines for Basic Neonatal Resuscitation Equipment in Resource-Limited Settings* by PATH can be found on the PATH website at http://www.path.org/publications/detail.php?i=2601.

User feedback

Key questions

- Are there any issues with the commodities?
- Is there a mechanism for users to report back to the central level?

When a new commodity is introduced into the health system it is useful to obtain feedback from health care workers, particularly about the quality of the product. If a product has a performance issue or if it seems to break easily, a discussion with the manufacturer may help to improve future products. For example, when curative autodisable syringes were first introduced to Kenya there were complaints that the plunger broke easily. When investigated, findings revealed that this was not a product problem, but rather caused by the way that health care workers were opening the package. Feedback to the vendor resulted in a tear mark being added to the package, making it easier to open, with less risk of damaging the syringe plunger.

Many commodities come with a warranty which may be held in the procurement department at the central level. If information is not relayed to the central level in a timely manner, a warranty may expire and the chance to return damaged commodities lost.

Donation guidelines

Key questions

- Are donation guidelines in place that correspond to country policy? For example, Tanzania does not allow the use of single-use suction devices; therefore, donations of these devices should no longer be allowed for training purposes.

Not all LMICs have existing donation guidelines. When a country develops a policy or has new regulatory requirements for medical devices, it is useful to inform stakeholders. Otherwise stakeholders may continue to import inappropriate products that do not meet government specifications.

Section III: Quality of Medical Devices

Neonatal resuscitation devices are lifesaving commodities. Unfortunately, the level of quality of these products varies. For example, during an assessment in a West African country in 2014, resuscitation bags and masks were found in hospitals with no indication of who the manufacturer was, whether they were single-use or reusable, or whether they were an appropriate size for resuscitating a newborn. Additionally, other important information, such as cleaning instructions and assembly instructions, were not included.

A number of measures can be taken to ensure that high-quality neonatal commodities are procured. The following are key considerations during the procurement process to help ensure that high-quality neonatal resuscitation devices are used in a country:

- Standards
- Importation requirements
- Commodity market
- Tender considerations
- Product specifications

These product quality assurance factors are discussed in more detail in the following sections.

Standards

Safety, quality, and product standards published by international or national regulatory authorities or standards bodies establish the minimum quality for products that are made, imported, or sold within a particular country or region. Product standards only address the safety and performance of the product; design features that are a matter of choice or discretion are not normally included in a standard.

Selecting a good-quality product begins with determining whether the product meets the applicable standards set forth by the International Organization for Standardization (ISO). In addition to the ISO standards, there are internationally recognized national standards that would indicate a high-quality product. Two well established and well-known domestic market clearances are the United States Food and Drug Administration (USFDA) 510(k) and the EU CE marking scheme. Most countries, including those that are also part of the International Medical Device Regulators Forum, have their own regulatory procedures that should also cite published standards.

At times an international standard may be referenced in a country's national standard (e.g., *product must adhere to ISO xxx*) or another domestic standard may be a requirement for product registration in a country (e.g., *product must be CE marked*). Neonatal resuscitation devices are not currently WHO prequalified. Prequalification does, however, provide a strong product quality assurance process and should be considered if, in the future, neonatal resuscitation products are prequalified under this system.

International Organization for Standardization

The ISO is a world federation of national standards bodies responsible for drafting international standards based on the best available evidence and practice. ISO 13485 is the international standard for medical devices and was updated in March 2016. ISO 13485-2016 replaces ISO 13485-2013 (or the European ISO, EN 13485:2012). As of the publication of this Toolkit, however, ISO is recommending a transition period of three years in which 13485:2003 and 13485:2016 coexist. It is recommended that two years after publication of ISO 13485:2016, all accredited certifications issued will be to ISO 13485:2016. After three years of publication, any existing certification issued to ISO 13485:2003 will not be valid. It is recommended that procurers periodically check in with ISO for any final determinations.

For more information about ISO and to procure any of the standards, go to http://www.iso.org/iso/home.html.

International Medical Device Regulators Forum

The International Medical Device Regulators Forum (IMDRF) is a voluntary group of medical device regulators from around the world who came together in 2011 to build on the foundation of the Global Harmonization Task Force. The IMDRF is an international effort to harmonize medical device regulation, with current members from Australia, Brazil, Canada, China, Europe, Japan, Russia, and the United States.

The purpose of the IMDRF is to encourage convergence in regulatory practices related to ensuring the safety, effectiveness, performance, and quality of medical devices; promoting technological innovation; and facilitating international trade. The regulatory authorities in each of the member countries are internationally recognized. The IMDRF Management Committee comprises regulatory authority representatives from the jurisdictions shown in Table 1. For more information about IMDRF, visit www.imdrf.org.

Table 1. International Medical Device Regulators Forum regulatory authority representatives.

Current IMDRF members	Regulatory authority representative
Australia	Therapeutic Goods Administration
Brazil	National Health Surveillance Agency (ANVISA)
Canada	Health Canada
China	China Food and Drug Administration
European Union	European Commission Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (small and medium-sized enterprises)
Japan	Pharmaceuticals and Medical Devices Agency, Ministry of Health, Labor and Welfare

Current IMDRF members	Regulatory authority representative
Russia	Russian Ministry of Health
United States	US Food and Drug Administration

Importation requirements

Many LMICs are beginning to set stricter regulatory requirements for medical devices, and each country has its own requirements, which may differ from those of other countries. Some countries now require that the device be registered in country before the product can be imported. Some countries require pre-inspection prior to medical device importation, which can entail a physical inspection or simply an inspection of documents. As a procurer, it is important to know a country's regulatory requirements before importing medical devices.

It is also important to check with a country's Bureau of Standards to establish whether a national standard exists for the particular commodity being imported. If there is a national standard, it is important to understand the contents. In Kenya, for example, when a national standard for curative-size autodisable syringes was written, it called for adherence to ISO 13485.

In some countries the Bureau of Standards may conduct a physical inspection at the time of import, which is another quality check to help ensure that only high-quality medical devices enter the country.

Commodity market

There are many neonatal resuscitation devices on the current market, but not all are of high quality. It is important to know which manufacturers produce high-quality products, and what other reliable organizations, such as UN agencies and wholesalers, sell high-quality devices. Knowing which manufacturers adhere to international and national standards is imperative to obtain high-quality products.

Manufacturers newly entering LMIC markets might not be aware of how to respond to tenders, know where tenders are published, know how to register a device (or be unwilling to do so until they are aware of a country's requirements), or understand import requirements and procedures. In these instances, procurement personnel can help manufacturers to better understand the process, and/or they can work with wholesalers of high-quality commodities or UN organizations who are aware of each country's particular requirements.

Tender considerations

The way that a tender is written and organized can also play an important role in receiving quality-assured commodities. In many LMICs, non-pharmaceutical products are usually written on a separate tender from

pharmaceuticals, and the goods are listed in "lots." Typically, any organization bidding on the lot must be able to bid on the entire section or they are disqualified. For example, if a number of suction devices—such as a reusable manual suction device, an electric suction machine, and a foot pump—are listed in one lot, manufacturers would not be able to bid directly, as there is not a known manufacturer producing all three types of suction devices. Wholesalers/distributors would be able to bid, as they can usually supply a broad range of products, but because cost is often the bottom line, high-quality products might not be selected unless product specifications are well written and wholesalers/distributors of high-quality products are able to respond.

Writing the tender so that appropriate commodities are listed together in a lot can open competition to manufacturers, and writing detailed product specifications will help to ensure high-quality product offers from wholesalers/distributors. An alternative is to issue a restricted tender to only known manufacturers and wholesalers of high-quality neonatal resuscitation commodities.

Product specifications

A product specification covers all of the product attributes necessary for the buyer's requirements. Product specifications include the essential, general, and performance requirements, as well as how to verify product quality. Specifications may call for a higher level of quality than a standard. It is important to write a detailed specification in order to ensure not only that a high-quality product is procured, but that the product also meets performance requirements.

The product description must be detailed. For example, it is critical to request the correct resuscitation bag and mask sizes to ensure that the lifesaving devices will fit a newborn and are not meant to fit an older child.

Following are WHO product specifications for neonatal resuscitation bags and masks and suction bulbs, both single-use and reusable. Because a neonatal manikin specification has not yet been developed by WHO, some basic considerations have been provided by PATH.

Key aspects of WHO technical specifications for bags and masks and suction bulbs

The following information (Tables 2, 3, and 4) is based on the WHO neonatal resuscitation technical specifications and contains key features that may be noted on a tender or request for quotation for each of the neonatal devices featured in this user guide.

For detailed standardized WHO technical specifications please refer to the *WHO Technical specifications of Neonatal Resuscitation Devices that can be found at http://apps.who.int/iris/bitstream/10665/206540/1/9789241510264_eng.pdf.* WHO will begin the French and Spanish translations and develop a neonatal manikin specification starting May 15, 2016.

Table 2. Self-inflating neonatal resuscitation bag with masks: key aspects of specifications.

Key aspects of specifications: Neonatal resuscitation bag with masks	
Key resuscitation bag features	• Size 200 mL to 320 mL. • For full-term babies, preterm and low-weight infants less than 5 kg. • Reusable. • Self-inflating. • Hand-operated. • Portable. • Made of silicone or other materials specified in ISO 10651-4 or equivalent. • Ventilation can be done with ambient air or with oxygen. • Intake valve with optional nipple for O_2 tubing, material made of polycarbonate/polysulfone or any other material fulfilling ISO 10651-4 or equivalent.
Key mask features	• Size 0 for preterm and low-weight baby, round type, outer diameter 35 mm to 50 mm. • Size 1 for term baby, round type, outer diameter 50 mm to 65 mm. • Translucent. • Fulfilling ISO 10993-1:2009, ISO 10993-5:2009, ISO 10993-10:2010, or USP Class V (or equivalents).
Bundling instructions	• Resuscitator bag and masks supplied as a complete set along with the following: Non-rebreathing patient valve with a pressure-limiting valve so that the airway pressure does not exceed 4.5 kPa (45 cmH_2O) and can generate an airway pressure of at least 3 kPa (=30 cmH_2O).
Materials	• All parts manufactured from high-strength, long-life materials that require no special maintenance or storage conditions and comply with national standards. • The mask is made of silicone rubber or any material fulfilling ISO 10993-1:2009; ISO 10993-5:2009; ISO 10993-10:2010 or equivalent or USP Class V. • The bag is made of polysulfone and the valve of polycarbonate/polysulfone or any materials fulfilling ISO 10651-4 or equivalent.
Packaging	• Primary packaging: unit of use; one resuscitator set in a plastic bag + box with manufacturer's instruction for use. • Labeling on the primary packaging: name and/or trademark of the manufacturer; manufacturer product reference; type of product and main characteristics. • If the packaging is not transparent, it must bear a diagram (preferably actual size) showing the essential parts of the product and indicating the position of the product in the packaging. • Lot number prefixed by the word "LOT" (or equivalent harmonized symbol). • Information for particular storage conditions (temperature, pressure, light, humidity, etc.) as appropriate (or equivalent harmonized symbol). • Information for handling, if applicable (or equivalent harmonized symbol).
Language	• English and/or any language preferred by users.

Key aspects of specifications: Neonatal resuscitation bag with masks	
Assembly and reassembly instructions	• Resuscitator can be totally disassembled. • Clear instructions/diagrams for assembly and reassembly instructions must be included in and/or on the packaging.
Cleaning instructions	• Easy to clean, disinfect, and sterilize. • Clear instructions/diagrams for cleaning instructions must be included in and/or on the packaging.
Warranty	• Minimum 1 year.
Reference to international standards	• ISO 13485:2012 Medical devices—Quality management systems—Requirements for regulatory purposes. • ISO 10651-4:2002 Lung ventilators—Part 4: Particular requirements for operator-powered resuscitators (EN 13544-2 implied); oxygen-related clauses are optional. For facemask (if not made of silicone): • ISO 10993-1:2009 Biological evaluation of medical devices—Part 1: Evaluation and testing for mask. • ISO 10993-5:2009 Biological evaluation of medical devices—Part 5: Tests for in vitro cytotoxicity. • ISO 10993-10:2009 Biological evaluation of medical devices—Part 10: Tests for irritation and delayed-type hypersensitivity (or classified as USP class V). Optional: • ISO 14971:2012 Medical devices—Application of risk management to medical devices. • ISO 5356-1:2004 Anaesthetic and respiratory equipment – Conical connectors—Part 1: Cones and sockets. • BS EN 980:2008 Graphical symbols for use in the labelling of medical devices. • ISO 15223-1:2012 Medical devices—Symbols to be used with medical device labels, labelling and information to be supplied—Part 1: General requirements. • BS EN 1041:2008 Information supplied by the manufacturer with medical devices.
Regulatory approvals	• To comply with the regulatory requirements of the National Regulatory Agency; or • Registered in country of import, if applicable; or • Approval from the National Regulatory Agency of the manufacturer's country; or • FDA registration (United States); or • CE mark (EU) for class IIa, with notified body number, or approval from other regulatory body in an IMDRF founding member country.

NOTE FROM PATH: ISO 13485:2016 replaces ISO 13485:2003 (European Standard EN ISO 13485:2012). ISO 13485:2016 was published in March 2016. ISO is recommending a transition period of three years in which 13485:2003 and 13485:2016 coexist. It is recommended that two years after publication of ISO 13485:2016 all accredited certifications issued will be to ISO 13485:2016. After three years of publication, any existing certification issued to ISO 13485:2003 will not be valid. It is recommended that procurers periodically check in with ISO for any final determinations.

Table 3. Single-use suction device: key aspects of specifications.

Key aspects of specifications: Single-use suction device (bulb)	
Key features	• Oral, nasal. • Manual or handheld. • Compressible bulb with a tip that can be inserted into the nares.
Clinical purpose	• Evacuate secretions and liquids from the nasal cavity or from high infant airways.
Materials	• Non-latex.
Packaging	• Ensure the device is clean and in a sealed package. • Note any special markings/information required on the packaging.
Color	• Any.
Reference to international standards	• ISO 13485:2003 Medical devices—Quality management systems – Requirements for regulatory purposes, or equivalent.
Regulation requirement	• Approval to comply with the regulatory requirements from national regulatory agency. Optional: • Registered in country of import, if applicable. • Approval by regulatory body of the country of the manufacturer. • FDA registration (United States), CE Mark (EU).

NOTE FROM PATH: ISO 13485:2016 replaces ISO 13485:2003 (European Standard EN ISO 13485:2012). ISO 13485:2016 was published in March 2016. ISO is recommending a transition period of three years in which 13485:2003 and 13485:2016 coexist. It is recommended that two years after publication of ISO 13485:2016 all accredited certifications issued will be to ISO 13485:2016. After three years of publication, any existing certification issued to ISO 13485:2003 will not be valid. It is recommended that procurers periodically check in with ISO for any final determinations.

Table 4. Reusable suction device: key aspects of specifications.

Key aspects of specifications: Reusable suction device	
Key features	• Oral, nasal. • Manual or handheld. • Compressible bulb with a tip that can be inserted into the nares.
Clinical purpose	• Evacuate secretions and liquids from the nasal cavity or from high infant airways.
Materials	• Silicone or any material fulfilling ISO 10993-4:2002 and USP Class V or equivalent. • Latex-free.
Packaging	• Insert any relevant information regarding packaging and labeling of packaging.
Color	• Any.
Cleaning	• Can be subjected to boiling HLD and sterilization, including autoclaving. • Clear instructions/diagrams for cleaning instructions must be included in and/or on the packaging.
Reference to international standards	• ISO 13485:2003 Medical devices – Quality management systems—Requirements for regulatory purposes (Australia, Canada, EU) or equivalent. • ISO 10079-2:1999 Medical suction equipment—Part 2: Manually powered suction equipment or ISO 10079-2:2014 or equivalent.
Regulation requirement	• Approval to comply with the regulatory requirements from the national regulatory agency. Optional: • Registered in country of import, if applicable. • Approval by regulatory body of the country of the manufacturer. • FDA registration (United States), CE Mark (EU).

NOTES FROM PATH: ISO 13485:2016 replaces ISO 13485:2003 (European Standard EN ISO 13485:2012). ISO 13485:2016 was published in March 2016. ISO is recommending a transition period of three years in which 13485:2003 and 13485:2016 coexist. It is recommended that two years after publication of ISO 13485:2016 all accredited certifications issued will be to ISO 13485:2016. After three years of publication, any existing certification issued to ISO 13485:2003 will not be valid. It is recommended that procurers periodically check in with ISO for any final determinations.
Other recommended key features are: Can be opened, cleaned and sterilized. Optional: Translucent.

Key aspects of specifications for training manikins

Specifications for training manikins have not yet been developed by WHO; the following basic considerations (Table 5) are provided by PATH and are partially based on the neonatal training manikin specifications issued by UNFPA.

Table 5. Training manikins: key aspects of specifications.

Key aspects of specifications: Training manikin	
Key features	• A specially constructed manikin with simulated respiratory functions designed to demonstrate and teach neonatal resuscitation techniques. • Full-term, anatomically accurate newborn manikin. • Visible chest rise when correctly ventilated through mouth. • Independent activation of chest rise (e.g., by squeeze bulb) for initiation of spontaneous breaths by the trainer. • Head tilt/chin lift to open the airway. Air entry limited if neck overflexed/overextended. • Use without electricity. Optional: • Cardiovascular functions such as umbilical pulse and heart sound.
Bundling instructions (optional)	• Neonatal resuscitation bag with circular masks size 0 and 1.* • Manual reusable suction device.* • Stethoscope. Optional: • Umbilical cord and umbilical cord ties. **See WHO specifications above for neonatal resuscitation bag with masks and reusable suction device specifications.*
Other features (optional)	• Skin color of manikin (i.e., dark, medium, light).
Materials	• All parts are manufactured from high-strength, long-life materials that require no special maintenance or storage conditions (e.g., polyurethane, polyvinyl chloride, [free from restricted phthalate plasticizers], silicone rubber, synthetic and natural rubber). • Texture of the simulator: soft and smooth, friction-free to demonstrate the desired procedures. Realistically sculpted to resemble and simulate a baby, anatomically accurate and resilient, and suitable for simulation. • Materials and component parts: withstand extreme temperature up to 45°C and humid conditions.
Packaging	• Primary packaging: unit of one manikin in a box or carry case to protect from damage from environmental conditions and handling during transportation with manufacturer's instructions for use. • Labeling on the primary packaging: name and/or trademark of the manufacturer; manufacturer product reference; type of product and main characteristics; lot number prefixed by the word "LOT" (or equivalent harmonized symbol if applicable); information for specific storage requirements such as temperature, light, humidity, etc., as appropriate (or equivalent harmonized symbol). • Information for particular storage conditions (temperature, pressure, light, humidity, etc.) as appropriate (or equivalent harmonized symbol). • Information for handling, if applicable (or equivalent harmonized symbol).

Key aspects of specifications: Training manikin	
Language	• English and/or any language preferred by users.
Assembly and disassembly instructions	• Clear instructions/diagrams for assembly and disassembly instructions must be included in and/or on the packaging if applicable.
Cleaning instructions	• Clear instructions/diagrams for cleaning instructions must be included in and/or on the packaging.
Warranty	• Minimum 1 year.
Reference to international standards	• The manufacturing units must have an internal system of quality control, and supplier should produce the process and relevant certificates from the manufacturers for the production of the model and any other additional equipment, accessories, and consumables supplied with the model.

Section IV: Basic Tender/Request for Quotation Requirements

Most countries or organizations already have their own templates and are familiar with their country policies and practices. For those who do not, Table 6 provides general guidelines on the key information that should be included in a tender/RFQ document.

Table 6. Key information to include in a tender/request for quotation.

Information to include in RFQ	Comments
Title of tender/RFQ	• Provide a title and/or number for the tender/RFQ and request that the bidder put the information in the subject line of their response to help with easier identification of responses.
Summary of deadlines	A summary of deadlines may include: • Release date of tender/RFQ. • Intent to respond date. This is a date that asks any interested bidders to let you know that they intend to respond to the tender/RFQ by a certain date. This eliminates waiting until the tender/RFQ close date and finding that there was a lack of interest. • Fact-finding questions date. This is a date by which bidders may ask questions in relation to the tender/RFQ. All questions should be in writing, and all questions and answers should be shared in writing with all bidders who responded to the intent to respond unless a response contains proprietary information. • Proposal due date. • Conclusion of process date.
Instructions for responding	• Include information on all the items listed in the summary of deadlines (e.g., how the intent to respond and fact-finding questions should be sent, to whom, and in what language). Note that any questions and answers will be shared with all bidders unless the information is considered propriety. • Correspondence during the tender/RFQ process should be in writing—either electronically or via mail—not via telephone. • Inform bidders of the response format. • Provide a template for the bidders to complete, or state your requirements. For example: *"Bids should include a minimum of three sections: (1) Qualifications, (2) Technical specifications (3) Cost of products/cost of shipping."* • Stipulate the currency that the bids must be written in and the validity period for the bid (if you need more than 30 days, be sure to state this in the tender/RFQ).
Qualifications	• Cover any qualifications that the bidders are expected to adhere to (e.g., regulatory requirements, etc.).
Delivery schedule	• Identify the delivery schedule needed to support the purchaser's program activities. • Request that the bidder outline the routing of the delivery, if applicable, along with the estimated time of departure (ETD) from the origin country and the estimated time of arrival (ETA) of the receiving country.

Information to include in RFQ	Comments
Specifications and description of product	• Include FULL product specifications as well as any quality assurance requirements. For further information on quality assurance and technical specifications, see *Section III: Quality of Medical Devices.* • Include the quantities of each product to be ordered and ensure that the unit of measure is correctly stated.
Other requirements	Include a list of other requirements, which may include, but is not limited to: • Packaging and labelling information . • Cleaning instructions. • Assembly and reassembly instructions, including diagrams. • Warranty. You may also want to request that the following information be addressed in the bids: • Country of export. • Brand name of products and full description, including specifications. • Number of packages, weight, and dimensions. (This will be required if you want to do a comparison quotation for freight or intend to hire your own international freight forwarder. It is also useful information to provide the consignee for storage purposes once the goods arrive in country.) • Size and number of ocean containers, if applicable. • Payment terms.
Product cost information	Include a list of all costs that you are requesting, and request that the costs be broken down by line item. For example: • Cost of goods. • Cost of freight to the country of import. • Cost of insurance (stipulate the amount of insurance that should be applied to the goods and the freight—usually 100% airfreight and 110% ocean freight). • Customs clearance charges. • Import duties and taxes. • Final delivery costs. • Other.
Shipping and delivery information	• State whether shipping/delivery is required as part of the bid response. If it is, identify the Incoterms® that will apply to the shipment of goods. • See *Section VII: Shipping* for more information about Incoterms® 2010 and other general shipping information.
Evaluation criteria	It is important to let bidders know how they will be evaluated. For example: • Adherence to product specifications and certifications. • Availability of product. • Cost. • Tender/RFQ response (i.e., response is thorough and complete, response was in keeping with the requirements of the tender/RFQ, etc.).
Terms and conditions	• Attach or outline any general and special terms and conditions.

Section V: Organizations, Manufacturers, and Wholesalers Selling Neonatal Resuscitation Commodities and/or Training Materials

A variety of companies, organizations, and partnerships offer devices, educational products/materials, and services to countries interested in procuring neonatal resuscitation commodities and training programs. This section provides a general overview of some organizations with known quality-assured neonatal resuscitation commodities and services that work with LMICs.

Types of products and services provided by each organization are summarized below, followed by detailed information on each organization. The list of organizations covered in this toolkit **is not comprehensive; it is for informational purposes only**.

The companies listed all have a minimum of USFDA 510(k) approval or CE marking for their medical devices. All companies listed have had their medical devices and training commodities (manikin) on offer by UNICEF and/or UNFPA through long-term agreements and/or the international wholesalers listed in this toolkit. The UN agencies and the international wholesalers in this toolkit all have stringent quality requirements. The wholesalers selected have been reviewed and approved by USAID for procuring and supplying pharmaceuticals, and the best practices they use in procuring pharmaceuticals are also used for procurement of medical devices and supplies.

Only reusable resuscitation bags and masks that can be supplied with a neonate preterm size mask (size 0) AND a neonate full-term size mask (size 1) have been included in this toolkit. Single-use suction bulbs have not been included in this section, as they can usually be procured locally. If procuring single-use suction bulbs, however, it is important to remember to procure enough so that these items are not reused.

Types of products/services provided by selected organizations

Organizations that supply/sell training materials

- Helping Babies Breathe (HBB): Manufactures the HBB educational materials but does not sell them. Website has resources and free downloads to neonatal-related printed matter.
- American Academy of Pediatrics (AAP): Sells the HBB training materials in small quantities (see Laerdal Global Health for larger quantity needs) and provides free access for printing the materials in resource-limited countries.
- Laerdal Global Health (LGH): Sells the HBB educational materials.

Manufacturers that sell reusable neonatal resuscitation bag and masks

- Ambu
- Laerdal Global Health

- VBM Medizintechnik GmbH

Manufacturers that sell reusable resuscitation suction devices

- Laerdal Global Health

Manufacturers that sell neonatal manikins

- 3B Scientific
- Ambu
- Gaumard Scientific Company
- Laerdal Global Health

UN organizations

The following UN organizations service LMICs and are able to provide basic neonatal resuscitation commodities:

- UNICEF
- UNFPA

Wholesalers

The following wholesalers service LMICs and are approved USAID wholesalers of pharmaceuticals that are regulated by USAID due to the high level of their quality assurance practices:

- action medeor
- IDA Foundation
- Imres Medical Solutions
- Medical Export Group (MEG)

These wholesalers responded to a request for information from PATH and confirmed that they have the capability to procure neonatal devices and training manikins upon request. Some include basic neonatal commodities in their catalogs as standard products. Current products offered at the time of writing this toolkit are listed in the detailed information below.

Organization and product information

The following information is provided in this section:

- Brief description of the organization.
- Brief description of the neonatal devices and/or training commodities and materials supplied that are covered in this toolkit, with part numbers where available. Products and part numbers frequently change, so it is important to contact the organization for an update of products before ordering.
- Order and contact information.

More detailed specifications and costing information (when it is publicly available) is shown in *Section VI, Detailed Commodity Information.* Section VI lists the same organizations and products shown in this section but presents the information in a table arranged by product for easier product comparison.

Helping Babies Breathe (HBB)

Helping Babies Breathe is a training program that teaches the essential skills of caring for healthy babies and assisting babies who do not breathe on their own. The goal is to train birth attendants in LMICs in the essential skills of newborn resuscitation by 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. Table 7 details relevant resources available from HBB. For more information about HBB, visit http://www.helpingbabiesbreathe.org/.

Table 7. Training materials and resources available from HBB.

Training materials and resources	Description
Implementation Guide	A free tool for advancing sustainable national programs for newborn and maternal health. The guide shows how countries can implement HBB as a stand-alone program or integrate it into existing training programs, depending on the country's priorities. The entire Implementation Guide can be downloaded for free at: http://www.helpingbabiesbreathe.org/implementationguide.html.
Courses	To register for a course that is offered or to view a history of courses, go to: http://www.helpingbabiesbreathe.org/CoursesConducted.html.
HBB educational materials. HBB is the publisher of the HBB educational materials that can be procured through Laerdal Global Health and/or AAP.	*HBB Facilitator Set* Contents: • Action plan wall poster • Small action plan • Clinical reminder • Facilitator flip chart (includes 26 illustrations) • Learner workbooks (set of 20) *HBB Flip Chart Set*: Includes the items above with the exception of the learner workbooks. *Learner workbooks* *HBB extra posters, small*
Helping Babies Breathe: Lessons Learned: Guiding the Way Forward	A five-year report from the HBB Global Development Alliance that can be downloaded for free from the HBB website along with other resources, including but not limited to: • Implications of the revised Basic Newborn Resuscitation Guidelines from WHO, Susan Niermeyer, MD; May 2012 • Healthy Newborn Network (HNN) partner page for HBB • Presentations • Journal articles • Reports, country and regional

HBB contact information

Email general questions or comments about the HBB curriculum to HPP@aap.org. You may also contact your country HBB representative. A current list of contacts can be found at http://www.helpingbabiesbreathe.org/contacts.html or via the main webpage under "Contacts."

American Academy of Pediatrics (AAP)

The AAP is an organization of 64,000 pediatricians whose mission is to attain optimal physical, mental, and social health and well-being for all infants, children, adolescents, and young adults. The organization provides a number of guidance documents and strategic planning assistance through policy and clinical guidance, advocacy, community-based initiatives, research, publications, education, and collaboration. The AAP created the Neonatal Resuscitation Program (NRP), which is an educational program specifically designed for health care professionals who care for newborns at the time of delivery. They also have developed a suite of educational materials under the Helping Babies Survive initiative for resource-limited countries. Table 8 lists relevant products and materials available from AAP. More information and information about AAP can be found at https://www.aap.org/en-us/Pages/Default.aspx.

Educational materials are now available through free access for printing in resource-limited countries. An account will need to be created to access this site. You can create an account or login at http://internationalresources.aap.org/.

Table 8. Educational materials and commodities available from AAP.*

Educational materials	Description
HBB Facilitator Set	Product code HBB00002 Includes: • Action plan wall poster, Qty 1 • Small action plan, Qty 1 • Clinical reminder, Qty 1 • Facilitator flip chart (includes 26 illustrations), Qty 1 • Learner workbooks, set of 20
HBB Flip Chart Set	Product code HBB00008 Includes the HBB Facilitator Set items (listed above), with the exception of the learner workbooks.
NeoNatalie Learner Workbook/Provider Newborn Educational Manikin	Product codes: • Light-skinned model, HBB00005 • Dark-skinned model, HBB00001
HBB Provider Guide	Product code HBB00003

*To order large quantities of HBB materials, see Laerdal Global Health in this section.

Contact information for AAP HBB program

Information for the HBB materials can be found at http://shop.aap.org/product-list/?q=Helping%20Babies%20Breathe. An account will need to be created to log in and place an order.

AAP Division of Life Support Programs
Toll-free phone USA: 1-800-433-9016, ext. 4798
Fax USA: 1-847-228-1350
Email: lifesupport@aap.org

Laerdal Global Health (LGH)

Laerdal Global Health was established in 2010 as a not-for-profit offshoot of parent company Laerdal Medical AS. LGH is a developer of resuscitation devices and helps to implement both equipment and training programs through partnerships with other organizations and countries.

In support of the Millennium Development Goals, LGH has offered to provide neonatal resuscitation commodities (including bag-and-mask resuscitators, manual reusable suction devices, and training manikins) on a not-for-profit basis to the countries with the highest maternal and newborn mortality. See http://www.countdown2015mnch.org/country-profiles for the list of the 75 countries that qualify.

Other countries may order through Laerdal Medical AS, although not at a reduced price, at http://www.laerdal.com/us/. LGH also has several customers in the United States who procure products for use in LMICs. These customers also receive the no-profit pricing. For more information about LGH and further resources, visit http://www.laerdalglobalhealth.com/.

LGH offers products for each commodity type featured in this toolkit, with the exception of the single-use suction bulb. The commodities in Table 9 are offered at not-for-profit sales prices. Also in Table 9 are HBB training materials.

Table 9. Products and materials available from LGH.

Products and materials	Description
Neonatal resuscitation bag (Simplified Resuscitator) with masks size 0 and 1	Catalog number 846040 *http://www.laerdalglobalhealth.com/doc/2551/Simplified-Resuscitator*
Upright resuscitation bag with masks size 0 and 1	Catalog number 846050 *http://www.laerdalglobalhealth.com/doc/2558/Upright*
Reusable suction device (Penguin Suction Device)	Catalog number 986000 *http://www.laerdalglobalhealth.com/doc/2552/Penguin-Suction-Device*
Manikin training set (NeoNatalie)	Available in either dark or light, and as a basic model or as a complete model with either an upright resuscitator or a simplified resuscitator. Catalog numbers: • 104-10001 NeoNatalie Basic (Dark) • 104-10002 NeoNatalie Basic (Light) • 104-10007 NeoNatalie Complete (Dark) with Upright • 104-10008 NeoNatalie Complete (Light) with Upright • 104-1005 NeoNatalie Complete (Dark) with Simplified • 104-1006 NeoNatalie Complete (Light) with Simplified *http://www.laerdalglobalhealth.com/doc/2528/NeoNatalie*

Products and materials	Description
HBB Facilitator Set	Catalog number 990-000xx* Includes: • Action plan wall poster, Qty 1 • Small action plan, Qty 1 • Clinical reminder, Qty 1 • Facilitator flip chart (includes 26 illustrations), Qty 1 • Learner workbooks, set of 20
HBB Facilitator Flip Chart Set	Catalog number 990-002xx* Includes all of the HBB Facilitator Set materials (listed above), with the exception of the learner workbooks.
HBB Provider Guides (also called learner workbooks)	Catalog number 990-001xx* Qty 20
HBB Extra Posters (small)	Catalog number 990-004xx* Qty 5

* Required language can be ordered using the catalog numbers shown above and replacing "xx" with the numeric code for the relevant language: English = 33, Spanish = 29, French = 07, Swahili = 61.

All medical devices are CE marked. Further details, including product information, can be found at the links provided above or at http://www.laerdalglobalhealth.com/ by clicking on "Products," then "Helping Babies Breathe," and then the specific product to be viewed. Product information includes images, specifications, product brochure downloads, and pricing. There is also a link to the order form.

A more detailed description of these products can be found in *Section VI: Detailed Commodity Information* of this toolkit.

HBB education materials available through LGH are available in English, Spanish, and French. In addition, Swahili versions of the HBB Facilitator Flip Chart set and HBB Provider Guides are available.

A more complete description of these materials can be found in *Section VI: Detailed Commodity Information* as well as on the LGH website at http://www.laerdalglobalhealth.com/doc/2527/Helping-Babies-Breathe or at http://www.laerdalglobalhealth.com/ by clicking on "Products," then "Helping Babies Breathe," and "Educational Materials." The website also includes pricing and a link to the LGH order form.

How to order from LGH and other relevant information:

There are two ways to order from LGH—via the order form on their website or via email.

To request a quotation or place an order using LGH's order form, access the order form at https://laerdal.wufoo.eu/forms/lgh-purchase-order-form/ or by clinking on the Order Form link on the LGH webpage. Once the order form has been completed, email a copy to lgh@laerdal.com.

To contact LGH for a price or queries and to place an order via email, contact lgh@laerdal.com. When requesting a quotation, it is helpful to include the catalog numbers if possible and to ensure that the correct Incoterms are being requested for the shipping quotation if required.

- The order form provided is generally for small orders and for organizations that do not have their own order form or purchase order. LGH can accept purchase orders and contracts from organizations. Because products are sold "at cost" there is no volume discount. Prices are published on the LGH website.
- There are no minimum or maximum orders, although a small administration fee of US$50 may be attached to a small order with an order value less than US$1,000.
- Lead times will vary according to the amount to be procured. For example, orders up to 200 resuscitator bag-and-masks will typically take two weeks. Larger orders may take longer.
- LGH can arrange shipping for countries if requested. Small orders are generally shipped through DHL or TNT, who handle customs clearance. LGH will calculate and compare the freight to decide which forwarder will be used for each order. Larger orders are generally shipped to the port or airport, and the country usually handles customs clearance and final delivery.
- The LGH country of manufacture is China. LGH also has a distributor in South Africa and a warehouse in the United States. A warehouse in India is being established.
- LGH has mainly sold to NGOs and the United Nations, which has included shipping to LMICs. LGH can respond to email requests from governments and can respond to tenders when requested to join in a process.

LGH contact information

For questions related to ordering or to receive a written quotation, contact LGH at lgh@laerdal.com.

Phone: +47 51 51 17 00 / +47 51 51 17 00
Address:
Laerdal Global Health AS
Tanke Svilands gate 30
4002 Stavanger, Norway

3B Scientific

The international group of companies 3B Scientific specializes in the manufacturing and marketing of didactic material for scientific, medical, and patient education. The mother company was founded 1948 in Hamburg. The brand name 3B Scientific® is represented in more than 100 countries worldwide in the medical and educational sector. For more information regarding 3B Scientific, please refer to https://www.a3bs.com/.

3B Scientific offers a variety of neonatal manikins that can be viewed by going to the 3B Scientific homepage and typing *neonatal manikin* in the search bar. Table 10 below shows 3B Scientific manikins specific to newborn resuscitation. Product information is more fully described in *Section VI: Detailed Commodity Information* of this toolkit as well as on 3B Scientific's webpage.

Table 10. Products available from 3B Scientific.

Product	Description
Newborn CPR Manikin	Item no. W44541 [1005728]
CPR Cathy™ Basic Infant Manikin	Item no. W44040
CPR Cathy™ Infant Manikin with Electronics	Item no. W44041 [1017247]
Newborn CPR and Trauma Care Simulator—with Code Blue Monitor	Item no. W45135 [1017560]

How to order from 3B Scientific

Terms are payment in advance by check or credit card.

Allow 7 to 10 days for delivery.

Customers outside of the United States:

1.770.492.9111 for ordering instructions and other information.

US customers:

Phone: 1.866.448.5846
Fax: 1.866.992.1514
Email: sales@3bscientific.com

Online order form: https://www.3bscientific.de/medialibrary/downloads/a3bs_orderform.pdf, or click on the "Quick Order" link at the top of the webpage.
Mail orders: American 3B Scientific, 2189 Flintstone Drive Unit O, Tucker, Georgia 30084 USA

3B Scientific contact information

Head of Customer Service:
Brad Butkovich
brad.butkovich@a3bs.com

Managing Director:
Zach Montgomery
zach.montgomery@a3bs.com

Ambu

Ambu is headquartered in Denmark, with sales offices in Australia, China, India, Japan, the United States, and countries across Europe. Their production companies are in China, Malaysia, and the United States. Ambu's products are sold worldwide. Exports account for 98% of sales, and sales are handled via Ambu's foreign subsidiaries or via distributors. Ambu has been in business since 1937.

For more information about Ambu, see http://www.ambu.com and click on the country that you are interested in viewing or on products, etc. For resuscitation bags and masks, click on "Products," then "Anesthesia," and then scroll down to the relevant product. For the training manikin, click on "Products," then "Emergency Care," and then scroll down to the relevant product. Once you click on the product you wish to review, you will have access to general information, downloads that include specifications and product numbers, related products, spare parts, and a tab where you can request a quotation. Table 11 illustrates the bag and masks and manikin products available on the Ambu website. All of these products are USFDA 510(k) approved.

Table 11. Products available from Ambu.

Products	Description
Ambu® Oval Silicone Resuscitator Neonate.	Product numbers: • A288 002 000—resuscitation bag with a full-term size mask (size 1) • A288 003 000—resuscitation bag with a preterm size mask (size 0) The resuscitator comes with a variety of choices for mask type (size 0, 1, or no mask). If Ambu neonatal resuscitators are ordered from the manufacturer or from a distributor/wholesaler, it is essential that the appropriate quantity and sizes of masks be ordered in addition. Masks can be procured separately (see Ambu® Open Cuff Silicon Face Masks below).
Ambu® Oval Plus Silicone Resuscitator Neonate	Product number A288 103 000—resuscitation bag with a preterm size mask (size 0). To order the size 1 mask, see the Ambu® Open Cuff Silicone Face Masks below.
Ambu® Open Cuff Silicone Face Masks	Designed for use with manual and automatic resuscitators and ventilators. Part numbers: • 000 251 001—preterm size mask (size 0) • 000 251 002—full-term size mask (size 1)
Spare parts for resuscitators	Ambu offers spare parts for their resuscitators. A list can be found under the "Spare Parts" tab listed for each Ambu product.
Ambu® Baby Manikin	• Life-like manikin that simulates babies up to the age of one year. • Product number: 256 001 000. • Spare parts are also available.

A more detailed description and product information, including current item numbers, can be found in *Section VI: Detailed Commodity Information.*

Ambu contact information

Ambu has a worldwide network of distributors who service Ambu's customers locally. To find a distributor in your country go to http://www.ambu.com/Default.aspx?ID=5520. Open the dropdown list and type the first letter of the country you wish to find. Then scroll down the list until you see it. Mark it and click "Go."

If your preferred business area is not represented by a distributor in your country please contact:

Ambu Corporate Sales (Denmark)
Phone: +45 7225 2000
Fax: +45 7225 2050

Gaumard Scientific Company

Gaumard Scientific Company has designed, manufactured, and marketed simulators for health care education for more than 60 years, with users including the military, emergency medical services, major teaching hospitals, and nursing schools. Gaumard manufactures its products at its world headquarters in the United States in Miami, Florida, and sells simulators through its own representatives in North America and through 200 distributors in 70 countries. To see this information and receive further details, see http://www.gaumard.com/about/.

Gaumard Scientific Company has a variety of neonatal manikins that can be viewed by selecting "Products" from their homepage followed by "Pediatric/Neonatal Care." The following neonatal manikin is specific to resuscitation are described in Table 12.

Table 12. Product available from Gaumard Scientific Company.

Product	Description
S 320 Newborn Pediatric Airway Trainer	Neonatal manikin with a full body and a realistic chest cavity containing realistic organs. To view, go to www.gaumard.com/ and click on "Products," and then to "Respiratory/Airway/CPR" followed by "Pedi/Newborn Airway Trainers."

Product information is more fully described in *Section VI: Detailed Commodity Information*. For details on ordering from Gaumard, use one of the contact methods shown below.

Gaumard contact information

Gaumard Scientific
14700 SW 136 Street
Miami, Florida 33196 USA

International: +1-305-971-3790
United States: +1-800-882-6655
Fax: +1-305-252-0755

Sales: Sales@gaumard.com
Support: Support@gaumard.com
Inquiries: Sima@gaumard.com

Gaumard can also be contacted via their webpage at http://www.gaumard.com/contact/.

VBM Medizintechnik GmbH

VBM Medizintechnik GmbH was founded more than 30 years ago and is headquartered in Germany. VBM distributes their products via national and international trade partners as well as via their sales offices in the United States, France, and the Czech Republic. They develop and produce innovative products in the area of airway management, accessories for anesthesia, and intensive-care medicines, as well as tourniquets for surgical procedures in the bloodless field. For more information on VBM Medizintechnik GmbH, go to http://www.vbm-medical.com/company/company-portrait/.

VBM supplies a number of resuscitation bags and masks, both single-use and reusable that are USFDA 510(k) approved and are CE marked. A neonatal resuscitation bag and mask that fits within the WHO specifications is described in Table 13 below. To view these products, click on "Products" on VBM's main page, www.vbm-medical.com, and then "Airway Management." From here, click on "Resuscitation bags" or "Face Masks." A more complete description is also provided in *Section VI: Detailed Commodity Information* of this toolkit.

Table 13. Products available from VBM.

Products	Description
Silicone resuscitation bag, reusable	250-ml bag with a 40 cmHz0 pressure relief. Part Number 80-10-300 Masks must be procured separately.
Pediatric mask, round	Part Numbers: • 80-11-000—size 0 • 80-11-001—size 1 Masks are supplied in boxes of 10.

VBM contact information

VBM can be contacted via email, phone, their contact form, or mail. See http://www.vbm-medical.com/contact-1/contact-info/ for contact information.

National Sales Germany:

Phone: +49 (0)7454 / 95 96 50
Fax: +49 (0)7454 / 95 96 33
Email: verkauf@vbm-medical.de

Postal address:
VBM Medizintechnik GmbH
Einsteinstr. 1
72172 Sulz am Neckar, Germany

International Sales:

Phone: +49 (0)7454 / 95 96 10
Fax: +49 (0)7454 / 95 96 33
Email: info@vbm-medical.de

US Sales:

VBM Medical Inc.
524 Herriman Court
Noblesville, IN 46060 USA

Tel.: +1 317 776 1800 +1 317 776 1800
Fax: +1 317 776 1881
Email: info@vbm-medical.com

United Nations Children's Fund (UNICEF) Supply Division

UNICEF is a global health agency working in 191 countries to date. Approximately 88 percent of UNICEF's posts are located in the field. UNICEF headquarters are located in New York, and the Supply Division is located in Copenhagen, Denmark.

From 2008 to 2013, UNICEF procured approximately US$1.4 million in neonatal resuscitation devices and training models. The Every Newborn Action Plan (known as ENAP), published by UNICEF in conjunction with the WHO, includes resuscitation program implementation and scale-up recommendations. ENAP was approved by the World Health Assembly in May 2014. A copy of *Every Newborn: An Action Plan to End Preventable Deaths* and further information can be found at: http://www.everynewborn.org/.

In August 2014, the UNICEF Supply Division published a report titled *Neonatal Resuscitation Devices: Market & Supply Update*. The report, which supplies an overview of the neonatal resuscitation device market situation, issues, challenges, and quality considerations, and UNICEF's next steps in monitoring and shaping the market alongside partner organizations, can be found by typing the report name into an internet browser search bar.

UNICEF undertakes procurement on behalf of governments, NGOs, UN agencies, international financial institutions, philanthropic organizations, and universities. UNICEF does not undertake procurement on behalf of individuals or profit-making entities. For more information about UNICEF, visit their official site at http://www.unicef.org.

Currently, the UNICEF catalog contains the following (Table 14) neonatal commodities that are covered in this toolkit:

Table 14. Products available from UNICEF.

Product	Description
Neonatal resuscitation bag with three masks: size preterm, newborn, and infant.	Specification information can be found under product number S0845003. Note that the costs are indicative only, and UNICEF should be contacted to receive a full quotation (contact information below).

The cost of shipment and insurance of the goods is included in the cost estimate. UNICEF's freight forwarders deliver the goods to the port or airport of entry closest to the project site. The seaport of entry for landlocked countries varies on a case-by-case basis.

Access the product information on the UNICEF page https://supply.unicef.org/. Go to Medical Equipment → Resuscitation/anaesth. Equipment → Other resuscitation equipment → on the left-hand side of the site to find the neonatal resuscitator.

Further information can also be found in *Section VI: Detailed Commodity Information* of this toolkit.

How to order from UNICEF

UNICEF does not respond to government tenders. A country can, however, contact UNICEF directly.

There are two different ways commodities can be supplied by UNICEF:

- Through UNICEF country offices: An order is placed directly with the UNICEF country office.
- Through the UNICEF Supply Division Procurement Services: This is for large orders only (more than US$5,000). An order is placed through the UNICEF Supply Division and price breaks may be available.

Placing an order through the UNICEF Supply Division Procurement Services/country offices

There are six key steps related to purchasing supplies and/or services through UNICEF Procurement Services. For your convenience, the description of these steps has been copied from the UNICEF webpage (http://www.unicef.org/supply/index_purchasing.html). See Box 1.

Box 1. Six steps for purchasing supplies and/or services through UNICEF Procurement Services.*

1. **Planning**
   - A new request for a Cost Estimate should be discussed between the Partner, the UNICEF Country Office and/or Supply Division.
   - The UNICEF Procurement Services Request Form must be submitted for all new requests. A copy of the request form is attached at the end of this section for your convenience.
   - Submit the Request by email, fax or mail to the appropriate UNICEF Country Office and/or directly to UNICEF Procurement Services.
   - Commodities are identified via the online UNICEF Supply Catalogue.
2. **Cost Estimate**
   Upon receipt of the Request Form, the enquiry is reviewed, and if it meets all of the necessary criteria, a draft Cost Estimate is prepared by Supply Division. Information included in the Cost Estimate:
   - Cost of goods/services
   - Handling fee
   - Freight and insurance
   - 10% contingency buffer
   - Incoterms

   A cover letter accompanies the Cost Estimate providing information and instruction.
3. **Commitment**
   Upon Partner's acceptance of the Cost Estimate, a Memorandum of Understanding is signed. Information included in the MOU:
   - UNICEF Procurement Services processes
   - Terms and Conditions for the transactions
   - Validity or termination information for either party

   Upon acceptance of the Cost Estimate partner must transfer the full payment in advance to the UNICEF bank account stated in the Cost Estimate as required by UNICEF's Financial Regulations and Rules.
4. **Procurement and Delivery**
   - Upon receipt of funds Supply Division will initiate the procurement activities.
   - Supplies are delivered to the consignee.
5. **Accounts Settled**
   - Invoices to supplier(s) and freight forwarder are paid.
   - Financial Statement of Accounts is prepared and sent to the partner after the delivery of all supplies and/or provision of the services, and within 30 days of payment of the last expenditure.
   - Any remaining contingency buffer and/or balances can be reprogrammed or returned.
6. **Monitoring and Evaluation**
   - The monitoring of Procurement Services supplies is part of the ongoing efforts of country offices to oversee the availability and accessibility of essential supplies for children.
   - Evaluation is undertaken through ongoing dialogue with Procurement Services partners at various levels.

* Source: http://www.unicef.org/supply/index_purchasing.html.

For information on UNICEF procurement services go to: http://www.unicef.org/supply/index_procurement_services.html. This link will provide further information, including:

- Procurement Services partners
- Commodities and services
- Handling fees
- How to use Procurement Services
- Memoranda of understanding
- World Bank memorandum of understanding
- Questions and answers
- Procurement Services contacts

For a list of frequently asked questions and answers, see http://www.unicef.org/supply/index_faq.html.

UNICEF contact information

UNICEF must be contacted in order to obtain pricing and other related procurement information.

To receive a cost estimate through UNICEF Procurement Services, or for any queries, contact the Procurement Services Centre at UNICEF Supply Division or contact your local office.

Procurement Services Centre:

UNICEF Supply Division
Oceanvej 10-12
2150 Nordhavn
Copenhagen, Denmark

Phone: +45 4533 5500
Fax: +45 3526 9421
Email: psid@unicef.org

UNICEF country office information and contact details can be found at http://www.unicef.org/infobycountry/

United Nations Population Fund (UNFPA)

UNFPA is a leading UN agency, established in 1969. Today, UNFPA operates in 150 countries, helping countries use population data to predict needs and provide strategic technical guidance. The organization focuses its efforts on ensuring that every pregnancy is wanted, supporting maternal health, and helping young people fulfill their potential.

The UNFPA Procurement Services Branch provides procurement services for customers, such as low- and middle-income governments and ministries, UN agencies, and NGOs. According to UNFPA, devices,

supplies, and anatomical models make up about 7.6 percent of their products and services distribution. Medical devices procured by UNFPA comply with the quality standards set by WHO recommendations and the Global Harmonization Task Force. Medical devices are evaluated on the following criteria:

- Manufacturer maintains valid marketing licenses.
- Manufacturer maintains valid ISO 13485 and/or ISO 9001 certifications.
- Product meets essential and specific ISO requirements.
- Certificates of Conformity specifying the standard and validity period.
- Product sampling and testing during the bid evaluation stage.
- Product pre-shipment inspection for each purchase order.

For further information about UNFPA, go to: http://www.unfpa.org/.

Table 15 illustrates the neonatal resuscitation commodities in the UNFPA catalogue that are covered in this toolkit:

Table 15. Products available through UNFPA.

Product	Description
Neonate training manikin	See "How to access product information" below.
Neonate resuscitation bag with three mask sizes: preterm, newborn, and small infant.	See "How to access product information" below.

How to access product information

For more detailed information about these products, visit the UNFPA AccessRH catalog at https://www.myaccessrh.org/web/site/home. This link contains information about AccessRH, products offered by UNFPA, planning, and ordering. To view the aforementioned products do the following:

For the neonate training manikin:

- Click on "Products" at the top of the UNFPA AccessRH page (you may also need to click on "Product Catalogue").
- Under "Medical Devices" on the left-hand side of the page, click on "Anatomical Models."
- Products are listed in alphabetical order. Scroll down to MODELNEORUSUS. Click on the product link for full specifications and prices.

For the neonate resuscitation bag and masks:

- Click on "Products" at the top of the UNFPA AccessRH page (you may also need to click on "Product Catalog").
- Under "Medical Devices" on the left-hand side of the page, click on "Anaesthesia & Resus. Equip."
- Products are listed in alphabetical order. Scroll down to RESUSCITATNEONATE. Click on the product link for full specifications and prices.

The AccessRH product catalog contains contraceptives, pharmaceuticals, medical devices, and kits related to reproductive health. The catalog is updated on an ongoing basis, providing the most recent information regarding new products, product details, as well as current pricing.

The AccessRH price only includes the cost of the selected reproductive health items (in US dollars). To calculate your total budget, use the estimate provided by the budget planner. The lead time calculator will provide an estimate for how long it will take for your order to arrive. Both of these tools can be found under "Plan" at the top of the UNFPA AccessRH page.

Detailed product information can also be found in *Section VI: Detailed Commodity Information* of this toolkit.

How to order from UNFPA

Items can be purchased three ways from UNFPA:

- Through a country office (contact information below).
- Through UNFPA headquarters (contact information below).
- Online through the AccessRH catalog by clicking "Order" at the top of the UNFPA AccessRH main page or through the following link: http://www.myaccessrh.org/order;jsessionid=8C8FBD3D3F2EED0329AE4F534EA4D8BC.

All channels offer the same low prices. Orders must total more than US$5,000 although there are no minimum or maximum quantity allowances.

To order from the AccessRH catalog:

- Select product(s) from the AccessRH catalog (or contact UNFPA directly if the product is not listed in the catalog).
- Request a Proforma invoice from UNFPA. Download the Request for Proforma Invoice form and send the completed request form to your regional UNFPA regional focal point. A form can be downloaded in English, Spanish, or French by clicking "Request a Pro Forma Invoice," which can be found under "Order" on the main AccessRH page or at https://www.myaccessrh.org/request-a-pro-forma-invoice. The link to download an invoice can be found on the right-hand side of the page under "Resources."
- Confirm order and transfer funds.

For your convenience, Box 2 contains order information from the UNFPA webpage (https://www.myaccessrh.org/request-a-pro-forma-invoice).

Box 2. Order information from the UNFPA webpage.*

Questions to consider before ordering

- Are the products registered in the country where they will be used?
- Is the consignee eligible to utilize UNFPA procurement services? The consignee needs to be a governmental or not-for-profit organization working in a developing country.
- Will the consignee charge for the products? Products procured by UNFPA may not be sold to or in the private sector, unless the client can provide proof that the private-sector entity is a non-profit organization.

Things to remember before sending Request for Proforma Invoice

Please make sure that the Request for Proforma Invoice includes the following information:

- Complete name and delivery address of the consignee and details for all other parties that need to be notified of the order
- Detailed item specifications
- Product quantities
- Correct units of measure for all products

If customized artwork or printing is required, include specifications as part of your request.

If special import documents are required, include this in the details field of the form (some countries may require pre-shipment inspection for customs purposes, not for quality assurance).

If post-shipment testing will take place, please note the invoice.

*Source: https://www.myaccessrh.org/request-a-pro-forma-invoice

If you have any questions, please contact your UNFPA focal point as listed in contacts below or at https://www.myaccessrh.org/contact.

UNFPA contact information

UNFPA Procurement Services Branch
Marmorvei 51
2100 Copenhagen, Denmark
Telephone: +45 45335000; email: procurement@unfpa.org

UNFPA also has regional and country offices; information can be found at http://www.unfpa.org/worldwide/.

International wholesalers

The international wholesalers listed below have experience working with LMICs. They are approved USAID wholesalers of pharmaceuticals that are regulated by USAID due to their high-level quality assurance practices. PATH issued a request for information to the six USAID-approved wholesalers to obtain information for this toolkit. Five wholesalers responded to the request and four confirmed that they are able to provide the neonatal resuscitation commodities covered in this toolkit.

Some of the wholesalers feature the neonatal resuscitation commodities listed in this toolkit as standard catalog items, while others do not. All of the following wholesalers are able to provide these commodities, and if you do not find what you are looking for in their catalogs, please contact the wholesalers directly. All of the wholesalers are able to respond to international tender requests from governments.

action medeor

action medeor is a charitable NGO based in Germany. The organization was established in 1964 to provide basic drugs and medical equipment to people in LMICs. Today action medeor supports around 10,000 health care centers, particularly small facilities, in 140 countries.

For more than 40 years, action medeor has been providing medical supplies and advisory services to mission hospitals in Tanzania. In order to be more efficient and cost-effective, action medeor Germany initiated the establishment of a branch in Tanzania—action medeor International Healthcare Tanzania. The Tanzanian office and warehouse for medical products was opened in Dar es Salaam in September 2005. In addition, action medeor opened a branch in Lilongwe, Malawi, in 2015.

Further information about action medeor can be found at https://medeor.de/en. For information regarding International Healthcare Tanzania and the action medeor Malawi branch, click on “Branches” and then the relevant country.

Table 16 illustrates the current action medeor offering for a neonatal resuscitation bag with mask.

Table 16. action medeor products.

Product	Description
Resuscitation bag, silicone, Ambu brand	Catalog number 61110 For premature babies and neonates, with single-membrane patient valve and open cuff mask, size 0. A size 1 mask can be ordered separately through action medeor. Further information about this product along with pricing can be found in *Section VI: Detailed Commodity Information* of this toolkit or in action medeor’s catalog.

How to access product information

To view action medeor's catalog go to https://medeor.de/catalog. Products are listed in article number order, and as of the writing of this toolkit, the neonatal resuscitation bag is under item number 61110.

The Malawi catalog can be found at https://medeor.de/en/medeor-tanzania/malawi/online-catalog-malawi.html, and the neonatal resuscitation bag-and-mask is listed under product number 10114.

How to order from action medeor

Headquarters:

To obtain a quotation and/or place an order from the headquarters in Germany, contact info@medeor.de or Iris.Koch@medeor.org.

Tanzania:

action medeor International Healthcare Tanzania has the following guidelines, which have been copied below in Box 3 from their website (https://medeor.de/en/medeor-tanzania/tanzania/purchasing-information.html) for your convenience.

Malawi:

After viewing the catalog, contact sales@medeormw.com for assistance.

Box 3. Ordering guidelines from action medeor International Healthcare Tanzania.*

We request you to send orders in advance, preferably by mail, e-mail or fax. We will provide you with a pro-forma invoice indicating the value and the size of the consignment and the availability of supplies. After your confirmation the order will be processed immediately and you will be informed about the time of collection.

- All orders presented to action medeor have to be signed and stamped by the Medical officer in-charge of the hospital or the in-charge of the health facility.
- All orders have to be collected by an authorized person.
- Prices in the price indicator should be considered as a fair guideline to the actual prices, but since we are operating in a dynamic mix of exchange rates, freight costs and suppliers costs, you may find deviations up- or downwards.
- Prices are exclusive VAT. Medicines registered in Tanzania and medical supplies are VAT exempted by the Tanzanian Revenue Authority (TRA); however other items attract 20%VAT. VAT items will be indicated in the invoice.
- Prices are not negotiable. action medeor operates on a nonprofit basis. The margins added to the cost of our products are to cover our operating cost.
- action medeor operates on a cash and carry basis, which means payment on delivery or pre-payment.
- Invoices may be settled by cash, bank draft or cheque written out in the name of action medeor International Healthcare Tanzania.
- We encourage customers to transfer money in advance to our bank account in Dar es Salaam; the amount will then be credited to the customer's account. Detailed statements showing transactions over a period of time are available on request.
- Payments from payees/donors from abroad on behalf of a Tanzanian customer should be made to the Euro Account of action medeor eV Germany (Deutsche Bank Krefeld, Germany, account No 011 8000, Swift Code DEUTDEDD 320, IBAN DE62 920 700 80 011 8000 00). The amount will then be credited to the customer's account concerned.
- Please inform us in advance who from your health facility is authorized to withdraw against your credit balance.

*Source: https://medeor.de/en/medeor-tanzania/tanzania/purchasing-information.html

action medeor contact information

Headquarters:

German Medical Aid Organization action medeor e.V.
St. Töniser Str. 21, 47918 Tönisvorst
Germany
Phone: +49 2156 9788-100
Fax: +49 2156 9788-88
Email: info@medeor.de

Export Department/Service d'exportation:

Iris Koch
German Medical Aid Organization action medeor e.V.
St. Töniser Straße 21, 47918 Tönisvorst
Germany
Phone: +49 2156 9788-143
Fax: +49 2156 9788-88

Email: Iris.Koch@medeor.org

Tanzania:

action medeor International Healthcare Tanzania
PO Box 72305
Dar es Salaam
Phone: +255 22 286-3136
Telefax: +255 22 286-3007
Email: director@medeortz.co.tz or medeortz@medeortz.co.tz

Malawi:

sales@medeormw.com or director@medeormw.com

For further questions contact Dr. Gerhard Kunath, medeor's coordinator for East Africa, in Germany via telephone at +49 9381 7169787, or email at medeor-wuerzburg@t-online.de.

IDA Foundation

IDA Foundation was founded in 1972 and is a not-for profit supplier of quality-assured medicines and medical supplies to LMICs. IDA Foundation's Procurement and Quality Assurance Departments work closely to provide high-quality products at affordable prices and to create sustainable supplier partnerships, while the Supply Chain Department supports warehousing and stock, local stock, and transportation logistics.

IDA Foundation is headquartered in Amsterdam and has offices in India, China, Nigeria, and DR Congo, with more than 30 global representative agents.

IDA Foundation offers the following services:

- Quality assurance/quality control system, including approval of source materials, GMP of manufacturing site, quality control monitoring, and analysis of final product.
- Certified for GMP, GDP and ISO 9001:2000.
- Not-for-profit pricing.
- Product registration in destination countries.

For more information about IDA, go to http://www.idafoundation.org/.

Products available from IDA Foundation

As of the updating of this toolkit, while IDA Foundation has some resuscitation bags and masks in their catalog, they are not a 100% match with the products featured in this toolkit. However, on a quarterly basis IDA updates their catalog with new products, which can be checked by going to: http://www.idafoundation.org/account/login/page/web-catalogue2.html. You will need to be a customer to review the catalog and can sign up or log in from this page. IDA Foundation can also email you a copy of their e-catalog on a quarterly basis; you can sign up at http://www.idafoundation.org/e-catalogue.html or by going to the home page and clicking on "E-catalogue."

IDA Foundation is able to provide other neonatal commodities not shown in the catalog upon request.

How to order from IDA Foundation

A Request for Quotation can be placed directly through the e-catalogue once a customer is registered. Indicate the quantities of products on the form and complete the delivery and order instructions on the second tab. The form should then be submitted to IDA, who will forward a quotation that is usually valid for 30 days.

Prior to viewing and purchasing medicines and medical supplies through the IDA Foundation e-catalogue, you must first register as a customer at the following address: http://www.idafoundation.org/e-multi.html. Alternatively, IDA Foundation can be contacted directly using the contact information shown below. IDA can respond to government tenders as well as answer general requests or provide a request for quotation.

IDA Foundation contact information

<u>IDA Foundation headquarters</u>

Slochterweg 35
1027 AA Amsterdam
P.O. Box 37098
1030 AB Amsterdam
The Netherlands

Phone: +31 20 4033051
Fax: +31 20 4031854
Email: info@idafoundation.org
Emergency Phone Line 24 hours a day, 7 days a week: +31 6 54387985

Customer services

Phone: +31 20 403351
Fax: +31 20 4031854
Email: service@idafoundation.org

Or write directly to Cristina Colombo at ccolombo@idafoundation.org.

Imres Medical Solutions

Imres Medical Solutions is a medical and pharmaceutical wholesale organization providing high-quality medical solutions to UN organizations, NGOs, and ministries of health. Imres is based in the Netherlands and has more than 35 years of global experience providing high-quality medical products covering the full range of affordable pharmaceuticals, medical disposables and equipment, and custom-made kits.

To ensure high-quality products, Imres only collaborates with manufacturers and suppliers who meet international quality standards. Vendors are audited on a regular basis, and products are only purchased and released after receiving full documentation about the manufacturer's quality system. Imres' quality system is based on ISO principles and follows WHO and USAID guidelines. Imres is ISO 9001:2008 certified. More information about Imres can be found at www.imres.nl.

Products available from Imres Medical Solutions

Imres' product catalog does not contain neonatal resuscitation bags and masks, training manikins, or manual suction devices, although they are able to provide a price and specifications for these products upon request.

How to order from Imres Medical Solutions

Imres participates in a wide variety of tenders and long-term agreements with NGOs and ministries of health. Their contact information is provided below.

Imres contact information

Physical address:
Imres b.v.
Larserpoortweg 26
8218 NK Lelystad
The Netherlands

Phone: +31 (0)320 29 69 69
Fax: +31 (0)320 29 69 29
Email: info@imres.nl

Postal address:
P.O. Box 214
8200 AE Lelystad
The Netherlands

Or write directly to Jarno de Lange at deLange@imres.nl.

Medical Export Group (MEG)

The Medical Export Group (MEG) is headquartered in the Netherlands and supplies a wide variety of pharmaceuticals, medical and laboratory equipment, and consumables and other high-quality medical products to organizations dedicated to the development of health care worldwide. All medical devices procured from MEG are CE marked, and all of their vendors are ISO-certified. Important qualifications for MEG, among others, are the USAID approval status and being a supplier to UN organizations (especially UNICEF, UNDP, WHO, and UNFPA). It is also important to MEG that a company has a QA system for medical devices as well as pharmaceuticals. More information about MEG can be found at http://www.meg.nl/about-us/about-us/.

Products available from MEG

MEG does not currently have the neonatal commodities covered in this toolkit in their catalog. They can, however, procure Ambu resuscitation bags and masks upon request. Training manikins can be procured from a number of sources, depending on what type is required. To view MEG's catalog, click on "Products" from the home page and then click on the relevant category of supplies.

Prices vary according to quantities; therefore, MEG always works on the basis of custom-made quotes. See contact information below to request a quotation.

MEG contact information

Contact MEG directly via email to obtain a quotation and/or to place an order.

The Medical Export Group–Sales

Papland 16 – P.O. Box 598 4200
AN Gorinchem
The Netherlands

Phone: +31 (0)183 356100
Fax: +31 (0)183 356122
Email: info@meg.nl
Web: www.meg.nl

Account Manager

Angelique van den Heuvel
Phone: + 31 183 356 100
Email: a.vendenheuvel@meg.nl

Section VI: Detailed Commodity Information

This section lists all the commodities as discussed throughout Section V.

Neonatal resuscitation bag-and-masks

Table 17. Neonatal resuscitation bag-and-mask manufacturer information.

Product name, description (per mfr.), manufacturer, website	Specifications	Procurement options Item no./price (US$)	Quality assurance
Upright Resuscitation Bag ***Description:*** Upright and the new Newborn Masks (size 0 and 1) are designed to make it easier to obtain mask seal and provide effective ventilations. With few parts, Upright is simple to disassemble and clean. It is available with the NeoNatalie Complete Kit and can also be ordered separately. ***Manufacturer:*** Laerdal Medical AS ***Website:*** http://www.laerdalglobalhealth.com/doc/2516/Upright	***Number of parts:*** 6 ***Materials:*** silicone and polysulfonate, autoclavable ***Bag volume:*** 320 ml ***Mask type:*** round ***Mask size(s):*** 0 and 1 ***Oxygen reservoir bag:*** no ***Pressure release valve:*** yes; set at 30–45 cm H_2O ***Note:*** Designed for ventilation of neonates < 10 kg	***Item no.:*** Laerdal Global Health: 846050 ***Price:*** $20 ***Note:*** Can also be ordered with the NeoNatalie Complete Kit	CE mark
NeoNatalie Resuscitation Bag ***Description:*** The bag-valve-mask unit is made of silicone and polysulfonate, can be boiled or autoclaved, and is extremely durable. Comes with two mask sizes. Time-proven design and quality. An oxygen kit is an optional extra. ***Manufacturer:*** Laerdal Medical AS ***Website:*** http://www.laerdalglobalhealth.com/doc/2528/NeoNatalie	***Number of parts:*** 9 ***Materials:*** silicone and polysulfonate, autoclavable ***Bag volume:*** 220 ml ***Mask type:*** Round ***Mask size(s):*** 0 and 1 ***Oxygen reservoir:*** No ***Pressure release valve:*** yes; set at 30–45 cm H_2O ***Note:*** Designed for ventilation of neonates < 10 kg	***Item no.:*** Laerdal Global Health: 846040 ***Price:*** $20 ***Note:*** Can also be ordered with the NeoNatalie Complete Kit	CE mark

Product name, description (per mfr.), manufacturer, website	Specifications	Procurement options Item no./price (US$)	Quality assurance
Ambu Oval Silicone Resuscitator, Neonate (no mask included) ***Description:*** Ambu Oval Silicone Resuscitator, Neonate, with patient valve, pressure-limiting valve and standard O_2 reservoir tube. ***Manufacturer:*** Ambu ***Website:*** http://www.ambu.com/corp/products/anaesthesia/product/oval_silicone_resuscitator-prod13780.aspx	***Materials:*** silicone rubber, autoclavable at 134°C ***Bag volume:*** 220 ml ***Mask type:*** no mask included ***Mask size(s)*:** no mask included ***Oxygen reservoir:*** bag, translucent plastic, 100 ml ***Pressure-release valve:*** yes; set at 40 mbar, which can be blocked if higher pressure indicated ***Note:*** Designed for ventilation of neonates < 10 kg (1 year)	***Item no.:*** Ambu: A288 001 000 ***Price range:*** Not published ***Note:*** Masks sizes 0 and 1 can be ordered separately from Ambu at: http://www.ambu.com/corp/products/anaesthesia/product/open_cuff_silicone_face_masks-prod867.aspx	FDA 510K approved
Ambu Oval Silicone Resuscitator, Neonate (with open cuff silicone mask size 1) ***Description:*** Ambu Oval Silicone Resuscitator, Neonate, with neonate patient valve, pressure-limiting valve, open cuff silicone face mask size 1, and standard O_2 reservoir tube ***Manufacturer:*** Ambu ***Website:*** http://www.ambu.com/corp/products/anaesthesia/product/oval_silicone_resuscitator-prod13780.aspx	***Materials:*** silicone rubber, autoclavable at 134°C ***Bag volume:*** 220 ml ***Mask type:*** open cuff silicone mask ***Mask size(s):*** 1 ***Oxygen reservoir bag:*** translucent plastic, 100 ml ***Pressure release valve:*** yes; set at 40 mbar, which can be blocked if higher pressure indicated ***Note:*** Designed for ventilation of neonates < 10 kg (1 year)	***Item no.:*** Ambu: A288 002 000 ***Price range:*** Not published ***Note:*** Masks sizes 0 and 1 can be ordered separately from Ambu or the wholesaler/distributor	FDA 510K approved
Ambu Oval Silicone Resuscitator, Neonate (with open cuff silicone mask size 0) ***Description:*** Ambu Oval Silicone Resuscitator, Neonate, with neonate patient valve, pressure-limiting valve, open cuff silicone face mask size 0 and standard O_2 reservoir tube. ***Manufacturer:*** Ambu ***Websites:*** *Ambu:* http://www.ambu.com/corp/products/anaesthesia/product/oval_silicone_resuscitator-prod13780.aspx *action medeor:* https://portal.medeor.de/catalog/Lists/Articles/Details.aspx?ID=__bk41006300130013000300	***Materials:*** silicone rubber, autoclavable at 134°C ***Bag volume:*** 220 ml ***Mask type:*** open cuff silicone mask ***Mask size(s):*** 0 ***Oxygen reservoir:*** bag, translucent plastic, 100 ml ***Pressure release valve:*** yes; set at 40 mbar, which can be blocked if higher pressure indicated ***Note:*** Designed for ventilation of neonates < 10 kg (1 year)	***Item no.:*** Ambu: A288 003 000 action medeor: 61110 ***Price:*** EUR 132.05 ***Note:*** Masks sizes 0 and 1 can be ordered separately from Ambu or the wholesaler/distributor	FDA 510K approved

Product name, description (per mfr.), manufacturer, website	Specifications	Procurement options Item no./price (US$)	Quality assurance
Resuscitator, hand-operated, neonate, set ***Description:*** Resuscitator, hand-operated, neonate, set. ***Manufacturer:*** Not available ***Websites:*** *UNICEF:* https://supply.unicef.org/ *UNFPA:* http://www.myaccessrh.org/rhi-home	***Bag volume:*** 200–250 ml ***Mask type:*** silicone, round type ***Mask size(s):*** preterm, newborn, and infant small ***Oxygen reservoir:*** no ***Pressure release valve:*** yes; set at 40 ± 5 cm H_2O ***Note:*** Designed for ventilation of neonate 0 kg to 7 kg	***Item no.:*** UNICEF: S0845003 UNFPA: NEORESUS ***Price range:*** $51.29 (indicative) – $210	CE marking conforms to MMD 93/42/EEC
Ambu Oval Plus Silicone Resuscitator, Neonate (no mask included) ***Description:*** Ambu Oval Plus Silicone Resuscitator, Pediatric, with patient valve, pressure-limiting valve, Mark IV Baby inlet valve, Mark IV Baby O_2 tube reservoir. ***Manufacturer:*** Ambu ***Website:*** http://www.ambu.com/corp/products/anaesthesia/product/oval_plus_silicone_resuscitator-prod13861.aspx	***Materials:*** silicone, semi-transparent ***Bag volume:*** 220 ml ***Mask type:*** no mask included ***Oxygen reservoir:*** tube ***Pressure release valve:*** yes ***Note:*** Designed for ventilation of neonates < 10 kg (1 year)	***Item no.:*** Ambu: A288 101 000 ***Price range:*** Not published ***Note:*** Masks sizes 0 and 1 can be ordered separately from Ambu at: http://www.ambu.com/corp/products/anaesthesia/product/open_cuff_silicone_face_masks-prod867.aspx	FDA 510K approved
Ambu Oval Plus Silicone Resuscitator, Neonate (with open cuff silicone mask size 0) ***Description:*** Ambu Oval Plus Silicone Resuscitator, Pediatric, with patient valve, pressure-limiting valve, Mark IV Baby inlet valve, Mark IV Baby O_2 tube reservoir, and open cuff silicone mask size 0. ***Manufacturer:*** Ambu ***Website:*** http://www.ambu.com/corp/products/anaesthesia/product/oval_plus_silicone_resuscitator-prod13861.aspx	***Materials:*** silicone, semi-transparent ***Bag volume:*** 220 ml ***Mask type:*** open cuff silicone ***Mask size(s):*** 0 ***Oxygen reservoir:*** tube ***Pressure-release valve:*** yes ***Note:*** Designed for ventilation of neonates < 10 kg (1 year)	***Item no.:*** Ambu: A288 103 000 ***Price range:*** Not published ***Note:*** Masks sizes 0 and 1 can be ordered separately from Ambu at: http://www.ambu.com/corp/products/anaesthesia/product/open_cuff_silicone_face_masks-prod867.aspx	FDA 510K approved

Product name, description (per mfr.), manufacturer, website	Specifications	Procurement options Item no./price (US$)	Quality assurance
Ambu Oval Plus Silicone Resuscitator, Neonate (with silicone face mask size 0) ***Description:*** Ambu Oval Plus Silicone Resuscitator, Pediatric, with patient valve, pressure-limiting valve, Mark IV Baby inlet valve, Mark IV Baby O_2 tube reservoir, and silicone face mask size 0. ***Manufacturer:*** Ambu ***Website:*** http://www.ambu.com/corp/products/anaesthesia/product/oval_plus_silicone_resuscitator-prod13861.aspx	***Materials:*** silicone, semitransparent ***Bag volume:*** 220 ml ***Mask type:*** silicone, round type ***Mask size(s):*** 0 ***Oxygen reservoir:*** tube ***Pressure release valve:*** yes ***Note:*** Designed for ventilation of neonates < 10 kg (1 year)	***Item no.:*** Ambu: A288 104 000 ***Price range:*** Not published ***Note:*** Masks sizes 0 and 1 can be ordered separately from Ambu at: http://www.ambu.com/corp/products/anaesthesia/product/open_cuff_silicone_face_masks-prod867.aspx	FDA 510K approved
Ambu Oval Plus Silicone Resuscitator, Neonate (no mask included) ***Description:*** Ambu Oval Plus Silicone Resuscitator, Pediatric**,** with patient valve, pressure-limiting valve, Mark IV Baby inlet valve, and Mark IV Baby O_2 reservoir bag ***Manufacturer:*** Ambu ***Website:*** http://www.ambu.com/corp/products/anaesthesia/product/oval_plus_silicone_resuscitator-prod13861.aspx	***Materials:*** silicone, semi-transparent ***Bag volume:*** 220 ml ***Mask type:*** no mask included ***Oxygen reservoir:*** bag ***Pressure release valve:*** yes ***Note:*** Designed for ventilation of neonates < 10 kg (1 year)	***Item no.:*** Ambu: A288 201 000 ***Price range:*** Not published ***Note:*** Masks sizes 0 and 1 can be ordered separately from Ambu at: http://www.ambu.com/corp/products/anaesthesia/product/open_cuff_silicone_face_masks-prod867.aspx	FDA 510K approved
Ambu Oval Plus Silicone Resuscitator, Neonate (open cuff silicone mask size 0) ***Description:*** Ambu Oval Plus Silicone Resuscitator, Pediatric, with patient valve, pressure-limiting valve, Mark IV Baby inlet valve, Mark IV Baby O_2 reservoir bag, and open cuff silicone mask size 0. ***Manufacturer:*** Ambu ***Website:*** http://www.ambu.com/corp/products/anaesthesia/product/oval_plus_silicone_resuscitator-prod13861.aspx	***Materials:*** silicone, semi-transparent ***Bag volume:*** 220 ml ***Mask type:*** open cuff silicone ***Mask size(s):*** 0 ***Oxygen reservoir:*** bag ***Pressure release valve:*** yes ***Note:*** Designed for ventilation of neonates < 10 kg (1 year)	***Item no.:*** Ambu: A288 203 000 ***Price range:*** Not published ***Note:*** Masks sizes 0 and 1 can be ordered separately from Ambu at: http://www.ambu.com/corp/products/anaesthesia/product/open_cuff_silicone_face_masks-prod867.aspx	FDA 510K approved

Product name, description (per mfr.), manufacturer, website	Specifications	Procurement options Item no./price (US$)	Quality assurance
Silicone Resuscitation Bag, reusable ***Description:*** Resuscitation mask reusable up to 134°C. ***Manufacturer:*** VBM Medizintechnik GmbH ***Website:*** http://www.vbm-medical.com/products/airway-management/resuscitation-bags/	***Materials:*** silicone ***Bag volume:*** 250 ml ***Mask type:*** See pediatric mask information below ***Mask size(s):*** See pediatric mask information below ***Oxygen reservoir:*** bag ***Pressure-release valve:*** yes ***Other:*** 40 cm H_2O pressure relief	***Item no.:*** VBM Medizintechnik GmbH: 80-10-300 ***Price range:*** Not published ***Note:*** Resuscitation bag is NOT provided with masks. Masks must be procured separately (see information below).	CE Mark FDA 510(k) approved
Pediatric Mask, Round ***Description:*** Silicone Mask (Reusable) ***Manufacturer:*** VBM Medizintechnik GmbH ***Website:*** http://www.vbm-medical.com/products/airway-management/face-masks/	***Materials:*** silicone ***Mask type:*** silicone, round. ***Mask size(s):*** Available in size 0 and size 1	***Item no.:*** VBM Medizintechnik GmbH: 80-11-000 for size 0 80-11-001 for size 1 ***Price range:*** Not published ***Note:*** Mask options for the above resuscitation bag.	CE Mark

Disclaimer: Price ranges are those published by the manufacturer in February 2016. Prices and price ranges do not include cost of shipping. Contact the manufacturer or supplier directly to receive an actual quotation.

Reusable suction bulbs

Table 18. Multiuse suction bulb manufacturer information.

Product name, description (per mfr.), manufacturer, website	Specifications	Procurement options item no./price (USD)	Quality assurance
Penguin Suction Device ***Description:*** The suction unit is made in one piece of silicone, can be boiled or autoclaved, and withstands hundreds of uses. Shaped like a penguin, its beak is ideal for newborn oral and nasal suction. Head can be tilted aside for easy emptying and cleaning. ***Manufacturer:*** Laerdal Medical AS ***Website:*** http://www.laerdalglobalhealth.com/doc/2528/NeoNatalie	***Number of pieces:*** one piece ***Size:*** 75 ml ***Material:*** silicone, transparent ***Cleaning:*** can be boiled or autoclaved	***Item no.:*** Laerdal Global Health: 986000 ***Price:*** $4.50	CE marked

Disclaimer: Price ranges are those published by the manufacturer in February 2016. Prices and price ranges do not include cost of shipping. Contact the manufacturer or supplier directly to receive an actual quotation.

Neonatal training manikins

Table 19. Neonatal training manikin manufacturer information.

Product name, description (per mfr.), manufacturer, website	Specifications	Procurement options item no., price (USD)	Quality assurance
NeoNatalie Newborn Simulator (Basic Model) ***Description:*** NeoNatalie Newborn Simulator, dark complexion or light complexion with standard accessories. ***Manufacturer:*** Laerdal Medical AS ***Website:*** http://www.laerdalglobalhealth.com/doc/2528/NeoNatalie	***Standard accessories:*** • Simulation squeeze bulbs with tubing and connectors • Umbilical cord with connector and two ties • Two sheets to simulate towels • Transport/storage bag • Head cap • Tube for topping body filling • Directions for use • Transport/storage bag • Color choice of light or dark	***Item no.:*** Laerdal Global Health: • NeoNatalie Basic Model (Dark): 104-10001 • NeoNatalie Basic Model (Light): 104-10002 ***Price:*** $60	Contact mfr. or LGH
NeoNatalie Newborn Simulator (Complete Kit) ***Description:*** NeoNatalie Newborn Simulator, dark complexion or light complexion with standard accessories and resuscitation care kit. ***Manufacturer:*** Laerdal Medical AS ***Websites:*** LGH: http://www.laerdalglobalhealth.com/doc/2527/Helping-Babies-Breathe APP: http://shop.aap.org/product-list/?q=Helping%20Babies%20Breathe	***Standard accessories:*** • Simulation squeeze bulbs with tubing and connectors • Umbilical cord with connector and two ties • Two sheets to simulate towels • Transport/storage bag • Head cap • Tube for topping body filling • Directions for use • Transport/storage bag ***Resuscitation care kit:*** • NeoNatalie Resuscitator • Mask size 0 • Mask size 1 • NeoNatalie Suction • Training stethoscope • Color choice of light or dark	***Item no.:*** Laerdal Global Health: • NeoNatalie Complete Kit (Dark): 104-10005 • NeoNatalie Complete Kit (Light): 104-10006 APP: • NeoNatalie Complete Kit (Dark): HBB00001 • NeoNatalie Complete Kit (Light): HBB00005 ***Price range:*** $83–$125	Contact mfr. or LGH

Product name, description (per mfr.), manufacturer, website	Specifications	Procurement options item no., price (USD)	Quality assurance
NeoNatalie Newborn Simulator (Complete with Upright Bag-Mask) ***Description:*** NeoNatalie Newborn Simulator, dark complexion or light complexion with standard accessories, 1 Upright Newborn Bag-mask, 1 mask size 0, 1 mask size 1, directions for use. ***Manufacturer:*** Laerdal Medical AS ***Websites:*** LGH: http://www.laerdalglobalhealth.com/doc/2527/Helping-Babies-Breathe	***Standard accessories:*** • Simulation squeeze bulbs with tubing and connectors • Umbilical cord with connector and two ties • Two sheets to simulate towels • Transport/storage bag • Head cap • Tube for topping body filling • Directions for use • Transport/storage bag ***Resuscitation care kit:*** • Upright Newborn Bag-Mask • Mask size 0 • Mask size 1 • NeoNatalie Suction • Training stethoscope • Color choice of light or dark	***Item no.:*** Laerdal Global Health: • NeoNatalie Complete (Dark) with Upright Newborn Bag-Mask: 104-10007 • NeoNatalie Complete (Light) with Upright Newborn Bag-Mask: 104-10008 ***Price:*** $83	Contact mfr. or LGH
Ambu Baby Manikin ***Description:*** The Ambu Baby is a lifelike manikin that simulates babies up to the age of one year. ***Manufacturer:*** Ambu ***Website:*** http://www.ambu.com/corp/search/product/baby_manikin-prod113.aspx?PID=22206	***Length:*** 40 cm ***Weight:*** 2.5 kg ***Note:*** Simulates babies up to the age of one year.	***Item no.:*** Ambu: 256 001 000 ***Price range:*** unknown Ambu: unavailable The Medical Export Group: unavailable ***Note:*** Spare parts available for purchase.	FDA 510K
Newborn CPR Manikin ***Description:*** Economically priced, this manikin of a newborn has a lightweight, rugged, foam-filled body with no internal parts to break. ***Manufacturer:*** 3B Scientific ***Website:*** https://www.a3bs.com/newborn-cpr-manikin-w44541,p_159_5127.html	***Weight:*** 5.07 lb ***Dimensions:*** 26.0 x 8.0 x 8.0 in ***Features include:*** • Life-like anatomical landmarks such as nipples, xiphoid process and substernal notch • Easy-to-replace mouth/nose pieces • Disposable airways with unidirectional valves • Soft carrying bag	***Item no.:*** 3B Scientific: W44541 [1005728] ***Price:*** $330 ***Note:*** 3B Scientific has a number of neonatal manikins. See https://www.a3bs.com/neonatal+manikin/q/?SearchText=neonatal manikin for additional products.	Contact mfr.

Product name, description (per mfr.), manufacturer, website	Specifications	Procurement options item no., price (USD)	Quality assurance
CPR Cathy™ Basic Infant Manikin ***Description:*** This infant CPR manikin, newborn, can be filled with water to approximate the same weight and "feel" as a real child of corresponding size. ***Manufacturer:*** 3B Scientific ***Website:*** https://www.a3bs.com/cpr-cathy-basic-infant-manikin-w44040,p_159_4916.html	***Features include:*** • Lifelike rib cage, sternum, xiphoid process, and suprasternal notch to help train effective compression technique • Rugged design for effective flow-through cleaning and sanitizing without disassembly • Dressed • Rugged nylon carrying bag • 12 disposable lungs • Three-year warranty	***Item no.:*** 3B Scientific: W44040 ***Price:*** $1,041 ***Note:*** 3B Scientific has a number of neonatal manikins. See https://www.a3bs.com/neonatal+manikin/q/?SearchText=neonatal manikin for additional products.	Contact mfr.
CPR Cathy™ Infant Manikin with Electronics ***Description:*** This infant CPR manikin, newborn, can be filled with water to approximate the same weight and "feel" as a real child of corresponding size. ***Manufacturer:*** 3B Scientific ***Website:*** https://www.a3bs.com/cpr-cathy-infant-manikin-with-electronics-w44041,p_159_4917.html	***Features include:*** • Realistic rise and fall of the chest • Lifelike rib cage, sternum, xiphoid process, and suprasternal notch to help train effective compression technique. • Rugged design for effective flow-through cleaning and sanitizing without disassembly • Optional trouble-free electronics housed outside of the manikin (a unique, patented system for monitoring correct performance during CPR training) • Sensors activate lights and/or an audio signal to indicate correct lung ventilation, depth of compression, and correct finger or hand placement • Dressed manikin • Rugged nylon carrying bag • 12 disposable lungs • Three-year warranty	***Item no.:*** 3B Scientific: W44041 [1017247] ***Price range:*** $1,240	Contact mfr.

Product name, description (per mfr.), manufacturer, website	Specifications	Procurement options item no., price (USD)	Quality assurance
Newborn CPR and Trauma Care Simulator – with Code Blue Monitor ***Description:*** This manikin is designed to teach the fundamentals of infant CPR and trauma care. ***Manufacturer:*** 3B Scientific ***Website:*** https://www.a3bs.com/newborn-cpr-and-trauma-care-simulator-with-code-blue-monitor-w45135,p_155_5341.html	***Weight:*** 5.51 lb ***Features include:*** • Fully articulating head and jaw with tongue • SAFE CPR™ individual disposable airways • Airway blocked when head is forward • Easily accessible chest cavity with molded ribcage, lungs, and heart • Realistic chest rise during ventilation • Omni™ Code Blue® pack monitors and logs the cadence and depth of cardiac compression and airway ventilation • Realistic eye sockets for ophthalmic purposes • Intraosseous infusion • Bilateral brachial, right femoral, and left popliteal arterial pulse points • Soft, lifelike face skin with molded hair • Diaper and body suit • Instruction manual • Custom nylon carrying bag	***Item no.:*** 3B Scientific: W45135 [107560] ***Price:*** $795	Contact mfr.

Product name, description (per mfr.), manufacturer, website	Specifications	Procurement options item no., price (USD)	Quality assurance
S320 Newborn Pediatric Airway Trainer ***Description:*** This fully bodied manikin comes in three skin tones: light, medium and dark. ***Manufacturer:*** Gaumard Scientific ***Website:*** http://www.gaumard.com/s320	***Features include:*** • Realistic chest cavity containing realistic organs • Fully articulating head, neck and jaw permitting head tilt/chin lift, jaw thrust and neck extension into the sniffing position • Anatomically accurate mouth, tongue, airway and esophagus designed to illustrate the profound differences between intubating an infant, a child or an adult • Soft neck with cricoid cartilage permits classic Sellick maneuver • Realistic chest rise during ventilation • Realistic trachea, bronchi and lungs. Observable bilateral lung expansion under positive-pressure ventilation • Airway narrows below vocal cords • Realistic vocal cords with "fish-eye" appearance • Airway diameter: 3.8 mm • Nasal passage permits placement of NP tube	***Item no.:*** Gaumard Scientific S320 ***Price:*** $595	Contact mfr.

Disclaimer: Price ranges are those published by the manufacturer in February 2016. Prices and price ranges do not include cost of shipping. Contact the manufacturer or supplier directly to receive an actual quotation.

Training materials

Table 20. Training material information.

Product name, description (per mfr.), manufacturer, website	Specifications	Procurement options item no., price (USD)
HBB Facilitator Set ***Description:*** The HBB Facilitator Set is an educational tool for HBB master trainers and facilitators (teachers) to teach neonatal resuscitation to health care providers (e.g., trained birth attendants) in resource-limited environments. ***Manufacturer:*** Helping Babies Breathe ***Websites:*** LGH: http://www.laerdalglobalhealth.com/doc/2527/Helping-Babies-Breathe APP: http://shop.aap.org/product-list/?q=Helping%20Babies%20Breathe	***Includes:*** • Action Plan Wall Poster: 1 • Small Action Plan: 1 • Clinical Reminder: 1 • Facilitator Flip Chart (includes 26 illustrations): 1 • Learner Workbooks: set of 20	Laerdal Global Health: 990-000XX (33 for English, 29 for Spanish, 07 for French, 61 for Swahili) APP: HBB00002 ***Price range:*** $45–$105 ***Note:*** HBB Education Materials are also available in French, Spanish, and Swahili
HBB Flip Chart Set ***Description:*** The HBB Facilitator Flip Chart is an educational tool for HBB master trainers and facilitators (teachers) to teach neonatal resuscitation to health care providers (e.g., trained birth attendants) in resource-limited environments. ***Manufacturer:*** Helping Babies Breathe ***Websites:*** LGH: http://www.laerdalglobalhealth.com/doc/2527/Helping-Babies-Breathe APP: http://shop.aap.org/product-list/?q=Helping%20Babies%20Breathe	***Includes:*** • Action Plan Wall Poster: 1 • Small Action Plan: 1 • Clinical Reminder: 1 • Facilitator Flip Chart: 1	Laerdal Global Health: 990-002XX (33 for English, 29 for Spanish, 07 for French, 61 for Swahili) APP: HBB00008 ***Price range:*** $27–$85 ***Note:*** HBB Education Materials are also available in French, Spanish, and Swahili

Product name, description (per mfr.), manufacturer, website	Specifications	Procurement options item no., price (USD)
HBB Learner Workbook /HBB Provider Guides ***Description:*** The HBB Learner Workbook is an educational tool for HBB learners who are neonatal resuscitation health care providers (e.g., trained birth attendants) in resource-limited environments. Normally, a quantity of workbooks is purchased by the HBB facilitator at the same time as the HBB Facilitator Flip Chart. ***Manufacturer:*** Helping Babies Breathe ***Websites:*** LGH: http://www.laerdalglobalhealth.com/doc/2527/Helping-Babies-Breathe APP: http://shop.aap.org/product-list/?q=Helping%20Babies%20Breathe	Set of 20	Laerdal Global Health: 990-001XX (33 for English, 29 for Spanish, 07 for French, 61 for Swahili) APP: HBB00003 ***Price range:*** $18–$20 ***Note:***: HBB Education Materials are also available in French, Spanish, and Swahili
HBB Extra Posters, Small, Qty 5 ***Manufacturer:*** Helping Babies Breathe ***Website:*** http://www.laerdalglobalhealth.com/doc/2527/Helping-Babies-Breathe	Small Action Plans: 10 Clinical reminders: 10	Laerdal Global Health: 990-004XX (33 for English, 29 for Spanish, 07 for French, 61 for Swahili) ***Price:*** $6 ***Note:*** HBB Education Materials are also available in French, Spanish, and Swahili

Disclaimer: Price ranges are those published by the manufacturer in February 2016. Prices and price ranges do not include cost of shipping. Contact the manufacturer or supplier directly to receive an actual quotation.

Section VII: Shipping

This section has been written with a focus on providing basic information for organizations importing neonatal resuscitation devices into LMICs.

One of the challenges of importing a medical device, whether the device is being shipped via air or ocean, is being able to clear the shipment through customs in a timely manner in order to avoid demurrage charges. Situations that can cause customs clearance delays and thus incur demurrage include the following:

- The country's regulatory requirements are not followed.
- Pre-shipment inspection was not completed at origin before shipment departure.
- Shipping and import documents are incorrect or incomplete.
- Shipping documents and invoice/packing list and/or certificate of donation do not conform.
- The details of who is handling customs clearance and who is paying import duties and taxes are not clearly specified.
- Finances are not available in a timely manner to pay customs duties and taxes and other customs clearance charges.
- Incompetent customs brokers.

While the shipping process to LMICs can appear daunting, consistent importation success can be achieved by breaking down the complexity into clear actionable and accountable parts. By identifying the regulatory requirements, producing accurate and compliant shipping documentation, providing clear shipping instructions to all parties involved, and closely managing each step of the shipment, delays and additional costs can be minimized and the process will become regular and manageable.

Identifying regulatory requirements

Before importing a medical device, it is important to know the country's regulatory requirements for the device. This can be done by contacting the local regulatory authority of the importing country or by working with an international freight forwarder who has experience shipping into the importing country. Regulating medical devices is a vast and rapidly evolving field, and while some countries only require a notification, others require that the manufacturer and device(s) be registered. Some countries may have additional requirements, such as a visual pre-inspection of the shipment and/or a pre-inspection of the shipping documents. While some manufacturers may have extensive experience shipping into LMICs, others may not. In this instance, it is better to hire your own freight forwarder.

If the devices are being procured from an international wholesaler, the wholesaler should be aware of the regulatory requirements of the destination country and work with agents who can assist with importing the shipment. Some international wholesalers are also able to register devices in country.

If a medical device is shipped into a country that requires registration and the manufacturer and device are not registered, then the shipment will not be allowed to enter the country. If, however, the device is being donated to the ministry of health or being used for training purposes, it may be possible to work with the ministry of health to obtain an import waiver for a shipment. You will still need to adhere to all other import requirements, and you will need to substantiate why a nonregistered device is being imported and prove that it is a quality-assured device.

Producing accurate and compliant shipping documents

In addition to regulatory requirements, there are other import requirements that apply to all commodities being imported into a country. Again, it is important to know what the requirements are before sending a shipment. Either check with a customs broker in-country or hire an international freight forwarder, who can not only advise on the import requirements but can also arrange for the import clearance to be handled. Do not rely on the manufacturer to have this information unless they ship to the country on a regular basis and are familiar with the country's import laws for medical devices.

The number and kind of documents that the exporter will need to issue will vary depending on the destination of the shipment. Each country has different import regulations, so the exporter must ensure that they provide all proper documentation.

The most common documents required for import are as follows:

- Commercial invoice
- Packing list
- Certificate of origin
- Ocean bill of lading or air waybill

As mentioned earlier, however, other documents might be required, such as a pre-shipment inspection certificate, an import duty waiver authorization, certificate of conformance, proof of quality assurance (such as copy of CE mark certificate), etc.

If the devices are being donated, a certificate of donation should also be issued. A certificate of donation usually describes what the goods are, who they are being donated from and to, the reason for the donation, and a statement that the devices are being donated and are not for resale.

An example of a certificate of donation is provided below.

Certificate of Donation

Description of Goods: _____

This hereby certifies that the goods supplied under the invoice listed below are donated supplies from PATH to aid training on a newborn resuscitation program in Ghana.

The donated supplies are not for resale in Ghana or any other country.

The Government of Ghana is receiving these supplies without cost.

The supplies are to be utilized during training in June 2016 and then to remain at the health facilities for their future use.

Signed: _____

(title)

Invoice number: _____

Some countries also have labeling rules, so these also should be checked. Note that donor labeling requirements also need to be followed if the goods are being procured with donor funding. For example, USAID requires that a USAID emblem be attached to each outer carton.

Issuing shipping instructions

It is important to provide detailed shipping instructions so that it is clear to everybody where the goods are being shipped from, who they are going to, and who the responsible party is at any given time during the process. Following is some key information that the freight forwarder or shipping company will require.

Exporter, also known as shipper

This information will be on the commercial invoice and packing slip and is required for the air waybill or ocean bill of lading. If the goods are being picked up from a different address, provide that information also. The freight forwarder or shipper will need to know where to collect the goods as well as a contact name and details to arrange a day and time for pick-up.

Importer, also known as consignee

The correct consignee is important for a number of reasons, including the following:

- The consignee becomes the legal owner of the goods.
- Import duty and tax. Most shipments are subject to import duty and tax. If however, the consignee has import duty and tax exemption, then the shipment can be imported tax and duty free. To receive the

exemption, the shipment MUST be consigned to the party who has this exemption. Note that duty and tax exemption does not exclude customs clearance charges.

- Incorrectly consigned freight documents must be corrected at the point of origin and typically require legal confirmation with the exporter to change, which can take days and delay the customs clearance process and incur high demurrage charges at the destination airport that must be paid before the shipment is released.

Notify party

The notify party is the person or organization in country who will be contacted when the goods arrive. The notify party may be the consignee or may be a different party (such as a clearing agent). Ensure that a contact name, phone number, and email are provided so that the shipping company or freight forwarder can make contact when the shipment arrives. Notify party information is often found in the notes of an air waybill. The consignee listed is not automatically notified when a shipment arrives.

Customs clearing agent

If hiring an in-country customs clearing agent (broker), provide the freight forwarder with the clearing agent's information, including a contact name, phone number, and email.

Goods

Provide a description of the goods being shipped. This information will be on the commercial invoice and packing slip but must also appear on the air waybill or bill of lading. Ensure that ALL shipping documents contain the same information.

Harmonized tariff code

Have the product vendor provide the harmonized tariff code (HTS code) that corresponds to the commodity being shipped and include pack list and commercial invoice. The HTS code is used to determine tariff class and is used by many customs groups to compile import data for various commodities. Even if the articles shipped are intended for donation, include the HTS code to prevent any delays due to lack of information in the customs entry. Including the HTS code will not cause the shipment to be assessed duty if it is accepted as a duty-free entry.

Marks and numbers

A shipping mark is a symbol, word, or number written on the shipment for easy identification of cargo. It shows the handler what type of product the shipment contains and other useful information, such as weight, size, destination, country of origin, and consignee.

The marks and numbers are written on an air waybill or bill of lading to assist with identifying the shipment when it is picked up and when it arrives in country. For example, the air waybill or bill of lading might read:

Addressed to consignee
Box 1/10 – 10/10
Each box: 65cm x 65cm x 89cm / 32kgs

Overseeing each step of the shipment

It is important to provide instructions to the manufacturer/exporter and also the freight forwarder, if you are hiring a freight forwarder, about the types of documents and alerts that you require.

For example:

Commercial invoice*
Packing list
Certificate of donation (supplied by PATH)
Certificate of origin
Air waybill or ocean bill of lading
CE mark certificate

* The following statement should be shown on the Commercial Invoice: *"Goods are being sold to PATH, who is providing these items as a donation to the Government of Ghana. These goods are not for resale. The value shown is for insurance purposes."*

Usually the exporter will provide the commercial invoice, packing slip, certificate of origin, and in this example, a copy of the CE mark certificate. The freight forwarder or shipper would issue the air waybill or ocean bill of lading, and the procurer (in this example, PATH) would usually supply the certificate of donation.

Document distribution instructions

Often a customs broker can begin the customs clearance process before the goods arrive. It is therefore good practice to ask the person preparing the documents to email a copy to the procurer (in this example, PATH) and to the notify party.

Also provide instruction on the number of original documents that need to be produced and where they should be sent. For example, for an airfreight shipment, they might be forwarded with the goods. For an ocean shipment, it might be prudent to courier the original documents to the consignee so that they can be endorsed (signed for) and given to the customs broker prior to the shipment arriving.

Incoterms® 2010 rules

It is important to clearly outline the Incoterms so that all parties are aware of who is responsible for the goods at any given time. Incoterms are a series of pre-defined commercial terms published by the International Chamber of Commerce (ICC) and are widely used in international commercial transactions or procurement processes. Full information about Incoterms® 2010 can be found at http://www.iccwbo.org/products-and-services/trade-facilitation/incoterms-2010/the-incoterms-rules/.

The following Incoterms Rules (Boxes 4 and 5) have been copied from the ICC site (link provided above) for your convenience.

Box 4. Incoterms rules for any mode of transport.*

EXW Ex Works
"Ex Works" means that the seller delivers when it places the goods at the disposal of the buyer at the seller's premises or at another named place (i.e., works, factory, warehouse, etc.). The seller does not need to load the goods on any collecting vehicle, nor does it need to clear the goods for export, where such clearance is applicable.

FCA Free Carrier
"Free Carrier" means that the seller delivers the goods to the carrier or another person nominated by the buyer at the seller's premises or another named place. The parties are well advised to specify as clearly as possible the point within the named place of delivery, as the risk passes to the buyer at that point.

CPT Carriage Paid To
"Carriage Paid To" means that the seller delivers the goods to the carrier or another person nominated by the seller at an agreed place (if any such place is agreed between parties) and that the seller must contract for and pay the costs of carriage necessary to bring the goods to the named place of destination.

CIP Carriage and Insurance Paid To
"Carriage and Insurance Paid to" means that the seller delivers the goods to the carrier or another person nominated by the seller at an agreed place (if any such place is agreed between parties) and that the seller must contract for and pay the costs of carriage necessary to bring the goods to the named place of destination.

The seller also contracts for insurance cover against the buyer's risk of loss of or damage to the goods during the carriage. The buyer should note that under CIP the seller is required to obtain insurance only on minimum cover. Should the buyer wish to have more insurance protection, it will need either to agree as much expressly with the seller or to make its own extra insurance arrangements.

DAT Delivered at Terminal
"Delivered at Terminal" means that the seller delivers when the goods, once unloaded from the arriving means of transport, are placed at the disposal of the buyer at a named terminal at the named port or place of destination. "Terminal" includes a place, whether covered or not, such as a quay, warehouse, container yard or road, rail or air cargo terminal. The seller bears all risks involved in bringing the goods to and unloading them at the terminal at the named port or place of destination.

Customs clearance and payment of duties and taxes is the responsibility of the consignee unless otherwise agreed and clarified in writing (i.e., "DAT – seller to provide customs clearance, duties and taxes for the account of the consignee.")

DAP Delivered at Place
"Delivered at Place" means that the seller delivers when the goods are placed at the disposal of the buyer on the arriving means of transport ready for unloading at the named place of destination. The seller bears all risks involved in bringing the goods to the named place.

Customs clearance and payment of duties and taxes are the responsibility of the consignee unless otherwise agreed and clarified in writing (i.e., "DAP – seller to provide customs clearance, duties and taxes for the account of the consignee."

DDP Delivered Duty Paid
"Delivered Duty Paid" means that the seller delivers the goods when the goods are placed at the disposal of the buyer, cleared for import on the arriving means of transport ready for unloading at the named place of destination. The seller bears all the costs and risks involved in bringing the goods to the place of destination and has an obligation to clear the goods not only for export but also for import, to pay any duty for both export and import and to carry out all customs formalities.

*Source: http://www.iccwbo.org/products-and-services/trade-facilitation/incoterms-2010/the-incoterms-rules/

Box 5. Incoterms rules for for sea and inland waterway transport.*

FAS Free Alongside Ship

"Free Alongside Ship" means that the seller delivers when the goods are placed alongside the vessel (e.g., on a quay or a barge) nominated by the buyer at the named port of shipment. The risk of loss of or damage to the goods passes when the goods are alongside the ship, and the buyer bears all costs from that moment onwards.

FOB Free On Board

"Free On Board" means that the seller delivers the goods on board the vessel nominated by the buyer at the named port of shipment or procures the goods already so delivered. The risk of loss of or damage to the goods passes when the goods are on board the vessel, and the buyer bears all costs from that moment onwards.

CFR Cost and Freight

"Cost and Freight" means that the seller delivers the goods on board the vessel or procures the goods already so delivered. The risk of loss of or damage to the goods passes when the goods are on board the vessel. The seller must contract for and pay the costs and freight necessary to bring the goods to the named port of destination.

CIF Cost, Insurance and Freight

"Cost, Insurance and Freight" means that the seller delivers the goods on board the vessel or procures the goods already so delivered. The risk of loss of or damage to the goods passes when the goods are on board the vessel. The seller must contract for and pay the costs and freight necessary to bring the goods to the named port of destination.

The seller also contracts for insurance cover against the buyer's risk of loss of or damage to the goods during the carriage. The buyer should note that under CIF the seller is required to obtain insurance only on minimum cover. Should the buyer wish to have more insurance protection, it will need either to agree as much expressly with the seller or to make its own extra insurance arrangements.

*Source: http://www.iccwbo.org/products-and-services/trade-facilitation/incoterms-2010/the-incoterms-rules/

Ten action steps for successfully managing shipments

1. Use email groups to keep all involved informed about shipment status but clearly state task responsibility at all times.
2. Identify and collect all documentation required for customs clearance first.
3. Make sure all documents conform for shipper, consignee, piece count, value, and description.
4. Confirm that the vendor and the freight forwarder are in communication about the required physical configuration to fit the routing to destination.
5. Ask the freight forwarder to obtain approval of all document drafts from destination clearing agent BEFORE the shipment is routed.

6. AVOID shipment arrival at destination or just prior to the weekend to minimize risk of pilferage and demurrage.
7. Ensure that original documents arrive with the shipment or are couriered to arrive by the time of shipment arrival at destination to prevent customs delays and demurrage.
8. Do not rely solely on air or ocean carrier notice of arrival, and ask freight forwarder to be proactive in confirming arrival of entire shipment at destination pending customs clearance.
9. Engage freight forwarder immediately if there are any changes, issues of delay, or communication that is not completely understood.
10. Pay duties/taxes and present additionally requested documentation in an expedited fashion to save demurrage fees and shipment delays.

Monitoring the process

While the above information provides general guidance on the steps to be taken and the documents to be provided to support an effective shipping and importation process for medical devices, it is also important that the importing party take responsibility to closely monitor the progress and completion of each step and activity in the process. As seen from the information provided in this section, there are multiple parties involved in the international shipping and customs clearance processes and many opportunities for problems to arise during this process. Through vigilant monitoring of these activities the importing party will be in a better position to respond quickly to issues that may arise, which in turn will help to move the process forward in a timely manner.

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Annex: Quantification Tool

Quantification Tool for Basic Neonatal Resuscitation Commodities: Version 2

The Quantification Tool for Basic Neonatal Resuscitation Commodities can be found on the PATH website at *http://www.path.org/publications/detail.php?i=2401. The tool, which is in the form of an Excel spreadsheet, guides users through a simple step-by-step process of entering data (such as number of health facilities) and calculating the results. Following is a hard copy of the tool.*

1. Introduction

Welcome to the Quantification Tool for basic neonatal resuscitation commodities developed by PATH with funding from the United States Agency for International Development (USAID). More information on resuscitation commodities and the latest version of this tool can always be found at: *http://www.path.org/publications/detail.php?i=2401*.

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PATH would like to give special thanks to the Helping Babies Breathe (HBB) partnership and health care workers and ministries of health in Uganda and Tanzania for their insights and testing of the tool during development.

Purpose

This tool is a national-level quantification tool for basic neonatal resuscitation commodities, although it can also be helpful for the district and facility levels. It is designed only to provide estimates of commodity quantities for planning and cost simulations and is not intended for planning detailed distribution.

The tool is designed to develop initial estimated needs for basic neonatal resuscitation commodities for a one-year period. It is advisable that the tool be adjusted in future years to accommodate for the average lifespan of each commodity, which will be based on the quality of the product, how often it is used, and how it is cleaned. It is also advisable that some reserves be stocked at the central level and at the health facility level to cover additional needs, breakages, losses, etc.

The estimated statistics in these cells are based upon assumptions collected from global implementers and trainers from the HBB partnership, health care workers, and the Ministries of Health (MOHs) in Tanzania and Uganda. For more information regarding data sources and assumptions used in this tool, please see the appendix, Definitions and Assumptions.

Commodities

Quantification is provided for the following commodities:

Basic neonatal resuscitation commodities, reusable:

- Self-inflating neonatal resuscitation bag with masks for preterm and full term babies (sizes 0 and 1)
- Reusable manual suction devices
- Neonatal training manikins

Basic neonatal resuscitation devices, single-use:

- Single-use manual suction devices (also known as suction bulbs)

The option for either type of suction device has been included in the tool for a country to choose their preferred device (reusable or single-use). A reusable suction device is one that can be opened, cleaned, and disinfected. If opting for a single-use suction device, it is imperative that enough are on hand at every facility as these types of suction devices should NOT be reused in order to avoid the spread of infection.

Definitions and specifications for each device can be found in the appendix, Definitions and Assumptions.

Country-specific Alterations

Cells containing information or formulas have been locked. Changing the formulas is not recommended. It is encouraged, however, for countries to adjust quantities based on the country's individual situation and needs. **For information on how formulas and estimations were reached, please refer to the appendix, Definitions and Assumptions.**

If you need to modify the spreadsheet for formatting, printing, etc., the password is "newborn." Instructions on how to unlock the spreadsheet for modifications including formatting for printing purposes can be found here: http://office.microsoft.com/en-us/excel-help/lock-or-unlock-specific-areas-of-a-protected-worksheet-HA010096837.aspx#_Toc296590752.

Considerations

This national-level quantification tool can be used to develop estimated needs for basic neonatal resuscitation commodities. It is designed only to provide estimates of commodity quantities for planning and cost simulations and is not intended for planning detailed distribution. The following points, therefore, should be considered when using this tool, particularly if it is being used beyond the national level.

The algorithms in this quantification tool have been developed as guidelines based on information received from Tanzania and Uganda. Other countries may be different, and the tool should be adapted accordingly. For example, during an assessment in Ghana, it was determined that the average number of rooms where newborns were typically located in a district hospital was four (4) or five (5) and not seven (7) (as in the case of Tanzania and Uganda).

It should also be noted that not all rooms in a health facility have the same number of babies in attendance. For example, a busy delivery ward in a tertiary level hospital may need more neonatal resuscitation bag-and-masks and reusable suction devices than an emergency room or a second theatre. In the example provided in this tool, a tertiary hospital in Tanzania and Uganda is estimated to have 10 rooms where a newborn may be located and the minimum quantity of resuscitation bag-and-masks and reusable suction devices should be three (3) per room due to the high number of births at this type of hospital. The hospital would therefore order 30 neonatal bag-and-masks and 30 reusable suction devices. However, at the hospital level, the devices might be distributed differently, for example:

Areas	Per the algorithm	Example of how a hospital might choose to distribute based on volume of newborns per room
Delivery room/area 1	3	8
Delivery room/area 2	3	3
Delivery room/area 3	3	2
Delivery room/area 4	3	2
Theater 1	3	3
Theater 2	3	2
Emergency area	3	2
Neonatal ward	3	3
NICU/Special care 1	3	3
NICU/Special care 2	3	2
TOTAL	30	30

Distribution of basic neonatal resuscitation devices by room/area should be well thought through by each

unit to ensure that enough functional devices are available at all times, and that adequate reprocessing (disinfection) takes place between uses. Remember, however, that a minimum of two (2) resuscitation bag-and-masks and two (2) reusable suction devices should be available in every room where a newborn may be located.

Health centers can vary greatly, so quantities of devices need to be adjusted accordingly. For example, when performing a regional quantification exercise in Ghana, it was decided that 10 of the larger health centers should be calculated as hospitals, as they were much closer in size to a hospital in the number of births they delivered than to a standard health center.

The way that delivery wards/areas are counted may differ from one health facility to another and from country to country. For example, there may be a large room with four delivery beds and a curtain dividing the beds. Or there may be a large room with four small rooms off to the side with a delivery bed in each room. In both of these instances, the quantification tool considered these to be four delivery rooms/areas, regardless of whether there were one or four resuscitation tables in the center area. Using the algorithm of three resuscitation bags per room, the large delivery room in this example should have 12 of each type of device. Ideally, a set of devices would be placed next to a delivery bed. Even if there are not four resuscitation surfaces, it is important that there be at least enough devices in the area should more than one baby need resuscitating, and should some of the devices not be available while they are being disinfected.

The above points have been included in this section in the hope that they will demonstrate that the algorithms are a general guideline and are most useful for national-level quantification. The main aim of the algorithms is to ensure that there are a MINIMUM of TWO DEVICES in EACH ROOM where a newborn may be located and that there are at least THREE PER ROOM in large health facilities. However, a country or an individual health facility will need to adjust according to their own unique situation, and a health facility will need to distribute the devices according to the usage within each area.

2. Data Entry Instructions

Green cells are REQUIRED. You must enter a value in these cells in order for the quantification tool to work. Information for these cells is generally accessible through the MOH.

Orange cells are OPTIONAL. You may use the existing values or enter your own according to country policy, practice, and budget.

Step 1: Health Facility

Considerations	Regional hospital	Provincial hospital	District hospital	Health center	Health post	Other
Number of health facilities in country						
Average number of delivery rooms/areas per facility	4	2	2	1	1	0
Average number of theaters per facility	2	2	2	0	0	0
Average number of emergency areas per facility	1	1	1	1	0	0
Average number of neonatal wards per facility	1	2	1	0	0	0
Average number of NICU*/special care units per facility	2	2	1	1	0	0
Other	0	0	0	0	0	0
Other	0	0	0	0	0	0

**NICU=neonatal intensive care unit.*

Enter the number of each level of health facility to be quantified (green cells) and change the average number of rooms where a newborn may need resuscitation per facility (orange cells) as appropriate.

Because health facility names change from country to country, the facility names in the top row of the above table have been taken from World Health Organization (WHO) definitions; these facility definitions can be found in the annex, Definitions and Assumptions. The first column is the tertiary hospital, the second is the secondary hospital, the third is the primary hospital, and the remaining are lower-level heath facilities. If desired, the names of the health facilities may be changed to reflect the common names used in individual countries.

Note: The numbers shown in the orange cells are based on findings in Tanzania and Uganda and are for example purposes. Each country should be assessed, and the average number of rooms per facility type changed accordingly. If there are no trained personnel in a health facility and/or babies are not delivered, change the number to zero. For example, health posts might not be applicable in some countries. Alternatively, if there is more than one type of health center, change the column names to suit your country setting. The names of the health facilities shown in these examples are based on WHO definitions that can be found on the annex at the end of this tool, titled, Definitions and Assumptions.

Step 2: Multi-Use Device

Considerations	Regional hospital	Provincial hospital	District hospital	Health center	Health post	Other
Number of resuscitation bags per room/area	3	2	2	2	2	0
Number of resuscitation masks size 0 per room/area	3	2	2	2	2	0
Number of resuscitation masks size 1 per room/area	3	2	2	2	2	0
Number of reusable suction devices per room/area	3	2	2	2	2	0
Number of training manikins per health facility (in-service)	3	3	3	1	0	0

The numbers above should be changed according to country policy, practice, and budget.

Note: If selecting single-use suction devices, change the corresponding cells for reusable suction devices to zero and complete Step 3. It is recommended, however, that a MINIMUM of two resuscitation bags and masks plus two reusable suction devices be placed in EVERY room where a newborn may be. If there are no trained personnel in a health facility and/or babies are not delivered, change the number to zero. For example, health posts might not be applicable in some countries.

Step 3: Single-Use Device

Considerations	
Number of births per year	
% of births attended by a skilled birth attendant	
% of babies estimated to need a single-use suction bulb	10%

This section should ONLY be completed if a country decides to procure single-use suction devices rather than reusable suction devices. If completing this section, fill in the green cells and change the orange cell as appropriate.

Step 4: Training Manikin (pre-service)

Considerations	
Number of nursing and medical schools	
Average number of students per class	
Number of students per manikin	6

Enter the number of nursing and medical schools being quantified and the average number of students per class in the green cells and change the orange cell as appropriate.

Step 5: Pricing

Commodities	Unit price (USD)
Resuscitation bag	$20.00
Resuscitation mask size 0	$0.00
Resuscitation mask size 1	$0.00
Reusable suction device	$4.50
Single-use suction device	$0.75
*Training manikin + resuscitation bag + masks + multi-use suction device	$83.00

The cost of the devices should be changed according to tender offers received.

Note: Some manufacturers may sell these items separately and others will sell them as a package. Training materials (workbooks, flip charts, posters, etc.) also need to be considered, whether they are obtained from the Helping Babies Breathe Global Development Alliance, from within country, or from another supplier.

« PLEASE CHECK YOUR NUMERICAL INPUTS BEFORE PROCEEDING »

3. Results

National-Level Quantification

Grand Total	No. of facilities	Estimated no. of rooms in facility	Total no. of rooms in country	Resusc. bag	Mask (size 0)	Mask (size 1)	Suction device (reusable)	Suction device (single-use)	Training manikin + accessories (in-service)	Training manikin + accessories (pre-service)	Total costs of all products
Regional hospitals	0	10	0	0	0	0	0	n/a	0	n/a	
Provincial hospitals	0	9	0	0	0	0	0	n/a	0	n/a	
District hospitals	0	7	0	0	0	0	0	n/a	0	n/a	
Health centers	0	3	0	0	0	0	0	n/a	0	n/a	
Health posts	0	1	0	0	0	0	0	n/a	0	n/a	
Other	0	0	0	0	0	0	0	n/a	0	n/a	
No. of devices required	n/a	n/a	n/a	0	0	0	0	0	0	0	
Approximate Cost (US$)	n/a	n/a	n/a	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00

Tertiary Hospitals

Number of devices required	Number of facilities	Estimated number of rooms in facility	Total number of rooms in country	Resusc. bag	Mask (size 0)	Mask (size 1)	Suction device (reusable)	Suction device (single-use)	Training manikin (in-service)	Training manikin (pre-service)
REGIONAL HOSPITALS	0									
Delivery rooms/areas		4	0	0	0	0	0	n/a	n/a	n/a
Theaters		2	0	0	0	0	0	n/a	n/a	n/a
Emergency areas		1	0	0	0	0	0	n/a	n/a	n/a
Neonatal wards		1	0	0	0	0	0	n/a	n/a	n/a
NICU/special care units		2	0	0	0	0	0	n/a	n/a	n/a
Other		0	0	0	0	0	0	n/a	n/a	n/a
Other		0	0	0	0	0	0	n/a	n/a	n/a
TOTAL		10	0	0	0	0	0		0	

Secondary Hospitals

Number of devices required	Number of facilities	Estimated number of rooms in facility	Total number of rooms in country	Resusc. bag	Mask (size 0)	Mask (size 1)	Suction device (reusable)	Suction device (single-use)	Training manikin (in-service)	Training manikin (pre-service)
PROVINCIAL HOSPITALS	0									
Delivery rooms/areas		2	0	0	0	0	0	n/a	n/a	n/a
Theaters		2	0	0	0	0	0	n/a	n/a	n/a
Emergency areas		1	0	0	0	0	0	n/a	n/a	n/a
Neonatal wards		2	0	0	0	0	0	n/a	n/a	n/a
NICU/special care units		2	0	0	0	0	0	n/a	n/a	n/a
Other		0	0	0	0	0	0	n/a	n/a	n/a
Other		0	0	0	0	0	0	n/a	n/a	n/a
TOTAL		9	0	0	0	0	0		0	

Primary Hospitals

Number of devices required	Number of facilities	Estimated number of rooms in facility	Total number of rooms in country	Resusc. bag	Mask (size 0)	Mask (size 1)	Suction device (reusable)	Suction device (single-use)	Training manikin (in-service)	Training manikin (pre-service)
DISTRICT HOSPITALS	0									
Delivery rooms/areas		2	0	0	0	0	0	n/a	n/a	n/a
Theaters		2	0	0	0	0	0	n/a	n/a	n/a
Emergency areas		1	0	0	0	0	0	n/a	n/a	n/a
Neonatal wards		1	0	0	0	0	0	n/a	n/a	n/a
NICU/special care units		1	0	0	0	0	0	n/a	n/a	n/a
Other		0	0	0	0	0	0	n/a	n/a	n/a
Other		0	0	0	0	0	0	n/a	n/a	n/a
TOTAL		7	0	0	0	0	0		0	

Lower-level health facilities 1

Number of devices required	Number of facilities	Estimated number of rooms in facility	Total number of rooms in country	Resusc. bag	Mask (size 0)	Mask (size 1)	Suction device (reusable)	Suction device (single-use)	Training manikin (in-service)	Training manikin (pre-service)
HEALTH CENTERS	0									
Delivery rooms/areas		1	0	0	0	0	0	n/a	n/a	n/a
Theaters		0	0	0	0	0	0	n/a	n/a	n/a
Emergency areas		1	0	0	0	0	0	n/a	n/a	n/a
Neonatal wards		0	0	0	0	0	0	n/a	n/a	n/a
NICU/special care units		1	0	0	0	0	0	n/a	n/a	n/a
Other		0	0	0	0	0	0	n/a	n/a	n/a
Other		0	0	0	0	0	0	n/a	n/a	n/a
TOTAL		3	0	0	0	0	0		0	

Lower-level health facilities 2

Number of devices required	Number of facilities	Estimated number of rooms in facility	Total number of rooms in country	Resusc. bag	Mask (size 0)	Mask (size 1)	Suction device (reusable)	Suction device (single-use)	Training manikin (in-service)	Training manikin (pre-service)
HEALTH POSTS	0									
Delivery rooms/areas		1	0	0	0	0	0	n/a	n/a	n/a
Theaters		0	0	0	0	0	0	n/a	n/a	n/a
Emergency areas		0	0	0	0	0	0	n/a	n/a	n/a
Neonatal wards		0	0	0	0	0	0	n/a	n/a	n/a
NICU/special care units		0	0	0	0	0	0	n/a	n/a	n/a
Other		0	0	0	0	0	0	n/a	n/a	n/a
Other		0	0	0	0	0	0	n/a	n/a	n/a
TOTAL		1	0	0	0	0	0		0	

Other

Number of devices required	Number of facilities	Estimated number of rooms in facility	Total number of rooms in country	Resusc. bag	Mask (size 0)	Mask (size 1)	Suction device (reusable)	Suction device (single-use)	Training manikin (in-service)	Training manikin (pre-service)
OTHER	0									
Delivery rooms/areas		0	0	0	0	0	0	n/a	n/a	n/a
Theaters		0	0	0	0	0	0	n/a	n/a	n/a
Emergency areas		0	0	0	0	0	0	n/a	n/a	n/a
Neonatal wards		0	0	0	0	0	0	n/a	n/a	n/a
NICU/special care units		0	0	0	0	0	0	n/a	n/a	n/a
Other		0	0	0	0	0	0	n/a	n/a	n/a
Other		0	0	0	0	0	0	n/a	n/a	n/a
TOTAL		0	0	0	0	0	0		0	

Appendix: Definitions and Assumptions

This section provides definitions and explains the assumptions behind the quantification tool as well as details on where information can usually be obtained.

Definitions

Term	Definition	Source
Commodities	Reusable and single-use basic neonatal resuscitation and related training commodities	
Self-inflating neonatal resuscitation bag with masks	A resuscitator is used to ventilate a neonate with a body weight below 5 kg. A resuscitator is operated by hand. Ventilation can be done with ambient air or with oxygen. A resuscitator can be totally disassembled and is easy to clean and disinfect. All parts are manufactured with durable and high-quality materials that can withstand a variety of cleaning methods and a range of storage conditions. A resuscitator should be procured as a complete set with: Non-rebreathing patient valve with pressure-limiting valve so that airway pressure does not exceed 4.5 kPa (45 cm H2O) and can generate an airway pressure of at least 3 kPa (= 30 cm H_2O). Masks, translucent, in two different sizes: (1) size 0—preterm and low-birthweight baby, round type, diameter 35 to 50 mm; (2) size 1—term baby, round type, 50 to 65 mm. The mask is made of silicone rubber or any other material fulfilling ISO 10993-1: 2009; ISO 10993-5:2009; ISO 10993-10:2010 or equivalent or USP Class V. Bag size: 200 ml to 320 ml. Intake valve with optional nipple for oxygen tubing, material made of polycarbonate/polysufone or any other materials fulfilling ISO 10651-4 or equivalent.	World Health Organization (WHO) Technical Specifications of Neonatal Resuscitation Devices.

Term	Definition	Source
Masks	Size 0 (for preterm and low-birthweight babies) diameter 35 to 50 mm, and size 1 (for term babies) diameter 35 mm to 50 mm; translucent and round type. Silicone rubber or any material fulfilling standards ISO 10993-1: 2009; ISO 10993-5: 2009; ISO 10993-10: 2010 or USP Class V (or equivalents).	WHO Technical Specifications of Neonatal Resuscitation Devices.
Reusable manual suction devices	A reusable suction device is a portable, hand-held, manual suction device designed to enable an adult to gently suction and clear excessive mucus from the nasal passage of an infant or child to facilitate easier breathing. The reusable suction bulb can be opened and subjected to decontamination, cleaning, high-level disinfection/sterilization, and proper storage until subsequent use.	WHO Technical Specifications of Neonatal Resuscitation Devices.
Single-use manual suction devices	A single-use suction device is a portable, hand-held, manual suction device that provides the suction in a manually operated bulb that draws mucus out of the child's nose. The single-use device needs to be discarded after use.	WHO Technical Specifications of Neonatal Resuscitation Devices.
Training manikin	A specially constructed doll with simulated respiratory and cardiovascular functions designed to demonstrate and teach resuscitation techniques that include mouth-to-mouth resuscitation and heart compressions (CPR) and sometimes manual pulse registration..	PATH
Health facilities	The health facilities have been defined per the WHO framework (regional hospital, provincial hospital, district hospital, health center, health post), although countries may differ.	WHO. Medical devices; country data. Available at http://www.who.int/medical_devices/countries/en/. Accessed January 21, 2014.
Regional hospital	Tertiary-level hospital: Highly specialized staff and technical equipment (e.g., cardiology, intensive care unit, and specialized imaging units); clinical services highly differentiated by function; could have teaching activities; size ranges from 300 to 1,500 beds. Alternative terms commonly found in the literature include national hospital; central hospital; and academic, teaching, or university hospital.	Hensher M, Price M, Adomakoh S. Referral hospitals. In: Jamison DT, Breman JG, Measham AR, et al., eds. Disease Control Priorities in Developing Countries. Washington, DC: World Bank; 2006:1230–1239. Available at: http://www.ncbi.nlm.nih.gov/books/NBK11

Term	Definition	Source
Provincial hospital	Secondary-level hospital: Highly differentiated by function, with five to ten clinical specialties; size ranges from 200 to 800 beds. Alternative terms commonly found in the literature include regional hospital, provincial hospital (or equivalent administrative area such as county), and general hospital.	Hensher M, Price M, Adomakoh S. Referral hospitals. In: Jamison DT, Breman JG, Measham AR, et al., eds. Disease Control Priorities in Developing Countries. Washington, DC: World Bank; 2006:1230–1239. Available at: http://www.ncbi.nlm.nih.gov/books/NBK11
District hospital	Primary-level hospital: Few specialties; mainly internal medicine, obstetrics and gynecology, pediatrics, and general surgery, or just general practice; limited laboratory services available for general, but not specialized, pathological analysis. Alternative terms commonly found in the literature include district hospital, rural hospital, community hospital, and general hospital.	Hensher M, Price M, Adomakoh S. Referral hospitals. In: Jamison DT, Breman JG, Measham AR, et al., eds. Disease Control Priorities in Developing Countries. Washington, DC: World Bank; 2006:1230–1239. Available at: http://www.ncbi.nlm.nih.gov/books/NBK11
Health center	Lower-level health facilities: Some countries may have one level of health center, whereas others have more (Uganda, for example, has four). Each level and each country will usually differ according to whether they have in-patient services, theaters, etc.	WHO. Medical devices; country data. Available at http://www.who.int/medical_devices/countries/en/. Accessed January 21, 2014.
Health post	Lowest-level health facilities: Also referred to as dispensaries. Health posts do not usually have inpatient services, although there may be skilled birth attendants working at a facility.	WHO. Medical devices; country data. Available at http://www.who.int/medical_devices/countries/en/. Accessed January 21, 2014.
Room type	The types of rooms/areas shown on the tool are the main areas where a newborn may be present and may need resuscitation devices. Two rows have been listed as "Other" for countries to complete should they have additional rooms/areas.	
Delivery room/area	Area dedicated to providing care and treatment for mother and baby during and/or after the childbearing process.	Established through interviews and meetings with global implementers/trainers from the HBB partnership, health care workers, and the MOH in Tanzania and Uganda.
Theater	A room in which surgical operations (such as cesarean section) are performed.	Established through interviews and meetings with global implementers/trainers from the HBB partnership, health care workers, and the MOH in Tanzania and Uganda.

Term	Definition	Source
Emergency area	Typically a department of a hospital that provides immediate treatment for acute illnesses and trauma. Note: In Uganda and Tanzania, each hospital visited had an emergency area where a mother may give birth or a mother and/or newborn may need assistance. Examples include the reproductive health unit, where mothers may arrive with newborns after giving birth at home, or an area near the reception where a mother might give birth when there is not enough time to get to the delivery room.	Established through interviews and meetings with global implementers/trainers from the HBB partnership, health care workers, and the MOH in Tanzania and Uganda.
Neonatal ward	Area provided for babies who need medical treatment or who are not well enough to be cared for at their mother's bedside.	Established through interviews and meetings with global implementers/trainers from the HBB partnership, health care workers, and the MOH in Tanzania and Uganda.
Neonatal intensive care units (NICUs)/special care units	Area provided for babies with serious problems, including premature and low-birthweight babies.	Established through interviews and meetings with global implementers/trainers from the HBB partnership, health care workers, and the MOH in Tanzania and Uganda.
Other		
Skilled health personnel	Nurses, doctors, and midwives can all be categorized as skilled birth attendants.	WHO Indicator and Measurement Registry version 1.7.0. WHO website. Available at http://apps.who.int/gho/indicatorregistry/App_Main/view_indicator.aspx?iid=25. Accessed January 15, 2014.
Pre-service training	Training activities which take place before a person takes up a job that requires specific training (i.e., before a person "enters service").	Page on Pre-service eduation. WHO website. Available at http://www.emro.who.int/child-health/IMCI-preservice-training/what-is-it. Accessed January 30, 2014.
In-service training	Training of persons already employed (e.g., health providers already working in the public or private sector).	Page on Pre-service eduation. WHO website. Available at http://www.emro.who.int/child-health/IMCI-preservice-training/what-is-it. Accessed January 30, 2014.

Note: Each country tends to have different terms for the rooms in which newborns may need resuscitation. It was found that, in some countries, the name of a ward/area may differ between facilities. The names used in this tool may be changed according to country terms. Other terms used may include, but are not limited to, kangaroo room, lying-in room, and recovery room.

Assumptions

Variables	Assumptions	Source
Step 1: Health facility information		
Number of health facilities in country	This information is usually available at the MOH, although it is also important to understand the country policies around what resuscitation devices are approved for use in the country, as well as where the skilled birth attendants are located. WHO maintains country information, which can be found at http://www.who.int/medical_devices/countries/en/. Although this information can be helpful, it is imperative to also know country policies and practices when supplying neonatal resuscitation commodities.	Established through interviews and meetings with global implementers/trainers from the HBB partnership, health care workers, and the MOH in Tanzania and Uganda.
Number and types of rooms per health facility	The number and types of rooms per health facility are estimates from field visits in Tanzania and Uganda. Each facility may be different, but the number of rooms shown are the averages for these two countries. It is HIGHLY recommended that the quantifier complete these numbers for the country they are quantifying. If, however, this information is not readily available, the numbers shown on the quantification tool can be used as a BASIC GUIDELINE. An "Other" column has been added for countries that need to include an additional level of health facility. For example, in Uganda, health centers four, three, and two require neonatal resuscitation commodities and would use the Health Center, Health Post, and Other columns.	Established through interviews and meetings with global implementers/trainers from the HBB partnership, health care workers, and the MOH in Tanzania and Uganda.

Variables	Assumptions	Source
Step 2: Reusable commodity information for health facilities		
Number of devices per room	The number of devices per room was established through interviews with the HBB partnership and visits to health facilities in Tanzania and Uganda. The conclusion was that a MINIMUM of two (2) resuscitation bag-and-masks (sizes 0 and 1) and two (2) reusable suction devices need to be available at any time in EVERY ROOM where a newborn might be located. Due to the high number of births at regional hospitals, it was concluded that a minimum of three (3) resuscitation bag-and-masks and three (3) multi-use suction devices should be quantified per room in these countries. It should be noted that, in some hospitals, a "room" may also be referred to as an "area" or "cubicle." Note that if selecting a reusable suction device, Step 3 may be skipped. If, however, selecting a single-use suction device, go to Step 3 and ensure that the number of multi-use suction devices has been changed to zero (0) in Step 2 so that the device is not calculated twice.	Established through interviews and meetings with global implementers/trainers from the HBB partnership, health care workers, and the MOH in Tanzania and Uganda.
Number of training manikins per health facility (in-service)	This section is for those countries requiring a training manikin in health facilities for students and staff to practice their skills. The optional numbers shown in the quantification tool are three (3) for hospitals and one (1) for health centers. Three manikins per hospital are recommended due to the high number of students in these facilities. Health centers are shown with one (1) manikin because often students are also at this level, and practice and supervision is provided for both the health care worker and students. Health posts are shown with zero (0) manikins, although a country should complete this cell if a training manikin is required at this level. These numbers should be changed according to country practice, policy, and budget.	Established through interviews and meetings with global implementers/trainers from the HBB partnership, health care workers, and the MOH in Tanzania and Uganda.

Variables	Assumptions	Source
Step 3: Single-use device information		
Single-use suction devices per newborn	It is difficult to quantify the number of single-use suction devices per room, as information is not available regarding the number of babies per room at any given time (delivery, theater, NICU, etc.), and this would be difficult to model for a national-level quantification tool. The quantification for single-use suction devices is based on the number of births per year multiplied by the percentage of births attended by a skilled birth attendant. This information is usually found at the MOH. The percentage of babies estimated to need a suction device should be based on the following WHO guidelines on when to use a suction device: • In neonates born through clear amniotic fluid who do not start breathing after thorough drying and rubbing the back two to three times, suctioning of the mouth and nose should not be done routinely before initiating positive-pressure ventilation. Suctioning should be done only if the mouth or nose is full of secretions. • In neonates born through meconium-stained amniotic fluid who do not start breathing on their own, suctioning of the mouth and nose should be done before initiating positive-pressure ventilation. • In settings where mechanical equipment to generate negative pressure for suctioning is not available and a newly born baby requires suctioning, a device syringe (single-use or easy to clean and sterilize) is preferable to a mucus extractor with a trap in which the provider generates suction by aspiration. Given that 5% to 10% of newborns require some degree of resuscitation and that health care workers in Tanzania and Uganda who were following WHO suctioning guidelines estimated that 10% of babies needed suctioning at birth, the cell has been prefilled to reflect the 10% estimate. It is highly recommended, however, that a country maintain records on the number of babies requiring suctioning and that suctioning be done per current WHO and HBB guidelines.	WHO. Guidelines on basic newborn resuscitation. Geneva:WHO;2012. Available at http://www.who.int/maternal_child_adolescent/documents/basic_newborn_resuscitation/en/

Variables	Assumptions	Source
Step 4: Training commodity (pre-service) information		
Number of training manikins (pre-service) per number of students	This section should be completed if quantifying training manikins for nursing and medical schools. The number of nursing and medical schools, along with the average number of students per class, are often available at the MOH or the Ministry of Education. Various stakeholders from the HBB partnership and from the MOHs in Tanzania and Uganda agreed that it is ideal to not have more than six (6) students per manikin for practicing purposes. This number should be changed according to country policy, practice, and budget..	Established through interviews and meetings with global implementers/trainers from the HBB partnership, health care workers, and the MOH in Tanzania and Uganda.
Step 5: Pricing		Due to confidentiality issues around supplying, we cannot disclose the sources used.
Resuscitation bag and two masks	The current price for a resuscitation bag and two masks has been estimated as of March 2016 at US$20 for all three items based on costs from an international supplier. Some manufacturers sell these items together, while others may sell them separately. The quantification tool has columns for the masks in the event that these items are procured separately.	
Reusable suction device	A reusable suction device has been estimated as of March 2016 at US$4.50 from an international. supplier.	
Single-use suction device	Single-use suction device prices vary from country to country but an average cost estimate as of March 2016 is approximately US$0.75 per device.	
Training manikin	The current estimated cost of the training manikin includes a resuscitation bag, two (2) masks (sizes 0 and 1), and a reusable suction device and is estimated as of March 2016 at US$83. This estimate is based on costs from an international supplier. When ordering the training manikin, it is important to remember to also order a neonatal resuscitation bag and mask and a manual suction device if they are not supplied as a set. Training materials (workbooks, flip charts, posters, etc.) also need to be considered whether they are obtained from the HBB Global Development Alliance, from within country, or another supplier.	

Variables	Assumptions	Source
Total cost estimate	The total estimated cost of the commodities and the total number of commodities required will be shown as a total cost estimate on the Results page, once the Data Entry page has been populated with data.	

Quantification Tool Exercise

The following exercise has been provided so that anybody wishing to practice using the quantification tool can do so. The answers can be found after the exercise instructions.

Instructions

Read through the instructions below and enter your responses into the quantification tool which can be found at: http://www.path.org/publications/detail.php?i=2401. When you have completed the four steps, check your answers against the quantification tool exercise answer sheet. The answers are shown for each type of health facility.

Remember: When using the quantification tool, you MUST complete the green cells; completing the orange cells is optional. The orange cells are currently populated with information from Tanzania and Uganda. In the example you are provided for this exercise, you will be populating the tool for Ghana using estimated quantities so the orange cells will need to be changed, too, in some instances.

Exercise

1. You are procuring basic neonatal resuscitation commodities in Ghana for the following number of public-health facilities who have staff currently trained to perform neonatal resuscitation:
   - Four (4) regional hospitals/teaching hospitals (tertiary level hospitals)
   - Ten (10) provincial hospitals (secondary level hospitals)
   - 128 district hospitals (primary level hospitals)
   - 838 health centers (lower-level health facilities)*

**Note: Approximately 100 health centers are of similar size to district hospitals so should be quantified as district hospitals.*

2. A health facility assessment has been performed by your program and the average number of rooms/areas where a newborn may be located at any given time are as follows:

   Regional hospital
   - Delivery: 2
   - Theatre: 2

- Emergency: 1
- Neonatal: 3
- Neonatal intensive care unit (NICU): 1

TOTAL: 9

Provincial hospital

- Delivery: 2
- Theatre: 2
- Emergency: 1
- Neonatal: 3
- NICU: 1

TOTAL: 9

District hospital

- Delivery: 1.5*
- Theatre: 1
- Emergency: 1
- Neonatal: 1

TOTAL: 4.5

**Note: Of the district hospitals assessed, some had 1 delivery room while others had 2 delivery rooms. The split was about 50/50.*

Health center

- Delivery: 2

TOTAL: 2

3. Your program will supply the following amount of basic neonatal resuscitation commodities:

   - Three (3) neonatal bags and masks (masks size zero [0] and size one [1]) and 3 reusable suction devices PER ROOM to every national and regional hospital.

- Two (2) neonatal bags and masks (masks size zero [0] and size one [1]) and 2 reusable suction devices PER ROOM to every district hospital.
- Two (2) neonatal bags and masks (masks size zero (0) and size one [1]) and 2 reusable suction devices PER ROOM to every health center.
- Two (2) neonatal manikins for in-service training for every level of hospital and one (1) neonatal manikin for in-service training for every health center.

4. You have also been asked to procure pre-service manikins for pre-service training for four (4) medical schools and 32 midwifery schools. The average number of students per class is 30.

Questions:

- What quantity of each type of commodity do you need?
- What is the **total** cost of the products?

	Resuscitation Bag	**Mask (size 0)**	**Mask (size 1)**	**Suction Device (Reusable)**	**Training Manikin (in-service)**	**Training Manikin (pre-service)**
Quantity Required						
Total Cost						

Quantification Tool Exercise Answer Sheet

After completing the exercise using the quantification tool found at: http://www.path.org/publications/detail.php?i=2401, check your answers with the answers below.

1. You are procuring basic neonatal resuscitation commodities in Ghana for the following number of public-health facilities who have staff currently trained to perform neonatal resuscitation:

   - Four (4) regional hospitals/teaching hospitals (tertiary level hospitals)—*Total number of regional hospitals: 4*
   - Ten (10) provincial hospitals (secondary level hospitals)—*Total number of provincial hospitals: 10*
   - 128 district hospitals (primary level hospitals)—**Total number of district hospitals: 228*
   - 838 health centers (lower-level health facilities)—**Total number of health centers: 738*

** Remember! Approximately 100 health centers are of similar size to district hospitals so should be quantified as district hospitals.*

2. A health facility assessment has been performed by your program and the average number of rooms/areas where a newborn may be located at any given time are as follows:

   Regional hospital
   - Delivery: 2
   - Theatre: 2
   - Emergency: 1
   - Neonatal: 3
   - NICU: 1

   TOTAL: 9

   Provincial hospital
   - Delivery: 2
   - Theatre: 2
   - Emergency: 1
   - Neonatal: 3

- NICU: 1

TOTAL: 9

District hospital

- Delivery: 1.5*
- Theatre: 1
- Emergency: 1
- Neonatal: 1

TOTAL: 4.5

**Note: Of the district hospitals assessed, some had 1 delivery room while others had 2 delivery rooms. The split was about 50/50.*

Health center

- Delivery: 2

TOTAL: 2

Considerations	Regional hospitals	Provincial hospitals	District hospitals	Health centers	Health posts	Other
Number of health facilities in country	4	10	228	738		
Average number of delivery rooms/areas per facility	2	2	1.5	2	0	0
Average number of theaters per facility	2	2	1	0	0	0
Average number of emergency areas per facility	1	1	1	0	0	0
Average number of neonatal wards per facility	3	3	1	0	0	0
Average number of NICU*/special care units per facility	1	1	0	0	0	0
Other	0	0	0	0	0	0
Other	0	0	0	0	0	0

3. Your program will supply the following amount of basic neonatal resuscitation commodities. They have requested a sole source procurement from Laerdal Global Health whose current pricing is the same pricing shown in this tool:

   - Three (3) neonatal bags and masks (masks size zero [0] and size one [1]) and 3 reusable suction devices PER ROOM to every national and regional hospital.
   - Two (2) neonatal bags and masks (masks size zero [0] and size one [1]) and 2 reusable suction devices PER ROOM to every district hospital.
   - Two (2) neonatal bags and masks (masks size zero [0] and size one [1]) and 2 reusable suction devices PER ROOM to every health center.
   - Two (2) neonatal manikins for in-service training for every level of hospital and one (1) neonatal manikin for in-service training for every health center.

Remember! The masks have been shown separately in the quantification tool to remind you to procure them if the vendor sells them separately. Additionally, when procuring neonatal training manikins, you should also bundle with a resuscitation bag and masks and a suction device. If the vendor you procure the manikin from does not sell these other commodities, you may need to issue separate purchase orders/contracts. Training materials may also be required. For the purposes of this exercise, you were only required to report the number of manikins, as we are making the assumption that you are procuring as a kit from Laerdal Global Health.

Considerations	Regional hospitals	Provincial hospitals	District hospitals	Health centers	Health posts	Other
Number of resuscitation bags per room/area	3	3	2	2	0	0
Number of resuscitation masks size 0 per room/area	3	3	2	2	0	0
Number of resuscitation masks size 1 per room/area	3	3	2	2	0	0
Number of reusable suction devices per room/area	3	3	2	2	0	0
Number of training manikins per health facility (in-service)	2	2	2	1	0	0

4. You have also been asked to procure pre-service manikins for pre-service training for four (4) medical schools and 32 midwifery schools. The average number of students per class is 30.

Considerations	
Number of nursing and medical schools	36
Average number of students per class	30
Number of students per manikin	6

Questions:

- What quantity of each type of commodity do you need?
- What is the total cost of the products?

	Resuscitation Bag	Mask (size 0)	Mask (size 1)	Suction Device (Reusable)	Training Manikin (in-service)	Training Manikin (pre-service)
Quantity Required	5,382	5,382	5,382	5,382	1,222	180
Total Cost	**$ 248,225**					

Grand Total	Number of facilities	Estimated number of rooms in facility	Total number of rooms in country	Resuscitation bag	Mask (size 0)	Mask (size 1)	Suction device (reusable)	Suction device (single-use)	Training manikin + accessories (in-service)	Training manikin + accessories (pre-service)	Total cost of all products
Regional hospitals	4.0	9.0	36.0	108	108	108	108	n/a	8	n/a	
Provincial hospitals	10.0	9.0	90.0	270	270	270	270	n/a	20	n/a	
District hospitals	228.0	4.5	1,026.0	2,052	2,052	2,052	2,052	n/a	456	n/a	
Health centers	738.0	2.0	1,476.0	2,952	2,952	2,952	2,952	n/a	738	n/a	
Health posts	0.0	0.0	0.0	0	0	0	0	n/a	0	n/a	
Other	0.0	0.0	0.0	0	0	0	0	n/a	0	n/a	
Number of devices required	n/a	n/a	n/a	5,382	5,382	5,382	5,382	0	1,222	180	
Approximate cost (US$)	n/a	n/a	n/a	$107,640.00	$0.00	$0.00	$24,219.00	$0.00	$101,426.00	$14,940.00	$248,225.00

Number of devices required	Number of facilities	Estimated number of rooms in facility	Total number of rooms in country	Resuscitation bag	Mask (size 0)	Mask (size 1)	Suction device (reusable)	Suction device (single-use)	Training manikin (in-service)	Training manikin (pre-service)
Regional hospitals	4									
Delivery rooms/areas		2.0	8.0	24	24	24	24	n/a	n/a	n/a
Theaters		2.0	8.0	24	24	24	24	n/a	n/a	n/a
Emergency areas		1.0	4.0	12	12	12	12	n/a	n/a	n/a
Neonatal wards		3.0	12.0	36	36	36	36	n/a	n/a	n/a
NICU/special care units		1.0	4.0	12	12	12	12	n/a	n/a	n/a
Other		0.0	0.0	0	0	0	0	n/a	n/a	n/a
Other		0.0	0.0	0	0	0	0	n/a	n/a	n/a
TOTAL		**9.0**	**36.0**	**108**	**108**	**108**	**108**		**8**	

Number of devices required	Number of facilities	Estimated number of rooms in facility	Total number of rooms in country	Resuscitation bag	Mask (size 0)	Mask (size 1)	Suction device (reusable)	Suction device (single-use)	Training manikin (in-service)	Training manikin (pre-service)
Provincial hospitals	10									
Delivery rooms/areas		2.0	20.0	60	60	60	60	n/a	n/a	n/a
Theaters		2.0	20.0	60	60	60	60	n/a	n/a	n/a
Emergency areas		1.0	10.0	30	30	30	30	n/a	n/a	n/a
Neonatal wards		3.0	30.0	90	90	90	90	n/a	n/a	n/a
NICU/special care units		1.0	10.0	30	30	30	30	n/a	n/a	n/a
Other		0.0	0.0	0	0	0	0	n/a	n/a	n/a
Other		0.0	0.0	0	0	0	0	n/a	n/a	n/a
TOTAL		**9.0**	**90.0**	**270**	**270**	**270**	**270**		**20**	