

HealthTech Report

Market sizing estimates for neonatal resuscitation equipment

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Introduction

Birth asphyxia, defined as the failure of the newborn to establish breathing immediately after birth, kills 814,000 newborns every year and accounts for almost a quarter of all newborn deaths.ⁱ In addition, there are an estimated 1.02 million intrapartum stillbirths every year, an unknown number of whom may be live born alive but misclassified as fresh stillbirths when no resuscitation has been provided.ⁱⁱ More than 98 percent of these deaths occur in low- and middle-income countries.

Approximately 10 million babies do not breathe immediately at birth, and about 6 million require basic neonatal resuscitation. According to the World Health Organization (WHO), basic newborn resuscitation requires a bag-and-mask resuscitator for ventilation, a mucus extractor (suction bulb) for suctioning, a source of warmth for thermal protection, and a clock. Sixty million home- or community-based births occur every year, but most do not have access to any resuscitation resources.ⁱⁱⁱ The key to reducing deaths due to birth asphyxia is to make “appropriate care for birth asphyxia”—both neonatal resuscitation skills and appropriate devices—available to all skilled birth attendants (SBAs) and ideally to community health workers if SBAs are not available. In addition, a consistent program targeting ongoing training and local mentoring is needed to impact clinical management and patient outcome.

In order to address this issue, Helping Babies Breathe (HBB)—a USAID-funded Global Development Alliance—initiated an effort in 2010 to increase neonatal survival by offering evidence-based educational programs and high-quality, affordable neonatal resuscitation devices to SBAs in developing countries. HBB now includes 20 global alliance and implementing partners from both the private and public sectors and has attained remarkable success. The HBB training curriculum that was co-developed by the American Academy of Pediatrics, Laerdal Medical AS, and other HBB members, has been introduced in 60 countries. Global demand for newborn resuscitation has been increased by training and equipping over 130,000 health workers. Laerdal Global Health has offered developing-country programs the low-cost, high-quality neonatal resuscitation devices that were developed for low-resource settings by Laerdal Medical AS. To date, 120,000 bag-and-mask resuscitators (includes one self-inflating resuscitation bag and masks sizes 0 and 1), 150,000 Penguin Suction Devices (a multi-use suction bulb), and 50,000 NeoNatalie training manikins have been supplied to low-resource countries on a not-for-profit basis.^{iv}

Objectives

In September 2012, the UN Commission on Life-Saving Commodities for Women and Children (UNCoLSC) was launched as part of the Every Woman Every Child movement with the overall goal to increase access to 13 lifesaving commodities in 50 of the world’s poorest countries. Neonatal resuscitation devices were identified as one of the selected 13 lifesaving commodities.

The objective of market sizing is to estimate the total market size for the newborn resuscitation commodities for the eight UNCoLSC pathfinder countries (Democratic Republic of the Congo [DRC], Ethiopia, Malawi, Nigeria, Senegal, Sierra Leone, Tanzania, and Uganda) to aid with the following:

- Demonstrate to program planners and implementers the total number of commodities that are needed to effectively provide neonatal resuscitation in their country.
- Provide manufacturers with information on potential production capacity.
- Determine market size data for private and public segments to assist in determining effective distribution strategies.

Methodology

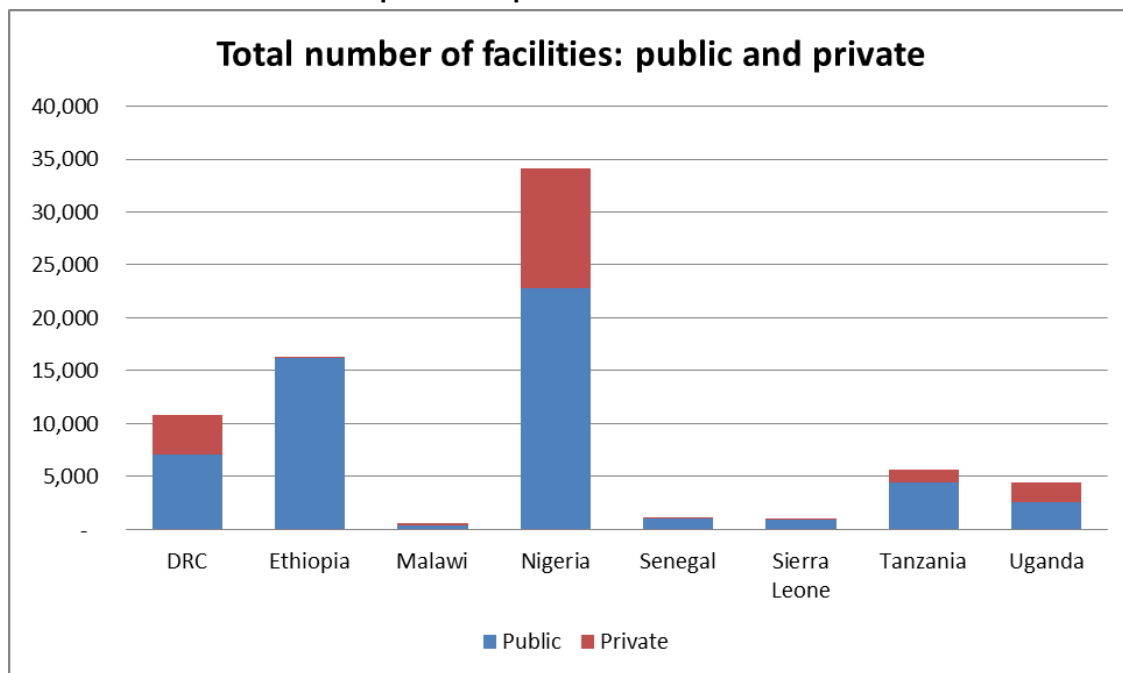
PATH developed a model framework to estimate the market size for newborn resuscitation commodities for the eight UNCoLSC pathfinder countries. The market size estimates provided in this report reflect the total number of commodities each country needs to provide resuscitation care to newborns being born in facilities; it does not take into consideration what already exists in each country. All sources and assumptions for the variables used to model market size are in the appendix.

Reusable resuscitation commodities

The market sizing for the reusable resuscitation commodities (bag-and-mask resuscitators, multi-use suction bulbs, and training manikins) is based on the number of health care facilities in each UNCoLSC pathfinder country and the number of newborn resuscitation commodities needed in each facility. The market size estimates are for the initial stocking decision; the frequency of repurchases is not forecasted. In addition, to be consistent with the resuscitation guidelines in most countries, the market size estimates exclude use of resuscitation commodities at the community level.

PATH collected data on the number of facilities in each of the eight UNCoLSC pathfinder countries using secondary data. We collected information for the following five facility levels: health post, health center, district hospital, provincial hospital, and regional hospital. These facility levels were chosen because WHO has collected data on the number of health care facilities in many low-resource countries using these designations.^v In cases where WHO has not collected data on the number of health care facilities, PATH performed a literature review to obtain the information. We attempted to collect data for private and public facilities. Private facilities may include for-profit, nonprofit, faith-based, or nongovernmental organization facilities. The information on the number of facilities in each country that was used to estimate market size is displayed in Figure 1.

Figure 1: Total number of facilities: public and private



In addition to collecting data on the number of facilities in each UNCoLSC pathfinder country, We estimated the number of rooms (by facility type) that would need newborn resuscitation commodities and also estimated the number of commodities that are needed in each room. To obtain this information we consulted newborn resuscitation experts and performed field observations in eight facilities in Uganda and seven in Tanzania in 2013. Through this process, PATH identified the following rooms as needing resuscitation commodities: delivery rooms/wards, operation theaters, emergency areas, neonatal wards, and neonatal intensive care units (NICU)/special care units. The estimated number of rooms for each facility type is listed in Table 1, and the estimated number of commodities needed in each room is listed in Table 2.

Table 1: Number of rooms needing resuscitation equipment by facility type^{vi}

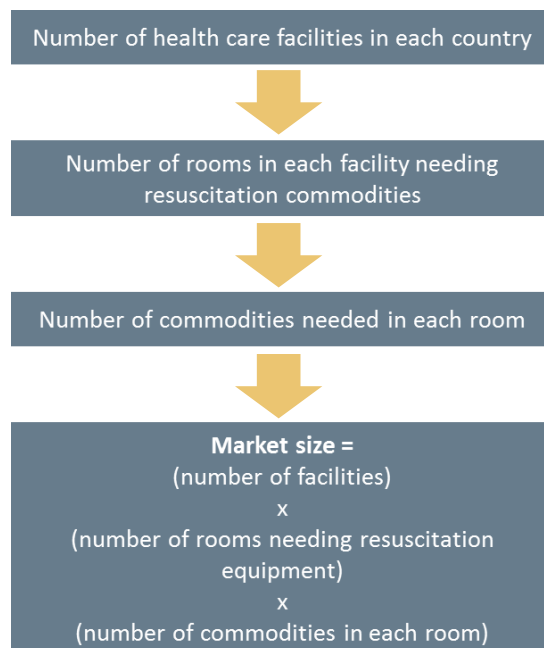
Room type	Regional hospital	Provincial hospital	District hospital	Health center	Health post
Delivery room/ward	4	2	2	1	1
Operation theater	2	2	2	0	0
Emergency area	1	1	1	1	0
Neonatal ward	1	2	1	0	0
NICU/special care	2	2	1	1	0
Total number of rooms	10	9	7	3	1

Table 2: Number of resuscitation commodities needed per room by facility type^{vii}

Number of commodities	Regional hospital	Provincial hospital	District hospital	Health center	Health post
Resuscitation bags	3	2	2	2	2
Size 0 masks	3	2	2	2	2
Size 1 masks	3	2	2	2	2
Multi-use suction bulbs	3	2	2	2	2
Training manikins (per facility)	3	3	3	1	0

A summary of our market size framework for reusable resuscitation commodities (bag-and-mask resuscitators and multi-use suction bulbs) is shown in Figure 2. Given that different facility levels have different numbers of rooms needing resuscitation commodities, all information was collected and calculated at the facility level. Facility market size information was summed in each country to estimate the total market size. The market size estimates for training manikins are based on the number of facilities in each country rather than the number of rooms. Manikin estimates do not include potential use in teaching centers.

Figure 2: Market size framework (reusable resuscitation commodities)

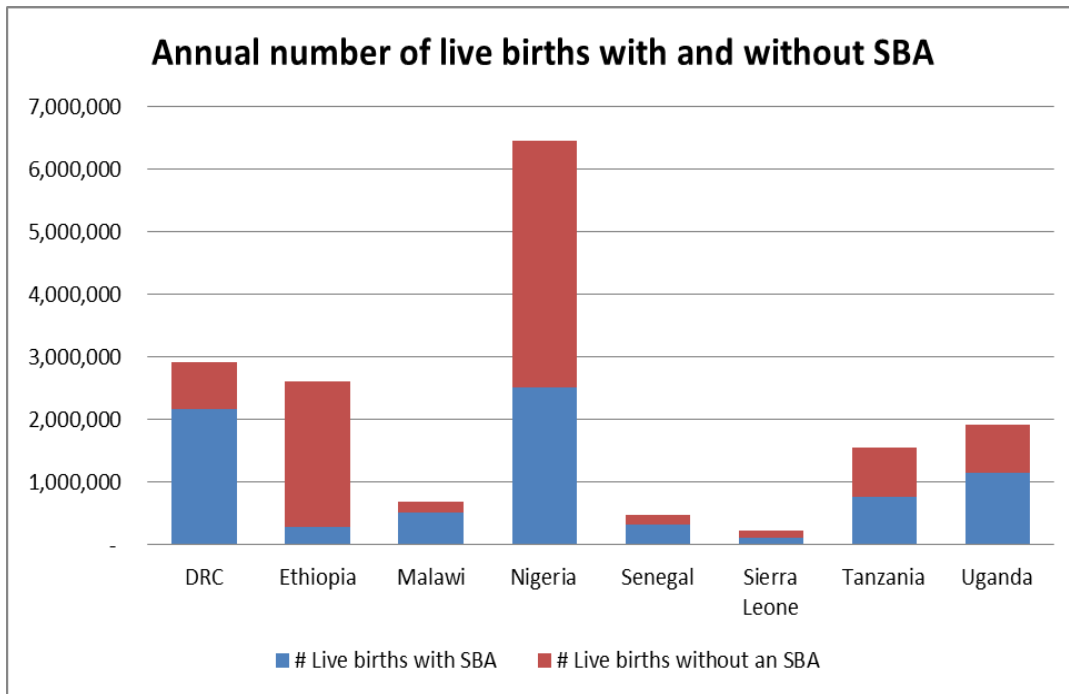


Training manikins are estimated by the number of facilities rather than the number of rooms.

Single-use suction bulbs

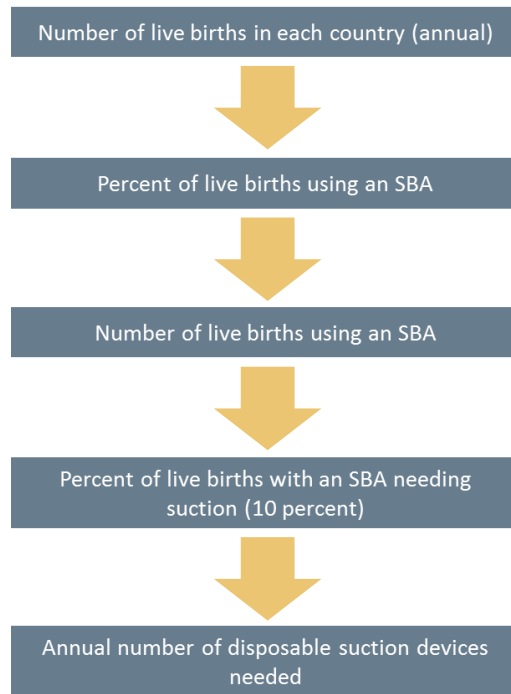
Both multi-use and single-use suction bulbs are available. We estimated the number of single-use devices as a potential alternative to multi-use devices. The framework that we used to estimate single-use suction bulbs is based on the number of live births in each UNCoLSC pathfinder country and the proportion of births that have an SBA. This information was collected using secondary data.^{viii} The information on the number of live births and the proportion of live births with an SBA that we used to estimate the market size for single-use suction bulbs is shown in Figure 3.

Figure 3: Annual number of live births^{viii} with and without an SBA^{ix}



We also consulted resuscitation experts to estimate the number of live births that might need suction bulbs. The model assumes that 10 percent of live births delivered by an SBA will need suctioning. A summary of our market size framework for single-use suction bulbs is shown in Figure 4.

Figure 4: Market size framework (single-use suction bulbs)



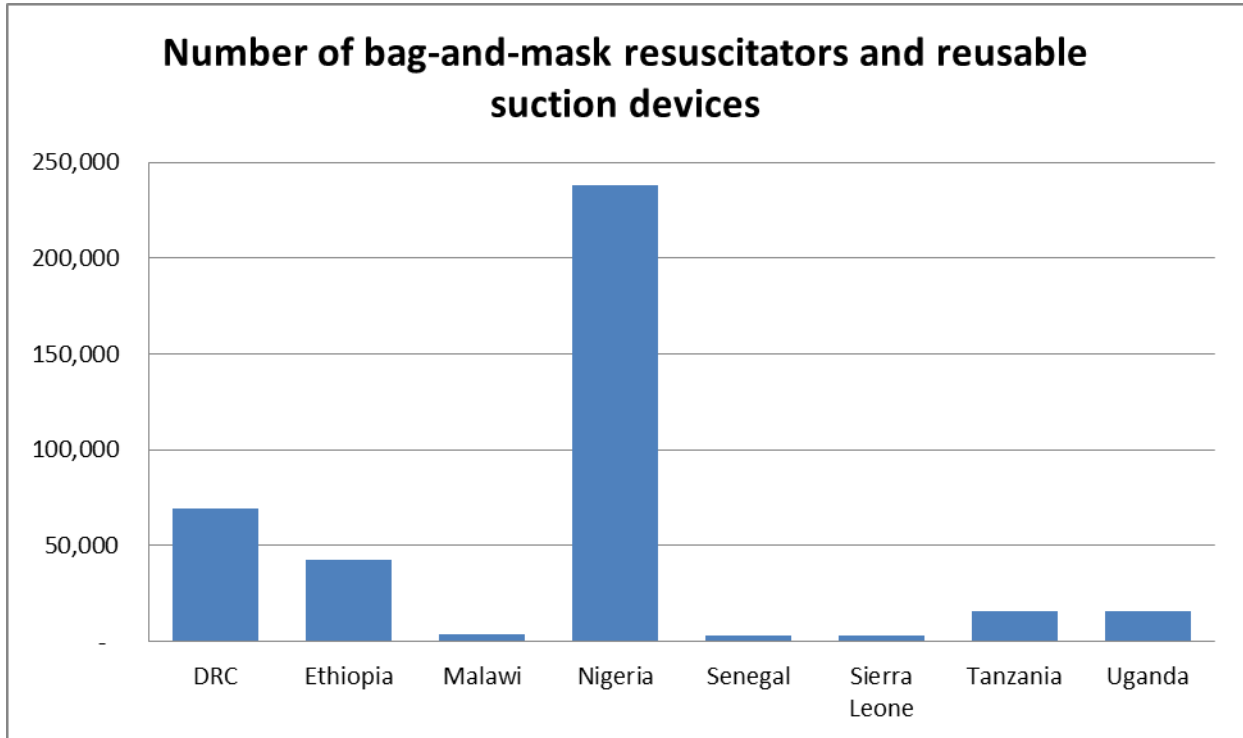
Framework should only be used if single-use suction bulbs are preferred over multi-use suction bulbs.

Results

The market size for all eight UNCoLSC pathfinder countries is nearly 400,000 for bag-and-mask resuscitators and nearly 400,000 for multi-use suction bulbs. Nigeria has the largest market size of the countries under investigation with an estimated market size of 240,000 for each commodity (see Figure 5). Nigeria’s market size accounts for more than 60 percent of the estimated market size for the eight countries and is more than three times larger than the second-largest country under evaluation, the DRC. The market size for training manikins, which is estimated at the facility level rather than the room level, is substantially lower. Using the methodology described in this report, approximately 60,000 training manikins are needed for all eight UNCoLSC pathfinder countries (see Figure 6).

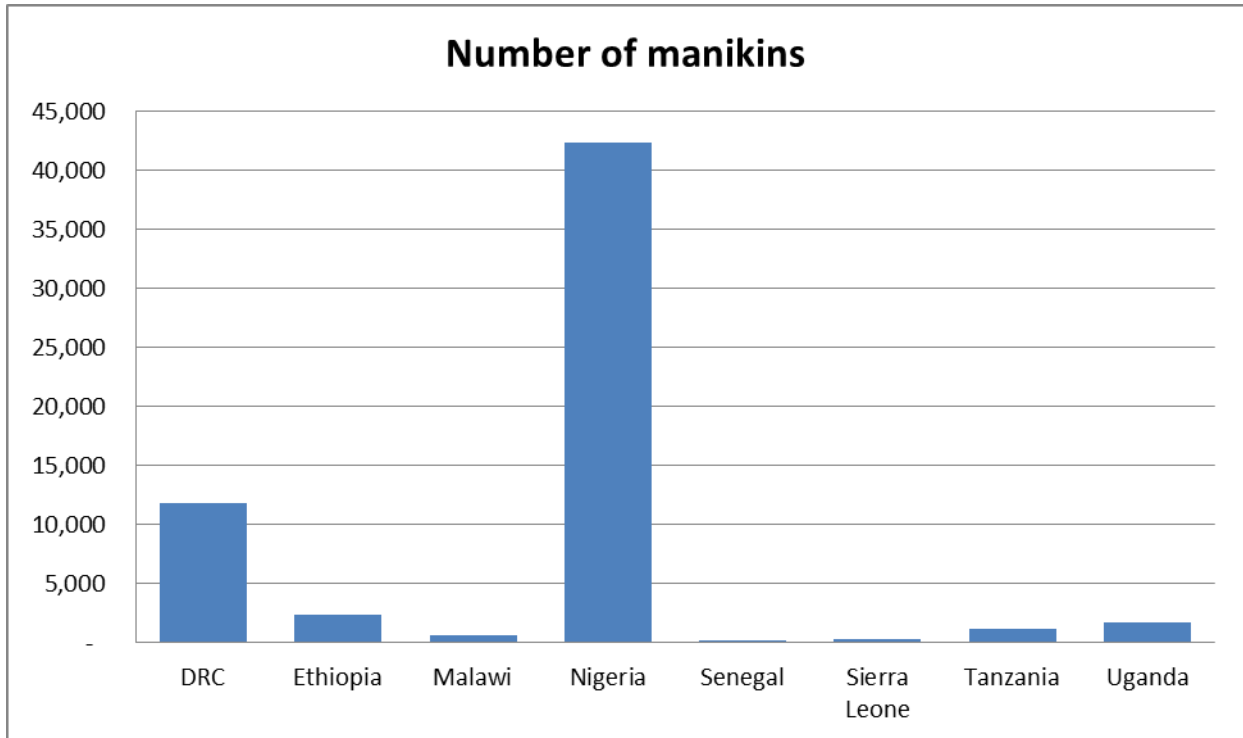
Private-sector facilities are common and make up a substantial proportion of the estimated number of facilities in each of the UNCoLSC pathfinder countries (Figure 1). In the DRC, Nigeria, and Uganda more than 35 percent of the total health care facilities are estimated to be private sector. Distribution strategies will need to focus on reaching both public- and private-sector facilities.

Figure 5: Estimated number of bag-and-mask resuscitators and suction bulbs



Estimates are for each commodity separately (e.g., in Nigeria 238K bag-and-mask resuscitators and 238K suction bulbs are needed).

Figure 6: Estimated number of manikins



As discussed previously, we also estimated the annual number of single-use suction bulbs and compared these to the estimated number of multi-use suction bulbs (see Table 3). Single-use suction bulbs are a

potential alternative commodity to multi-use suction bulbs, and market size estimates for these two commodities should not be summed. In most cases, the annual number of single-use suction bulbs is estimated to be substantially higher than the number of multi-use suction bulbs. Indeed, in half of the UNCoLSC pathfinder countries the estimated number of single-use suction bulbs needed is five times or greater than the estimated number of multi-use suction bulbs needed. Furthermore, in two additional countries the estimated number of single-use suction bulbs needed is three times greater than the number of multi-use suction bulbs.

While in-country cost analysis (e.g., price of commodities, shipping costs, and import duties) and durability data for multi-use suction bulbs is needed to understand the cost of providing both types of devices, these data suggest that multi-use suction bulbs may make more sense in many of the UNCoLSC pathfinder countries given the large magnitude of difference between single-use and multi-use devices. The only country where the number of single-use suction bulbs is estimated to be less than multi-use suction bulbs is Ethiopia, which has a very low percentage of births using an SBA.

While the cost of providing suction bulbs is important, there are other factors that may influence a country’s decision between providing multi-use or single-use suction bulbs including in-country preferences and guidelines (including infection control) and the likelihood of reusing single-use devices.

Table 3: Comparison of the estimated number of single-use and multi-use suction bulbs

Commodity type	DRC	Ethiopia	Malawi	Nigeria	Senegal	Sierra Leone	Tanzania	Uganda
Single-use	215,488	28,220	50,078	251,216	30,709	9,648	75,551	113,441
Multi-use	69,054	42,284	3,936	237,970	2,796	3,016	16,072	15,456
Difference	146,434	(14,604)	46,142	13,246	27,913	6,632	59,479	97,985

Limitations

Health system variation

There is wide variation globally in health outcomes and health system performance.^x A health system review was not part of the scope of this work. The market size estimates for reusable resuscitation commodities is based on the estimated number of health posts, health centers, district hospitals, provincial hospitals, and regional hospitals per country. The number of rooms needing resuscitation equipment and the number of resuscitation commodities per room were also estimated for each facility level. However, not all of the UNCoLSC pathfinder countries have a five-tier health care system as described above, and in some countries assumptions had to be made on how to categorize facilities (see Appendix).

Differences in health systems can impact market size estimates. For example, a district hospital in one country may have an average of three labor wards needing resuscitation commodities while the other UNCoLSC pathfinder countries may have an average of two labor wards needing resuscitation commodities (current model assumption). In this case, the market size will be underestimated for the country with the higher number of labor wards in district hospitals.

Data on the number of facilities

While PATH attempted to capture private and public facilities to estimate the market size for reusable commodities, we recognize that some facility types (e.g., private for-profit) may be underrepresented. All information collected is from secondary data sources.

Uncertainty regarding estimates

While reasonable efforts were undertaken to estimate the market size using secondary data, all information in this report should be viewed as estimates. PATH recommends recalculating the estimated quantities using the framework outlined in this report if different data sources are preferred.

Conclusions

The market size estimates provided in this report reflect the total number of commodities (bag-and-mask resuscitators, suction bulbs, and training manikins) each country will need to provide resuscitation care to newborns being born in facilities. The market size estimates are for the initial stocking decision; the frequency of repurchases is not forecasted. In addition, to be consistent with current resuscitation guidelines in most countries, the market size estimates exclude resuscitation commodity use at the community level.

Our results estimate that 400,000 bags-and-masks resuscitators and multi-use suction bulbs are needed to provide resuscitation care to newborns in facilities in the eight UNCoLSC pathfinder countries. Nigeria has the largest market size, and this country alone accounts for over 60 percent of the estimated number of commodities for the eight pathfinder countries. In most cases, the market size for multi-use suction bulbs is substantially lower than single-use suction bulbs (Ethiopia is an exception) and from a cost perspective, multi-use devices may make more sense to adopt. Private-sector facilities are common, and distribution strategies will need to focus on reaching both public- and private-sector facilities.

While we feel that our systematic market size framework for resuscitation commodities is helpful for estimating, comparing, and contrasting the number of resuscitation commodities needed across the different UNCoLSC pathfinder countries, we recommend additional due diligence on the health care systems be conducted if precise market sizing information is required. All market size information in this report should be viewed as estimates.

Other Resources

In support of UNCoLSC, PATH has created a quantification tool for resuscitation commodities. The quantification tool facilitates planning for procurement at the national level and will be incorporated into the quantification guideline that Recommendation 6 (Supply and Awareness) under UNCoLSC has developed for dissemination. The quantification tool can be found there.

ⁱ Black R, Cousens S, Johnson HL, et al. Global, regional, and national causes of child mortality in 2008: a systematic analysis. *The Lancet*. 2010;375(9730):1969–1987.

ⁱⁱ Lawn J, Shibuya K, Stein C. No cry at birth: global estimates of intrapartum stillbirths and intrapartum related neonatal death. *Bulletin of the World Health Organization*. 2005;409–417.

ⁱⁱⁱ Lee A, Cousens S, Wall, S, et al. Neonatal resuscitation and immediate newborn assessment and stimulation for the prevention of neonatal deaths: a systematic review, meta-analysis and Delphi estimation of mortality effect. *BMC Public Health*. 2011;11(3):S12.

^{iv} Helping Babies Breath Global Development Alliance (HBB GDA). Annual Status Report November 2013. HBB GDA;2013. Available at: http://www.healthynewbornnetwork.org/sites/default/files/resources/HBB%20Annual%20report%2021%20Nov%202013%20Final_0.pdf

^v Medical devices; country data. World Health Organization (WHO) website. Available at: http://www.who.int/medical_devices/countries/en/. Accessed December 26, 2013.

^{vi} This information is consistent with the Recommendation 6 quantification guideline.

^{vii} This information is consistent with the Recommendation 6 quantification guideline.

^{viii} UN Data website. Available at: <http://data.un.org/Explorer.aspx?d=WHO>. Accessed December 26, 2013.

^{ix} Demographic Health Survey (DHS) Stat Compiler. DHS website. Available at: <http://www.statcompiler.com/>

^x Murray C, Frenk J. A WHO Framework for Health System Performance Assessment. World Health Organization (WHO). 2006. Available at <https://www.google.com/url?sa=t&ret=j&q=&esrc=s&source=web&cd=1&cad=rja&ved=0CDQQFjAA&url=http%3A%2F%2Fwww.who.int%2Fhealthinfo%2Fpaper06.pdf&ei=4rG8Ut3zOY3woATDioCgCw&usq=AFOjCNFDL7bd9w5jgMarRgxC2zX0Q1x06w&bvm=bv.58187178.d.cG.%20Accessed%20December%2026.%202013U>. Accessed December 26, 2013U.

Appendix

Variable	Key Sources	Assumptions/Additional information
Information used to derive number of facilities		
Democratic Republic of the Congo	<p>Tshisungu LA, O'Connell K. Outlet survey: the Democratic Republic of the Congo 2009 survey report. Population Services International (PSI); 2009. Available at http://www.actwatch.info/countries/dr-congo/outlet-reports/2009.</p> <p>Kintaudi L. Churches and health care in DR Congo. The SANRU Rural Health Program of DR Congo. Available at: http://www.sanru.org/reports.htm. Accessed December 30, 2013.</p>	<ul style="list-style-type: none"> • 515 health zones • 1 hospital per zone and 20 health centers per zone • Of the 515 hospitals, assume 11 are provincial and the rest are district • 35% are private
Ethiopia	World Health Organization (WHO). Medical devices; country data; Ethiopia. WHO. Available at http://www.who.int/medical_devices/countries/en/ .	<ul style="list-style-type: none"> • N/A

Malawi	<p>Mtonya B, Chizimbi S. Systemwide effects of the Global Fund in Malawi: final report. Bethesda, MD; 2006. The Partners for Health Reform <i>plus</i> Project, Abt Associates Inc. Available at: pdf.usaid.gov/pdf_docs/PNADF197.pdf</p> <p>Levey I R, Gitonga N, Smith M, et al. Malawi Private Health Sector Assessment. Bethesda, MD: United States Agency for International Development (USAID);2011. Available at: http://www.shopsproject.org/sites/default/files/resources/Malawi%20Private%20Health%20Sector%20Assessment%20Final.pdf.</p>	<ul style="list-style-type: none"> • Ministry of Health and Population and Local government are public • Assume that health posts include clinics, dispensary, and maternity • Assume that hospitals (without a label) are provincial
Nigeria	Federal Ministry of Health. A directory of health facilities in Nigeria. 2011.	<ul style="list-style-type: none"> • N/A

<p>Senegal</p>	<p>World Health Organization (WHO). Medical devices; country data; Senegal. WHO. Available at http://www.who.int/medical_devices/countries/en/.</p> <p>Ministere de la Sante et de la Prevention. Plan national de developpement sanitaire PND 2009-2018. Republique du Senegal:2009. Available at: http://www.unfpa.org/sowmy/resources/docs/library/R242_MOH_SENEGAL_2009_NatHealthPlan_09_18.pdf</p> <p>MacAuslan I, Salam Fall A. Children in poverty reduction strategy papers and budgets: Senegal perspectives. United Nations Children's Fund (UNICEF); 2010. Available at: http://www.unicef.org/wcaro/documents_publications_3605.html</p>	<ul style="list-style-type: none"> • UNICEF information was used for private-sector numbers
<p>Sierra Leone</p>	<p>Government of Sierra Leone Ministry of Health and Sanitation. National Health Sector Strategic Plan; 2010-2015. 2009. Available at: https://www.google.com/search?q=national+health+sector+strategic+plan+sierra+leone&rlz=1C1CHFX_en_US491US491&oq=national+health+sector+strategic+plan+sierra+leone&aqs=chrome..69i57.31244j0j4&sourceid=chrome&espv=210&es_sm=122&ie=UTF-8#</p>	<ul style="list-style-type: none"> • All nongovernment facilities are private • Clinics are health centers • All hospitals are district hospitals (not broken down further)

Tanzania	Online health facility registry page. The United Republic of Tanzania Ministry of Health and Social Welfare website. Available at: http://hfr.ehealth.go.tz/ . Accessed December 20, 2013.	<ul style="list-style-type: none"> • Dispensaries are health posts • Health clinics are health centers • Hospitals are district hospitals
Uganda	World Health Organization (WHO). Medical devices; country data; Uganda. WHO. Available at http://www.who.int/medical_devices/countries/en/ .	<ul style="list-style-type: none"> • N/A
Information about other metrics used		
Live births for each country	UN Data website. Available at: http://data.un.org/Explorer.aspx?d=WHO . Accessed December 26, 2013. http://www.unicef.org/statistics/index_24183.html .	<ul style="list-style-type: none"> • N/A (used to calculate single-use suction bulbs)
Skilled birth attendants (SBAs)	Demographic Health Survey (DHS) Stat Compiler. DHS website. Available at: http://www.statcompiler.com/	<ul style="list-style-type: none"> • Used data for births in five years preceding the survey • Doctors and other health professionals are assumed to be SBAs.
Number of rooms by facility type	PATH field visits in Uganda and Tanzania (July-August 2013).	<ul style="list-style-type: none"> • Visited eight facilities in Uganda and seven in Tanzania in 2013
Number of commodities in each room	PATH field visits in Uganda and Tanzania. Expert consultations (July-August 2013). Oral communication).	<ul style="list-style-type: none"> • Consultations occurred in 2013