A HealthTech Report

Summary of Results of Market Assessment of Neonatal Resuscitation Devices in Southern Africa Development Community Countries

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1455 NW Leary Way
Seattle, WA 98107-5136 USA
Tel: 206.285.3500 Fax: 206.285.6619
www.path.org

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Evolutions Research Solutions (Pty), Ltd., of Rivonia, South Africa, conducted the regional research with close oversight and participation from HealthTech staff.

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INTRODUCTION

Birth asphyxia refers to a baby who does not begin or sustain adequate breathing at birth.[1] Birth asphyxia is estimated to account for 23 percent of the estimated 4 million neonatal deaths that occur annually[2] in the world. This results in almost 1 million neonatal deaths and an unknown number of children with long-term neurological disability due to birth asphyxia. About three-quarters of all neonatal deaths occur in the first week of life, and 90 percent of these neonatal deaths occur in developing countries in Asia and Africa.[2] Limited data suggest that deaths due to birth asphyxia have remained relatively unchanged in developing countries.

A large proportion of deliveries in developing countries take place at home. In less developed countries, 62 percent of births take place each year without skilled care.[3] In sub-Saharan Africa, less than 40 percent of women deliver with skilled care and less than 30 percent of women in South Asia deliver with skilled care. During home births, referral of asphyxiated infants is not feasible, since they will usually die before reaching the health center/hospital. Therefore, a provider who is trained and equipped to manage birth asphyxia and other complications must also attend births that occur at home.[2]

The key to reducing death due to birth asphyxia is to provide appropriate care to underserved populations during delivery. Appropriate care for birth asphyxia requires that neonatal resuscitation skills and appropriate technology must be made accessible to all skilled birth attendants and to community-level workers where skilled attendants are not available. According to the World Health Organization (WHO), basic newborn resuscitation requires a bag and a mask resuscitator for ventilation, a mucus extractor for suctioning, a source of warmth for thermal protection, and a clock.[4] Neonatal resuscitation devices are also available in a tube and mask design.

Increasing the availability and use of such lifesaving resuscitation devices in developing countries may allow for improved care for neonates experiencing birth asphyxia. At the request of PATH, Evolutions Research Solutions of Rivonia, South Africa, conducted a market assessment to increase understanding of the availability and supply of neonatal resuscitators in the Southern Africa Development Community (SADC) region. SADC member countries include Angola, Botswana, Democratic Republic of Congo (DRC), Lesotho, Malawi, Mauritius, Mozambique, Namibia, Republic of South Africa, Swaziland, Tanzania, Zambia, and Zimbabwe. In addition, Madagascar was included in this research because it is often classified as a southern African country.

Detailed research objectives were as follows:

1. Obtain an overview of the market for neonatal resuscitation devices in SADC countries, including an understanding of existing availability, prices, manufacturers, distribution channels, purchasers, and current and potential market size.
2. Determine if there are common distribution channels for medical devices in SADC countries.
3. Identify, screen, and rank potential distributors and manufacturers of existing neonatal resuscitation devices.
4. Recommend ways to increase availability, use, and access to high-quality and affordable resuscitators in the region.

In addition, specific research objectives for South Africa included:

1. Identify current Department of Health (DOH) policy and future trends affecting availability and use of neonatal resuscitators.
2. Conduct primary research to determine the availability of neonatal resuscitators as well as actual use in public-sector clinics.
3. Conduct interviews with key purchasers (or potential purchasers) to determine if they would be interested in buying an affordable (<US$30), high-quality device.

The information collected during this market study will be used to develop strategies to expand accessibility, availability, and use of appropriate and effective neonatal resuscitator devices throughout SADC countries and in KwaZulu-Natal province in South Africa specifically. In KwaZulu-Natal province results will be incorporated into ongoing project work being implemented by the PATH Maternal and Newborn Health Technology Initiative (known as MNTI), which aims to provide essential maternal and newborn care in the intra- and immediate postpartum periods—crucial stages at which effective interventions such as neonatal resuscitation can prevent the leading causes of maternal and newborn deaths.

METHODS

The research design employed a combination of qualitative and quantitative approaches, incorporating both secondary and primary research (see Table 1).

Table 1: Research Methods Overview

<table>
<tr><th rowspan="2">Component</th><th colspan="3">Descriptions</th></tr>
<tr><th>Secondary Research</th><th>Qualitative Research</th><th>Quantitative Research</th></tr>
<tr><td>Sources, sampling and participants</td><td>Secondary sources consulted included existing PATH and Evolutions Research Solutions documents, and published information contained in national libraries, available electronically via the Internet or available from key informants.</td><td>Targeted respondents included:
• 10 nongovernmental organizations (NGOs) and key purchasers in South Africa. Based on desk research and SADC primary research, ERS in consultation with PATH identified the following organizations working with neonatal health in Southern Africa: Save the Children, JHPIEGO, CARE, World Relief, PLAN International, Salvation Army World Service Office, Catholic Relief Services, Medical Care Development International, World Vision, Project HOPE, and UNICEF.
• 11 key informants from the South African national and provincial DOHs and Departments of Trade and Industry (DOTIs), and two per other SADC country</td><td>Targeted respondents included 30 South African public-sector health care facilities. Quota sampling was employed as follows:
a) A combination of rural and urban hospitals, clinics, and community health care centers were selected to target municipal areas with the largest number of births in South Africa in 2005, taking into account the population of each province in South Africa.
b) 11 rural facilities and 10 urban facilities, 11 clinics/community health care centers, and 10 hospitals participated.
c) Quotas to target were constituted and then realized in terms of completed interviews as follows, within the available time frame:
<table>
<tr><th>Province</th><th>2005 Live Births Ratio</th><th>Quota</th><th>Realized Sample</th></tr>
<tr><td>Eastern Cape</td><td>14.2%</td><td>4</td><td>3</td></tr>
<tr><td>Free State</td><td>6.1%</td><td>2</td><td>2</td></tr>
<tr><td>Gauteng</td><td>19.9%</td><td>6</td><td>6</td></tr>
<tr><td>Kwazulu-Natal</td><td>19.2%</td><td>6</td><td>4</td></tr>
<tr><td>Limpopo</td><td>12.5%</td><td>4</td><td>3</td></tr>
<tr><td>Mpumalanga</td><td>7.2%</td><td>2</td><td>0</td></tr>
<tr><td>Northern</td><td>2.0%</td><td>1</td><td>1</td></tr>
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<table>
<tr><th>Component</th><th colspan="3">Descriptions</th></tr>
<tr><th></th><th>Secondary Research</th><th>Qualitative Research</th><th>Quantitative Research</th></tr>
<tr><td></td><td></td><td>(n=11+28=39).
• 15 key informants from the neonatal resuscitator device supply industry (i.e., manufacturers and distributors) in SADC countries.</td><td><table><tr><td>Cape</td><td></td><td></td><td></td></tr><tr><td>North West</td><td>7.9%</td><td>2</td><td>1</td></tr><tr><td>Western Cape</td><td>11.1%</td><td>3</td><td>3</td></tr><tr><td>Total</td><td>100.1%</td><td>30</td><td>23</td></tr></table>
d) Non-random replacement was employed to adhere to need and quota criteria.</td></tr>
<tr><td>Data collection instruments</td><td>For the purpose of capturing and analyzing secondary data, data coding templates were developed to categorize and summarize relevant information.</td><td>Eight semi-structured discussion guides were developed for interviewing the above sources.</td><td>A structured research questionnaire was developed, consisting primarily of closed-ended questions.</td></tr>
<tr><td>Data collection procedure</td><td></td><td>Initial contact with key informants was established via phone or email to encourage participation and prepare respondents. Interviews with key informants from DOHs and DOTIs, NGOs, and key purchasers were conducted by phone.</td><td>Sampled clinics were contacted by phone to identify relevant contact persons, encourage participation, and collect data about sampled sites.</td></tr>
<tr><td>Data processing and analysis</td><td>Secondary data was used mainly to develop sampling frames, and to guide, compare with, and add to primary data.</td><td>Verbatim transcripts were produced from interview recordings, and translated into English, when relevant. Thematic content analysis was employed to analyze primary data.</td><td>Primary data was coded prior to data collection and captured in spreadsheet format. All data were checked and edited before processing. Data were analyzed using univariate descriptive statistics.</td></tr>
</table>

In summary, the strategy followed was descriptive, and survey methods were employed for telephone interviews with DOH and DOTI officials in all SADC countries, relevant NGOs, and key purchasers of neonatal resuscitation devices, potential (existing) manufacturers and distributors in SADC countries, short-listed manufacturers and distributors in SADC countries, and public-sector health care facilities in South Africa.

KEY FINDINGS

Is there a perceived need for neonatal resuscitation devices in SADC countries?

- ❖ All SADC country representatives and key informants, as well as all of the provinces in South Africa, reported a need for high-quality and affordable neonatal resuscitation devices in their area.

The consensus among respondents was that improved availability and use of neonatal resuscitation devices could positively impact neonatal mortality rates in SADC countries. For example, one respondent mentioned, "Every health facility needs a neonatal resuscitator." Only one participant at the provincial level in South Africa indicated that the demand for neonatal resuscitation devices is currently adequately addressed. All other participants reported supply problems such as devices being bought at high cost from Europe, not being in working order, being of poor quality, not being readily available in emergency situations, and not being available in every health facility. In addition, many SADC country representatives (i.e., Botswana, DRC, Malawi, Mauritius, Mozambique, Swaziland, and Tanzania) mentioned increasing birth rates as a driver for expected demand increases and reliance on donor funding for medical equipment supply.

Respondents also identified additional opportunities that could positively impact neonatal mortality rates, including the development of protocols and standards for neonatal resuscitation, and ensuring that staff at health care facilities are skilled in neonatal resuscitation.

Are neonatal resuscitation devices currently available in SADC countries?

- ❖ Most neonatal resuscitation devices used in SADC countries are silicone bag and mask type manual resuscitation devices that are imported from Japan, China, and India, with secondary suppliers (manufacturers and distributors) in South Africa and the United States.
- ❖ Neonatal resuscitation devices available in SADC countries range in price from US$10 to US$225.
- ❖ Of the 23 South African facilities surveyed that deliver babies, all but two rural facilities had neonatal resuscitation devices available.
- ❖ The neonatal resuscitation devices most often found in South Africa facilities were the Adcock Ingram Samson SSR 0010 and Laerdal 0305 Silicon Reusable resuscitators.

Many SADC countries (i.e., Botswana, DRC, Mauritius, Mozambique, South Africa, Swaziland, Tanzania, and Zambia) currently obtain neonatal resuscitation devices that cost more than US$30 and are imported from the United States and Europe (see Table 2). Only key informants for Malawi and Zimbabwe reported obtaining neonatal resuscitation devices solely from South Africa and Asian countries (i.e., Japan, China, and India). However, these two countries also reported obtaining smaller numbers of neonatal resuscitation devices in comparison to other SADC countries. Respondents mentioned Japan, India, and China most often as suppliers of neonatal resuscitation devices, whereas they reported that larger quantities of neonatal resuscitation devices were obtained from the United States and Europe. Neonatal resuscitation devices purchased from China and India were at the lower end of the price scale.

In general, neonatal resuscitation devices are available in public health care facilities in South Africa—all but two (rural) facilities indicated that they have neonatal resuscitation devices—with an average of three neonatal resuscitation devices per facility. However, the neonatal resuscitation devices are often not used. Concerns regarding neonatal resuscitation devices not being in working order, being of poor quality, not being readily available in emergency situations, and not being available at health care facilities seem to be unfounded in South Africa. However, the number of neonatal resuscitation devices available per facility seems mostly inadequate (e.g., 9 neonatal resuscitation devices for 30 maternity beds, 4 neonatal resuscitation devices for 59, 7 neonatal resuscitation devices for 72) with the lowest availability at 2 percent. Also of concern is:

- The reported use of tube and mask neonatal resuscitation devices and the Adcock Ingram Samson SSR 0010, both no longer recommended for use.
- Low prevalence of in-service trainings (including refresher courses).

Training for neonatal resuscitation is standard for pre-service training, but in-service and refresher training seldom takes place and is not required.

Table 2: Neonatal Resuscitation Devices Obtained by SADC Countries in 2007

Manufacturer	Model	Description	Web site	Origin	Key Informant Country	Price (2007)
Adcock Ingram	SSR 0010 Samson*	Bag and mask, silicone	www.adcock.co.za	South Africa	South Africa	<US$30
Ambu	Ambu® Silicone Resuscitator (Neonate)	Semi-transparent with a pressure limitation valve, textured surface, silicone/latex free, autoclaveable	www.ambu.com	Denmark	South Africa	US$175-US$193
Blue Cross	Neonatal Silicone Manual Resuscitator	Black or semi-transparent white bag and mask, with air pressure release valve, can be used with oxygen supply, autoclaveable	www.bluecross-e.co.jp	Japan	South Africa, Mauritius, Tanzania	US$100
East Coast Medical Equipment	Besmed Silicone Manual Resuscitator	Light green bag and mask, with air pressure release valve, autoclaveable	www.eastcoastmedical.co.za	South Africa	South Africa	US$10-US$20
Fisher and Paykel Healthcare, Inc.	Gas powered	Not applicable	www.fphcare.com	United States,Japan	Mauritius	Not applicable
Gabler Medical	Unknown	-	www.gablermedical.com	United Kingdom	South Africa	<US$30
Headstar Medical Products	HS-9788A Infant Silicone Manual Resuscitator	Silicone, polysulfone bag and mask, with pop-off	www.headstarmedical.com	Taiwan	South Africa	US$15-US$20

Manufacturer	Model	Description	Web site	Origin	Key Informant Country	Price (2007)
Laerdal	Preterm Silicone Resuscitator, Bag Disposable Silicone Resuscitator	Transparent silicone bag and mask, pressure relief valve, latex-free, disposable, transparent PVC	www.laerdal.com	Europe, Asia	South Africa	US$225
Nakamuso Medical Industry Company	Unknown	-	Unknown	Japan	Malawi	Unknown
Philips	Electronic	Not applicable	www.philips.com	Netherlands	Botswana, Seychelles	Not applicable
Unomedical, Inc.	Hospitak MPR and Mouth to Mask Resuscitators	Clear housing bag and mask, patient valve, with PMP and pop-off, disposable	www.unomedical.com	Denmark, United States	Botswana, Seychelles, Swaziland, Tanzania, Zimbabwe,	<US$30
VBM	Silicone Resuscitation Bag, and PVC	Transparent blue silicone bag; polysulfone valves	www.vbm-medical.de	Germany	South Africa	<US$30
Zeal Medical	Infant Resuscitator	Silicone bag and mask, autoclaveable, non re-breathing valve and H_2O pressure release, PVC oxygen reservoir	www.zealmedical.com	India	Malawi	US$15

*The SSR 0010 Samson is no longer listed as a product in the supplier catalogue.

Who purchases and uses neonatal resuscitation devices in SADC countries?

- Purchasers in SADC countries are at the national government level except for South Africa, where purchasing is completely decentralized to the health care facility level.
- The availability of high-quality, affordable devices would change purchasing decisions for current neonatal resuscitation device purchases, provided that such devices are available within a reasonable time after ordering.
- Most SADC countries use public-sector tendering for neonatal resuscitation device procurement and require adherence to international and national standards.
- UNICEF was identified (unprompted) by all key informants as playing a critical role in the supply of medical devices to SADC countries. However, UNICEF requires a minimum order of $5,000, which could pose a challenge for making a low-cost device widely available through this channel.

In SADC countries other than South Africa, governments appear to be the primary purchaser and user of neonatal resuscitation devices. Most SADC countries reported requirements for

adherence to International Organization for Standardization (ISO) guidelines. In addition to international standards for manufacturing, a smaller number reported requiring approval by national standards entities (e.g., Botswana Bureau of Standards), which approve devices before they can be imported, used, or sold in the country.

Private and church/mission hospitals were identified as the user market with the most potential (e.g., 40 percent of Tanzanian health services are provided in private-sector facilities such as mission hospitals). Private health care plays an important role in most SADC countries where between 7 percent (Namibia) and 74 percent (Malawi) of the poorest 20 percent of the population use private facilities when a child is sick, and at least a third of all health services are provided by the private sector.[5]

SADC governments generally receive neonatal resuscitation devices as donations and often do not pay for the devices directly. Most respondents noted that organizations such as UNICEF are viable options for soliciting devices due to a lack of government funds. In particular, UNICEF was identified as playing a critical role in the supply of medical supplies and equipment to SADC countries, although no SADC country reported that they had procured, or were in the process of procuring, neonatal resuscitator devices through this channel. UNICEF offers primarily procurement, purchasing, and distribution of medical equipment (with training), and national governments can request such assistance directly at local UNICEF offices.

Neonatal resuscitation devices are included in the UNICEF reference list of supplies, equipment and drugs, and 500 UNICEF Midwifery Kits were distributed internationally in 2003 (see Appendix 1 for detailed contents of kits including a resuscitation device). Local UNICEF offices are authorized to undertake local procurement up to US$50,000 for items such as medical devices. UNICEF has local offices in Angola, Botswana, DRC, Lesotho, Namibia, Madagascar, Malawi, Mozambique, Seychelles, South Africa, Swaziland, Tanzania, Zambia, and Zimbabwe (the Mauritius office closed at the end of 2003).

Most neonatal resuscitation devices obtained in SADC countries were distributed only to larger health care facilities. Tendering processes are not well known, developed, and/or described, which could contribute to corruption and long purchasing and import processes.

Participants identified governmental (rather than nongovernmental) organizations and private-sector health care as the main users for manual neonatal resuscitation devices in South Africa. In addition, a user market may also exist among neonatal resuscitation training projects and providers (e.g., not-for-profit training projects and the 367 nursing schools dispersed throughout the country).

How are neonatal resuscitation devices procured in South Africa's decentralized context?

- Procurement is currently completely decentralized and takes place at the health care facility level, although a process is underway to centralize procurement at the provincial level.
- The national DOH does not know which medical devices, supplies, and equipment (including neonatal resuscitation devices) the provincial DOHs and the health care facilities are using.
- There is support at the national level for making available and using neonatal resuscitation devices, both from the national DOH and the Nursing Council of South Africa. This is not likely to change in the next three to five years.
- National treasury funds allocated for purchasing medical devices are mostly underutilized (or entirely unused).
- The national DOH in South Africa does not currently prescribe specific medical devices to health care facilities, although recommendations made by the national DOH regarding medical devices are usually implemented by the provincial DOH. Provincial DOHs currently also do not prescribe specific medical devices to health care facilities.
- At the facility level, a medical device list is often used to purchase neonatal resuscitation devices; the medical device list is also generated at the facility level and does not necessarily consider product quality criteria.

The health system operates in a decentralized way with the national DOH taking responsibility for strategy and policy formulation, and assigning responsibility for management and implementation to the provincial DOH. Only when the national DOH deems a matter to be of national significance does it get involved in the management of strategy and policy implementation at provincial and local level. This is not likely to change in the near future.

Regarding the use of neonatal resuscitation devices, the national DOH maternal care guidelines include what facilities should have available for neonates and mothers. The national DOH is currently developing guidelines for neonatal immediate care, which may include recommended neonatal resuscitators, but will not prescribe any. In most cases, if the national DOH makes a recommendation to health care facilities and providers (e.g., regarding national protocols and guidelines), such facilities and providers will implement the recommendation and purchase the recommended medical devices, supplies, and equipment, if any are mentioned or specified.

The national DOH does not prescribe which medical devices, supplies and equipment (including neonatal resuscitation devices) the provincial DOHs must purchase, and will only recommend what they determine is a standard need. Detailed information about the procurement process being used in all nine provinces of South Africa is available upon request.

There was no evidence that the national DOH has purchased any neonatal resuscitation devices in the past five years, and this is unlikely to change. The only time that the national DOH would purchase medical devices is when they want to accelerate implementation in a priority area, and this is usually done in a facilitative capacity (e.g., securing funds for medical devices from UNICEF).

What is the current and potential market size for neonatal resuscitation devices in SADC countries?

- ❖ Based on the reported number of neonatal resuscitation devices obtained in the past year by either purchase or donation, the 2007 market demand was at least 72,000 neonatal resuscitation devices in SADC countries.
- ❖ Future market potential taking into account existing number of devices available and need, is estimated to be lower, at 38,000 devices.
- ❖ Although there is clearly a need for neonatal resuscitation devices in SADC countries (i.e., a latent market of organizations that share a need for high quality, affordable neonatal resuscitation devices that is currently not addressed), market attractiveness may be limited due to limited purchasing power and excessive importation procedures.

2007 Market Demand for Neonatal Resuscitation Devices

The estimated number of devices obtained either through procurement or donation in SADC countries in 2007 (*excluding* South Africa) was 72,000. The estimated monetary value of these devices is US$5.54 million. These estimates are based on:

- The number of reported neonatal resuscitators obtained from key informants. When a range was provided, the lowest number was used.
- The average per unit cost of a neonatal resuscitator per country was estimated based on information from informants as well as what devices were available in that respective country and at what price. The purchasing price ranged from US$10 to US$225 with an overall average of US$77.

No estimates of 2007 devices obtained were available for South Africa, given its decentralized structure.

Future Market Potential

Based on country health care facility figures, there are at least 19,100 facilities in the SADC region (figures includes South Africa). In 2006, the World Bank estimated the total population in SADC countries at approximately 202 million with an average annual population growth rate of 1.89 percent. This translates into an estimated 5.2 million births per year. That would mean, on average, roughly 272 babies delivered per year per health care facility in SADC.

While the number of neonatal resuscitation devices procured in 2007 would theoretically allow for every health care facility to have at least one device, data suggests that distribution is not uniform and that neonatal resuscitators are heavily concentrated at larger facilities. Qualitative data, however, suggests that facilities with the least amount of resources see the most people and may in fact deliver babies in the event that a patient cannot be referred to a more appropriate institution. Given there are currently no standards available for the recommended number of

neonatal resuscitators per facility, it was estimated that every facility should have at least two devices, for a total of 38,000.[*]

The potential market was therefore estimated to be 38,000 neonatal resuscitators. At a cost of US$30 per unit, this amounts to approximately US$1.15 million. This potential market size aligns with qualitative data gathered from participants that the future market size would be less than the 2007 estimates of devices purchased or obtained.

Which importation channels are used for neonatal resuscitation devices in SADC countries?

- ❖ Exports and imports between SADC countries are more cumbersome than exports and imports from other countries.

Exports and imports between SADC countries are more cumbersome than exports and imports from other countries outside the SADC region. It takes less time to import from non-SADC countries to SADC countries, that is, if importation is not within the SADC region.

Most SADC countries require adherence to specific medical device import regulations, usually governed by revenue services, ISO-equivalent standards, and internal standards authority approval (e.g., Botswana Bureau of Standards, Mauritius Safety and Standards Body, Mauritius Foods, Drugs and Pharmaceutical Board, South African Bureau of Standards, Swaziland Safety and Quality Standards Bureau, Swaziland Quality Authority, Swaziland Medical Technical Committee, Tanzania Food and Drug Authority, International Electrotechnical Commission, and Zambia Bureau of Standards).

Importation requirements differ among countries and can be complicated. For example:

- The number of documents required for imports range between 7 (Mauritius) and 19 (Zambia), with the smallest number of documents required for imports into Botswana, Lesotho, Mauritius, and South Africa.
- The time it takes to import goods ranges from 16 (Mauritius) to 92 (DRC) days.
- Import tariffs range from an average of 0 percent (Mauritius) to 120 percent (Tanzania) final bound *ad valorem* duties, with lowest tariffs in Mauritius, Botswana, Namibia, South Africa and Swaziland. For most favored nations imported from, tariffs range between 20 percent and 30 percent.

SADC countries' diversity in income (South Africa accounts for 69 percent), population size, and geography is reflected in their import and export profiles, regulations, and tariffs. For example, Botswana, Lesotho, Namibia, Swaziland, Malawi, Mozambique, Zambia, and Zimbabwe depend heavily upon SADC for imports. In contrast, Angola, DRC, Madagascar, Mauritius, Seychelles, South Africa, and Tanzania trade extensively with countries outside of the SADC region. South Africa has the most exports and is the largest importer in SADC bilaterally.

[*] Larger facilities that already have neonatal resuscitation devices available were not eliminated because it is likely that they have older devices that need to be replaced.

What is the distribution and manufacturing capacity for neonatal resuscitation devices in SADC countries?

- ❖ Distribution channels vary by country with international aid organizations (i.e., UNICEF and missionary organizations through their hospitals) playing an important role in all SADC countries except South Africa. The main distributor was reported to be the government, except in Zambia and South Africa.
- ❖ No distributors were identified that supply medical devices to all SADC countries. Two distributors provide technical support to all SADC countries.
- ❖ Most SADC country representatives felt that their country did not have manufacturing capacity, except in Zambia and South Africa where representatives indicated that they could probably manufacture locally.
- ❖ Only one device reported to be in use was manufactured locally—the Samson bag and mask device—manufactured by Adcock Ingram. This device is prohibited from being used in at least one province in South Africa.
- ❖ The top three manufacturers and distributors identified as candidates for further discussion were (in rank order):
    1. Brittan Health Care (manufacturing and distribution)
    2. TecMed Africa (distribution)
    3. VIASYS International/Cardinal Health (manufacturing and distribution)

Seventy-five potential manufacturers and distributors of neonatal resuscitation devices were identified in consultation with PATH. The following screening criteria were then applied:

1. Existing distribution of neonatal resuscitation devices in any SADC country or countries.
2. Existing neonatal resuscitation device manufacturing, with any SADC presence.
3. Other distributors and manufacturers mentioned in SADC.

This process resulted in narrowing the group down to 17 manufacturers and distributors (see Table 3 below).

Table 3: Screened Manufacturers and Distributors

Manufacturer	Device	Distributor
1. Ambu	Silicone resuscitators	SSEM Mthembu Medical (South Africa)
2. Atom, Galemed	Resuscitators	*STAT Medical (South Africa)**
3. Besmed	Silicone manual resuscitator	East Coast Medical Equipment (South Africa)
4. Nellcor/Tyco Healthcare	PMR 2 reusable resuscitation bag	Covidian/Trigate (South Africa)
5. Spiracle	Disposable bag mask resuscitators Silicone bag mask resuscitators	*Brittan Health Care (South Africa)**
6. Adcock Ingram (South Africa)	SSR 0010 Samson	Adcock Ingram (South Africa)
7. Cardinal Health	Cardinal Health disposable resuscitation bags	*VIASYS International**
8. Smiths Medical	Portex® 1st Response™ infant manual resuscitators	Smiths Medical (Mauritius, South Africa)
9. Unspecified	Pre-hospital emergency care equipment	Dismed Group (South Africa)
10. Unspecified	Unspecified	*TecMed Africa (South Africa)**
11. Enter Medical Corporation (Taiwan)	Enter medical resuscitator	Enter Medical Corporation (Mid-East / Africa Market)

Manufacturer	Device	Distributor
12. Zeal Medical* (India)	Infant resuscitator RSB 1001	
13. VBM (Germany)	Silicone resuscitation Bag, and PVC	VBM (Germany)
14. Gabler Medical (South Africa)	Unspecified	*Gabler Medical (South Africa)**
15. Unomedical (Australia)	Hospitak MPR and mouth to mask resuscitators	Unomedical (Australia)
16. Headstar Medical Products	HS-9788A silicone manual resuscitator (Infant)	*PALMED Medical and Surgical Supplies**
17. Laerdal Medical	Laerdal silicone manual resuscitator	Duromed (South Africa)

**Placed on short-list of manufacturers/distributors.*

After making initial contact with all the manufacturers and distributors identified above, eight were short-listed, based on interest and willingness to extend their markets to SADC countries. These companies were ranked, based on presence in SADC countries, existing distribution systems appropriate to the type of device, a means of supporting technical sales, the capacity to facilitate national device registrations, the ability and experience in responding to national procurement and tender processes, and financial stability (company information and ranking details are available upon request).

Based on the final ranking, companies were contacted to establish their interest and willingness to initiate discussions with PATH and to confirm the best point of contact. The top three manufacturers and distributors identified as candidates for further discussion were:

1. Brittan Health Care (manufacturing and distribution)
2. TecMed Africa (distribution)
3. VIASYS International/Cardinal Health (manufacturing and distribution)

In Zambia and South Africa, key informants mentioned several manufacturers that might have potential for medical device production—Philips Healthcare[†], Brittan Health Care[‡], Guido Rayos X, S.A.[§], and Gabler Medical.[**] Further investigation would be needed to determine the feasibility of integrating production of neonatal resuscitators into their ongoing operations.

RECOMMENDATIONS

Recommendations for improving the availability and access to high-quality, affordable neonatal resuscitation devices in the SADC region have been formulated based on the findings from this report. The recommendations focus on establishing purchasing standards and channels and increasing demand. The recommendations delineate a multipronged approach specific to SADC countries, South Africa, and UNICEF. We believe that this strategic approach will be necessary to ensure maximum availability and access of neonatal resuscitation devices in the region.

Specific recommendations for SADC, South Africa, and UNICEF are as follows:

[†] www.philips.co.za/about/company/local/index.page
[‡] http://www.bhc.co.za/
[§] www.guidorx.com/ingles/htm/index htm
[**] www.gablermedical.com

South African Development Community

1. Explore the level of interest and willingness of the top three candidate distributors of high-quality, affordable devices, all of which are based in South Africa, namely Brittan Health Care, TecMed Africa, and VIASYS International/Cardinal Health, to:
    - Form links between distributors and manufacturers of high-quality, affordable neonatal resuscitation devices for distribution in SADC countries.
    - Expand distribution capacity of existing SADC neonatal resuscitation device distributors to include all SADC countries.
    - Submit tenders and be listed as suppliers to each SADC country, as appropriate.
2. Explore the level of interest and willingness of an additional group of distributors based in South Africa that were not responsive to market survey requests for additional information but that may have potential to form necessary distribution linkages with SADC countries. An additional group of distributors includes East Coast Medical and PALMED Medical and Surgical Supplies. East Coast Medical distributes the Besmed device which was rated highly in prior user testing.[6] PALMED Medical and Surgical Supplies is already one of the preferred suppliers listed in the South Africa national tender for resuscitation devices.
3. Explore level of interest, willingness, and feasibility of having Zeal Medical, based in India, set up distribution and local support networks for their resuscitation products (bag and mask and tube and mask designs) in SADC countries.
4. Investigate the feasibility of integrating production of reusable neonatal resuscitators into ongoing operations of Brittan Health Care medical devices production line through their original equipment manufacturing division.
5. Advocate with national governments in SADC countries for suitable warehousing to ensure stock availability.

South Africa

1. Advocate at the national DOH level, specifically with the Maternal, Child, and Women's Health and Nutrition Cluster, to ensure that:
    - Maternal and newborn care guidelines specifically recommend the availability of high-quality, affordable, bag and mask neonatal resuscitation devices, and possibly specific brands and models, manufacturers and/or distributors.
    - Standards and protocols for neonatal resuscitation, neonatal resuscitation devices, and the ideal number of devices per health care facility are adopted.
    - Standards and protocols for neonatal resuscitation, neonatal resuscitation devices, and the ideal number of devices per health care facility are disseminated to all public health care facilities.
2. If procurement is centralized at the provincial level, advocate with manufacturers and distributors of high-quality, affordable neonatal resuscitation devices to:
    - Ensure that they submit tenders and are listed as suppliers to each of the nine provinces in South Africa.
    - Establish suitable warehousing to ensure stock availability (distributors only).
3. Advocate at the public health care facility level to:
    - Increase procurement department awareness of national treasury funding available for purchasing neonatal resuscitation devices.
    - Ensure that high-quality, affordable neonatal resuscitation devices are available on medical supplies ordering lists kept by procurement departments.

- Lobby for policy development that requires funding for regular in-service training (including refresher) in the use of neonatal resuscitation devices.
- Facilitate the provision of regular in-service training (including refresher) in the use of neonatal resuscitation devices.

UNICEF

UNICEF plays a pivotal role in neonatal resuscitation device procurement and purchasing, and was mentioned in relation to medical device supply by all SADC country representatives interviewed. Local UNICEF offices are authorized to undertake local procurement up to US$50,000 for items such as medical devices. UNICEF has local offices in Angola, Botswana, DRC, Lesotho, Namibia, Madagascar, Malawi, Mozambique, Seychelles, South Africa, Swaziland, Tanzania, Zambia, and Zimbabwe (the Mauritius office closed at the end of 2003). Key actions related to UNICEF include:

- Advocate with UNICEF Copenhagen to ensure that high-quality, affordable neonatal resuscitation devices are available through their supply catalog.
- Seek inclusion of high-quality, affordable neonatal resuscitation devices in the UNICEF reference list of supplies, equipment, and drugs being used at the country level through UNICEF Procurement Services.
- Determine the best way to encourage development agencies or governments in the SADC region to request UNICEF Procurement Services (i.e., medical devices focus area) to order and purchase high-quality, affordable neonatal resuscitation devices
- Bundle distribution efforts to include neonatal resuscitation devices purchased through UNICEF with other UNICEF medical supplies to public and private health care facilities in SADC countries (excluding South Africa).

Furthermore, it will be important to liaise with other key international stakeholders to advocate for the inclusion of high-quality, affordable neonatal resuscitation devices in standardized protocols for neonatal resuscitation, and to determine the ideal number of neonatal resuscitation devices per health care facility (based on number of deliveries). Key international stakeholders include the Neonatal Resuscitation Program Global Task Force of the American Academy of Pediatrics; WHO; NICHD Global Network; International Pediatric Association; Laerdal Foundation for Acute Medicine; Partnership for Maternal, Newborn, and Child Health; Saving Newborn Lives; and USAID.

RESOURCES

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APPENDIX 1

UNICEF Complete Midwifery Kit

(Retrieved from http://www.supply.unicef.dk/catalogue/bulletin4.htm on July 11, 2008)

A complete UNICEF Midwifery Kit includes the following component kits:

Catalogue number	Item	Amount
9902217	Midwifery Kit, 1 – Drugs	1 unit
9902220	Midwifery Kit, Supplementary 1a – Drugs	1 unit
9902218	Midwifery Kit, 2 – Equipment	1 unit
9902219	Midwifery Kit, 3 – Renewable	1 unit
9908200	Sterilisation Kit C	1 unit
9908400	Resuscitation Kit, Basic	1 unit

Detailed Kit Information

Midwifery Kit, 1 – Drugs

Technical Specifications: This kit represents the basic requirements of drugs to facilitate around 50 normal deliveries.

Note: Drugs which need import authorizations and/or cold chain, are packed separately. Please refer to catalogue number 9902220 – Midwifery kit, supplementary 1a – Drugs.

Kit contents/Description:
5 x 1505040 - Amoxicillin 250 mg caps/tabs /PAC-1000
2 x 1555650 - Metronidazole 250 mg tabs /PAC-1000
20 x 1510000 - Tetracycline eye ointment 1% /TBE-5g
5 x 1555205 - Lidocaine inj 1% 50 ml vial /BOX-5
1 x 1564326 - Sodium chl.inj 0.9% 500 ml w/giv.s /BOX-20
1 x 1552106 - Glucose inj 5% 500 ml w/giv.set /BOX-20
1 x 1560811 - Sod.lactat.comp.inj 500 ml w/g.set /BOX-20
1 x 1543805 - Water for inj. 10 ml amp /BOX-50
2 x 1531505 - Chlorhexidine conc. sol. 5% /BOT-1000 ml
5 x 1553105 - Povidone iodine sol 10% /BOT-500 ml
1 x 0584005 - Test strips, urinalysis, gluc/prot /PAC-100
5 x 1550025 - Fe(as fum.)+folic 60+0.4mg tab/PAC-1000
1 x 1559360 - Magn.sulph.inj 500mg/ml 10ml amp /BOX-100

Midwifery Kit, supplementary 1a – Drugs.

Technical Specifications: The Supplementary 1a – Drugs contains medicines that normally need import authorizations (narcotic/psychotropic substances). Since this kit is usually urgently required and needs to be shipped within 24 hours, it does not allow time to apply for import and export authorizations. *Note:* This kit is complementary to catalogue number 9902217 – Midwifery Kit, 1 – Drugs.

Kit contents/Description:
5 x 1562020 - Salbutamol oral inh. 0.1 mg/ds 200 ds
5 x 1545300 - Oxytocin inj 10 IU 1 ml amp /BOX-10
1 x 1543625 - Diazepam inj 5 mg/ml 2 ml amp /BOX-10

Midwifery Kit, 2 – Equipment

Technical Specifications: This kit consists of basic medical equipment (initial investment) for one delivery room and/or one maternity ward.

Kit contents/Description:
1 x 0683200 - Sphygmomanometer (adult), aneroid
1 x 0686000 - Stethoscope, binaural, complete
2 x 0686500 - Stethoscope, foetal, Pinard
2 x 0567000 - Tape-measure, vinyl-coated, 1.5 m/5 feet
2 x 0211000 - Basin, kidney, stainless steel, 825 ml
2 x 0279000 - Tray, dressing, ss, 300 x 200 x 30 mm
2 x 0225000 - Bowl, stainless steel, 600 ml
2 x 0216000 - Bowl, round, stainless steel, 4 L
2 x 0214020 - Bowl, round, polypropylene, 6 L
2 x 0333500 - Jar, forceps, pp, 180 mm, w/o cover
2 x 0334200 - Jar, thermometer, pp, 11 cm, w/o cover
2 x 0722500 - Forceps, dressing, Cheron, 250 mm
4 x 0270000 - Tray, instr, ss, 225 x 125 x 50 mm,w/cover
2 x 0514000 - Brush, hand, scrubbing, plastic
2 x 0361020 - Drawsheet, plastic, 90 x 180 cm
2 x 0305000 - Apron, protection, plastic
2 x 0385000 - Tourniquet, latex rubber, 75 cm
5 x 0575000 - Towel, huck, 430 x 500 mm
1 x 0557000 - Scale, infant, springtype, 5 kg x 25 g
1 x 0557200 - Sling for use w/0145555, 0557000, 0557100
1 x 4460005 - Pen,ball-point,blue/BOX-10
1 x 4410010 - Book,exercise,A5,ruled-8mm,48 pgs/PAC-20
10 x 0481053 - Thermometer,clinical,digital,32-43ºC
2 x 9910003 - Surg.inst., delivery /SET:

Set contents:
1 x 0770500 - Scissors, Mayo, 140 mm, cvd, b/b
1 x 0774700 - Scissors, gyneco, 200 mm, cvd, b/b
2 x 0726000 - Forceps, artery, Kocher, 140 mm, str
2 x 9910004 - Surg.inst., suture /SET:

Set contents:
1 x 0773550 - Scissors, Deaver, 140 mm, cvd, s/b
1 x 0743600 - Needle holder, Mayo-Hegar, 180 mm, str
1 x 0726000 - Forceps, artery, Kocher, 140 mm, str
1 x 0745500 - Scalpel handle, no.4
1 x 0737000 - Forceps, tissue, standard, 145 mm, str
1 x 0759820 - Probe, double-ended, 145 mm

Midwifery Kit, 3 – Renewable

Technical Specifications: This kit represents the basic requirements of renewable medical supplies (consumables) to facilitate around 50 normal deliveries. Most of the items are sterile and disposable.

Kit contents/Description:
36 x 0552000 - Soap, toilet, bar, 110 g, wrapped
25 x 0328501 - Gloves, surg, 7, ster, disp, pair
25 x 0329510 - Gloves, surg, 8, ster, disp, pair
25 x 0330102 - Gloves, gynaeco, 7.5, ster, disp, pair
2 x 0330011 - Gloves, exam, latex, medium, disp /BOX-100
2 x 0566005 - Tape, umbilical, 3 mm x 50 m, non-ster
50 x 0322010 - Catheter, urethral, CH12, ster, disp
50 x 0319000 - Extractor, mucus, 20 ml, ster, disp
50 x 0374015 - Tube, suction, CH10, L50 cm, ster, disp
25 x 0374025 - Tube, suction, CH14, L50 cm, ster, disp
10 x 0366010 - Syringe, feeding, 50 ml, conical, ster
1 x 0564040 - Sut, abs, DEC4, need 3/8 50mm, round /BOX-36
1 x 0564004 - Sut, abs, DEC2, need 3/8, 26 mm, tri /BOX-36
50 x 0709220 - Cannula, IV short, 20 G, ster, disp
50 x 0744400 - Needle, scalp vein, 21 G, ster, disp
120 x 0523055 - Compress, gauze, 10 x 10 cm, ster. /PAC-5
5 x 0523005 - Compress, gauze, 10 x 10 cm, n/ster, PAC/100
12 x 0503010 - Tape, adhesive, Z.O., 2.5 cm x 5 m
1 x 0782413 - Syringe, dispos, luer, 10 ml, ster /BOX-100
1 x 0782205 - Syringe, dispos, luer, 2 ml, ster /BOX-100
1 x 0747432 - Needle, disp, 21 G x 1.5", ster /BOX-100
1 x 0747420 - Needle, disp, 19 G x 1.5", ster /BOX-100
5 x 0519600 - Cotton wool, 500 g, roll, non-ster

1 x 0782208 - Safety box f.used syrgs/ndls, 5 lt /BOX-25
5 x 0572510 - Blanket, survival, 220 x 140 cm
5 x 0521425 - Envelope, plastic, 10 x 15 cm, /PAC-100
100 x 0746510 - Scalpel blade, ster, disp, no.22

Sterilization Kit C

Technical Specifications: This kit consists of basic steam sterilization equipment to ensure foolproof sterilization facilities in all types of environment, including emergency situations.

Kit contents/Description:
1 x 0170000 - Stove, kerosene, single-burner, pressure
1 x 0156000 - Sterilizer, steam, 39 L
1 x 0983400 - Timer, 60 min x 1 min
1 x 0558100 - Indicator TST control spot /PAC-300
2 x 0106000 - Drum, cylindrical, 165 mm diameter
2 x 0107700 - Drum, cylindrical, 260 mm diameter
2 x 0108000 - Drum, cylindrical, 290 mm diameter
1 x 0726000 - Forceps, artery, Kocher, 140 mm, str.

Resuscitation Kit, Basic

Technical Specifications: This kit consists of basic resuscitation equipment to facilitate resuscitation in all types of environment, including emergency situations.

Kit contents/Description:
1 x 0760640 - Pump, suction, foot-operated
1 x 0845000 - Resuscitator, hand oper., infant/child
1 x 0845001 - Resuscitator, hand-oper., adult
1 x 0390010 - Airway, Guedel, size 00
1 x 0390020 - Airway, Guedel, size 0
1 x 0390030 - Airway, Guedel, size 1
1 x 0390040 - Airway, Guedel, size 2
1 x 0390050 - Airway, Guedel, size 3
1 x 0390060 - Airway, Guedel, size 4