Comparative Study of the Functionality and Acceptability of Four Neonatal Resuscitation Devices

Maternal and Newborn Technology Initiative Project PATH, Durban, South Africa

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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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Introduction

Perinatal outcomes are much worse in South Africa than in other upper-middle-income countries; the estimated newborn mortality rate is 24 deaths per 1,000 live births. This number is indefensible considering that over 95 percent of women attend antenatal care and 84 percent of women give birth in a medical facility.[1] Causes of neonatal mortality in under-resourced countries include prematurity, birth asphyxia (hypoxia), sepsis, and congenital abnormalities. An estimated five million babies sustain birth asphyxia in under resourced countries each year, of which one million die and another million live with mental and physical sequelae.[2] In South Africa birth asphyxia is responsible for up to one in three neonatal deaths.[3] Specifically, intrapartum asphyxia and birth trauma account for 23 percent of fresh stillbirths in South Africa while Perinatal Problem Identification Project data attribute 37 percent of neonatal death in babies over 1,000 grams to birth asphyxia.[3] This impact can be mitigated through improved antenatal care; better intrapartum monitoring; and effective neonatal resuscitation, including provision of high-quality, affordable resuscitation equipment. According to the World Health Organization (WHO), the essential requirements for basic newborn resuscitation are a bag-and-mask resuscitator for ventilation, a mucus extractor for suctioning, a source of warmth for thermal protection, and a clock.[4]

Ensuring that appropriate neonatal resuscitators are available at every birth and used correctly, as stated in current South Africa Department of Health (DOH) policy, is critically important in the management of birth asphyxia and in minimizing its associated sequelae. In South Africa, the lack of adequate neonatal resuscitation equipment and poor neonatal resuscitation skills amongst health care providers have been identified as contributing factors in these often avoidable neonatal deaths.[5,6] All health care workers who conduct deliveries should be equipped and able to provide neonatal resuscitation to prevent birth asphyxia. This has been a recommendation of the *Saving Babies: Perinatal Care Survey of South Africa* reports for the last three years.[3] This participatory evaluation of neonatal resuscitation devices served as a crucial first step to expand accessibility, availability, and use of appropriate and effective neonatal resuscitator devices to those South African populations in need.

Research Goal and Objective

The goal of this study was to reduce neonatal mortality and childhood disability in South Africa by ensuring that health care providers have access to affordable, high-quality neonatal resuscitation devices and have appropriate skills in neonatal resuscitation. This study used a participatory methodology to engage users and potential users within the health system in the evaluation of the functionality and acceptability of a select group of resuscitators and to gather input from a focus group discussion about the relative merits of each device. The objective of this assessment was the identification by local stakeholders of appropriate and cost-effective neonatal resuscitators for use by South African health care providers. This evaluation report will provide information to government and industry—both manufacturers and distributors and other relevant stakeholders involved in the supply chain—to ensure that the most appropriate neonatal resuscitators are being purchased and used. Specifically, this report will be directed to the KwaZulu-Natal (KZN) provincial DOH detailing

recommendations on the preferred neonatal resuscitators for all maternity units in the province.

Methods

Participatory decision-making processes often generate individual and organizational investment in health system improvements. Involving district-level health care workers in participatory approaches allows them to provide constructive input about real-life challenges incurred during the provision of routine services and to take ownership of appropriate solutions they create. Further, the participatory approach is often used in interventions aimed at strengthening health systems because it increases the sustainability of quality improvements.

This study employed participatory methodology by engaging providers and potential providers of neonatal care in the evaluation of four resuscitation devices during a one-day workshop for health care providers from a variety of service levels. The workshop reviewed the pathophysiology of neonatal asphyxia and principles of neonatal resuscitation, updated participant neonatal resuscitation skills, and allowed providers to voice their preferences with regard to specific preselected resuscitation devices. Providers evaluated four neonatal resuscitation devices with respect to ease of use including disassembly, reassembly, cleaning, and functionality. They also generated and agreed on the minimum requirements for appropriate and affordable neonatal resuscitation devices to be used at all levels of the health system.

Four, one-day workshops were conducted in collaboration with the local DOH in KZN and included midwives, advanced midwives, and doctors. In each district, the maternal, child, and women's health coordinator was asked to identify appropriate workshop participants. Selection criteria included participants from both district hospital and community health center facilities (primary health care level was not included because a large proportion of these clinics do not conduct deliveries) as well as staff with varying experience in neonatal resuscitation. In addition, in each district, we invited the individual designated as the "Primary Health Care Trainer." Participants were not paid although refreshments/snacks were offered to them during the workshop. The study protocol underwent ethical review and received ethical approval from the Nelson R. Mandela School of Medicine, University of KZN.

The workshops were held in Durban, iLembe, Sisonke and uMzinyathi districts. The workshops were designed to allow participants to review and standardize their neonatal resuscitation knowledge and practice their resuscitation skills. All participants received a copy of the South African Paediatric Association *Handbook of Resucitation of the Newborn* which served as the basis for the refresher course and allowed for standardization of the resuscitation techniques used in the simulation exercise to evaluate the resuscitation devices.[7] Current best practices for neonatal resuscitation include fitting the mask to the mannequin's face, proper respiration rate, proper breath pressure (for mouth-to-mask resuscitators), and chest observation were covered.

After the refresher course, participants were asked to use and evaluate four different resuscitation devices in turn, using infant mannequins at four different stations. In particular they were requested to use each device according to current best practice (e.g., correct airway positioning, observation of chest during resuscitation, correct position of facemask, etc.) in a simulated resuscitation scenario and disassemble and reassemble the device without instructions. Participants recorded their observations about individual devices using a structured 5-point Likert-type scale instrument before moving on to the next station.

Participants identified their individual device preferences first by completing a form and thereafter by sharing their preferences with the group by recording their "votes" (coloured dots) on newsprint. The votes were tallied to identify the top three devices chosen by each group. A focus group discussion followed, and participants were encouraged to explore and share their preferences and concerns with the devices that they had evaluated. Finally, participants broke into smaller groups to identify desirable features of neonatal resuscitators for their clinical conditions and to distill from this a set of minimum standards for appropriate and affordable resuscitation devices.

Prior to the beginning of each workshop, research staff obtained informed consent from all participants. Once informed consent was obtained, research staff collected demographic data from each participant (Appendix A). All data collection was carried out in health care facility meeting rooms in an appropriate location in each district. The meeting rooms were located away from the patient wards so that privacy was ensured.

Throughout this process, two medical doctors who are well versed in neonatal resuscitation facilitated the workshops. One of these doctors facilitated the focus group discussion, and a second research staff person took notes. Focus group discussions were audio taped and transcribed. A focus group discussion guide (Appendix D) consisting of open-ended topics was used to facilitate/guide the group discussions. Discussions were conducted in English, and notes were taken in same. The qualitative information generated through the workshop activities was used as the basis of a discussion to generate and agree on minimum requirements for appropriate and affordable resuscitation devices to be used at all appropriate levels of the health system.

The first workshop, which took place in Durban, pretested the assessment methodology. Based on the pretest experience, research staff made several adjustments in workshop logistics and flow.

Materials

Neonatal resuscitation equipment is manufactured in various locations around the world (although not in sub-Saharan Africa) with the intent of global distribution. Providers evaluated the following four reusable bag-and-mask devices (Figures 1,2,3,4):

Figure 1: Laerdal silicone bag and mask.
(Norwegian manufacture, US$225; www.laerdal.com)

Figure 2: Headstar medical product silicone bag and mask.
(Taiwanese manufacture, US$20; www.headstarmedical.com)

Figure 3: Besmed bag and mask.
(Taiwanese manufacture, US$20; www.besmed.com)

Figure 4: HI-CARE bag and mask.
(Italian manufacture, US$56; website unavailable.)

Data Collection Procedures

Four designated device stations were created (one for each device); they were labeled with the device name, manufacturer, cost, and information related to projected availability in South Africa. Three devices were placed at the designated device station (Figure 5). Participants were divided into groups of three to four people. Each group went to all device stations. While at the device station, participants took turns using the designated device for two and five minutes. Other members in their group timed the simulated use session and assessed the respiration rate during each session using a stopwatch. Participants chose to use the resuscitator with mannequins on either the table or the floor. With no instruction, participants disassembled resuscitators to their primary components. After disassembly, participants reassembled the resuscitators. Participants recorded observations about each device on data-collection sheets utilizing a 5-point Likert-type scale to assess variables related to device usability (Appendix B). After each participant had evaluated all four devices, they completed the overall neonatal device evaluation form(Appendix C) to identify device preferences at the individual level.

Figure 5: Headstar device station.

Participants used nominal group process to identify preferred devices at the group level. First, participants chose their three most preferred devices. To do this, newsprint with the name of each device written on it was taped to the wall of the meeting room. Each participant received three round self-adhesive dots that acted as votes to indicate device preferences.

Participants put the dots on the newsprint next to their preferred devices. One to three dots could be used on a device. Research staff tallied the votes to identify the top three devices preferred by the group.

A focus group discussion explored the results of the nominal group process more thoroughly. During the focus group discussion, participants discussed their experience using the resuscitators, issues with assembly/disassembly, ergonomics, and correct use. Finally, participants were divided into two small groups to develop a set of minimum standards for neonatal resuscitation devices for each level of service delivery. Each small group presented their list to the larger group; the lists were then compiled into one list of minimum standards.

Data Analysis

All data was analyzed using SPSS 12.0 for Windows. Descriptive statistics were generated in order to provide statistical background on each study participant. Device usability was measured as the mean of scores generated from a 5-point Likert-type scale for human factor variables related to mask size and shape, materials, and ease of use. A similar set of scores was generated for variables related to disassembly/reassembly and affordability. A summary device usability score was measured as the mean of all scores on the device usability index.

Statistical tests were carried out to explore differences in quantitative variables related to medical qualification, gender, and district. Qualitative data from the focus group discussions were cleaned and coded following transcription of the data. A set of codes was developed, and data were manually sorted into like-coded blocks of text. Text blocks associated with codes were analyzed for association with other codes. For central themes, data matrices were used to examine differences by medical qualification, gender, and district.

The primary outcome indicator for device preference was the proportion of users who ranked each device as their first choice (individual level) and the proportion of groups that selected each device as their top choice (group level).

Results

A total of 34 health workers participated in one of three workshops held in uMzinyathi, iLembe, or Sisonke districts. Demographic data were collected for all but one participant. Participant characteristics are described in Table 1. The participants were primarily midwives (79 percent) and some medical officers (21 percent). Most participants (80 percent) were affiliated with district-level institutions. Many (59 percent) but not all participants had prior resuscitation experience with the Laerdal resuscitation device. About three-fourths (76 percent) of participants had been trained in neonatal resuscitation at least once since their basic medical training. 14 of the 19 participants who reported their most recent neonatal resuscitation training date had been trained less than three years ago.

Table 1: Participant characteristics.

	Midwife/advanced midwife (n=26)*		Medical officers (n=7)*	
	n	percent	n	percent
Gender				
Male	1	4	4	57
Female	25	96	3	43
Institutional affiliation				
Regional	2	8	0	0
District	19	79	5	83
Community health center	1	4	1	17
District office	2	8	0	0
Years since qualification				
Mean + standard deviation	14.6+8.6		8.7+5.6	
Range	1-30		3-18	
Years in maternity/neonatal services				
Mean + standard deviation	10.8+6.5		4.5+3.6	
Range	1-25		0-10	
Estimated number deliveries per month				
Mean + standard deviation	188.1+152.2		19.4+34.2	
Range	0-500		0-80	
Estimated number resuscitations per month				
Mean + standard deviation	6.9+4.2		7.2+7.0	
Range	0-15		2-20	
Previous use of resuscitators, by type				
Laerdal	13	52	6	86
Samson/other devices**	12	48	1	14
Type of Previous resuscitation training				
Formal	11	61	5	71
In-house	7	39	1	14
Both	0	0	1	14

*Column totals are variable due to missing data.
**Ambu bag and mask was cited twice.

Each district workshop included both doctors and midwives of varying skill levels (Table 2).

Table 2: Number of participants by medical qualification and district.

	iLembe	Siskone	uMzinyathi	Total
Community service/medical officer	0	2	1	3
Principal medical officer	1	2	1	4
Midwife	5	4	3	12
Advanced midwife	5	3	6	14
Total participants	11	11	11	33

Devices were evaluated in five areas: (1) mask size and shape, (2) materials, (3) ease of use, (4) disassembly and reassembly, and (5) affordability. Mean and standard deviation for each relevant variable are displayed by device in the tables below. In addition, some data are

depicted as box plots (Figures 6,7,8,10). The box plot data are based on responses to a 5-point Likert-type scale where 1=very poor and 5=excellent. Each box plot shows the median, interquartile range, and extreme values (or outliers) for each of the four devices. The whiskers indicate the range of the data. The heavy horizontal bar depicts the height of the median. Devices are coded as follows:

A= Laerdal
B= Besmed
C= Headstar
D= HI-CARE

Two of our device evaluation parameters did not perform well. Participants did not feel able to assess (1) potential availability of the device and (2) quality of the use instructions. These variables were dropped from the analysis and are not reported here.

Mask Size and Shape

Generally, participants rated Laerdal as having the most appropriate size and shape of mask followed by Headstar, Besmed, and HI-CARE (Table 3).

Table 3: Mask characteristics.

	Laerdal			Besmed			Headstar			HI-CARE		
	n	Mean	sd*	n	Mean	sd*	n	Mean	sd*	n	Mean	sd*
Mask size	34	4.5	0.62	34	4.0	0.76	34	4.2	0.88	34	3.8	0.70
Mask shape	34	4.4	0.73	34	3.9	0.78	34	4.2	0.90	34	3.7	0.79

sd* = standard deviation.

Median scores for mask size were similar to the mean ranking; median score was highest for the Laerdal device (Figure 6). There was more variation in median scores for mask shape. The Headstar device was rated very favorably in this regard (Figure 7).

Figure 6: Median scores for mask size.

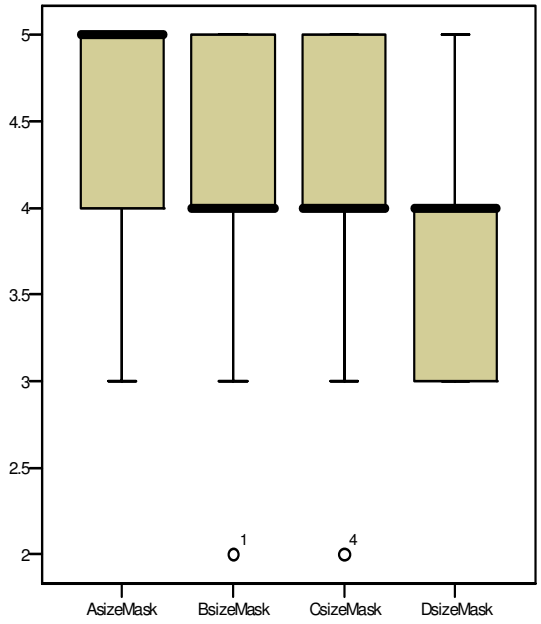
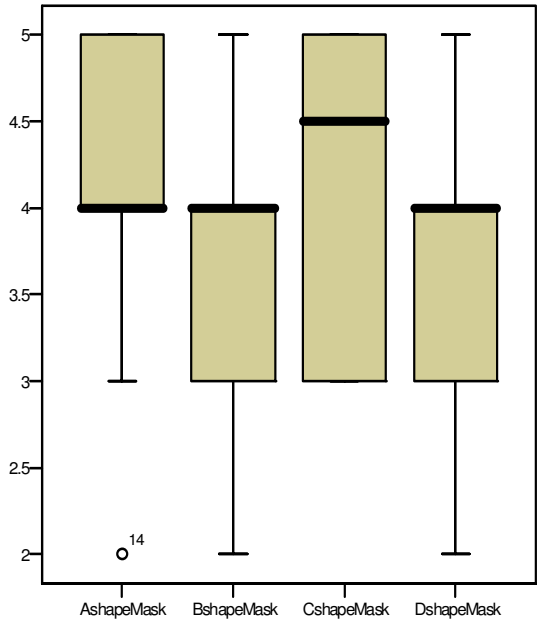


Figure 7: Median scores for mask shape.



Device Materials

Materials were assessed by two questions: (1) apparent durability of the device and (2) feel of device/bag material. In both aspects, participants rated the Laerdal device as being the most favorable (Table 4)(Figure 8).

Table 4: Materials.

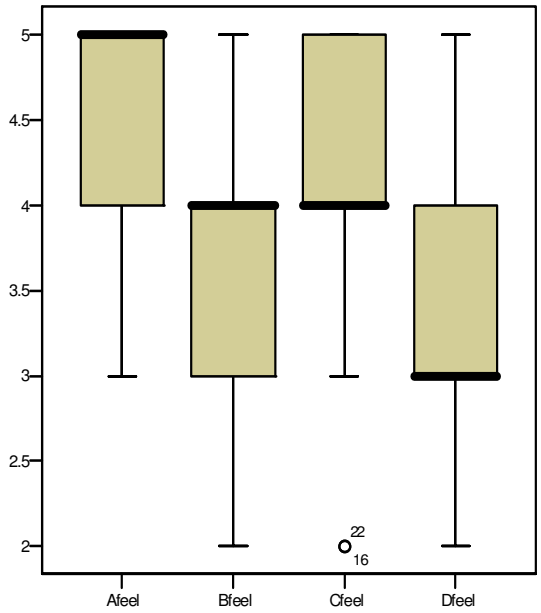
	Laerdal			Besmed			Headstar			HI-CARE		
	n	Mean	sd*	n	Mean	sd*	n	Mean	sd*	n	Mean	sd*
Feel device/bag material	34	4.5	0.62	34	3.6	1.05	33	4.1	0.86	34	3.3	0.96
Apparent durability	32	4.3	0.84	33	3.7	0.80	29	3.8	0.76	31	3.4	0.99

sd* = standard deviation.

At least one participant felt the bag material of the Besmed device to be too hard as described in the following quote from the focus group discussion:

> "For me, I did not like this bag [Besmed], it is hard and tough to use. By the time I finished, I actually needed resuscitation myself."

Figure 8: Median scores for device feel.



Ease of Use

Ease of use was assessed by the following seven variables: (1) ease of holding device, (2) comfort during use, (3) general ease of use, (4) ease of giving proper pressure/volume, (5) ease of giving proper frequency, (6) ability to observe neonate vital signs during use, and

(7) fatigue during use. The Laerdal device was consistently rated the highest in all variables related to ease of use (Table 5).

Table 5: Ease of use.

	Laerdal			Besmed			Headstar			HI-CARE		
	n	Mean	sd*	n	Mean	sd*	n	Mean	sd*	n	Mean	sd*
Ease of holding device	34	4.4	0.85	34	3.7	0.87	34	3.9	0.88	33	3.6	0.75
Comfort during use	34	4.4	0.74	34	3.8	0.99	34	3.8	0.96	32	3.3	0.96
General ease of use	33	4.3	0.68	33	3.6	0.78	33	3.9	0.89	34	3.3	0.98
Ease of giving pressure/volume	34	4.6	0.61	34	3.7	0.97	33	3.9	1.06	34	3.3	1.06
Ease of giving frequency	33	4.5	0.62	33	3.7	0.85	32	3.9	1.01	33	3.4	0.90
Ability to observe chest rise during use	34	4.4	0.50	34	4.2	0.78	33	4.3	0.80	33	3.8	0.83
Fatigue during use	34	4.5	0.83	34	3.8	0.94	34	3.9	0.95	32	3.6	1.07

sd* = standard deviation.

It must be noted that the Laerdal resuscitator used in this evaluation had a bag volume of 600 ml (paediatric size). Several participants worried that this might result in the delivery of inappropriately high volumes of air and barotrauma. Others countered that this would not be difficult with experienced users who would observe the neonate's chest rising and adjust the volumes accordingly. Interestingly, there was very little mention, across all focus group discussions, of the function and performance of pressure relief valves.

Disassembly and Reassembly

Disassembly and reassembly was assessed by two questions: (1) Ease of disassembly and reassembly and (2) need for instructions to successfully complete disassembly/reassembly. Participants rated the Laerdal device as being the most favorable option, followed closely by the Besmed device (Table 6).

Table 6: Disassembly and reassembly.

	Laerdal			Besmed			Headstar			HI-CARE		
	n	Mean	sd*	n	Mean	sd*	n	Mean	sd*	n	Mean	sd*
Ease of disassembly and reassembly	34	4.3	0.72	34	4.1	0.81	33	3.7	0.84	32	2.6	1.29
Need for instructions	34	4.3	0.81	33	4.4	0.71	33	4.0	0.85	32	3.4	1.31

sd* = standard deviation.

Figure 9: Disassembled Laerdal device.

One focus group discussion participant commented about the disassembled Laerdal device (Figure 9):

"The valve mechanisms are a different colour and quite distinct. They are all yellow. So when you are disassembling it is very easy and you do not lose sight of the parts."

Affordability

Affordability was the one category where the Laerdal device was rated lower than the other devices (Table 7).

Table 7: Affordability.

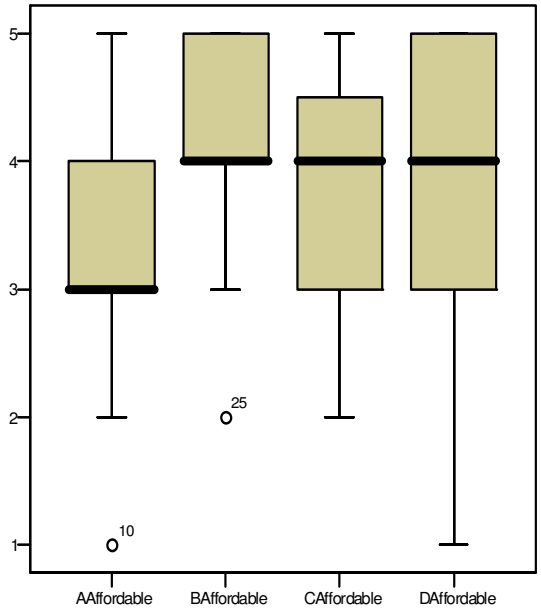
Laerdal			Besmed			Headstar			HI-CARE		
n	Mean	sd*	n	Mean	sd*	n	Mean	sd*	n	Mean	sd*
34	3.4	1.05	33	4.2	0.88	32	3.9	0.86	33	3.8	1.06

sd* = standard deviation.

This is likely due to the relatively high cost of the Laerdal device. Approximate prices for each of the devices that were evaluated range from around US$20 for the Besmed and Headstar device, to around US$56 for the HI-CARE device, and about US$225 for the Laerdal device. Median scores also reflected participant perspectives that the Laerdal device was less affordable than the other devices (Figure 10). Comments from the focus group discussion provide further elucidation:

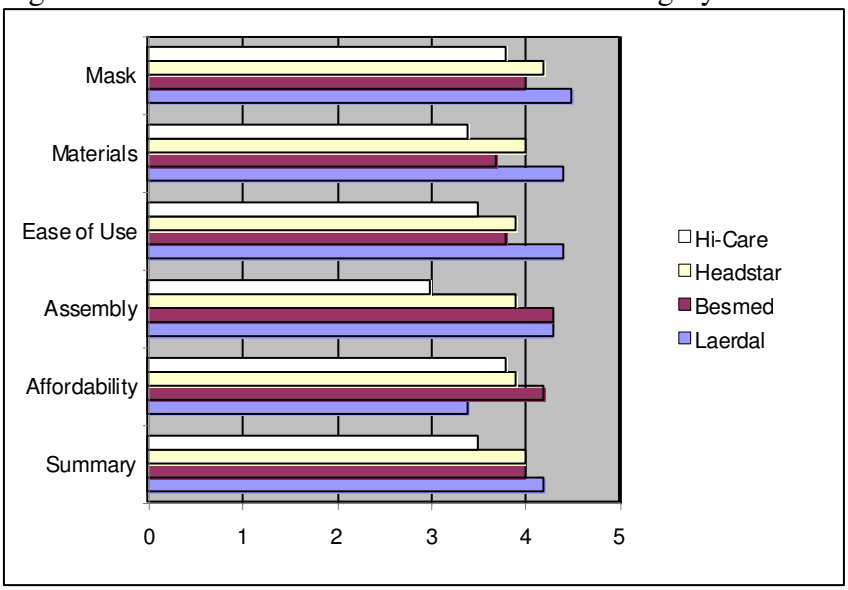
> "Device A [Laerdal] was a very good device to me but it was the most expensive compared to the other three. To be practical, I do not think our rural hospitals have budgets to buy this very good device."
>
> "So if money is the motivating factor, you could easily go for B [Besmed]."

Figure 10: Median scores for affordability.



In summary, the mean score for each evaluation category and a mean summary index score were calculated for each device (Figure 11). The mean summary index score is measured as the mean of all scores on the device usability index.

Figure 11: The mean score for each evaluation category.



Overall Device Preference

At the individual level, most users (82 percent) ranked the Laerdal device as their first choice (Table 8). The Besmed device was ranked as the second choice, followed by the Headstar device and then the HI-CARE device.

Table 8: Results from individual rankings (n=34).

	1st choice	2nd choice	3rd choice	4th choice
Laerdal	28	3	2	1
Besmed	3	17	11	2
Headstar	1	12	14	8
HI-CARE	2	2	7	23
Totals	34	34	34	34

During the nominal group process, the preference for the Laerdal device was expressed more strongly as all three groups selected the Laerdal device as their first choice. (Table 9). During the nominal group process, all but one participant (97 percent) ranked the Laerdal device as the first choice.

The primary outcome indicator for device preference was the proportion of users who ranked each device as their first choice (individual level) and the proportion of groups that selected each device as their top choice (group level).

Table 9: Results from nominal group process (n=34).

	1st choice	2nd choice	3rd choice
Laerdal	33	0	1
Besmed	0	21	13
Headstar	1	13	13
HI-CARE	0	0	7
Totals	34	34	34

The Laerdal resuscitator was the most recognized resuscitator despite the branding being obscured by tape; 33 out of 34 participants voted Laerdal as their preferred device. The participant who did not select the Laerdal device as her choice explained her reasoning in the focus group discussion:

> "Device A [Laerdal] was a very good device to me but it was the most expensive compared to the other three [Besmed, Headstar, and Hi-Care]. To be practical, I do not think our rural hospitals have budgets to buy this very good device. So I just said, let me choose between these other three which are more affordable. So, that is why my red dot [3rd choice] went to device A."

In general, the Laerdal resuscitator was perceived by participants to stand out from the rest of the devices by virtue of the high quality of the materials, effectiveness in delivering oxygen to the neonate, ease of disassembly and reassembly, and comfort. Participants discussed the

quality of materials and durability and highlighted the relative robustness of the smaller components such as the diapragms and o-rings. A participant explained:

> "It is not something that is going to wear out very quickly .You could easily clean it. Even the oxygen [reservoir] bag is very durable."

Participants commented that the Laerdal bag was tough but soft and comfortable to hold, provided good pressure feedback, and had good re-expansion properties:

> "I felt that it was the most comfortable to use. With device A [Laerdal] it is not too hard to keep the chest rising and at the same time you don't get too tired."

> "The bag itself was very nice to hold. It was comfortable it also provided a nice amount of resistance when you compress the bag."

Most groups, excluding the uMzinyathi group, described the Besmed resuscitator as the next best option after the Laerdal device. Participants noted that the Besmed resuscitator was a quality device and made of durable materials. They felt the bag was easy and comfortable to use and that the mask allowed for a good seal:

> "It was easy to deliver the breaths, easy to dismantle and assemble."

One participant commented that the firm rim of the bag (on the reservoir side) allowed him to rest his hand while compressing. Disassembly and reassembly was described as being easy:

> "Assembling and disassembling is very easy and it is straight forward."

Finally, participants noted that the Besmed device provided excellent quality for price:

> "If you knew that B [Besmed] was available on the market for a similar price there would be no reason why you would choose C [Headstar] and D [Hi-Care]."

> "So if money is the motivating factor, you could easily go for B [Besmed]."

However, participants were not unanimous in choosing the Besmed device as their second choice, and some concerns were raised about the device. The shape and feel of the bag provoked the most concerns. Many particpants found the bag awkward to hold; too big for small hands; and mentioned that the hard, unyielding texture made it difficult to compress. These features contributed to operator fatigue.

> "I absolutely hate device B [Besmed], I found it very difficult to hold it and administer the adequate pressure. My hand was very sore after about three seconds and I did not get enough seal either."

Participants also noted that the reservoir was flimsy and not durable. Participants shared one or two reports of parts being damaged or "melted" in the autoclave. A few participants also reported that they found disassembly and reassembly difficult.

Headstar was the second choice for one of the three groups and almost 40 percent of participants. Participants from units where the Headstar resuscitator is used viewed it favorably. Participants in the uMzinyathi workshop ranked it as their second choice (72 percent).

> "A [Laerdal] is the best but if I couldn't get A, I would get C [Headstar]."

> "Device A [Laerdal] and C [Headstar] I found quite similar."

Participants viewed the Headstar device as being durable although they thought the reseviour was flimsy. The diaphragms were seen as more robust than those of the Besmed and HI-CARE devices.

Participants evaluated the Headstar device as being easy to use, comfortable and not tiring. The bag fitted nicely into the hand and was softer than the Besmed resuscitator bag. It was perceived as being easy to disassemble and reassemble.

Several participants, however, commented that it was difficult to maintain a good mask seal with the Headstar device, and a few participants found this device tiring to use. Overall, most participants did not favor this device very highly.

> "I feel device C [Headstar] was just as easy to use as device A [Laerdal] but I prefer the mask on device B [Besmed]. It was difficult choice between A and C but if I had to make a choice A is better."

Rejection of the HI-CARE resuscitator was unanimous in all three workshops as noted:

> "Device D [HI-CARE] is a disaster!"

The Headstar and HI-CARE resuscitators look identical except for the fact that the Headstar plastic components are tinted and not clear. However, the difference between the devices is apparent as soon as you pick them up. The HI-CARE device is clearly of poorer quality. The plastic is brittle, the joints are over tight, and the o-rings unyielding. The HI-CARE device had deteriorated so much by the final workshop that the facilitators were worried that it would disintegrate.

One participant summarized the overall device preference well by saying:

> "At the end of the day it is a little infant's life that you are dealing with, so you should award that infant the best chance. A [Laerdal] and B [Besmed] would probably award that best chance of getting enough oxygen."

Focus Group Discussion Thematic Areas

In addition to device preference, participants discussed various aspects of neonatal resuscitation service delivery including device procurement, cleaning and disinfection procedures, and training.

Most participants felt that they are not consulted in the procurement process at their respective facilities. They expressed uncertainty about how they can have input into this process. Many participants felt that the chief consideration of procurement personnel is cost and that device effectiveness, durability, and user satisfaction are sacrificed to this. For example:

> "They buy anything that is cheap."
>
> "It often ends up that people still go with the cheapest options, not necessarily the best options."

Participants felt strongly that "end users" should be able to make recommendations about the selection of devices and vet orders before they are finalized.

> **"**It is better if the doctor and the midwives are involved so that there is a balance."

Participants stated that maternity units have different cleaning and disinfection practices. Very few participants were able to speak knowledgeably about the manufacturer's guidelines for cleaning the devices used in their units. They agreed that small components are most likely to get lost or damaged at this stage. The cleaning of the resuscitators is sometimes left in the hands of nonclinical staff who do not know how to disassemble and reassemble them correctly. Most participants felt that resuscitators are "mishandled" by autoclave staff since resuscitators can return from the autoclave with missing or melted components. Alternatively, staff reported few problems with lost or damaged resuscitators where specific staff members are responsible for cleaning, and aware of manufacturer guidelines.

To minimize lost or damaged components, some units dismantle, clean, and sterilize their resuscitators within the unit (using solutions such as Biocide, Cidex, and Autozyme). Other units dismantle and clean the resuscitator and then enclose it in a sealed autoclave bag before it is sent for sterilization. Then the bag returns from the autoclave unopened. While most units reported thorough cleaning and sterilization of devices after every use, some units do not dismantle the entire device for cleaning but only soak and clean the mask.

Participants noted that the frequency and structure of neonatal resuscitation training varies from unit to unit. They pointed out that neonatal resuscitation is a skill that needs to be honed through frequent practice and correction. Most participants felt that they do not get enough formal training around neonatal resuscitation. Often where formal training is available, staff members are unable to attend because of staff shortages. Participants felt that many colleagues avoid resuscitations because they are not confident and lack the skill to initiate resuscitation. There was some animated discussion about whether this reflected a lack of training or a lack of motivation and dedication.

Midwives often initiate resuscitations and then call for a doctor. However, midwives report that doctors are frequently inexperienced or unwilling to learn resuscitation skills or take direction from their more experienced midwife colleagues. This problem is compounded by the frequent rotation of doctors through various units.

All participants expressed that there is a great need for neonatal resuscitation training. The participants described how they would prefer on-site training within the maternity unit. The Participants noted that basic neonatal resuscitator training for new staff should be followed up with regular refresher sessions for all staff. Training events should be shorter and more frequent rather than single, longer events. Training should be practical and involve bedside teaching during real resuscitations. Doctors and nurses should be trained together. Further, an effort should be made to include on-call doctors outside the maternity unit who may respond to emergencies.

Proposed Minimum Standards for Resuscitation Devices

In the small group discussions to generate minimum standards relating to the desired features of resuscitation devices, participants reached consensus across all the sites (Table 10).

Table 10: Proposed minimum standards for resuscitation devices.

Bag	The ideal bag should be the right size to deliver the appropriate tidal volume for neonates (again the concern over the volume of the Laerdal bag was mentioned), afford a comfortable non-slip grip, and have good recoil.
Mask	The mask should be yielding enough to conform easily to the face of the neonate and create a good seal but not so soft as to collapse. The silicone should be clear and not “smoky” or “blue.” Masks should come in two sizes, for term and preterm neonates.
Durability	The resuscitation devices should withstand frequent disassembly, cleaning, and disinfection according to the manufacturer’s guidelines.
Disassembly and reassembly	The design of the resuscitation device must facilitate easy, intuitive disassembly and reassembly. In particular, the smaller components should be brightly coloured and highly visible and as robust as possible. Some groups recommended that the devices should have colour-coded joints.
Use instructions	Use instructions should be available with large, easy-to-understand pictorial guides, especially with regard to disassembly and reassembly, and acceptable methods of cleaning and disinfection.
After sales service	Spare components should be reasonably priced and readily available. Procurement decisions should take this into account. Facilities should keep stock of frequently used spare components.
Standardisation	The same resuscitation devices should be used in all maternity units within the district, district and regional hospitals, and clinics.

Price	All the groups asserted that quality design and "effectiveness" were paramount and that these should not be sacrificed in favour of competitive pricing. They highlighted the concept of cost-effectiveness and the importance of considering neonatal outcomes and durability in the procurement process.
Quantity	Each section of the maternity unit should have dedicated resuscitation devices, e.g., labour ward, nursery, high care, etc. The number of devices available should correlate with a worst case scenario estimate of the number of daily resuscitations that could occur in that section. Each section should stock spare resuscitation devices and commonly needed spare components.

Conclusions and Recommendations

Conclusions and recommendations from this study relate not only to resuscitation device preference and supply but also to process improvements in the delivery of neonatal resuscitation. As with any study, certain limitations were present. This study was limited in that it only assessed four devices. While we only included devices that are commonly available in South Africa, almost one dozen neonatal resuscitators are available in South Africa currently, and it did not make sense to include all devices. Instead, we chose devices that represent both ends of the cost spectrum. Additionally, we did not ask participants to evaluate pressure-relief valves independently of the overall device. Assessing valve integrity after prolonged use would have required a different study design.

Conclusions and recommendations are as follow:

- The Laerdal device was universally evaluated as superior, and most of the participants chose the Besmed resuscitator as their second choice. All sites rejected the HI-CARE device.
- Health care providers in many maternity units do not receive sufficient practical neonatal resuscitation training. Because of this, comprehensive neonatal resuscitation training is essential for all new staff and for all staff when a new resuscitator is introduced.
- Regular on-site bedside neonatal resuscitation training that includes midwives and doctors together should be integrated into routine clinical activities.
- Clinical staff members who conduct resuscitations should have input into the procurement process. Candidate devices should be tested thoroughly by them before selection.
- The KZN DOH should produce a document that contains photographs of and specifications for acceptable resuscitators.
- A reference group of neonatal resuscitator users should advise the KZN DOH about changes in neonatal resuscitation technology.

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