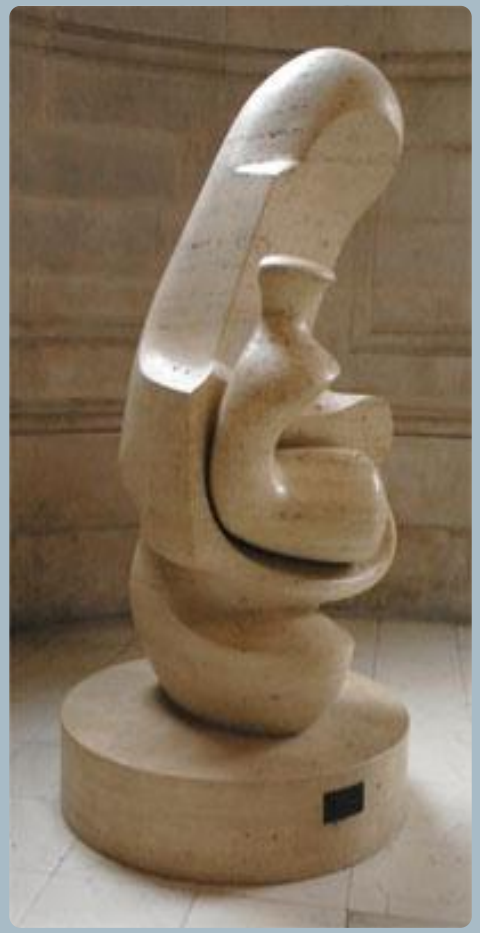

Technologies for Health Consultative Meeting: MNCH Pathways

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Labor Monitoring

Labor is a stressful time for a pregnant woman and her baby. While most women and babies tolerate labor well, some women will experience complications, and some fetuses will become distressed. The goal of monitoring the woman and fetus during labor is to ensure early identification and timely management of problems to prevent short- and long-term morbidity and mortality. Monitoring labor can be undertaken in various ways. One method commonly used in developing countries is the partograph (or partogram), a preprinted paper form that assists in identifying unsatisfactory progress in labor in a timely manner by charting cervical dilatation against time. In addition to cervical dilatation, most partographs also contain a fetal and maternal record. The fetal record may track fetal heart rate, descent of the fetal presenting part, condition of amniotic fluid, and molding of the fetal skull. The maternal record includes temperature/heart rate/blood pressure/urine (for protein and ketones), uterine contractions, and use of medications (such as oxytocin). This form allows health care providers to record, interpret, analyze, and use data to make decisions on labor management. Alert and action lines are printed on the partograph for the active phase of labor. An alert line starts at 4 cm of cervical dilatation and extends to the point of expected full dilatation at the rate of 1 cm per hour. In the active phase of labor, plotting of the cervical dilatation will normally remain on or to the left of the alert line. When dilatation crosses to the right of the alert line, it is a warning that labor may be prolonged. An action line is parallel and four hours to the right of the alert line. When cervical dilatation crosses this line, action must be taken immediately. The gold standard is the World Health Organization (WHO) partograph, though most countries design their own partographs based on the WHO partograph.

In 1990 and 1991, WHO conducted a prospective, nonrandomized, multicenter trial in Southeast Asia that involved more than 35,000 women and found that introduction of the partograph with a labor management protocol resulted in reductions in prolonged labor, augmented labors, emergency cesarean operations, and stillbirths.[1] Since then, WHO has recommended universal use of a partograph during labor to aid in clinical decision-making.[2] This WHO recommendation has not changed despite a 2009 Cochrane review of five randomized controlled trials (including both high- and low-resource countries) that found that using a partograph had no benefit on reducing cesarean section rates, instrumental vaginal delivery, or Apgar scores of less than seven at five minutes post-birth.[3] Cochrane reviewers, however, did concede that it is possible that partographs may be useful in settings with less access to health care resources as studies in Mexico and Africa showed some reduction in cesarean section rates with partograph use and early intervention for delayed progress in labor.

Use of and complete documentation on the partograph is notoriously low in low-resource countries.[4] One study found that less than 10 percent of providers (nurses, midwives, and community health care workers) routinely use the partograph in peripheral centers in Nigeria.[5] Factors that

were found to contribute to this low rate of partograph use include lack of awareness and lack of proper training,[6] lack of guidelines on partograph use, lack of availability of partographs, negative perceptions of the partograph, high patient load, low staffing at the facilities, lack of supervision, and negative attitudes among some of the health workers.[7] Additionally, some argue that use of the partograph is complex and too time consuming for effective use in low-resource countries that have inadequate health care staffing. These challenges highlight a need for strengthening providers' skills and/or developing new technologies that are suitable for low-resource countries and promote consistent, correct use of the partograph as well as identification of labor monitoring systems that could be used at the community level.

Other methods of labor monitoring are also being developed. These include a comprehensive approach to make sure that providers adhere to a set of interventions that address major causes of maternal and perinatal death by using a checklist and wireless technologies that monitor labor with biosensors.

The tables below illustrate various technologies/solutions appropriate for labor monitoring.

Supply Information	TECHNOLOGY/SOLUTION—TABLE 1			
	WHO partograph	**Paperless partograph**	**Pictorial partograph**	**ePartograph**
Description	Preprinted one-page form on which birth attendants record labor observations (does not include the latent phase of labor). Simplified version created for peripheral health care facilities that does not chart descent of fetal presenting part and only charts cervical dilatation graphically.	Providers calculate alert and action times by adding six hours to the time when a woman reaches 4 cm of dilatation (alert line) and adding four hours to the alert time (action line); based on rational that cervix should dilate 1 cm per hour between 4 cm and 10 cm. If no birth at alert time, refer for care. If no birth by action line, immediate delivery.	A picture-based paper tool to help families and less skilled birth attendants improve real-time decision-making during home births; novel picture-and-story format for semiliterate setting. Fetal condition is assessed by liquid color and baby after birth. Uses Muslim call to prayer for time orientation.	Handheld electronic device that monitors labor graphically. It has a sensor belt to measure uterine contractions and can transmit text message data using a cell phone network.[8] Has a lifespan of three years.
Characteristics applicable for low-resource settings	No power source required. Requires printing partographs (photocopier and paper if printed forms are in short supply).	No supplies required, uses simple math that can be completed in 20 seconds or less.	No power source required. Requires printing partographs (photocopier and paper if printed forms are in short supply).	Requires power source to cell phone and web-based server to access data.
Developer and/or manufacturer	World Health Organization (WHO).	Dr. AK Debdas; India.	Lutheran Aid to Medicine in Bangladesh Hospital, Bangladesh.	Center for Bioengineering Innovation & Design/Jhpiego.
Status	Available. Many countries use adapted versions of WHO form; no regulatory process.	Untested.	Prototype; high acceptability in a study among pregnant/postnatal mothers, family members, and trained traditional birth attendants in Bangladesh (n=193); need to assess if the prototype can correctly identify/measure length of labor and improve real-time decision-making in the unskilled home-birth setting.	Prototype; field testing is scheduled for early 2012 in Kenya; clinical study to determine accuracy of uterine contraction measurement with belt also planned for 2012. Regulatory pathway not ascertained.
Efficacy/ effectiveness	The WHO multicenter study in Southeast Asia showed reduction in prolonged/ augmented labor, emergency cesarean section, and stillbirths.[1] The WHO simplified version was more likely to be completed; fewer cesarean sections occurred in one trial in India.[9]	Untested.	Preliminary research has found that the tool was acceptable to semiskilled workers; studies about the impact of the partograph on birth outcomes have not yet been conducted.[10]	Based on WHO partograph. No data available on effectiveness of the device.

Supply Information	TECHNOLOGY/SOLUTION—TABLE 1			
	WHO partograph	**Paperless partograph**	**Pictorial partograph**	**ePartograph**
Manufacturing quality and capacity	Form can be printed/copied by anyone.	Methodology requires no materials.	Emory University.	Prototype—manufacturing not yet established.
Intellectual property (IP) ownership	Publicly available.	Methodology is publicly available.	Will likely be publicly available.	IP ownership undetermined at this time.
Cost and cost drivers	< US$0.10.[11]	< US$0.10.	US$0.03 each.	US$50 for device. US$20 for sensor belt, not including cell phone and data transmission fees.
Delivery/ procurement channels	Community.	Community.	Community. Designed for use by traditional birth attendants, skilled birth attendants, and family members.[12]	Community. Intended for midwives.
Sustainable business models	No revenue is generated.	No revenue is generated.	No revenue is generated.	Because the technology does not have developed-world applicability, the challenge is to create a sustainable business model while serving low-resource settings only.

Demand Information	TECHNOLOGY/SOLUTION—TABLE 1			
	WHO partograph	**Paperless partograph**	**Pictorial partograph**	**ePartograph**
Existing demand	Market size is driven by the number of late-stage pregnant women in developing countries.	Market size is driven by the number of late-stage pregnant women in developing countries.	Market size is driven by the number of late-stage pregnant women in developing countries.	Market size is driven by the number of late-stage pregnant women in developing countries.
Attractiveness	Freely available. Endorsed by WHO.	Freely available. Quick to implement.	Could be made freely available. Designed for those with low literacy.	Can store and transmit data.
Price sensitivity	Very inexpensive.	Very inexpensive.	Very inexpensive.	Will be difficult to convey the value proposition due to the presence of free/low-cost alternatives.
Policy environment	WHO recommended. Gold standard.	No endorsement by international bodies.	Policy deliberation would need to take place to recommend as an intervention.	Based on WHO standard.
Donors/ stakeholders	WHO. Ministries of health in countries often produce a modified version.	Rajkumari Foundation.	Emory University Engender Health Global Health Institute	Received a grant of US$250,000 from the Saving Lives at Birth Grand Development Challenge.
Pre- and post-sales support	Competency in partograph use requires ongoing learning and practice in the workplace over a period of months, not days.[10]	Intended to take only 20 seconds to calculate, so training will be minimal.	Minimal training required. Intended for those in the community or family members.	Competency in partograph use requires ongoing learning and practice in the workplace over a period of months, not days.[10]
Need for demand creation	Awareness of this method is low. Would require government support for adoption of this intervention.	No awareness of this method. Need to generate evidence to support use of method. Would require government support for adoption of this intervention.	No awareness of this method. Need to generate evidence to support use of method. Would require government support for adoption of this intervention; requires further evidence noted above.	No awareness of this method. Need to generate evidence to support use of method. Will require marketing on behalf of the manufacturer.

Supply Information	TECHNOLOGY/SOLUTION—TABLE 2		
	PartoPen	**Labor band**	**Safe-birth checklist**
Description	Commercial digital pen and paper product to analyze real-time data and check for data errors, audio warnings, reminders, and information scripts and time-stamped written notes; can be programmed for any partograph; can customize using facility/community data. Current prototype has no external connectivity. Future versions may have a USB (universal serial bus) port, blue-tooth, etc.[13]	Novel, wireless biosensing device intended to (1) detect the onset of labor; and (2) monitor maternal and fetal vital signs to prevent complications of labor; uses LifeBand platform (Ashametrics). Can transmit data wirelessly. Can be reused for up to three years but have to deal with issues of hygiene for reuse.	Preprinted checklist that covers 29 interventions on admission (including use of partograph) just before pushing or before cesarian, soon after birth (1 hour), and before discharge.
Characteristics applicable for low-resource settings	Requires laser printer, paper, computer, power source, and digital pen.	Requires a smart phone.	Requires printing a checklist (photocopier and paper if printed forms are in short supply).
Developer and/or manufacturer	University of Colorado at Boulder.	Massachusetts General Hospital Center for Global Health.	WHO.
Status	Prototype; seeking funding. In discussion with digital pen manufacturers.	Concept stage; initial funding being sought to conduct feasibility of remote monitoring, device acceptability, and performance analysis in Uganda and in Nagpur, India. Plan to use field testing to improve the device design, battery life, and cost. Regulatory pathway not ascertained.	Feasibility testing complete; conducted in 17 sites in 10 countries. Starting Better Birth Trial (four-year funded project through the Bill & Melinda Gates Foundation with Harvard) in 120 hospitals in Uttar Pradesh, India.[14]
Efficacy/ effectiveness	Tested in five clinics (rural, peri-urban, urban) in Kenya to determine the feasibility of the device in August 2011. Conducted two trials at Kenyatta Hospital that test the usability and design of both the training and use modes of the system. Feedback will be incorporated into the development process. Trials will occur in December 2011 and June 2012. Based on WHO partograph.	Untested. Focus group discussion suggests that Ugandan women like the device (they wore it for 1 hour) and found it acceptable—results not yet published.	Pilot test in one site in India with good results (150 percent increase in adherence to evidence-based practices; partograph use went from 4 percent to 42 percent).
Manufacturing quality and capacity	Several companies involved in the components of the PartoPen system.	No plan yet.	Checklist can be printed/copied by anyone.

Supply Information	TECHNOLOGY/SOLUTION—TABLE 2		
	PartoPen	**Labor band**	**Safe-birth checklist**
Intellectual property ownership	The pen is readily available on websites such as Amazon.com. The program is proprietary.	Working out issues with Massachusetts General Hospital Center for Global Health/Massachusetts Institute of Technology and University of California, Berkeley (software developer).	Once validated, the checklist will be publicly available.
Cost and cost drivers	The current price for the digital pen is US$50 to US$150. There is additional cost for pen ink fillers for pen, laser printer, paper, ink cartridges, and computer.	Target price is US$20; does not include cell phone.	< US$0.10.
Delivery/ procurement channels	Clinic.	Clinic, possibly community.	Community.
Sustainable business models	Because the technology does not have developed-world applicability, the challenge is to create a sustainable business model while serving low-resource settings only.	Because the technology does not have developed-world applicability, the challenge is to create a sustainable business model while serving low-resource settings only.	No revenue is generated.

Demand Information	TECHNOLOGY/SOLUTION—TABLE 2		
	PartoPen	Labor band	Safe-birth checklist
Existing demand	Market size is driven by the number of late-stage pregnant women in developing countries.	Market size is driven by the number of late-stage pregnant women in developing countries.	Market size is driven by the number of late-stage pregnant women in developing countries.
Attractiveness	Device notifies provider when mistakes are recorded. Relatively expensive with potential for price reduction through manufacturer negotiations.	Passive collection of data. Real time biofeedback.	Could be made freely available. Standardized easy-to-use checklist.
Price sensitivity	Will be difficult to convey the value proposition due to the presence of free/low-cost alternatives.	Will be difficult to convey the value proposition due to the presence of free/low-cost alternatives.	Very inexpensive.
Policy environment	Based on WHO standard.	Would need concerted effort to align policy to support use of wireless labor monitoring over partograph; not likely to occur in the near term.	Developed by WHO; currently collecting evidence that may likely lead to policy change.
Donors/ stakeholders	National Science Foundation and Atlas as funding the development and testing work to date. Currently seeking funding from the Bill & Melinda Gates Foundation.	Massachusetts General Hospital Center for Global Health, in discussion with Omidyar Network. May partner with West Wireless Health for their wireless maternal contraction sensor.	Gates Foundation Harvard School of Public Health WHO
Pre- and post-sales support	The pen itself can train the provider on the partograph form. Training on the digital pen is less than one day for a labor attendant who is already using the partograph.	Providers would monitor patient remotely and maintain electronic health records.	Initial training is 2 to 3 days; coaching after introduction is also particularly important (at least for some period of time) to maximize likelihood of adoption into practice and sustained use.
Need for demand creation	No awareness of this method. Need to generate evidence to support use of method. Cost reduction must occur to spark demand. Will require marketing on behalf of the manufacturer.	No awareness of this method. Need to generate evidence to support use of method. Cost reduction must occur to spark demand. Will require marketing on behalf of the manufacturer.	No awareness of this method. Need to generate evidence to support use of method. Cost reduction must occur to spark demand. Will require marketing on behalf of the manufacturer.

References

[1] World Health Organization (WHO). World Health Organization partograph in management of labour. World Health Organization Maternal Health and Safe Motherhood Programme. *Lancet.* 1994;343(8910):1399–1404.

[2] WHO. Effect of partogram use on outcomes for women in spontaneous labour at term page. WHO website. Available at: http://apps.who.int/rhl/pregnancy_childbirth/childbirth/routine_care/cd005461_sonibl_com/en/index.html. Accessed December 30, 2011.

[3] Lavender T, Hart A, Smyth RM. Effect of partogram use on outcomes for women in spontaneous labour at term. *Cochrane Database of Systematic Reviews*. 2008(4):CD005461.

[4] Burkhalter B, Edson W, Harvey S, et al. *Quality of Obstetric Care Observed in 14 hospitals in Benin, Ecuador, Jamaica, and Rwanda.* Washington, DC: Quality Assurance Project; 2006. Operations Research Results series.

[5] Oladapo OT, Daniel OJ, Olatunji AO. Knowledge and use of the partograph among healthcare personnel at the peripheral maternity centres in Nigeria. *Journal of Obstetrics and Gynaecology.* 2006;26(6):538–541.

[6] Tsu VD, Coffey PS. New and underutilised technologies to reduce maternal mortality and morbidity: what progress have we made since Bellagio 2003? *BJOG.* 2009;116(2):247–256.

[7] Ogwang S, Karyabakabo Z, Rutebemberwa E. Assessment of partogram use during labour in Rujumbura Health Sub District, Rukungiri District, Uganda. *African Health Sciences.* 2009;9(Supplement 1):S27–S34.

[8] Dekel S. ePartogram solution-based innovation. Presented at: EngenderHealth Conference, November 15, 2011; Dakar, Senegal.

[9] Mathews JE, Rajaratnam A, George A, Mathai M. Comparison of two World Health Organization partographs. *International Journal of Gynaecology and Obstetrics.* 2007;96(2):147–150.

[10] Revitalizing the partograph: Does the evidence support a global call to action page? The Fistula Care Project website. Available at: http://www.fistulacare.org/pages/index.php. Accessed February 8, 2011.

[11] Partograph for the prevention of prolonged labor page. MANDATE website. Available at: http://mnhtech.org/technology/technology-briefs/partograph/. Accessed February 7, 2012.

[12] Edwards C, Saha S. From home to hospital, a continuum of care: making progress towards Millennium Development Goals 4 and 5 in rural Bangladesh. *BJOG.* 2011;118(Suppl 2):88–92. Available at: http://onlinelibrary.wiley.com/doi/10.1111/j.1471-0528.2011.03116.x/full. Accessed February 8, 2012.

[13] Underwood H. *Using a Digital Pen to Improve Labor Monitoring and Reinforce Birth Attendant Training.* Boulder, CO: Atlas Institute; 2011.

[14] Harvard School of Public Health receives $14.1 million grant to reduce maternal, infant deaths in India [press release]. Boston: Harvard; July 26, 2011. Available at: http://www.hsph.harvard.edu/news/press-releases/2011-releases/gates-grant-maternal-infant-deaths-india.html. Accessed February 8, 2012.

Portable Ultrasound

Ultrasound is an electronic technology which uses the reflection of pulses of high frequency sound to produce an image. Ultrasound may be used in a variety of circumstances during pregnancy. An ultrasound scan is often used to monitor pregnancies in order to identify risk factors, complications, or indications of fetal distress. In the latter part of pregnancy, ultrasonography will allow assessment of the viability, size, and growth of the fetus and will assist in the diagnosis and management of intrauterine growth retardation (IUGR) and intrauterine fetal demise. In cases of third-trimester bleeding, particularly at onset of labor, ultrasonography assists in making a diagnosis or an exclusion of placenta previa and confirming fetal viability. Other obstetric conditions can be detected by ultrasound when the device is used by competent personnel, but each device calls for different timing of the scans, and few have clinically detectable signs to identify women at higher risk. Early scans are required if they are going to be used to date pregnancies more accurately and reduce post-term pregnancies or unintentional preterm inductions,[1] particularly in the case of gestational hypertension and preeclampsia. Using ultrasound to determine pelvic measurements and predict cephalopelvic disproportion (the primary cause of obstructed labor) has been suggested,[2] but limited sensitivity (30 percent) and only 50 percent positive predictive value were reported. Other potential conditions of interest are placental attachment problems (placenta previa and placenta accreta), multiple gestations (not detected clinically), fetal abnormalities, hydramnios and oligohydramnios, fetal viability, IUGR, and fetal malpresentation (breech and transverse lie). Multiple gestations are usually clinically detected about half the time and are not necessarily life-threatening to the mother. Breech and transverse presentations, estimated to occur in 2 percent to 3 percent of deliveries, are also detected at least half the time by clinical palpation within the last few weeks of pregnancy and would require ultrasound after the 37th week to ensure reliable detection, since the position changes up to that point.

It has been assumed that the routine use of ultrasound in early pregnancy will result in the earlier detection of problems and improved management of pregnancy complications when compared with selective use for specific indications such as after clinical complications (e.g. bleeding in early pregnancy) or where there are concerns about fetal growth. A recent review of the evidence for interventions that impact stillbirths concluded that in low-risk or unselected populations, there is little evidence that any form of routine Doppler velocimetry contributes to reductions in stillbirth rates. However, uterine artery Doppler waveform analysis accurately identifies compromised fetuses at risk of stillbirth although no studies have shown any ability of subsequent intervention to prevent stillbirth.[3,4] Likewise, a Cochrane review that included eight trials recruiting 27,024 women found that routine ultrasound, after 24 weeks gestation, in low-risk or unselected women does not provide any benefit for mother or baby.[5]

Nevertheless, many groups are promoting use of obstetric ultrasound imaging in low-resource settings.

Imaging the World (ITW) is promoting the training of community lay workers to do the actual scans and then either saving or transmitting them so specialists can read them.[6] While this could greatly shorten the training time and improve the quality of interpretation of images, it raises a host of questions about image transmission, timely feedback, and patient follow-up (or loss of follow-up). Appropriate strategies for using compact ultrasound for obstetric care with regard either to the timing of scans (early, mid, and/or late pregnancy), the best location for scans (referral hospital, peripheral facility, or periodic outreach to villages), or the appropriate target group (all pregnant women or a selected high-risk or symptomatic group) have not yet been formulated by international bodies.

Risks of expanded use of obstetric ultrasound include use in Asia and elsewhere for sex selection and female feticide,[7] the overuse of ultrasound and subsequent unnecessary interventions that result from inevitable false-positive scans,[8] and the inappropriate commercial promotion of ultrasound as a revenue-generating service either in the private or the public sector.[8,9,10] Several authors and experts have noted how popular ultrasound images are with pregnant women, making it easy to understand why women might use scarce resources to pay for ultrasounds, giving up other, potentially more useful, services or supplies.

Requirements for compact ultrasound in low-resource settings have been defined as the following: lightweight (less than 10 lb), durable, handheld ultrasound transducer (2 MHz to 5 MHz) and ultrasound, measuring calipers (accurate) on image screen, coupling gel or airless medium to conduct sound waves between the transducer (probe) and patient's skin, power supply, rechargeable batteries, trained operators (sonographers, nurses, physicians, health aides, midwives), image interpreters (physicians, sonographers, nurses), secure and stable physical environment, service or maintenance available on-site or transport to factory.[11] Key issues around the technology include its cost, power supplies, maintenance and supply needs, and training requirements. Desired features relate to ease of use (compact size, lightweight, simple controls), appropriateness of probes (transducers) for obstetric applications (3.5 MHz), ruggedness, and affordability. Most units have rechargeable batteries that can be used with wall outlets (mains), solar panels, vehicle batteries, inverters, or gas generators. One author noted that frequent power outages have a "tremendous impact on the life-span of the machines."[1] Another review article said that batteries are usually good for one to two years with frequent use and then need to be replaced at a cost of about US$200.[11] In addition, there is the cost of gel or other medium for enhancing transmission. In the area of training, there seems to be consensus that basic training to a doctor, midwife, or other clinical worker can be provided in a 2- to 3-week period, covering obstetric and general abdominal abnormalities.[11] Even shorter training—over a 3- to 4-day period—has been deemed feasible if the focus is on three or four key obstetric functions (pregnancy dating, confirming the site of the pregnancy is within the cavity of the uterus, obstetric measurements, looking for multiple gestations, checking fetal position).[11]

Ultrasound only has impact if effective and accessible services are available to address the problems identified. For obstetric problems, this could include access to surgery and blood transfusion. Studies in sub-Saharan Africa are demonstrating that use of ultrasound results in changes to clinical care. Midwives in rural Zambia were trained to perform basic ultrasound successfully and the use of ultrasound impacted clinical decision-making in 17 percent of cases (primarily non-vertex presentation, multiple gestation, and no fetal heart rate).[12,13] Likewise, nurses practicing in remote clinics in Mali were trained to do ultrasound successfully, and clinical decision-making was changed in 10.1 percent of ultrasounds, with a 3.5 percent referral rate to comprehensive maternity care facilities. Ultrasound was perceived as most useful for finding fetal position, sex, due date, and well-being.[14]

An evaluation of various ultrasound technologies can be found in the following tables.

Supply Information	TECHNOLOGY/SOLUTION—TABLE 1		
	Vscan	**Acuson P10™**	**Signos**
Description	1.7 MHz to 3.8 MHz probes. Pocket-size visualization tool providing black and white anatomic and color-coded blood flow images in real-time. Image quality is equivalent to that of a mid-range ultrasound console such as GE's Logiq line.[15]	Pocket size. Comes with memory card and viewer system, 2 to 4 MHz probe, 3.7-inch monitor, 1.6 lb hand unit and 2 lb docking unit, color-coded blood flow.	Palm-sized (PDA size) portable or handheld ultrasound machine. Still images only, Stores up to 10,000 images, touch-screen display, available with 3.5MHz and 7.5MHz single-element transducers, has USB connector and micro SD card slot.
Characteristics applicable for low-resource settings	Portable, pocket-sized. Battery has one hour of use. SD memory card; USB cable.	Portable, pocket-sized. Rechargeable battery. SD memory card; USB cable.	Portable, pocket-sized. Battery should be charged every six months at a minimum. Also has a charger that connects to a power source.
Developer and/or manufacturer	General Electric (GE).	Siemens.	Signostics Medical.
Status	Commercialized. Has United States Food and Drug Administration (USFDA) approval and CE Mark. Currently conducting study in a dozen sites in Asia, the United States and Europe to see how health-care personnel in primary care, critical care, and cardiology think the device can best be used.	Commercialized. Has USFDA 510(k) clearance, CE Mark in the European Union, and a medical device license from Health Canada.	USFDA approved in May 2009, has CE Mark, and Australia regulatory approval. The device has been on the market since October 2009.[16]
Efficacy/ effectiveness	Efficacy depends on user skill and timing of screening. Limitations in compact ultrasound resolution may be mitigated in low-resource settings where the imaging resolution may be enhanced by the prevalence of undernourished patients with considerably less body fat than found in patients in more developed nations.[11] A randomized trial of routine second-trimester ultrasounds of women without special risk factors in South Africa found no link between ultrasound use and improved obstetric outcome.[17] A Cochrane review reported routine late ultrasound (after 24 weeks, without clinical signs), had no measurable benefit for mother or baby.[5] A limitation was that it consisted of studies in countries where women deliver in well-equipped hospitals, rather than settings such as the home or simple maternity facilities and may need to be transferred to receive care. A review in Ghana came to a similar conclusion, obstetric ultrasound "does not result in reduction of maternal mortality or perinatal mortality," but it may still be useful for reducing referrals and diagnosing antepartum hemorrhage.[1] A subsequent Cochrane review found that Doppler ultrasound of the uterus or placenta in women in their second trimester and at low risk for hypertensive disorders resulted in no improvements for the baby or the mother[18], although there were no randomized studies in the first trimester, or in women at high risk. Most experts agree that ultrasound can be very valuable in diagnosing symptomatic women (e.g., with antenatal bleeding) or pregnant women with risk factors (e.g., history of obstructed labor), but they are relatively few, making it difficult to achieve the volumes needed to make the technology cost-effective. There is not sufficient data to calculate the actual number of lives that might be saved, but it appears to be a relatively small proportion of the maternal mortality that occurs.		

Supply Information	TECHNOLOGY/SOLUTION—TABLE 1		
	Vscan	**Acuson P10™**	**Signos**
Manufacturing quality and capacity	Believed to have 40 percent of global market.	German manufacturer.	Manufactured in Adelaide, South Australia. Sales and marketing office in Palo Alto, California.
Intellectual property ownership	Proprietary.	Proprietary.	Proprietary.
Cost and cost drivers	US$10,000.[19]	US$9,000 to US$11,000.	US$4,000.[19]
Delivery/ procurement channels	Does not have current distribution channels to low-resource settings, but are building capacity to reach low-resource settings through GE's Healthymagination initiative.	Data about specific channels is not available.	Veterinarian and human market in Australia, the United States, and Europe. Intended for hospital and clinic delivery, even in remote and rural locations.
Sustainable business models	Multinational corporation with multiple product lines. The challenge is to create a sustainable business model while serving low-resource settings.	Multinational corporation with multiple product lines. The challenge is to create a sustainable business model while serving low-resource settings.	Late stage start-up company with largely only one product.

Demand Information	TECHNOLOGY/SOLUTION—TABLE 1		
	Vscan	**Acuson P10™**	**Signos**
Existing demand	End users are health care providers. It is possible to have a technician take the image and have a provider interpret the image remotely. The application of this technology is broader than just obstetrician/gynecologist (OBGYN). Therefore, the market size is driven by the number of health facilities, providers, and communities.	End users are health care providers. It is possible to have a technician take the image and have a provider interpret the image remotely. The application of this technology is broader than just the OBGYN. Therefore, the market size is driven by the number of health facilities, providers, and communities.	End users are health care providers. It is possible to have a technician take the image and have a provider interpret the image remotely. The application of this technology is broader than just the OBGYN. Therefore, the market size is driven by the number of health facilities, providers, and communities.
Attractiveness	Portable. Price is still high. Screen size may be too small and may have a slow frame rate, making it difficult to capture the image.	Portable. Price is still high. Screen size may be too small and may have a slow frame rate, making it difficult to capture the image.	Portable. Price is still high. Screen size may be too small and may have a slow frame rate, making it difficult to capture the image.
Price sensitivity	A cost of less than US$2,000 could potentially be cost-effective at the rural clinic level.[20]	A cost of less than US$2,000 could potentially be cost-effective at the rural clinic level.[20]	A cost of less than US$2,000 could potentially be cost-effective at the rural clinic level.[20]
Policy environment	Policy has not yet been formulated by international bodies.	Policy has not yet been formulated by international bodies.	Policy has not yet been formulated by international bodies.
Donors/ stakeholders	GE has given the University of Washington a grant to conduct two pilots in Uganda with donated Logiqbooks (GE's older device).	None.	Signostics was awarded a US$1.96 million grant from the Australian Government to commercialize Signos in August 2011.[21]
Pre- and post-sales support	Weeks of training required. Maintenance of the product required.	Weeks of training required. Maintenance of the product required.	Weeks of training required.
Need for demand creation	Awareness in low-resource settings is growing around the usability for OBGYN indications. However, the cost of the product is prohibitive. A lower price product may become more cost-effective if it allows for task shifting of imaging to lower level trained individuals in the community. Abuse of the use of ultrasound for sex selection, especially in Southeast Asia and South Asia remains an issue. There is a need to generate more evidence related to the impact of ultrasound on obstetric outcomes. However, due to popularity of fetal images, consumer demand may be generated in the absence of these data.	Awareness in low-resource settings is growing around the usability for OBGYN indications. However, the cost of the product is prohibitive. A lower price product may become more cost-effective if it allows for task shifting of imaging to lower level trained individuals in the community. Abuse of the use of ultrasound for sex selection, especially in Southeast Asia and South Asia remains an issue. There is a need to generate more evidence related to the impact of ultrasound on obstetric outcomes. However, due to popularity of fetal images, consumer demand may be generated in the absence of these data.	Awareness in low-resource settings is growing around the usability for OBGYN indications. However, the cost of the product is prohibitive. A lower price product may become more cost-effective if it allows for task shifting of imaging to lower level trained individuals in the community. Abuse of the use of ultrasound for sex selection, especially in Southeast Asia and South Asia remains an issue. There is a need to generate more evidence related to the impact of ultrasound on obstetric outcomes. However, due to popularity of fetal images, consumer demand may be generated in the absence of these data.

Supply Information	TECHNOLOGY/SOLUTION—TABLE 2	
	MobiUS™SP1	**WED-3100**
Description	Smartphone-based ultrasound imaging system to practice better medicine and reduce costs. Data from the device can be transferred using WiFi, cellular, or USB sync to a personal computer (PC). The device has three probes: 3.5 MHz, 5.0 MHz, and 7.5 MHz.	5-inch monitor, 4 probes ranging from 3.5 to 7.5 MHz, net weight is 700 g.
Characteristics applicable for low-resource settings	Portable, pocket-sized. Rechargeable battery.	Portable, hand-held. Battery has three hours of use.
Developer and/or manufacturer	Mobisante.	Manufactured by Shenzhen Well.D Medical Electronics Co., Ltd.[22] Distributed by Health Power.[23]
Status	USFDA approved; plans to apply for CE Mark. Pilot projects in the Philippines and Nepal. Ultrasound4Africa to implement telemedicine approach with MobiUS in rural maternities of two districts in Burkina Faso and Mali with low emergency obstetric care to link rural maternities with specialists.	Commercialized. USFDA approved.
Efficacy/ effectiveness	Efficacy depends on user skill and timing of screening. Limitations in compact ultrasound resolution may be mitigated in low-resource settings where the imaging resolution may be enhanced by the prevalence of undernourished patients with considerably less body fat than found in patients in more developed nations.[11] A randomized trial of routine second-trimester ultrasounds of women without special risk factors in South Africa found no link between ultrasound use and improved obstetric outcome.[17] A Cochrane review reported routine late ultrasound (after 24 weeks, without clinical signs), had no measurable benefit for mother or baby.[5] A limitation was that it consisted of studies in countries where women deliver in well-equipped hospitals, rather than settings such as the home or simple maternity facilities and may need to be transferred to receive care. A review in Ghana came to a similar conclusion, obstetric ultrasound "does not result in reduction of maternal mortality or perinatal mortality," but it may still be useful for reducing referrals and diagnosing antepartum hemorrhage.[1] A subsequent Cochrane review found that Doppler ultrasound of the uterus or placenta in women in their second trimester and at low risk for hypertensive disorders resulted in no improvements for the baby or the mother[18], although there were no randomized studies in the first trimester, or in women at high risk. Most experts agree that ultrasound can be very valuable in diagnosing symptomatic women (e.g., with antenatal bleeding) or pregnant women with risk factors (e.g., history of obstructed labor), but they are relatively few, making it difficult to achieve the volumes needed to make the technology cost-effective. There is not sufficient data to calculate the actual number of lives that might be saved, but it appears to be a relatively small proportion of the maternal mortality that occurs.	
Manufacturing quality and capacity	Information not available.	Manufactured in Shenzhen, China.
Intellectual property ownership	Proprietary software. Patent pending.[24]	Chinese version of SonoSite.
Cost and cost drivers	US$7,000 to US$8,000.[25]	US$3,600.[19]

Supply Information	TECHNOLOGY/SOLUTION—TABLE 2	
	MobiUS™SP1	WED-3100
Delivery/ procurement channels	Exploring marketing the technology in the US, mostly to doctors who do not have access to ultrasound already, such as those in rural and community health practices. Also looking at Africa, Latin America and India.	Healthpower is one of their distributors. They are looking to sell in rural China and other low-resource settings.
Sustainable business models	Small company based in Redmond, WA. Funding from 700,000 angel investors and community clinics; US$400,000 in seed funding from venture firm WRF Capital.	Mid-size company with various ultrasounds technologies.

Demand Information	TECHNOLOGY/SOLUTION—Table 2	
	MobiUS™SP1	WED-3100
Existing demand	End users are health care providers. It is possible to have a technician take the image and have a provider interpret the image remotely. The application of this technology is broader than just the OBGYN. Therefore, the market size is driven by the number of health facilities, providers, and communities.	End users are health care providers. It is possible to have a technician take the image and have a provider interpret the image remotely. The application of this technology is broader than just the OBGYN. Therefore, the market size is driven by the number of health facilities, providers, and communities.
Attractiveness	Portable; price is still high; screen size may be too small; may have a slow frame rate, making it difficult to capture the image.	Portable; price is lower than the competition, but still high; screen size may be too small; may have a slow frame rate, making it difficult to capture the image.
Price sensitivity	A cost of less than US$2,000 could potentially be cost-effective at the rural clinic level.[20]	A cost of less than US$2,000 could potentially be cost-effective at the rural clinic level.[20]
Policy environment	Policy has not yet been formulated by international bodies.	Policy has not yet been formulated by international bodies.
Donors/ stakeholders	Ultrasound4Africa was a Saving Lives at Birth finalist using Mobisante devices to link care between rural maternities and specialists in Burkina Faso and Mali, coordinated by Institute for Tropical Medicine, Antwerp.[26] Won Global Mobile Award for application, MobiUS™, as Best mHealth Innovation at 2011 Mobile World Congress.	None.
Pre- and post-sales support	Weeks of training required. Maintenance of the product required.	Weeks of training required. Maintenance of the product required.
Need for demand creation	Awareness in low-resource settings is growing around the usability for OBGYN indications. However, the cost of the product is prohibitive. A lower price product may become more cost-effective if it allows for task shifting of imaging to lower level trained individuals in the community. Abuse of the use of ultrasound for sex selection, especially in Southeast Asia and South Asia remains an issue. There is a need to generate more evidence related to the impact of ultrasound on obstetric outcomes. However, due to popularity of fetal images, consumer demand may be generated in the absence of these data.	

Supply Information	TECHNOLOGY/SOLUTION—TABLE 3	
	180 PLUS	**InNovaSound**
Description	5.7 lb, rugged, 13 x 8 x 2.5 inches, 2D, 100 frames per second, storage of images, cable connection to PC, obstetrics calculation package.	USB-compatible probe. Allows all of the electronics to be built in to the probe. The probe then sends this data to a PC for display and processing. The software provides integrated training video clips and guides clinicians to ultrasound controls or the specific scan protocol. The system uses B-mode imaging and weighs just 7.5 ounces.[27]
Characteristics applicable for low-resource settings	Portable, hand-held. Battery has 1.5 to 4 hours of use. Claims to be durable; was developed for military applications.	Portable, however it requires a laptop for use. Computer needs to have Windows XP or Vista operating system.
Developer and/or manufacturer	SonoSite.	Direct Medical Systems.
Status	Commercialized; USFDA approved.	Has USFDA approval and CE Mark.
Efficacy/ effectiveness	Efficacy depends on user skill and timing of screening. Limitations in compact ultrasound resolution may be mitigated in low-resource settings where the imaging resolution may be enhanced by the prevalence of undernourished patients with considerably less body fat than found in patients in more developed nations.[11] A randomized trial of routine second-trimester ultrasounds of women without special risk factors in South Africa found no link between ultrasound use and improved obstetric outcome.[17] A Cochrane review reported routine late ultrasound (after 24 weeks, without clinical signs), had no measurable benefit for mother or baby.[5] A limitation was that it consisted of studies in countries where women deliver in well-equipped hospitals, rather than settings such as the home or simple maternity facilities and may need to be transferred to receive care. A review in Ghana came to a similar conclusion, obstetric ultrasound "does not result in reduction of maternal mortality or perinatal mortality," but it may still be useful for reducing referrals and diagnosing antepartum hemorrhage.[1] A subsequent Cochrane review found that Doppler ultrasound of the uterus or placenta in women in their second trimester and at low risk for hypertensive disorders resulted in no improvements for the baby or the mother[18], although there were no randomized studies in the first trimester, or in women at high risk. Most experts agree that ultrasound can be very valuable in diagnosing symptomatic women (e.g., with antenatal bleeding) or pregnant women with risk factors (e.g., history of obstructed labor), but they are relatively few, making it difficult to achieve the volumes needed to make the technology cost-effective. There is not sufficient data to calculate the actual number of lives that might be saved, but it appears to be a relatively small proportion of the maternal mortality that occurs.	
Manufacturing quality and capacity	Information not available.	United States manufacturer.
Intellectual property ownership	Proprietary.	Proprietary. The device has patents.
Cost and cost drivers	US$5,000 to US$10,000 refurbished; US$18,000 to US$20,000, new.	Information not available.
Delivery/ procurement channels	Does not have current distribution channels to low-resource settings but looking to build capacity in this area.	Has distribution agreements creating channels in a number of countries outside of the United States. Does not appear that the device was designed with low-resource settings in mind as it requires a computer with Windows XP or Vista operating system.
Sustainable business models	Multinational corporation with multiple product lines. The challenge is to create a sustainable business model while serving low-resource settings.	Small company with distribution partners.

Demand Information	TECHNOLOGY/SOLUTION—TABLE 3	
	180 PLUS	InNovaSound
Existing demand	End users are health care providers. It is possible to have a technician take the image and have a provider interpret the image remotely. The application of this technology is broader than just the OBGYN. Therefore, the market size is driven by the number of health facilities, providers, and communities.	End users are health care providers. It is possible to have a technician take the image and have a provider interpret the image remotely. The application of this technology is broader than just the OBGYN. Therefore, the market size is driven by the number of health facilities, providers, and communities.
Attractiveness	Larger screen size. Four SonoSite 180 PLUS portable ultrasound machines were used in a study in Zambia. During the 6-month study period, the portable ultrasounds functioned well in conditions including heat, humidity, dust and extensive travel to various rural regions. At the end of one year, two of the four machines had to be transported back to the United States for repair.[12]	Not as portable due to requirement of a laptop computer. Price is unknown.
Price sensitivity	A cost of less than US$2,000 could potentially be cost-effective at the rural clinic level.[20]	A cost of less than US$2,000 could potentially be cost-effective at the rural clinic level.[20]
Policy environment	Policy has not yet been formulated by international bodies.	Policy has not yet been formulated by international bodies.
Donor/ stakeholders	None.	World Missions Possible, Inc. used this device in clinics in West Africa.[28]
Pre- and post-sales support	Weeks of training required. Maintenance of the product required.	Weeks of training required.
Need for demand creation	Awareness in low-resource settings is growing around the usability for OBGYN indications; however, the cost of the product is prohibitive. A lower price product may become more cost-effective if it allows for task shifting of imaging to lower level trained individuals in the community. Abuse of the use of ultrasound for sex selection, especially in Southeast Asia and South Asia remains an issue. There is a need to generate more evidence related to the impact of ultrasound on obstetric outcomes. However, due to popularity of fetal images, consumer demand may be generated in the absence of these data.	Awareness in low-resource settings is growing around the usability for OBGYN indications; however, the cost of the product is prohibitive. A lower price product may become more cost-effective if it allows for task shifting of imaging to lower level trained individuals in the community. Abuse of the use of ultrasound for sex selection, especially in Southeast Asia and South Asia remains an issue. There is a need to generate more evidence related to the impact of ultrasound on obstetric outcomes. However, due to popularity of fetal images, consumer demand may be generated in the absence of these data.

Supply Information	TECHNOLOGY/SOLUTION—TABLE 4	
	SeeMore™	**Terason t3000™**
Description	3.5 MHz or 14 MHz probes, has USB connection to PC.[29] This device has no Doppler.	Two dimensional (2D) mode, obstetrics reporting package, plugs into laptop for display, approximately 9 lbs, 7 probes, color Doppler.
Characteristics applicable for low-resource settings	Portable, however it requires a laptop. Computer needs to have Windows 7 or XP operating system.	Portable, but not hand-held. Rechargeable battery. Runs on a Windows-based PC.
Developer and/or manufacturer	Interson Corporation.	Teratech Corporation.
Status	Commercialized; USFDA 510(k) clearance, a CE Mark by TUV Rhineland, Japan PAL NINSHO approval, and a medical device license from Health Canada.	2D mode, OB reporting package, plugs into laptop for display, approximately 9 lbs, 7 probes, color Doppler.
Efficacy/ effectiveness	Efficacy depends on user skill and timing of screening. Limitations in compact ultrasound resolution may be mitigated in low-resource settings where the imaging resolution may be enhanced by the prevalence of undernourished patients with considerably less body fat than found in patients in more developed nations.[11] A randomized trial of routine second-trimester ultrasounds of women without special risk factors in South Africa found no link between ultrasound use and improved obstetric outcome.[17] A Cochrane review reported routine late ultrasound (after 24 weeks, without clinical signs), had no measurable benefit for mother or baby.[5] A limitation was that it consisted of studies in countries where women deliver in well-equipped hospitals, rather than settings such as the home or simple maternity facilities and may need to be transferred to receive care. A review in Ghana came to a similar conclusion, obstetric ultrasound "does not result in reduction of maternal mortality or perinatal mortality," but it may still be useful for reducing referrals and diagnosing antepartum hemorrhage.[1] A subsequent Cochrane review found that Doppler ultrasound of the uterus or placenta in women in their second trimester and at low risk for hypertensive disorders resulted in no improvements for the baby or the mother[18], although there were no randomized studies in the first trimester, or in women at high risk. Most experts agree that ultrasound can be very valuable in diagnosing symptomatic women (e.g., with antenatal bleeding) or pregnant women with risk factors (e.g., history of obstructed labor), but they are relatively few, making it difficult to achieve the volumes needed to make the technology cost-effective. There is not sufficient data to calculate the actual number of lives that might be saved, but it appears to be a relatively small proportion of the maternal mortality that occurs.	
Manufacturing quality and capacity	US manufacturer.	Manufactured in Massachusetts.
Intellectual property ownership	Proprietary.	Based on proprietary software. Has patents protecting the integrated circuit technology.[30]
Cost and cost drivers	Approximately US$3,000 with an additional cost of a laptop computer.	US$25,000.
Delivery/ procurement channels	More than 15,000 Interson probes have been installed in offices, hospitals, and clinics around the world since 1989. Does not appear that the device was designed with low-resource settings in mind as it requires a computer with Windows XP or Vista operating system.	Purchasing agreement with Premier Purchasing Partners, LLC which supplies hospitals in the United States.[31] One unit was given to a team who traveled to Haiti in 2010 to help those injured by the 2010 earthquake.
Sustainable business models	Multinational corporation with multiple product lines. The challenge is to create a sustainable business model while serving low-resource settings.	Thousands of devices have been sold. Small company based in Massachusetts.[30]

Demand Information	TECHNOLOGY/SOLUTION—TABLE 4	
	SeeMore™	Terason t3000™
Existing demand	End users are health care providers. It is possible to have a technician take the image and have a provider interpret the image remotely. The application of this technology is broader than just the OBGYN. Therefore, the market size is driven by the number of health facilities, providers, and communities.	End users are health care providers. It is possible to have a technician take the image and have a provider interpret the image remotely. The application of this technology is broader than just the OBGYN. Therefore, the market size is driven by the number of health facilities, providers, and communities.
Attractiveness	Not as portable due to requirement of a laptop; price is lower than competition, but still high.	Larger screen size.
Price sensitivity	A cost of less than US$2,000 could potentially be cost-effective at the rural clinic level.[20]	A cost of less than US$2,000 could potentially be cost-effective at the rural clinic level.[20]
Policy environment	Policy has not yet been formulated by international bodies.	Policy has not yet been formulated by international bodies.
Donors/ stakeholders	None.	Partner with Siemens, BrainLab, and Endocare. Won the Technology Innovation Award in Portable Ultrasound from Frost and Sullivan in 2008.
Pre- and post-sales support	Weeks of training required.	Weeks of training required. Maintenance of the product required.
Need for demand creation	Awareness in low-resource settings is growing around the usability for OBGYN indications; however, the cost of the product is prohibitive. A lower price product may become more cost-effective if it allows for task shifting of imaging to lower level trained individuals in the community. Abuse of the use of ultrasound for sex selection, especially in Southeast Asia and South Asia remains an issue. There is a need to generate more evidence related to the impact of ultrasound on obstetric outcomes. However, due to popularity of fetal images, consumer demand may be generated in the absence of these data.	Awareness in low-resource settings is growing around the usability for OBGYN indications; however, the cost of the product is prohibitive. A lower price product may become more cost-effective if it allows for task shifting of imaging to lower level trained individuals in the community. Abuse of the use of ultrasound for sex selection, especially in Southeast Asia and South Asia remains an issue. There is a need to generate more evidence related to the impact of ultrasound on obstetric outcomes. However, due to popularity of fetal images, consumer demand may be generated in the absence of these data.

Supply Information	TECHNOLOGY/SOLUTION—TABLE 5	
	Dp-6600	**CX50 CompactXtreme**
Description	11 kg, 10-inch monitor, option of 5 transducers ranging from 2 to 10 MHz, has USB ports.	13 lbs, 15-inch monitor, 14 x 14 x 2.5 inches overall. Not yet adapted for obstetric use.
Characteristics applicable for low-resource settings	Portable, but not hand-held. Requires power source. Rechargeable battery available on the DP-6900 version only.	Portable, but not hand-held.
Developer and/or manufacturer	MindRay.	Philips.
Status	Commercialized. Has USFDA approval.	Commercialized; has USFDA approval. ITW completed testing of hardware and software, volume ultrasound scan protocols, and training. Currently, they are testing accuracy and acceptability of the software and hardware in three clinics in Uganda.
Efficacy/ effectiveness	Efficacy depends on user skill and timing of screening. Limitations in compact ultrasound resolution may be mitigated in low-resource settings where the imaging resolution may be enhanced by the prevalence of undernourished patients with considerably less body fat than found in patients in more developed nations.[11] A randomized trial of routine second-trimester ultrasounds of women without special risk factors in South Africa found no link between ultrasound use and improved obstetric outcome.[17] A Cochrane review reported routine late ultrasound (after 24 weeks, without clinical signs), had no measurable benefit for mother or baby.[5] A limitation was that it consisted of studies in countries where women deliver in well-equipped hospitals, rather than settings such as the home or simple maternity facilities and may need to be transferred to receive care. A review in Ghana came to a similar conclusion, obstetric ultrasound "does not result in reduction of maternal mortality or perinatal mortality," but it may still be useful for reducing referrals and diagnosing antepartum hemorrhage.[1] A subsequent Cochrane review found that Doppler ultrasound of the uterus or placenta in women in their second trimester and at low risk for hypertensive disorders resulted in no improvements for the baby or the mother[18], although there were no randomized studies in the first trimester, or in women at high risk. Most experts agree that ultrasound can be very valuable in diagnosing symptomatic women (e.g., with antenatal bleeding) or pregnant women with risk factors (e.g., history of obstructed labor), but they are relatively few, making it difficult to achieve the volumes needed to make the technology cost-effective. There is not sufficient data to calculate the actual number of lives that might be saved, but it appears to be a relatively small proportion of the maternal mortality that occurs.	
Manufacturing quality and capacity	Manufactured in Shenzhen, China.	Data not available.
Intellectual property ownership	Proprietary.	Proprietary.
Cost and cost drivers	Approximately US$9,000.	More than US$40,000.
Delivery/ procurement channels	Has a global distribution network with sales staff in Canada, China, India, Mexico, Russia, United Kingdom, United States, and more.[32]	Collaboration with ITW can potentially provide a channel to low-resource settings.
Sustainable business models	Public company.	Multinational corporation with multiple product lines. The challenge is to create a sustainable business model while serving low-resource settings.

Demand Information	TECHNOLOGY/SOLUTION—TABLE 5	
	Dp-6600	**CX50 CompactXtreme**
Existing demand	End users are health care providers. It is possible to have a technician take the image and have a provider interpret the image remotely. The application of this technology is broader than just the OBGYN. Therefore, the market size is driven by the number of health facilities, providers, and communities.	End users are health care providers. It is possible to have a technician take the image and have a provider interpret the image remotely. The application of this technology is broader than just the OBGYN. Therefore, the market size is driven by the number of health facilities, providers, and communities.
Attractiveness	Larger screen size.	Larger screen size.
Price sensitivity	A cost of less than US$2,000 could potentially be cost-effective at the rural clinic level.	A cost of less than US$2,000 could potentially be cost-effective at the rural clinic level.
Policy environment	Policy has not yet been formulated by international bodies.	Policy has not yet been formulated by international bodies.
Donors/ stakeholders	None.	Collaborator with ITW, recipient of US$100,000 grant from the Bill & Melinda Gates Foundation's Grand Challenges program.
Pre- and post-sales support	Weeks of training required. Maintenance of the product required.	Weeks of training required. Maintenance of the product required.
Need for demand creation	Awareness in low-resource settings is growing around the usability for OBGYN indications; however, the cost of the product is prohibitive. A lower price product may become more cost-effective if it allows for task shifting of imaging to lower level trained individuals in the community. Abuse of the use of ultrasound for sex selection, especially in Southeast Asia and South Asia remains an issue. There is a need to generate more evidence related to the impact of ultrasound on obstetric outcomes. However, due to popularity of fetal images, consumer demand may be generated in the absence of these data.	Awareness in low-resource settings is growing around the usability for OBGYN indications; however, the cost of the product is prohibitive. A lower price product may become more cost-effective if it allows for task shifting of imaging to lower level trained individuals in the community. Abuse of the use of ultrasound for sex selection, especially in Southeast Asia and South Asia remains an issue. There is a need to generate more evidence related to the impact of ultrasound on obstetric outcomes. However, due to popularity of fetal images, consumer demand may be generated in the absence of these data.

Supply Information	TECHNOLOGY/SOLUTION—TABLE 6	
	Fetal ultrasound belt	**Intelligent ultrasound**
Description	A fetal ultrasound belt with multiple imaging sensors woven into the blanket, blanket must be placed correctly to take images.[33]	"Image-free" ultrasound for assisting in the diagnosis and management of common medical conditions during pregnancy and childbirth.
Characteristics applicable for low-resource settings	Would reduce the training required for technicians. Current machines depend on a skilled technician to guide a probe over the abdomen.	Innovative, portable imageless ultrasound device with the ability to make diagnosis recommendations without the direct need of a skilled operator.
Developer and/or manufacturer	Art Center College of Design, Pasadena, CA.	PATH/Philips.
Status	Designed for a student project. Not taken into research and development by any organization.	Pre-clinical. Currently assessing feasibility of the concept, developing specifications, and evaluating possible economic models.
Efficacy/ effectiveness	Efficacy depends on user skill and timing of screening. Limitations in compact ultrasound resolution may be mitigated in low-resource settings where the imaging resolution may be enhanced by the prevalence of undernourished patients with considerably less body fat than found in patients in more developed nations.[11] A randomized trial of routine second-trimester ultrasounds of women without special risk factors in South Africa found no link between ultrasound use and improved obstetric outcome.[17] A Cochrane review reported routine late ultrasound (after 24 weeks, without clinical signs), had no measurable benefit for mother or baby.[5] A limitation was that it consisted of studies in countries where women deliver in well-equipped hospitals, rather than settings such as the home or simple maternity facilities and may need to be transferred to receive care. A review in Ghana came to a similar conclusion, obstetric ultrasound "does not result in reduction of maternal mortality or perinatal mortality," but it may still be useful for reducing referrals and diagnosing antepartum hemorrhage.[1] A subsequent Cochrane review found that Doppler ultrasound of the uterus or placenta in women in their second trimester and at low risk for hypertensive disorders resulted in no improvements for the baby or the mother[18], although there were no randomized studies in the first trimester, or in women at high risk. Most experts agree that ultrasound can be very valuable in diagnosing symptomatic women (e.g., with antenatal bleeding) or pregnant women with risk factors (e.g., history of obstructed labor), but they are relatively few, making it difficult to achieve the volumes needed to make the technology cost-effective. There is not sufficient data to calculate the actual number of lives that might be saved, but it appears to be a relatively small proportion of the maternal mortality that occurs.	
Manufacturing	Still in early concept stage.	Still in early concept stage.
Intellectual property ownership	Information not available.	Undetermined; the components have been developed by other companies
Cost and cost drivers	Information not available.	The technology would not have a screen, which would help to lower the costs; the major component is the transducer which currently costs US$3,000. Unless these costs decrease (which is not a focus in the scope of this project), the device will be slightly higher than US$3,000.
Delivery/ procurement channels	Delivery/ procurement channels to be determined for this technology.	Delivery/procurement channels to be determined for this technology.
Sustainable business models	This is a student project, not a company.	There is potential for Philips to take this product on for manufacturing and distribution, but this has not been discussed.

Demand Information	TECHNOLOGY/SOLUTION—TABLE 6	
	Fetal ultrasound belt	**Intelligent ultrasound**
Existing demand	End users are health care providers. It is possible to have a technician take the image and have a provider interpret the image remotely. The application of this technology is broader than just the OBGYN. Therefore, the market size is driven by the number of health facilities, providers, and communities.	End users are health care providers. It is possible to have a technician take the image and have a provider interpret the image remotely. The application of this technology is broader than just the OBGYN. Therefore, the market size is driven by the number of health facilities, providers, and communities.
Attractiveness	Designed to reduce error on behalf of the provider.	Imageless—does not allow for sex selection.
Price sensitivity	A cost of less than US$2,000 could potentially be cost-effective at the rural clinic level.	A cost of less than US$2,000 could potentially be cost-effective at the rural clinic level.
Policy environment	Policy has not yet been formulated by international bodies.	Policy has not yet been formulated by international bodies.
Donor/ stakeholders	GE Healthcare contest for students.	None.
Pre- and post-sales support	Weeks of training required.	Weeks of training required.
Need for demand creation	Awareness in low-resource settings is growing around the usability for OBGYN indications; however, the cost of the product is prohibitive. A lower price product may become more cost-effective if it allows for task shifting of imaging to lower level trained individuals in the community. Abuse of the use of ultrasound for sex selection, especially in Southeast Asia and South Asia remains an issue. There is a need to generate more evidence related to the impact of ultrasound on obstetric outcomes. However, due to popularity of fetal images, consumer demand may be generated in the absence of these data.	Awareness in low-resource settings is growing around the usability for OBGYN indications; however, the cost of the product is prohibitive. A lower price product may become more cost-effective if it allows for task shifting of imaging to lower level trained individuals in the community. Abuse of the use of ultrasound for sex selection, especially in Southeast Asia and South Asia remains an issue. There is a need to generate more evidence related to the impact of ultrasound on obstetric outcomes. However, due to popularity of fetal images, consumer demand may be generated in the absence of these data.

Supply Information	TECHNOLOGY/SOLUTION—TABLE 7
	Image the World (ITW) prototype
Description	ITW acknowledge the product does not produce as high quality images like the Philips CX50 CompactXtreme.
Characteristics applicable for low-resource settings	Plans are to make a low-cost product (in the US$2500 range).
Developer and/or manufacturer	Developed by Imaging the World (ITW), and licensed to Shenzhen Well.D Medical Electronics Co., Ltd. for manufacturing.
Status	Prototype. Currently testing the image quality and compression software to use with a netbook in Maryland. Accuracy and acceptability testing planned in Uganda in March 2012.
Efficacy/ effectiveness	Efficacy depends on user skill and timing of screening. Limitations in compact ultrasound resolution may be mitigated in low-resource settings where the imaging resolution may be enhanced by the prevalence of undernourished patients with considerably less body fat than found in patients in more developed nations.[11] A randomized trial of routine second-trimester ultrasounds of women without special risk factors in South Africa found no link between ultrasound use and improved obstetric outcome.[17] A Cochrane review reported routine late ultrasound (after 24 weeks, without clinical signs), had no measurable benefit for mother or baby.[5] A limitation was that it consisted of studies in countries where women deliver in well-equipped hospitals, rather than settings such as the home or simple maternity facilities and may need to be transferred to receive care. A review in Ghana came to a similar conclusion, obstetric ultrasound "does not result in reduction of maternal mortality or perinatal mortality," but it may still be useful for reducing referrals and diagnosing antepartum hemorrhage.[1] A subsequent Cochrane review found that Doppler ultrasound of the uterus or placenta in women in their second trimester and at low risk for hypertensive disorders resulted in no improvements for the baby or the mother[18], although there were no randomized studies in the first trimester, or in women at high risk. Most experts agree that ultrasound can be very valuable in diagnosing symptomatic women (e.g., with antenatal bleeding) or pregnant women with risk factors (e.g., history of obstructed labor), but they are relatively few, making it difficult to achieve the volumes needed to make the technology cost-effective. There is not sufficient data to calculate the actual number of lives that might be saved, but it appears to be a relatively small proportion of the maternal mortality that occurs.
Manufacturing quality and capacity	Shenzhen Well.D Medical Electronics Co., Ltd. currently manufactures several ultrasound products and sells these products to over 90 countries.[34]
Intellectual property ownership	ITW has patents on this technology.
Cost and cost drivers	US$2,500.
Delivery/ procurement channels	Delivery/procurement channels to be determined for this technology.
Sustainable business models	Sustainability is questionable as workers are currently volunteer-based. They aim to sell the device at prices that generate a profit, but the infrastructure itself is not sustainable.

Demand Information	TECHNOLOGY/SOLUTION—TABLE 7
	Image the World (ITW) prototype
Existing demand	End users are trained machine operators in the field; providers interpret the image remotely. The application of this technology is broader than just the OBGYN. Therefore, the market size is driven by the number of health facilities, providers, and communities.
Attractiveness	Low cost is the main attraction as is the telemedicine component, enabling the use of expert sonographers and physicians.
Price sensitivity	A cost of less than US$2,000 could potentially be cost-effective at the rural clinic level.
Policy environment	Policy has not yet been formulated by international bodies.
Donor/ stakeholders	ITW received a US$100,000 grant from the Bill & Melinda Gates Foundation's Grand Challenges program.
Pre- and post-sales support	Two days of training required for the machine operator.
Need for demand creation	Awareness in low-resource settings is growing around the usability for OBGYN indications; however, the cost of the product is prohibitive. A lower price product may become more cost-effective if it allows for task shifting of imaging to lower level trained individuals in the community. Abuse of the use of ultrasound for sex selection, especially in Southeast Asia and South Asia remains an issue. There is a need to generate more evidence related to the impact of ultrasound on obstetric outcomes. However, due to popularity of fetal images, consumer demand may be generated in the absence of these data.

References

[1] Seffah JD, Adanu RM. Obstetric ultrasonography in low-income countries. *Clinical Obstetrics and Gynecology*. 2009;52(2):250–255.

[2] Katanozaka M, Yoshinaga M, Fuchiwaki K, Nagata Y. Measurement of obstetric conjugate by ultrasonic tomography and its significance. *American Journal of Obstetrics and Gynecology*. 1999;180(1 Pt 1):159–162.

[3] Haws RA, Yakoob MY, Soomro T, Menezes EV, Darmstadt GL, Bhutta ZA. Reducing stillbirths: screening and monitoring during pregnancy and labour. *BMC Pregnancy and Childbirth.* 2009; 9(Suppl 1):S5.

[4] Whitworth M, Bricker L, Neilson JP, Dowswell T. Ultrasound for fetal assessment in early pregnancy. *Cochrane Database of Systematic Reviews*. 2010; 4.

[5] Bricker L, Neilson JP, Dowswell T. Routine ultrasound in late pregnancy (after 24 weeks' gestation). *Cochrane Database of Systematic Reviews*. 2008; 4.

[6] Imaging the World website. Available at: http://imagingtheworld.org. Accessed February 1, 2012.

[7] Ganatra B. Maintaining access to safe abortion and reducing sex ratio imbalances in Asia. *Reproductive Health Matters*. 2008;16(31, Supplement 1):90–98.

[8] Gammeltoft T, Nguyen HT. The commodification of obstetric ultrasound scanning in Hanoi, Viet Nam. *Reproductive Health Matters*. 2007;15(29):163–171.

[9] Harris A, Gao Y, Barclay L, et al. Consequences of birth policies and practices in post-reform China. *Reproductive Health Matters.* 2007; 15(30):114–124.

[10] Bashour H, Hafez R, Abdulsalam A. Syrian women's perceptions and experiences of ultrasound screening in pregnancy: Implications for antenatal policy. *Reproductive Health Matters*. 2005;13(25):147–154.

[11] Harris RD, Marks WM. Compact ultrasound for improving maternal and perinatal care in low-resource settings: Review of the potential benefits, implementation challenges, and public health issues. *Journal of Ultrasound in Medicine*. 2009; 28(8):1067–1076.

[12] Kimberly HH, Murray A, Mennicke M, et. al. Focused maternal ultrasound by midwives in rural Zambia. *Ultrasound in Medicine and Biology*. 2010;36(8):1267–1272.

[13] Adler D, Mgalula K, Price D, Taylor O. Introduction of a portable ultrasound unit into the health services of the Lugufu refugee camp, Kigoma District, Tanzania. *International Journal of Emergency Medicine*. 2008;1(4):261–266.

[14] Eckardt M, Ahn R, Reyes R, et. al. Impact of maternal ultrasound implementation in rural clinics in Mali. Presented at: APHA 139th Annual Meeting and Exposition, November 1, 2011; Washington, DC.

[15] Layne R. GE plans to sell phone-size ultrasound device in 2010 (Update 1). *Bloomberg*. October 20, 2009. Available at: http://www.bloomberg.com/apps/news?pid=newsarchive&sid=aVWwPivfTiMw. Accessed February 1, 2012.

[16] Signostics portable ultrasound machine page. Ultrasound Transducers Sensor Probe Display Images website. Available at: http://ultrasound-image.blogspot.com/2011/01/signostics-portable-ultrasound-machine.html. Accessed February 1, 2012.

[17] Van Dyk B, Motto JA, Buchmann EJ. Routine second-trimester ultrasound for low risk pregnancies in a South African community. *International Journal of Gynecology and Obstetrics*. 2007;98(3):257–258.

[18] Stampalija T, Gyte GML, Alfirevic Z. Utero-placental Doppler ultrasound for improving pregnancy outcome. *Cochrane Database of Systematic Reviews*. 2010;9.

[19] Portable ultrasound page. Maternal and Neonatal Directed Assessment of Technology website. Available at: http://mnhtech.org/technology/technology-briefs/portable-ultrasound/. Accessed February 1, 2012.

[20] Phone interview with Rob Nathan, School of Public Health, University of Washington. February 3, 2012.

[21] Signostics awarded $1.96 million to commercialize handheld ultrasound device [press release]. Palo Alto: Signostics; August 18, 2011.

[22] Shenzhen Well. D Medical Electronics Co., Ltd. website. Available at: www.welld.com.cn. Accessed February 1, 2012.

[23] Healthpower Technology Ltd. website. Available at: http://www.pw-health.net/about.asp. Accessed February 1, 2012.

[24] Product overview page. Mobisante website. Available at: http://www.mobisante.com/product-overview/. Accessed February 1, 2012.

[25] Timmerman L. Mobisante wins FDA approval for "Ultrasound on a Smartphone" technology. *Xconomy*. February 3, 2011. Available at: http://www.xconomy.com/seattle/2011/02/03/mobisante-wins-fda-approval-for-ultrasound-on-a-smartphone-technology/. Accessed February 1, 2012.

[26] Ultrasound4Africa web page. Saving Lives at Birth website. Availble at: http://www.savinglivesatbirth.net/summaries/92. Accessed February 1, 2012.

[27] DMS Medical Evaluation Tools website. Available at: http://www.innovasound.us/Medical%20Site/medical_index.html. Accessed February 1, 2012.

[28] Open letter recommending Innovasound. Innovasound website. Available at: http://www.innovasound.us/images/recommendation_InnovaSound_WMP_Dr%20%20Flowers.pdf. Accessed February 9, 2012.

[29] Hand held ultrasound comparison chart page. Interson Corporation website. Available at: http://www.interson.com/products/seemore-153-usb-probes-source/ultrasound-comparison-chart. Accessed February 1, 2012.

[30] About Terason page. Terason website. Available at: http://www.terason.com/aboutus/index.asp. Accessed February 1, 2012.

[31] Terason Announces Agreement with Premier Inc. [press release]. Burlington, MA: Terason; April 6, 2009.

[32] About us page. Mindray website. Available at: http://www.mindray.com/na/aboutus/aboutus01.html. Accessed February 1, 2012.

[33] Easy-use Fetal Ultrasound Belt. Maternova website. Available at: http://maternova.net/health-innovations/easy-use-fetal-ultrasound-belt. Accessed February 1, 2012.

[34] About us web page. Shenzhen Well.D Medical Electronics Co website. Available at: http://www.welld.com.cn/einfo.asp. Accessed February 9, 2012.

Assisted Delivery

Forceps or vacuum extractors (ventouse) are used to expedite birth for the benefit of either the woman or her baby or both. Their use, however, is sometimes associated with significant complications. Over the past two decades, many countries have observed a decline in instrumental delivery rates while cesarean rates have increased. Barriers to instrumental delivery are largely due to the concern about potential harm it causes newborns. Some medical schools no longer train their professionals to perform instrumental delivery. Vacuum extraction can be taught to mid-level practitioners (midwives, nurse practitioners, and general physicians), thereby increasing access to emergency obstetric care especially at the periphery. This allows women to give birth closer to home in mid-level facilities when hospitals are not easily accessible or are overcrowded. There is a recognized place for forceps and all types of ventouse in clinical practice. The choice of instruments for assistance of vaginal deliveries varies greatly around the world. These differences are explained by traditions, availability of the instruments, skill of birth attendants, and training.[1]

The World Health Organization (WHO) recommends vacuum extraction as the first-line method for assisted birth for vertex (cephalic) presentation and forceps as the instrument of choice for face presentation and after-coming head of the breech. Ventouse delivery also depends on the active participation of the woman to bear down and may be less appropriate when she is unable to do so.[2]

A Cochrane review of 32 studies (6,597 women) found that while forceps were less likely than the ventouse to fail to achieve a vaginal birth, there was a trend to more cesarean operations and significantly more third- or fourth-degree tears (with or without episiotomy), vaginal trauma, use of general anesthesia, and flatus incontinence or altered continence. Facial injury to the baby was more likely with forceps than vacuum extractors, but there was a trend towards fewer cases of cephalohematoma with forceps.[3] Although there are over 700 different types of forceps, most of the currently employed instruments were originally designed in the 19th and early 20th centuries. Gei and Pacheco suggest that the factor most likely to improve forceps would be a “scientific redesign.”[1] Due to specialized training required for forceps delivery and the limited presence of trained specialists, forceps are not widely used in low-resource settings.

Vacuum extractors have become a preferred alternative because although there is a higher failure rate than with forceps, they are associated with fewer complications for the woman and her baby, and they require less specialized training than forceps and may, therefore, be used more widely by midwives and nonspecialist doctors.[4,5,6] The equipment for vacuum extraction consists of a rigid or soft cup, anterior or posterior cup, a traction device, and a vacuum system. The cup is applied to the scalp by providing negative pressure. Cups of various designs and materials are

available, and hand pumps or electrical vacuum pump systems are available. Both systems have a regulator valve and pressure gauge. Prior to use, the vacuum extraction equipment must be assembled, inspected, and tested to make sure there are no leakages in the system. Electrical vacuum pumps with soft-touch cup are becoming more readily available in low-resource settings. However, unless there is a constant supply of electricity, it is advisable to have a hand pump available as a backup. In addition, all instrumental delivery efforts include an element of uncertainty, thus preparations for a cesarean or transfer to a facility that has operative capacity should be carried out in parallel to assisted delivery efforts in case the vaginal procedure does not proceed rapidly and easily.

Vacuum extractor cups may be metal, plastic, or silicone and are classified into three categories: (1) soft cup made of silicone or plastic and used for outlet or low occipito-anterior (OA) (<45 degrees) extractions; (2) rigid anterior cups made of plastic or metal also indicated for outlet or low OA (<45 degrees) extractions; and (3) rigid posterior cups of plastic or metal that are indicated for use in low OA (>45 degrees), occipito-posterior (OP), and occipito-lateral (OT) extractions. Vacuum cups are either mushroom-shaped cups, or soft, bell- or trumpet-shaped cups. A weakness of soft cups is that the combined and centrally located vacuum port and traction stem limit their maneuverability. Because the effectiveness of the vacuum extractor depends on correct placement of the cup on the flexion point of the infant's scalp, limited maneuverability leads to increased failure rates and increased risk of trauma to the infant and mother.[3,7,8] Although there are little or no data relating to vertical transmission of HIV and instrumental birth, there is a theoretical risk that breaches of the skin of the fetus or neonate may increase the risk of transmission. Soft vacuum cups would in theory be expected to be less harmful than rigid cups in this respect.[3] For OL or OP positions or where the need for greater traction force is anticipated, the metal vacuum cup has advantages.

One study indicated there were no significant differences found between the handheld and the standard vacuum; in all types of delivery, nonrotational and rotational, the handheld vacuum performed comparably to standard vacuum with no significant fetal injury or differences in maternal injuries.[9]

The Odon device is an emerging technology in the area of assisted vaginal deliveries that has potential to be transformational since it is an entirely different category from vacuum extractors and forceps. The device decreases the risk of fetal-maternal injury, contributes to the physiologic development of the second stage of labor, contributes to contraction forces and maternal pushing efforts, could reduce prolonged second stage of labor, could reduce PPH through a reduction in the second stage of labor, could significantly decrease operative delivery, could reduce the incidence of perineal damage, and could decrease perinatal infections acquired through the birth canal.[10]

The three tables below evaluate the more promising technologies available for assisted delivery.

Supply Information	TECHNOLOGY/SOLUTION—TABLE 1	
	Forceps	**Medela vacuum delivery system**
Description	Generally stainless steel medical-grade device. Various brands and designs are available.	This system offers reliability and flexibility whenever the birth process requires vacuum assistance. The system consists of an electric pump and choice of rigid or soft, reusable or disposable, anterior or posterior cups. The electric pump offered fast and efficient vacuum buildup, easy maintenance, and precise vacuum setting.
Characteristics applicable for low-resource settings	Not indicated for use in low-resource settings.	High-quality, high-cost system. Requires substantial training and electricity to run this complex system. Not very appropriate for low-resource settings.
Developer and/or manufacturer	Various.	Medela AG.
Status	Commercialized. Obstetric forceps require 510(K) clearance (Class II device).	Commercialized. CE Mark and 510(k) clearance (Class II device).
Efficacy/ effectiveness	Ten studies with 1,558 women compared the soft anterior cup ventouse with the metal cup. Results were in favor of the metal cup (8 studies with 1,076 women; RR 1.63, 95 percent CI 1.17 to 2.28). Apart from cephalohematoma (6 studies, 669 women; RR 0.61, 95 percent CI 0.39 to 0.95) and scalp injury (9 studies with 1517 women; RR 0.67, 95 percent CI 0.53 to 0.86) which were less likely with the soft cup, there was no significant difference in neonatal outcome with either group. There was no significant difference in maternal outcomes (i.e., cesarean section, episiotomy, perineal and vulval trauma) between these two groups.[3] A study comparing safety and efficacy of M-cups vs. forceps, the corrected efficacy rates were forceps 92% and M-cup 94%. The M-style cup deliveries were accomplished more rapidly than forceps deliveries and were associated with a lower rate of episiotomy, 3˚ and 4˚ lacerations. Forceps deliveries were associated with fewer clinically diagnosed cephalohematomas than M-cup deliveries. In conclusion, the M-cup vacuum extractor cup appears to be as efficient (and faster) than the obstetric forceps but is associated with significantly more fetal cephalohematomas, whereas maternal injuries are more common with the forceps.[11] A Malaysian random controlled trial (RCT) of 164 women found the Kiwi OmniCup is an effective alternative to the currently available Malmstrom metal cup for vacuum-assisted delivery with no increase in maternal or neonatal morbidity or mortality. Vacca Reusable OmniCup vs. Bird anterior and posterior metal cups found no significant differences in outcomes between devices.[12]	Ten studies with 1,558 women compared the soft anterior cup ventouse with the metal cup. Results were in favor of the metal cup (8 studies with 1,076 women; RR 1.63, 95 percent CI 1.17 to 2.28). Apart from cephalohematoma (6 studies, 669 women; RR 0.61, 95 percent CI 0.39 to 0.95) and scalp injury (9 studies with 1517 women; RR 0.67, 95 percent CI 0.53 to 0.86) which were less likely with the soft cup, there was no significant difference in neonatal outcome with either group. There was no significant difference in maternal outcomes (i.e., cesarean section, episiotomy, perineal and vulval trauma) between these two groups.[3] A study comparing safety and efficacy of M-cups vs. forceps, the corrected efficacy rates were forceps 92% and M-cup 94%. The M-style cup deliveries were accomplished more rapidly than forceps deliveries and were associated with a lower rate of episiotomy, 3˚ and 4˚ lacerations. Forceps deliveries were associated with fewer clinically diagnosed cephalohematomas than M-cup deliveries. In conclusion, the M-cup vacuum extractor cup appears to be as efficient (and faster) than the obstetric forceps but is associated with significantly more fetal cephalohematomas, whereas maternal injuries are more common with the forceps.[11] A Malaysian RCT of 164 women found the Kiwi OmniCup is an effective alternative to the currently available Malmstrom metal cup for vacuum-assisted delivery with no increase in maternal or neonatal morbidity or mortality. Vacca Reusable OmniCup vs. Bird anterior and posterior metal cups found no significant differences in outcomes between devices.[12]

Supply Information	TECHNOLOGY/SOLUTION—TABLE 1	
	Forceps	**Medela vacuum delivery system**
Manufacturing quality and capacity	Various.	Manufactured by Medela AG, a large international company. The manufacturing quality and capacity is unlikely to be an issue.
Intellectual property ownership	No data available.	No data available.
Cost and cost drivers	Forceps costs are approximately between US$190 and US$250.[13]	US$3,825 (including the pump system only) at www.medexsupply.com. Other cost includes electricity to run the system and cost for disposable cups or sterilization cost for reusable cups. Listed as US$849.89 in UNICEF Supply Catalogue (including a full set).[14]
Delivery/ procurement channels	Can be purchased on line. The UNICEF Supply Catalogue does not list obstetric forceps.	Can be procured through the manufacturer's subsidiaries and local distributors. The manufacturer has wide international distribution network.
Sustainable business models	Policy favors vacuum extraction. The demand for use of forceps for assisted delivery is likely to become smaller. Also, the cost for training is substantial. Due to these factors, it will be difficult to achieve sustainable business models in low-resource countries.	Distribution through private-sector channels is possible for this high-end device.

Demand Information	TECHNOLOGY/SOLUTION—TABLE 1	
	Forceps	**Medela vacuum delivery system**
Existing demand	The market size will be driven by the number of facilities that are capable of performing assisted delivery. Due to the training requirement, the use is likely to be limited to a handful of facilities.	The market size for the pump system will be driven by the number of facilities that are capable of performing assisted delivery. The market size for disposable cups is driven by the number of assisted deliveries. Due to the high price of the system, the use is likely to be limited to tertiary hospitals.
Attractiveness	Requires substantial training, which makes it difficult to use this device for assisted delivery in low-resource settings.	High quality product produced by a reputable company. However, the high price and requirement for electricity are likely to make this product unattractive for low-resource countries.
Price sensitivity	No data available on user acceptability on different methods, types of pumps, and cups.	No data available on user acceptability on different methods, types of pumps, and cups.
Policy environment	WHO recommends vacuum extraction as the first-line method for assisted birth for vertex (cephalic) presentation and forceps as the instrument of choice for face presentation and after-coming head of the breech.	WHO recommends vacuum extraction as the first-line method for assisted birth for vertex (cephalic) presentation and forceps as the instrument of choice for face presentation and after-coming head of the breech.
Donors/ stakeholders	WHO and obstetrician and gynecologist (OB/GYN) associations such as the International Federation of Gynecology and Obstetrics (FIGO).	WHO and OB/GYN associations such as FIGO.
Pre- and post-sales support	Requires substantial training on the correct use of the device and assisted delivery procedures.	Requires training on the correct use of the device and assisted delivery procedures. Requires training on the proper sterilization of reusable cups. The pump system requires maintenance and repair (in case of malfunction).
Need for demand creation	Vacuum extraction is recommended as the first-line method. It is unlikely that the use of forceps for assisted delivery will remain a viable option in low-resource settings.	Need to provide guidance to users and procurers on appropriate product selection. Requires training to promote a proper procedure and use of the product. Cost-effectiveness data may be necessary to understand the program cost between pump systems and between reusable and disposable cups.

Supply Information	TECHNOLOGY/SOLUTION—TABLE 2	
	Mystic® II pump and cups	**Mityvac® Vacuum Assisted Delivery Pumps**
Description	A fully disposable system. Installed with easy-to-read color-coded gauge. Does not require electricity. Can choose Mistic® II with M-Style® low-profile Mushroom® semi-rigid cup for non-OA deliveries or Mityvac® MitySoft® Bell Vacuum cup for OA deliveries.	The system is based on the reusable Mityvac® pump, with a variety of disposable cup configurations: M-Select® soft Mushroom® cup, Mityvac® MitySoft® Bell Vacuum Cup for OA deliveries, M-Sytye® Mushroom® cup for non-OA deliveries. To complete the offering, a reusable rigid cup is also available.
Characteristics applicable for low-resource settings	Does not require electricity. The pump is equipped with a gauge. However, recurring cost could be too high for low-resource setting since the system is fully disposable.	Does not require electricity. The pump is equipped with a gauge. Can choose a reusable cup, but if disposable cups are selected for versatility, recurring costs will be higher.
Developer and/or manufacturer	Cooper Surgical.	Cooper Surgical.
Status	Commercialized. United States Food and Drug Administration (USFDA) 510(k) clearance (Class II device).	Commercialized. USFDA 510(k) clearance (Class II device).
Efficacy/ effectiveness	Ten studies with 1,558 women compared the soft anterior cup ventouse with the metal cup. Results were in favor of the metal cup (8 studies with 1,076 women; RR 1.63, 95 percent CI 1.17 to 2.28). Apart from cephalohematoma (6 studies, 669 women; RR 0.61, 95 percent CI 0.39 to 0.95) and scalp injury (9 studies with 1517 women; RR 0.67, 95 percent CI 0.53 to 0.86) which were less likely with the soft cup, there was no significant difference in neonatal outcome with either group. There was no significant difference in maternal outcomes (i.e., cesarean section, episiotomy, perineal and vulval trauma) between these two groups.[3] A study comparing safety and efficacy of M-cups vs. forceps, the corrected efficacy rates were forceps 92% and M-cup 94%. The M-style cup deliveries were accomplished more rapidly than forceps deliveries and were associated with a lower rate of episiotomy, 3˚ and 4˚ lacerations. Forceps deliveries were associated with fewer clinically diagnosed cephalohematomas than M-cup deliveries. In conclusion, the M-cup vacuum extractor cup appears to be as efficient (and faster) than the obstetric forceps but is associated with significantly more fetal cephalohematomas, whereas maternal injuries are more common with the forceps.[12]	Ten studies with 1,558 women compared the soft anterior cup ventouse with the metal cup. Results were in favor of the metal cup (8 studies with 1,076 women; RR 1.63, 95 percent CI 1.17 to 2.28). Apart from cephalohematoma (6 studies, 669 women; RR 0.61, 95 percent CI 0.39 to 0.95) and scalp injury (9 studies with 1517 women; RR 0.67, 95 percent CI 0.53 to 0.86) which were less likely with the soft cup, there was no significant difference in neonatal outcome with either group. There was no significant difference in maternal outcomes (i.e., cesarean section, episiotomy, perineal and vulval trauma) between these two groups.[3] A study comparing safety and efficacy of M-cups vs. forceps, the corrected efficacy rates were forceps 92% and M-cup 94%. The M-style cup deliveries were accomplished more rapidly than forceps deliveries and were associated with a lower rate of episiotomy, 3˚ and 4˚ lacerations. Forceps deliveries were associated with fewer clinically diagnosed cephalohematomas than M-cup deliveries. In conclusion, the M-cup vacuum extractor cup appears to be as efficient (and faster) than the obstetric forceps but is associated with significantly more fetal cephalohematomas, whereas maternal injuries are more common with the forceps.[12]
Manufacturing quality and capacity	Manufactured by Cooper Surgical, a large international company. The manufacturing quality and capacity is unlikely to be an issue.	Manufactured by Cooper Surgical, a large international company. The manufacturing quality and capacity is unlikely to be an issue.

Supply Information	TECHNOLOGY/SOLUTION—TABLE 2	
	Mystic® II pump and cups	**Mityvac® Vacuum Assisted Delivery Pumps**
Intellectual property ownership	Some cup designs are protected by patent.	Some cup designs are protected by patent.
Cost and cost drivers	12 Mystic® II with M-Style® Mushroom® cup: US$372.00.[15] Listed as US$849.89 in the UNICEF Supply Catalogue (including a full set).[14]	Mityvac® pump: US$103.95. Disposables are priced separately (e.g., 12 M-style® Mushroom® cups: US$320.15).[15] Listed as US$849.89 in the UNICEF Supply Catalogue (including a full set).[14]
Delivery/ procurement channels	Can be procured through the manufacturer's subsidiaries and local distributors. The manufacturer has a wide international distribution network.	Can be procured through the manufacturer's subsidiaries and local distributors. The manufacturer has a wide international distribution network.
Sustainable business models	Distribution through private-sector channels is possible. The demand for this fully disposable device is likely to be small in low-resource countries; it might be difficult to create a sustainable business model.	Distribution through private-sector channels is possible. Bulk procurement will be necessary to reduce the price and increase the demand.

Demand Information	TECHNOLOGY/SOLUTION—Table 2	
	Mystic® II pump and cups	**Mityvac® Vacuum Assisted Delivery Pumps**
Existing demand	The market size will be driven by the number of facilities that are capable of performing assisted delivery.	The market size for the pump will be driven by the number of facilities that are capable of performing assisted delivery. The market size for disposable cups is drive by the number of assisted deliveries.
Attractiveness	High-quality product produced by a reputable company. Recurring cost to use this fully disposable device is likely to be too high for low-resource countries.	High-quality product produced by a reputable company. The reusable pump might be affordable, but recurring cost to purchase disposable cups is likely to be too high for low-resource countries. Using a reusable cup is a viable option.
Price sensitivity	No data available on user acceptability on different methods, types of pumps, and cups.	No data available on user acceptability on different methods, types of pumps, and cups.
Policy environment	WHO recommends vacuum extraction as the first-line method for assisted birth for vertex (cephalic) presentation and forceps as the instrument of choice for face presentation and after-coming head of the breech.	WHO recommends vacuum extraction as the first-line method for assisted birth for vertex (cephalic) presentation and forceps as the instrument of choice for face presentation and after-coming head of the breech.
Donors/ stakeholders	WHO and OB/GYN associations such as FIGO.	WHO and OB/GYN associations such as FIGO.
Pre- and post-sales support	Requires training on the correct use of the device and assisted delivery procedures.	Requires training on the correct use of the device and assisted delivery procedures. Requires training on the proper sterilization of reusable cups. The pump system requires maintenance and repair (in case of malfunction).
Need for demand creation	Need to provide guidance to users and procurers on appropriate product selection. Requires training to promote a proper procedure and use of the product. Cost-effectiveness data may be necessary to understand program cost between pump systems and between reusable and disposable cups.	Need to provide guidance to users and procurers on appropriate product selection. Requires training to promote a proper procedure and use of the product. Cost-effectiveness data may be necessary to understand program cost between pump systems and between reusable and disposable cups.

Supply Information	TECHNOLOGY/SOLUTION—TABLE 3		
	Kiwi Omni Cup	**Vacca Reusable OmniCup**	**Odon**
Description	A vacuum delivery system with a handheld pump (PalmPump™) for ease of use by a single operator. Comes with two different styles of disposable cups: the ProCup® for normal low OA and outlet procedures and the OmniCup® for low OP asynclitic and lateral fetal malpositions.	A vacuum delivery system with a handheld pump (PalmPump™) for ease of use by a single operator. Comes with reusable OmuniCup specifically for use in low-resource countries.[16]	Low-cost instrument. Made of film-like polyethylene material and may be potentially safer and easier to apply than forceps and vacuum extractor (contraindicated in cases of HIV infection). The device has been designed on the basis of a double physical phenomenon consisting of a conveyor belt and an air clamp. It consists of a polyethylene sleeve with a cuff-like fold on the fetal insertion edge, which fits the fetal head diameter. This sleeve is introduced using two flexible plastic spatulas 3-mm thick that allows placing the device in the adequate final position around the fetus' head.[10]
Characteristics applicable for low-resource settings	Do not require electricity. Can be used in all fetal positions. Traction force indicator is designed to measure the force exerted during traction. It allows the operator to correlate tactile sensation of traction force with a visual scale, which is especially valuable for training purposes. Single-use cups will increase recurring cost.	Do not require electricity. Reusable and could be affordable.	Does not require electricity. Low cost, simple, easy to use, requires less training, and is potentially much less damaging to the baby and mother than forceps and vacuum extractors since the inverter is easy to insert (point of application is 360 degrees around baby's head). Can be used at referral hospitals and clinics.
Developer and/or manufacturer	Clinical Innovations.	Clinical Innovations.	Partnership among World Health Organization (WHO); Centro de Educacion medica e Investigaciones Clinicas (CEMIC); province of Eastern Cape, South Africa; Centro Rosarino de Estudios Perinatales; and Des Moines University.
Status	Commercialized. USFDA 510(k) clearance (Class II device)	Commercialized. USFDA 510(k) clearance (Class II device)	Under development.

Supply Information	TECHNOLOGY/SOLUTION–Table 3		
	Kiwi Omni Cup	**Vacca Reusable OmniCup**	**Odon**
Efficacy/ effectiveness	Ten studies with 1,558 women compared the soft anterior cup ventouse with the metal cup. Results were in favor of the metal cup (8 studies with 1,076 women; RR 1.63, 95 percent CI 1.17 to 2.28). Apart from cephalohematoma (6 studies, 669 women; RR 0.61, 95 percent CI 0.39 to 0.95) and scalp injury (9 studies with 1517 women; RR 0.67, 95 percent CI 0.53 to 0.86) which were less likely with the soft cup, there was no significant difference in neonatal outcome with either group. There was no significant difference in maternal outcomes (i.e., cesarean section, episiotomy, perineal and vulval trauma) between these two groups.[3] A study comparing safety and efficacy of M-cups vs. forceps, the corrected efficacy rates were forceps 92% and M-cup 94%. The M-style cup deliveries were accomplished more rapidly than forceps deliveries and were associated with a lower rate of episiotomy, 3˚ and 4˚ lacerations. Forceps deliveries were associated with fewer clinically diagnosed cephalohematomas than M-cup deliveries. In conclusion, the M-cup vacuum extractor cup appears to be as efficient (and faster) than the obstetric forceps but is associated with significantly more fetal cephalohematomas, whereas maternal injuries are more common with the forceps.[11] A Malaysian RCT of 164 women found the Kiwi OmniCup is an effective alternative to the currently available Malmstrom metal cup for vacuum-assisted delivery with no increase in maternal or neonatal morbidity or mortality. Vacca Reusable OmniCup vs. Bird anterior and posterior metal cups found no significant differences in outcomes between devices.[12]	Ten studies with 1,558 women compared the soft anterior cup ventouse with the metal cup. Results were in favor of the metal cup (8 studies with 1,076 women; RR 1.63, 95 percent CI 1.17 to 2.28). Apart from cephalohematoma (6 studies, 669 women; RR 0.61, 95 percent CI 0.39 to 0.95) and scalp injury (9 studies with 1517 women; RR 0.67, 95 percent CI 0.53 to 0.86) which were less likely with the soft cup, there was no significant difference in neonatal outcome with either group. There was no significant difference in maternal outcomes (i.e., cesarean section, episiotomy, perineal and vulval trauma) between these two groups.[3] A study comparing safety and efficacy of M-cups vs. forceps, the corrected efficacy rates were forceps 92% and M-cup 94%. The M-style cup deliveries were accomplished more rapidly than forceps deliveries and were associated with a lower rate of episiotomy, 3˚ and 4˚ lacerations. Forceps deliveries were associated with fewer clinically diagnosed cephalohematomas than M-cup deliveries. In conclusion, the M-cup vacuum extractor cup appears to be as efficient (and faster) than the obstetric forceps but is associated with significantly more fetal cephalohematomas, whereas maternal injuries are more common with the forceps.[11] A Malaysian RCT of 164 women found the Kiwi OmniCup is an effective alternative to the currently available Malmstrom metal cup for vacuum-assisted delivery with no increase in maternal or neonatal morbidity or mortality. Vacca Reusable OmniCup vs. Bird anterior and posterior metal cups found no significant differences in outcomes between devices.[12] One study at Port Moresby General National Referral and Teaching Hospital in Papua New Guinea, found among 200 women that the Failure rates for both Omnicup (2/100) and Bird metal cups (6/100) were not statistically different and that rates of maternal trauma and fetal scalp trauma were similar in both groups.[7]	Being tested in a two-phased study in health care facilities in Argentina and rural South Africa. During Phase 1, the device will be tested for safety and feasibility under normal delivery conditions. Testing has already started at a tertiary care center in Argentina in the context of a WHO-approved study. Phase 2 should be complete in 18 to 24 months. Phase 3 trial will test large numbers of deliveries and will be conducted in 5 to 10 areas and take 1 to 2 years.

Supply Information	TECHNOLOGY/SOLUTION–Table 3		
	Kiwi Omni Cup	**Vacca Reusable OmniCup**	**Odon**
Manufacturing quality and capacity	Manufactured by Clinical Innovation. The manufacturing facility is ISO13485 certified.	Manufactured by Clinical Innovation. The manufacturing facility is ISO13485 certified.	Three entities are interested in marketing the device: a company of Johnson and Johnson, the Government of India, and Besins—a family-owned company. WHO is looking at expanding to include Brazil, China, Russia, South Africa, and where they expect government interest in identifying companies that could produce and market the device.
Intellectual property ownership	No data available.	No data available.	Not applicable; product under development.
Cost and cost drivers	US$30 (pump only). Listed as US$849.89 in the UNICEF Supply Catalogue (including a full set).[14]	€107.98 (US$142)[16] (pump, reusable cup, and other accessories). Listed as US$849.89 in the UNICEF Supply Catalogue (including a full set).[14]	Limited cost for the disposable sleeve: <US$1.00. No production cost estimates available.
Delivery/ procurement channels	Can be procured through the manufacturer's local distributors.	Can be procured through the manufacturer's local distributors.	Not applicable since the product is still under development.
Sustainable business models	Distribution through private-sector channels is possible. The demand for this fully disposable device is likely to be small in low-resource countries; it might be difficult to create a sustainable business model.	Distribution through private-sector channels is possible. Bulk procurement will be necessary to reduce the price and increase the demand.	Not applicable since the device is still under development.

Demand Information	TECHNOLOGY/SOLUTION—Table 3		
	Kiwi Omni Cup	**Vacca Reusable OmniCup**	**Odon**
Existing demand	The market size for the pump will be driven by the number of facilities that are capable of performing assisted delivery. The market size for disposable cups is drive by the number of assisted deliveries.	The market size will be driven by the number of facilities that are capable of performing assisted delivery.	The market size will be driven by the number of facilities that are capable of performing assisted delivery. The use could be extended to clinics.
Attractiveness	Has favorable data on product performance.	Has favorable data on product performance.	Easy to use. Has potential to be used in clinics by mid-level professionals.
Price sensitivity	No data available on user acceptability on different methods, types of pumps, and cups.	No data available on user acceptability on different methods, types of pumps, and cups.	No data available on user acceptability on different methods, types of pumps, and cups.
Policy environment	WHO recommends vacuum extraction as the first-line method for assisted birth for vertex (cephalic) presentation and forceps as the instrument of choice for face presentation and after-coming head of the breech.	WHO recommends vacuum extraction as the first-line method for assisted birth for vertex (cephalic) presentation and forceps as the instrument of choice for face presentation and after-coming head of the breech.	WHO recommends vacuum extraction as the first-line method for assisted birth for vertex (cephalic) presentation and forceps as the instrument of choice for face presentation and after-coming head of the breech.
Donor/ stakeholders	WHO and OB/GYN associations such as FIGO.	WHO and OB/GYN associations such as FIGO.	WHO and FIGO. Winner in the 2011 “Saving Lives at Birth: a Grand Challenge for Development” global competition.
Pre- and post-sales support	Requires training on the correct use of the device and assisted delivery procedures. The pump system requires maintenance and repair (in case of malfunction).	Requires training on the correct use of the device and assisted delivery procedures. Requires training on the proper sterilization of reusable cups. The pump system requires maintenance and repair (in case of malfunction).	No data available.
Need for demand creation	Need to provide guidance to users and procurers on appropriate product selection. Requires training to promote a proper procedure and use of the product. Cost-effectiveness data may be necessary to understand program cost between pump systems and between reusable and disposable cups.	Need to provide guidance to users and procurers on appropriate product selection. Requires training to promote a proper procedure and use of the product. Cost-effectiveness data may be necessary to understand program cost between pump systems and between reusable and disposable cups.	Need favorable evidence to generate demand.

References

[1] Gei AF, Pacheco LD. Forceps: still an option? *Current Women's Health Reviews*. 2008;4:56–75.

[2] Patel RR, Murphy DJ. Forceps delivery in modern obstetric practice. *British Medical Journal.* 2004;328:1302–1305.

[3] O'Mahony F, Hofmeyr GJ, Menon V. Choice of instruments for assisted vaginal delivery. *Cochrane Database of Systematic Reviews.* 2010;11:CD005455.

[4] Fauveau V. Is vacuum extraction still known, taught and practiced? A worldwide KAP survey. *International Journal of Gynecology and Obstetrics.* 2006;94:185–189.

[5] Johnson JH, Figueroa R, Garry D, et al. Immediate maternal and neonatal effects of forceps and vacuum-assisted deliveries. *Obstetrics and Gynecology*. 2004 Mar;103(3):513–518.

[6] World Health Organization. *Managing Prolonged and Obstructed Labour. Education Material for Teachers of Midwifery, Second Edition*. Geneva: WHO; 2008.

[7] Mola GDL, Kuk JM. A randomized controlled trial of two instruments for vacuum-assisted delivery (Vacca Re-Usable OmniCup and the Bird anterior and posterior cups) to compare failure rates, safety and use effectiveness. *Australian and New Zealand Journal of Obstetrics and Gynaecology.* 2010;50:246–252.

[8] McQuivey RW. Vaccum-assisted delivery: a review. *The Journal of Maternal-Fetal and Neonatal Medicine*. 2004;16;171–179.

[9] Hayman R, Gilby J, Arulkumaran S. Clinical evaluation of a "hand pump" vacuum delivery device. *Obstetrics & Gynecology.* December 2002;100(6):1190–1195.

[10] WHO. *Assisted Vaginal Delivery Instrument*. Geneva: WHO; 2011. Available at: http://www.who.int/medical_devices/en/index.html. Accessed February 8, 2012.

[11] Bofill JA, Rust,OA, Schorr SJ, et al. A randomized prospective trial of the obstetric forceps versus the M-cup vacuum extractor. *American Journal of Obstetrics and Gynecology*. 1996;1751325–30.

[12] Ismail NA, Saharan WS, Zaleha MA, et al. Kiwi Omnicup versus Malmstrom metal cup in vacuum assisted delivery: a randomized comparative trial. *Journal of Obstetrics and Gynaecological Research*. June 2008;34(3):350–353.

[13] MANDATE website. Available at: http://mnhtech.org/. Accessed February 7, 2012.

[14] NOTE: Vacuum extractor, hand-operated pump and kit is listed in the UNICEF Supply Catalogue. It includes: 3 Bird anterior suction cups (complete) stainless steel and in 3 different sizes; 2 soft vacuum extractor cups ("SILC-CUP" complete) in 2 different sizes; 2 extraction handles,

stainless steel; 1 vacuum pump hand-operated, stainless steel (with valve membrane and o-ring). Also included is gauge, tubing, connectors, and vacuum bottles.

[15] Mityvac® and Mystic® Vacuum Assisted Deliver price list web page. Cooper Surgical website. Available at: http://www.pmedicalonline.net/Brochures/CooperSurgical/CooperSurgical%20Obstetricia%20Price%20List.pdf. Accessed February 7, 2012.

[16] Vacca Reusable OmniCup web page. Doctors without borders website. Available at: ftp://195.20.146.30/permanent/LOG/ITC_Catalogues_&_Guidelines_2010/@L0045CATGCD/MSF_Docs/fra/catalog/volume2/EMEQ/EMEQVENT2--_fra.html. Accessed February 7, 2012.

Fetal Heart Monitoring

Improving intrapartum monitoring for fetal distress is a key pathway to reducing intrapartum stillbirth.[1] Fetal monitoring records changes in the fetal heart rate (FHR) and the temporal relationship to uterine contractions. It is commonly used to assess fetal distress due to lack of oxygen (hypoxia), which is commonly caused by prolonged or obstructed labor, and may indicate constriction of the umbilical cord, placental abruption, or uterine rupture. The aim is to identify babies who may be hypoxic and determine whether additional assessments of fetal well-being should be used and whether the baby should be delivered by instrumental vaginal birth or cesarean section (c-section).

Various technologies are used to monitor FHR including continuous electronic monitoring (cardiotocography), Doppler ultrasound, and auscultation devices. The gold-standard method to detect fetal distress is by fetal blood sampling using a blood sample from the fetal scalp. This process requires expensive blood gas analyzing equipment and a trained technician. Relatively few methods appropriate for low-resource settings are available. Continuous electronic fetal monitoring requires expensive equipment and a high level of skill to interpret the data. It is also associated with increased c-section and instrumental delivery, but not necessarily with improved perinatal outcomes relative to intermittent auscultation with Doppler ultrasound.[2] A randomized controlled trial (RCT) in Zimbabwe found that the use of hand-held Doppler devices resulted in similar c-section rates and fetal outcomes as continuous electronic monitoring.[3] Fetal monitoring methods that are recommended for use in low-resource settings include intermittent auscultation (such as with a Pinard stethoscope), simplified umbilical artery Doppler (portable, continuous wave device without ultrasound imaging), and hand-held Doppler device that detects fetal heart movement and either counts the FHR manually or displays it on an LED screen.[4] These electronic methods can detect FHR after about 10 weeks gestation and the Pinard can detect FHR after approximately 20 weeks.[5]

The American College of Obstetricians and Gynecologists states that specific interval intermittent auscultation of the FHR by competent, skilled health workers is equivalent to continuous electronic fetal monitoring in the rate of detecting fetal distress.[6] One of the challenges with fetal monitoring is the risk of misinterpretations and false positive reports. This can be decreased by the use of a more systematic approach in reading and interpreting the results. False positive results tend to increase the rate of surgical interventions that are more expensive and carry particular risks in developing countries.

Provision of costly fetal heart monitoring equipment is justified only in facilities where skilled health workers are present to monitor and interpret results correctly and take suitable actions based on findings. Such actions include expediting delivery with instruments or c-section,

either at the same site or by prompt referral to appropriate centers. Otherwise, it is likely that placement of such equipment may not have any significant benefits.[1]

The following three tables detail various fetal heart monitoring technologies.

Supply Information	TECHNOLOGY/SOLUTION—TABLE 1	
	Pinard Stethoscope	Simplified umbilical artery Doppler
		Sonicaid Cordflow Assist—umbilical cord Doppler
Description	Simple plastic or metal cones used to ausculate by placing the larger opening firmly on the mother's abdomen; the user can listen for the baby's heartbeat from the smaller end.	A modular system that combines a fetal monitor with a lightweight and easily portable color spectral Doppler system. Being simple to use; it does not require a qualified ultrasonographer and enables assessment in the community or in the hospital.
Characteristics applicable for low-resource settings	Inexpensive; no power source necessary.	Potential for reducing unnecessary referrals for duplex scanning. Battery operated. Uses telemedicine. Can be configured as a stand-alone system or as part of a fully integrated antenatal and labor management system.
Developer and/or manufacturer	Various.	Huntleigh.[7]
Status	Commercialized, widely available in low-resource settings.	Commercialized. CE Mark.
Efficacy/ effectiveness	Results from an RCT in Zimbabwe showed that the Pinard stethoscope was inferior to Doppler ultrasound in detecting abnormalities in FHR. In addition, lower apgar scores were more common in the Pinard stethoscope group, and neonatal seizures and hypoxic encephalopathy occurred only in the Pinard stethoscope group. Finally, the Pinard stethoscope was found to be uncomfortable for the woman as it sometimes required a change of position and that the woman remains still.	Abnormal umbilical artery waveforms have been linked to adverse perinatal outcomes[8] and Doppler in high-risk pregnancies has been linked to reduced risk of perinatal death (RR 0.71; 95% CI, 0.50–1.01) compared to no ultrasound.[9]
Manufacturing quality and capacitiy	Multiple manufacturers.	United Kingdom.
Intellectual property (IP) ownership	No IP barriers, generic product.	Proprietary.
Cost and cost drivers	~US$2	~US$1,000[10]
Delivery/ procurement channels	End-user is a provider.	End-user is a provider.
Sustainable business models	Widely available at a low price. Commodity product.	Part of the Getinge Group which is a large multinational company. Reach into low-resource settings is questionable.

Demand Information	TECHNOLOGY/SOLUTION—TABLE 1	
	Pinard Stethoscope	Simplified umbilical artery Doppler
		Sonicaid Cordflow Assist—umbilical cord Doppler
Existing demand	Market size is driven by the number of high-risk, late-stage pregnant women in developing countries.	Market size is driven by the number of high-risk, late-stage pregnant women in developing countries.
Attractiveness	Widely available.	Lower cost than traditional duplex scanning, but still high cost for low-resource settings. Could be used at various levels (community and facilities).
Price sensitivity	Very inexpensive technology.	Due to low use in developing countries, value proposition must be strong for users to purchase, adopt, and use the technology. A willingness-to-pay study would be needed.
Policy environment	Policy will need to be aligned with current recommendations as follows: grading of recommendations assessment, development, and evaluation (GRADE) evidence for fetal monitoring strategies for low-resource settings gave intermittent auscultation (Pinard stethoscope) and simplified umbilical artery Doppler a strong recommendation, and gave hand-held Doppler a weak recommendation (because it requires considerable provider training and skill to interpret).[4]	Policy will need to be aligned with current recommendations as follows: GRADE evidence for fetal monitoring strategies for low-resource settings gave intermittent auscultation (Pinard stethoscope) and simplified umbilical artery Doppler a strong recommendation, and gave hand-held Doppler a weak recommendation (because it requires considerable provider training and skill to interpret).[4]
Donors/ stakeholders	None.	None.
Pre- and post-sales support	Training in use of the device is required. Especially in interpretation of results, follow-up, and management of detected complications.	Training in use of the device is required. Especially in interpretation of results, follow up and management of detected complications.
Need for demand creation	Need favorable evidence on performance and impact of devices in order to create demand, and need to provide guidance to users and procurers to select an appropriate product.	Need favorable evidence on performance and impact of devices in order to create demand, and need to provide guidance to users and procurers to select an appropriate product.

Supply Information	TECHNOLOGY/SOLUTION—TABLE 2			
	Doptome hand-held Doppler			
	Freeplay/Powerfree Education Technology (PET)	**Angel Sounds**	**Hi Bebe**	**Sonicaid Obstetric Dopplers**
Description	A hand-held ultrasonic transducer is placed on a pregnant woman's abdomen with a gel to transmit and detect reflected 2 MHz to 3 MHz sound waves from the moving fetal heart with audio and digital display in beats per minute. Weighs 0.7 kg.[11]	A hand-held ultrasonic transducer is placed on a pregnant woman's abdomen with a gel to transmit and detect reflected 2 MHz to 3 MHz sound waves from the moving fetal heart with audio display in beats per minute.[12]	A hand-held ultrasonic transducer is placed on a pregnant woman's abdomen with a gel to transmit and detect reflected 2 MHz to 3 MHz sound waves from the moving fetal heart with audio and digital display in beats per minute.	A hand-held ultrasonic transducer is placed on a pregnant woman's abdomen with a gel to transmit and detect reflected 2 MHz to 3 MHz sound waves from the moving fetal heart with audio and digital display in beats per minute.
Characteristics applicable for low-resource settings	Hand crank device, no power source necessary.	Easy to use, lightweight, portable. No electric power source needed, but it requires 9-volt batteries. Designed to be used with either water or gel so there is no need to invest in additional transducer gel.	Small and lightweight unit that can be easily carried. Easy to use. No electric power source needed, but it requires batteries.	No electric power source needed, but it requires batteries. Some models are water-resistant.
Developer and/or manufacturer	Freeplay Energy, acquired in 2010 by Euro Suisse. Uses components from Ultrasound Technologies Ltd., Wales, UK.	Shenzhen Jumper Medical Equipment Co., Ltd.	Hi Bebe.	Various models manufactured by Huntleigh.[7]
Status	Commercialized in the United Kingdom, South Africa, and other African countries.[13] CE Mark.[14]	Commercialized. CE Mark, United States Food and Drug Administration (USFDA) certified, South Africa Department of Health certified, and has ISO certification.	Commercialized. USFDA certified, Health Canada certified, CE Mark, and has ISO certification.[15]	Commercialized. CE mark.

Supply Information	TECHNOLOGY/SOLUTION—TABLE 2			
	Doptome hand-held Doppler			
	Freeplay/Powerfree Education Technology (PET)	Angel Sounds	Hi Bebe	Sonicaid Obstetric Dopplers
Efficacy/ effectiveness	No data on effectiveness of simplified Doppler in low-resource settings is available. Currently being tested with cell-phone enabled mortality audit in ACT for Birth trial in Uganda with Save the Children.[16] A study of nine primary care maternity centers in South Africa assessed the preference of women for different methods of monitoring the fetal heart during labor. This device was preferred by a majority of the midwives over the Pinard fetal stethoscope or cardiotocography.[17]	No data on effectiveness to detect fetal distress in low-resource settings is available. However, the mode of action is similar to other battery operated hand-held ultrasounds. Data on other similar devices can be extrapolated. Doppler monitoring has shown some evidence of impact on stillbirths in selected high-risk populations, but requires larger RCTs to confirm impact.[18]	No data on effectiveness to detect fetal distress in low-resource settings is available. However, the mode of action is similar to other battery operated hand-held ultrasounds. Data on other similar devices can be extrapolated. Doppler monitoring has shown some evidence of impact on stillbirths in selected high-risk populations, but requires larger RCTs to confirm impact.[18]	An RCT in Zimbabwe showed that abnormalities in FHR were more reliably detected by Huntleigh pocket Doppler than with Pinard stethoscope, and its use resulted in good perinatal outcomes. In addition, asphyxia can be detected with a hand-held Doppler ultrasound scanner just as reliably as with intermittent electronic monitoring.[3] Doppler monitoring has shown some evidence of impact on stillbirths in selected high-risk populations, but requires larger RCTs to confirm impact.[18]
Manufacturing quality and capacity	South Africa. Components from Ultrasound Technologies Ltd., Wales, UK.	China. Joint venture by USA Jumper Company and Chinese Jumper Industry & Trading Development Co., Ltd.	Canada.	United Kingdom.
Intellectual property (IP) ownership	Has IP on technology that converts human, solar, and rechargeable energy into electricity.	Proprietary.	Proprietary.	Proprietary.
Cost and cost drivers	US$350	US$25 to US$30	US$75 to US$100	US$600
Delivery/ procurement channels	End-user is a provider or pregnant woman. Freeplay partners with PET, a nonprofit based in South Africa. Also available on the internet for purchase. Doctors Without Borders tested it in the Philippines and is likely to be Freeplay's client.	End-user is a provider or pregnant woman. Sold to over 60 countries and regions over the world and has established a stable marketing network in many countries and regions.[19]	End-user is a provider or pregnant woman. Sold only in Canada and the United States with a small set of distributors.	End-user is a provider or pregnant woman.
Sustainable business models	Small company with a variety of technologies. Most widely known for its Freeplay radios that are procured by United Nations Children's Fund (UNICEF).	Small company with established distribution network. Reach into low-resource settings is questionable; Jumper claims to have sold products to various governments and international agencies such as UNICEF.	Small company with a handful of distributors. Reach into low-resource settings is questionable.	Part of the Getinge Group which is a large multinational company. Reach into low-resource settings is questionable.

Demand Information	TECHNOLOGY/SOLUTION—TABLE 2			
	Doptome hand-held Doppler			
	Freeplay/Powerfree Education Technology	Angel Sounds	Hi Bebe	Sonicaid Obstetric Dopplers
Existing demand	Market size is driven by the number of high-risk, late-stage pregnant women in developing countries.	Market size is driven by the number of high-risk, late-stage pregnant women in developing countries.	Market size is driven by the number of high-risk late-stage pregnant women in developing countries.	Market size is driven by the number of high-risk late-stage pregnant women in developing countries.
Attractiveness	High cost.	Medium-high cost. Consumer product for developed-country markets; not likely to withstand use in low-resource settings.	High cost.	Very high cost.
Price sensitivity	Due to low use in developing countries, value proposition must be strong for users to purchase, adopt, and use the technology. A willingness-to-pay study would be needed.	Due to low use in developing countries, value proposition must be strong for users to purchase, adopt, and use the technology. A willingness-to-pay study would be needed.	Due to low use in developing countries, value proposition must be strong for users to purchase, adopt, and use the technology. A willingness-to-pay study would be needed.	Due to low use in developing countries, value proposition must be strong for users to purchase, adopt, and use the technology. A willingness-to- pay study would be needed.
Policy environment	Policy will need to be aligned with current recommendations as follows: GRADE evidence for fetal monitoring strategies for low-resource settings gave intermittent auscultation (Pinard stethoscope) and simplified umbilical artery Doppler a strong recommendation, and gave hand-held Doppler a weak recommendation (because it requires considerable provider training and skill to interpret).[4]	Policy will need to be aligned with current recommendations as follows: GRADE evidence for fetal monitoring strategies for low-resource settings gave intermittent auscultation (Pinard stethoscope) and simplified umbilical artery Doppler a strong recommendation, and gave hand-held Doppler a weak recommendation (because it requires considerable provider training and skill to interpret).[4]	Policy will need to be aligned with current recommendations as follows: GRADE evidence for fetal monitoring strategies for low-resource settings gave intermittent auscultation (Pinard stethoscope) and simplified umbilical artery Doppler a strong recommendation, and gave hand-held Doppler a weak recommendation (because it requires considerable provider training and skill to interpret).[4]	Policy will need to be aligned with current recommendations as follows: GRADE evidence for fetal monitoring strategies for low-resource settings gave intermittent auscultation (Pinard stethoscope) and simplified umbilical artery Doppler a strong recommendation, and gave hand-held Doppler a weak recommendation (because it requires considerable provider training and skill to interpret).[4]
Donors/ stakeholders	Freeplay won the Index Global Design Award in 2009. Freeplay partners with PET, a nonprofit based in South Africa that is funded by the Sir Halley Stewart Trust in the UK.[20] PET is partnering with Save the Children Foundation and is a Saving Lives at Birth award recipient.	None.	None.	None.

Demand Information	TECHNOLOGY/SOLUTION—TABLE 2			
	Doptome hand-held Doppler			
	Freeplay/Powerfree Education Technology	Angel Sounds	Hi Bebe	Sonicaid Obstetric Dopplers
Pre- and post-sales support	Some training is required; especially in interpretation of results, follow-up, and management of detected complications. PET developed an FHR handbook that was specifically written to accompany the wind-up FHR monitor and is a self-training and reference handbook for healthcare workers such as midwives and birth attendants.	Some training is required; especially in interpretation of results, follow-up, and management of detected complications.	Some training is required; especially in interpretation of results, follow-up, and management of detected complications.	Some training is required; especially in interpretation of results, follow-up, and management of detected complications.
Need for demand creation	Need favorable evidence on performance and impact of devices in order to create demand, and need to provide guidance to users and procurers to select an appropriate product.	Need favorable evidence on performance and impact of devices in order to create demand, and need to provide guidance to users and procurers to select an appropriate product.	Need favorable evidence on performance and impact of devices in order to create demand, and need to provide guidance to users and procurers to select an appropriate product.	Need favorable evidence on performance and impact of devices in order to create demand, and need to provide guidance to users and procurers to select an appropriate product.

Supply Information	TECHNOLOGY/SOLUTION—TABLE 3	
	Low-cost continuous electronic monitoring	
	Smartphone-based fetal monitor	**Sense4Baby™**
Description	Portable cardiotocography device. Software application runs on mobile phones; records heart rate, correlates it with fetal movement, and transmits data for remote analysis.[11]	A body-worn portable cardiotocography wireless device. Health care provider can monitor the patient anywhere there is cellular service.
Characteristics applicable for low-resource settings	Requires smartphone, fetal monitor (with battery), and access to network, phone, and energy sources.	Requires cellular service and batteries.
Developer and/or manufacturer	Researchers at Edith Cowan University and clinicians at the Mercy Hospital in Mount Lawley.	West Wireless Health Institute (WWHI).[21]
Status	Software still under development.	Device still under development.
Efficacy/ effectiveness	No data on efficacy/effectiveness is available. The current challenge is to conduct a large-scale trial in the field. Funds are needed to buy equipment for trials and to tailor the application for a specific country.[22] Piloted in Australia among 20 pregnant women for feasibility and accuracy. All could use the system with minimal training, and the diagnosis from the system matched the one from simultaneous monitoring by the hospital monitor.	Plan to study the device in 10 clinics in the second quarter of 2012 in the state of Yucatan, Mexico.[21]
Manufacturing quality and capacity	Manufactured in Australia. Software developed by Dr. Martin Masek and Dr. Alfred Tan. System uses existing mobile phone hardware and existing portable fetal monitors.[22]	WWHI is an independent nonprofit medical research organization founded by the Gary and Mary West Foundation. The technology is currently not licensed to any external entity.
Intellectual property (IP) ownership	Information not available.	WWHI currently owns all IP associated with the technology.
Cost and cost drivers	US$50[23]	Targets a lower price than other equivalent technologies.
Delivery/ procurement channels	End-user is a provider or pregnant woman.	End-user is a provider or pregnant woman.
Sustainable business models	Unclear if the software will be freely available or sold.	WWHI develops products and then does tech transfer.

Demand Information	TECHNOLOGY/SOLUTION—TABLE 3	
	Low-cost continuous electronic monitoring	
	Smartphone-based fetal monitor	Sense4Baby™
Existing demand	Market size is driven by the number of high-risk, late-stage pregnant women in developing countries.	Market size is driven by the number of high-risk, late-stage pregnant women in developing countries.
Attractiveness	Medium-high cost. Designed keeping low-resource settings in mind (indigenous women in rural and remote Australia) to overcome expense of existing products. Can store data or transmit data in real time. Continuous cardiotocography prevents mobility and restricts the use of massage, different positions, and/or immersion in water used to improve comfort, control, and coping strategies during labor.	Designed keeping low-resource settings in mind to overcome expense of existing products. Can store data or transmit data in real time. Continuous cardiotocography prevents mobility and restricts the use of massage, different positions, and/or immersion in water used to improve comfort, control, and coping strategies during labor.[2]
Price sensitivity	Due to low use in developing countries, value proposition must be strong for users to purchase, adopt, and use the technology. A willingness-to-pay study would be needed.	Due to low use in developing countries, value proposition must be strong for users to purchase, adopt, and use the technology. A willingness-to-pay study would be needed.
Policy environment	Policy will need to be aligned with current recommendations as follows: GRADE evidence for fetal monitoring strategies for low-resource settings gave intermittent auscultation (Pinard stethoscope) and simplified umbilical artery Doppler a strong recommendation, and gave hand-held Doppler a weak recommendation (because it requires considerable provider training and skill to interpret).[4]	Policy will need to be aligned with current recommendations as follows: GRADE evidence for fetal monitoring strategies for low-resource settings gave intermittent auscultation (Pinard stethoscope) and simplified umbilical artery Doppler a strong recommendation, and gave hand-held Doppler a weak recommendation (because it requires considerable provider training and skill to interpret).[4]
Donor/ stakeholders	Financial, software, and hardware support from Microsoft.	Partner with Carlos Slim Health Institute and Qualcomm.
Pre- and post-sales support	Usage instructions provided via the phone screen. Instructions take the mother step-by-step through the process. Provider located remotely would offer the interpretation.	The system has been designed to fit into the typical work flow of a community health worker and includes training modules on all elements of the system.
Need for demand creation	Need favorable evidence on performance and impact of devices in order to create demand, and need to provide guidance to users and procurers to select an appropriate product.	Need favorable evidence on performance and impact of devices in order to create demand, and need to provide guidance to users and procurers to select an appropriate product.

References

[1] Bhutta ZA, Darmstadt GL, Haws RA, Yakoob MY, Lawn JE. Delivering interventions to reduce the global burden of stillbirths: improving service supply and community demand. *BMC Pregnancy Childbirth.* 2009;9(Suppl 1):S7.

[2] Alfirevic Z, Devane D, Gyte GM. Continuous cardiotocography (CTG) as a form of electronic fetal monitoring (EFM) for fetal assessment during labour. *Cochrane Database of Systematic Reviews.* 2006;3:CD006066.

[3] Mahomed K, Nyoni R, Mulambo T, Kasule J, Jacobus E. Randomised controlled trial of intrapartum fetal heart rate monitoring. *British Medical Journal.* 1994;308(6927):497–500.

[4] Hofmeyr GJ, Haws RA, Bergstrom S, et al. Obstetric care in low-resource settings: what, who, and how to overcome challenges to scale up? *International Journal of Gynaecology and Obstetrics.* 2009;107(Suppl 1):S21–S25.

[5] Mandate website. Available at: http://mnhtech.org/. Accessed February 7, 2012.

[6] ACOG technical bulletin. Fetal heart rate patterns: monitoring, interpretation, and management. *International Journal of Gynaecology and Obstetrics.* 1995;51(1):65–74.

[7] Sonicaid Cordflow Assist—Umbilical Cord Doppler page. Huntleigh Diagnostics website. Available at: http://www.huntleigh-diagnostics.co.uk/diagnostics/int/Product.asp?PageNumber=2502&ProductCategory_Id=221&Product_Id=455. Accessed February 7, 2012.

[8] Baschat AA, Gembruch U, Weiner CP, Harman CR. Qualitative venous Doppler waveform analysis improves prediction of critical perinatal outcomes in premature growth-restricted fetuses. *Ultrasound in Obstetrics and Gynecology.* 2003;22(3):240–245.

[9] Alfirevic Z, Neilson JP. Doppler ultrasonography in high-risk pregnancies: systematic review with meta-analysis. *American Journal of Obstetrics and Gynecology.* 1995;172(5):1379–1387.

[10] Huntleigh Multi Dopplex II page. CheapEKG Machines website. Available at: http://www.cheapekgmachines.com/index.php?file=product/product_detail&product_id=847&category_id=164. Accessed February 7, 2012.

[11] World Health Organization (WHO). *Compendium of New and Emerging Health Technologies*. Geneva: WHO; 2011. Available at: http://whqlibdoc.who.int/hq/2011/WHO_HSS_EHT_DIM_11.02_eng.pdf. Accessed February 7, 2012.

[12] Fetal Heart Rate Monitor for intrapartum detection of hypoxemia page. Mandate website. Available at: http://mnhtech.org/technology/technology-briefs/fetal-heart-rate-monitor/. Accessed February 7, 2012.

[13] Medical devices: Call for innovative technologies for low-resource settings page. WHO website. Available at: http://www.who.int/medical_devices/en/index.html. Accessed February 7, 2012.

[14] The freeplay fetal heart rate monitor page. Index Award website. Available at: http://tinyurl.com/878wmp6. Accessed February 7, 2012.

[15] About page. Hi Bebe Fetal Dopplers website. Available at: http://www.hibebe.org/about.html. Accessed February 7, 2012.

[16] ACT for Birth web page. Saving Lives at Birth website. Available at: http://www.savinglivesatbirth.net/summaries/53. Accessed February 9, 2012.

[17] Mangesi L, Hofmeyr GJ, Woods D. Assessing the preference of women for different methods of monitoring the fetal heart in labour. *South African Journal of Obstetrics and Gynaecology.* 2009;15(2):58–59. Available at: http://www.ajol.info/index.php/sajog/article/download/50338/39025. Accessed February 7, 2012.

[18] Haws RA, Yakoob MY, Soomro T, Menezes EV, Darmstadt GL, Bhutta ZA. Reducing stillbirths: screening and monitoring during pregnancy and labour. *BMC Pregnancy Childbirth.* 2009;9(Suppl 1):S5.

[19] Company profile page. Jumper website. Available at: http://www.jumper-medical.com/en/about.asp. Accessed February 7, 2012.

[20] About us page. PET website. Available at: http://www.pet.org.za/about.php?view=1. Accessed February 7, 2012.

[21] Dolan B. West Wireless Health Institute studies Sense4Baby impact in Mexico. *MobiHealthNews* [serial online]. Available at: http://mobihealthnews.com/16086/west-wireless-health-institute-studies-sense4baby-impact-in-mexico/. Accessed February 7, 2012.

[22] Microsoft. Smartphone-based fetal monitors could save lives in remote areas. *Microsoft Research [serial online].* Available at: http://www.microsoft.com/asia/partnersolutionmarketplace/australia/CaseStudyDetail.aspx?casestudyid=4000004117. Accessed February 7, 2012.

[23] Tan A, Masek M, Cowan E. *Fetal Heart Rate and Activity Monitoring via Microsoft® Smart Phones.* Redmond, WA: Microsoft; 2009. Available at: http://research.microsoft.com/en-us/events/mhealth2009/tan-masek-presentation.pdf. Accessed February 7, 2012.

Suction Devices

Neonatal suction devices are used to clear the airway of the newborn in the presence of secretions and frequently as a part of resuscitation of babies who do not breathe properly at birth following intrapartum anoxia. Routine suctioning of the newborn at birth is not recommended as it can cause apnea or bradycardia due to vagal stimulation, especially if the negative pressure applied is high or applied roughly. Newborn care standard of practice is to clear the mouth first and then the nose. This is because the process of suctioning can stimulate the baby to initiate breathing, and if the nose is suctioned first and there are secretions in the throat, the process of breathing may result in inhalation of the secretions into the lungs.

In June 2011, the World Health Organization (WHO) led a technical consultation to update the evidence and recommendations on newborn resuscitation based on the Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) approach. These recommendations were conditionally approved by the WHO Guidelines Review Committee in December 2011.[1] Relevant recommendations from these guidelines regarding the suction bulb are below:

> "Suction Bulb: In newborns who require suctioning to clear the airway, a device with a mechanical source of negative pressure [appropriate for the newborn] is recommended. In settings where a device with a mechanical source of negative pressure is not available, suction by a single-use or easy-to-clean bulb syringe is preferable to a mucous extractor with a trap for newly born babies who require suction to clear the airway (because of lower risk of infection for the resuscitator with the former device). The expert group also recommended that only a single-use bulb syringe or mucous extractor should be used; if this is not possible, only those devices that can be easily and thoroughly cleaned should be used."

Several types of suction devices are available in low-resource settings. These include suction machines/vacuum pumps that create a negative pressure that can be applied to the mouth and nose to aspirate the secretions with the attachment of suitable suction tubes that for the term newborn are commonly size Fr 8 or 10. These appliances may be electrically operated or manually operated, preferably by the foot in order to have both hands free to care for the baby. Ideally a separate suction machine should be available for the newborn infant with a negative suction pressure that does not to exceed 100 mm Hg or 130 cm of water. Where a common suction machine is available in the delivery room for the mother and baby and where the negative pressure may be high (such as 400 mm Hg to 600 mm Hg or higher), it needs to be adjusted to the low 100 mm Hg or 130 cm of water setting when used for the baby. Clear indelible instructions need to be fixed to the suction machine to this effect.

Although far less common, a few advanced urban national hospitals in some developing countries have piped wall suction where the negative pressure can be varied according to the age of the patient.

Single-use or easy to clean suction bulbs with a pointed tip need to be emptied of air by squeezing before the tip is inserted into the mouth/nose. The bulb is released to create a vacuum to suck out the secretions. Squeezing the bulb when the pointed end is in the mouth can result in secretions being pushed into the trachea. The bulb is usually opaque and the device cannot be opened. It is meant for use for a single baby as it is extremely difficult to clean and disinfect. No ASTM reference standards are available for newborn bulb suction devices. The only partially relevant standard is ISO 10079-2; 1999; Medical Suction Equipment—Part 2: Manually Powered Suction Equipment. Suction device requirements include the following design parameters: (a) for use on neonates for mucus and amniotic fluid, (b) able to suction mouth and nose, (c) easy to use, (d) durable and reusable, (e) affordable, and (f) easily cleaned. WHO and the American Academy of Pediatrics also suggest that negative suction pressures not exceed 100 mm Hg or 130 cm of water. A soft wipe has also been recommended, but it is not as effective in removing secretions from the throat as the devices.

The De Lee Mucus Aspirator consists of a transparent cylindrical mucus trap to which are connected two soft suction catheters. One is introduced into the baby's mouth or nose and the other end into the care provider's mouth. The care provider applies suction with his/her mouth. The trap is meant to catch the secretions and prevent them from entering the health worker's mouth. However, the latter can happen if large amount of secretions are sucked out. While this is not likely to happen when only the throat and nose are cleared, if the tube is introduced into the esophagus and, especially into the stomach, large volumes may be aspirated out and overflow out of the trap into the tube placed in the care provider's mouth. Besides the unpleasantness, this carries a risk of infection, including HIV/AIDS if the mother is infected.

The method used to clear the airway depends on local availability and choices of devices. Hospitals in low-resource settings often have electric or manual vacuum pumps. De Lee suction devices and suction bulbs are more common in clinic settings. Suction bulb devices are intended for single patient use although they are often reused across multiple newborns. Neonatal resuscitation with bag and mask and suction device by professional health workers for babies who do not breathe at birth is considered an essential evidence-based intervention to reduce newborn mortality[2] at the primary and referral levels of care. Availability of the necessary equipment to support this intervention is not often available Lack of availability and use of appropriate suction devices, especially at the peripheral level, has been documented in various low-resource settings.[3,4,5]

The two tables below detail various suction devices for use with newborns.

Supply Information	TECHNOLOGY/SOLUTION—TABLE 1		
	Electric vacuum pump	**Human-powered vacuum pump**	**Bulb suction devices**
Description	Generates negative pressure which can be connected to a trap and soft suction catheter. Soft suction catheters are either disposable or autoclavable. Electric vacuum pumps for neonates require low suction power and catheters specially designed for neonates.	Generates negative pressure which can be connected to a trap and soft suction catheter. Can be foot or hand operated.	Various designs of reservoirs in bulb shapes that narrow to a tip. Can be one-piece bulb, bulb with removable plug, thumb-activated aspirator with removable top, or small aspirators with removable tips. User compresses the bulb and then inserts tip into the infant's nose/mouth before the bulb is released. Suction is created through the expansion of the bulb.
Characteristics applicable for low-resource settings	Vaccum pumps often available in surgery units. Requires electricity.	No power requirements. Ambu Uni-Suction Pump's container and tube parts are autoclavable at 121°C.	Inexpensive and widely available. Often opaque so not easy to see if cleaned properly. Single-patient use products that are often reused on many infants sequentially. No power requirement.
Developer and/or manufacturer	Multiple. Examples include: ATMOS medizinTechnik (ATOM C451), Fazzini, Allied Healthcare Products (Gomco® Suction Equipment)	Multiple. Examples include Ambu Uni-Suction Pump (Ambu), Foot Aspiration Pump (Fazzini)	Multiple. Examples include: Easy Grip Transparent Baby (DeRoyal), Newborn Nasal Aspirator (safety 1st Newborn)
Status of technology	Commercialized. ATMOS suction pump is sold in more than 70 countries with CE Mark and 510(K) clearance. Gomco Suction Equipment has 510(k) clearance (Class II device). Fazzini's devices have CE Mark.	Commercialized. Ambu Uni-Suction Pump was not found on the United States Food and Drug Administration (USFDA) website. However, Ambu Twin Pump (also non-electric powered) is exempt from premarket approval as this is classified as a Class I device.	Commercialized. Most bulb suction devices are available over the counter.

Supply Information	TECHNOLOGY/SOLUTION—TABLE 1		
	Electric vacuum pump	**Human-powered vacuum pump**	**Bulb suction devices**
Efficacy/ effectiveness	Neonatal resuscitation training in facilities reduces term intrapartum-related deaths by 30 percent.[6] Providing neonatal resuscitation (including cleaning of airway) for 90 percent of deliveries currently taking place in facilities would save more than 93,000 newborn lives each year.[7]	Neonatal resuscitation training in facilities reduces term intrapartum-related deaths by 30 percent.[6] Providing neonatal resuscitation (including cleaning of airway) for 90 percent of deliveries currently taking place in facilities would save more than 93,000 newborn lives each year.[7]	Community-based neonatal resuscitation has been assessed in several countries (Argentina, Democratic Republic of the Congo [DRC], India, Indonesia, Pakistan, Zambia) where births are attended by skilled birth attendants (SBAs), traditional birth assistants (TBAs), and community health workers (CHWs). They use a package of essential newborn care interventions—not resuscitation alone—although all had focus on resuscitation practice. Reduction in neonatal or perinatal mortality rates were in the range of 15 percent to 40 percent and reduction in intrapartum-related neonatal mortality rate ranged from 42 percent to 70 percent. First Breath, a multicenter study implemented by Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) in rural communities in six countries (Argentina, DCR, Guatemala, India, Pakistan, and Zambia) also showed reduction in stillbirth and perinatal mortality in deliveries by birth attendants including TBAs.[8] Over 686,200 newborn lives could be saved by achieving full coverage of comprehensive emergency obstetric care (EmOC) and neonatal resuscitation for all births.[7]
Manufacturing quality and capacity	Manufactured by multiple companies such as ATMOS, Fazzini, and Allied Healthcare Products. All these three companies are mid- to large-size international companies.	Manufactured by multiple companies such as Ambu and Fazzini. Both of these are large international companies.	Manufactured by numerous companies. Some are large international companies (e.g., Bard). Others are small companies that market products in local markets.
Intellectual property ownership	No data available.	No data available.	No data available. Although the design of simple bulb suction devices are unlikely to be protected by patent, some uniquely designed devices might have a design patent.

Supply Information	TECHNOLOGY/SOLUTION—TABLE 1		
	Electric vacuum pump	**Human-powered vacuum pump**	**Bulb suction devices**
Cost and cost drivers	~US$700. The United Nations Children's Fund (UNICEF) Supply Catalogue includes two electric pumps at US$127.65 and US$706 for public-sector purchases. Other cost drivers include training, maintenance and repair of equipment, and disposables. If tube and containers are reusable, then the cost of sterilization will be added.	US$816.62. The UNICEF Supply Catalogue lists one human-powered (foot-powered) suction pump at US$266.40 (indicative price). Other cost drivers include training and maintenance and repair of equipment. If tube and containers are reusable, then the cost of sterilization will be added.	Prices range from US$0.75 (Indonesia) to US$7.91 (US).[9] Other cost drivers include training. If devices are reused, cost of sterilization will be added.
Delivery/ procurement channels	Electric vacuum pumps are primarily sold through distributors. Public-sector procurers can purchase the equipment directly through manufacturers. The UNICEF Supply Catalogue lists two electric pump which can also be procured by the public sector.	Human-powered vacuum pumps are primarily sold through distributors. Public-sector procurers can purchase the equipment directly through manufacturers. The UNICEF Supply Catalogue lists one human-powered (foot-operated) pump, which can also be procured by the public sector.	Bulb suction devices can be purchased on-line or through local distributors. They are also available at drug or general stores.
Sustainable business models	Electric vacuum equipment is costly. Also, requirements for training and maintenance and repair will be added cost for low-resource countries. If permitted by regulations, leasing or loaning programs could be offered to reduce up-front cost borne by buyers.	Although less expensive than electric vacuum equipment, human-powered pumps are still expensive for low-resource countries. If permitted by regulations, leasing or loaning programs could be offered to reduce up-front cost borne by buyers.	Increasing sales volume will be a key to reduce production cost and compensate for a low profit margin that these suction bulbs are expected to generate. Suction bulbs could be included in midwifery or birth kits to increase the number of users. Also, these devices have demand in developed and emerging countries. However, the market in these countries appears to be saturated; and product differentiation by design and/or quality will be necessary.

Demand Information	TECHNOLOGY/SOLUTION—Table 1		
	Electric vacuum pump	**Human-powered vacuum pump**	**Bulb suction devices**
Existing demand	Electric pumps are primarily used by tertiary and secondary hospitals. Users could also be found in the ambulatory market segment if equipment is relatively small and portable. The demand is driven by the number of tertiary and secondary hospitals. More than one piece of equipment might be necessary per facility depending on the number of surgeries since the use of equipment is not limited to neonates.	Electric pumps are primarily used by tertiary and secondary hospitals. Users could also be found in the ambulatory market segment if equipment is relatively small and portable. The demand is driven by the number of tertiary and secondary hospitals. More than one piece of equipment might be necessary per facility depending on the number of surgeries since the use of equipment is not limited to neonates.	The equipment can be primarily used in clinics and communities. The primary users will be medical physicians, nurses, SBAs. Users could include TBAs. Although devices are either single-use or single-patient use only, they are often used for multiple patients; therefore, the demand will be driven by the number of clinics and birth attendants. For clinics, multiple devices might be necessary.
Attractiveness	Electric vacuum pumps are expensive and also require power supply. Therefore, their use is limited to referral facilities. Requirements for maintenance and repair and recurring cost for disposables also prevent these pumps from permeating into the lower level of health care facilities.	Does not require electric power.	Depends on the device. One-piece suction bulbs are easy to use, provide highest suction capacity, and easy to clean. The DeRoyal device scored well in a comparative functional evaluation of suction bulb devices conducted by PATH. All products in this category are labeled for single-patient use and do not claim they can be disinfected by boiling or autoclaving. Most manufacturers recommend washing in warm soapy water instead.
Price sensitivity	The price range of electric suction devices is US$2,038 to as much as US$2,250.[10] This indicates that there is a market segment that can afford this high pricing.	No data available.	The price ranges of unbranded bulb suction devices are from US$0.50 to US$0.85.[2] This may indicate high price sensitivity for unbranded bulb suction devices.

Demand Information	TECHNOLOGY/SOLUTION—Table 1		
	Electric vacuum pump	**Human-powered vacuum pump**	**Bulb suction devices**
Policy environment	In June 2011, WHO led a technical consultation to update the evidence and recommendations on newborn resuscitation based on the GRADE approach. These recommendations were conditionally approved by the WHO Guidelines Review Committee in December 2011. According to these recommendations, a device with a mechanical source of negative pressure is recommended. In settings where these devices are not available, suction by a single-use or easy-to-clean bulb syringe is preferable to a mucous extractor with a trap. Further, if it is not possible to use a single-use bulb syringe or mucous extractor, then devices that can be easily and thoroughly cleaned should be used.	In June 2011, WHO led a technical consultation to update the evidence and recommendations on newborn resuscitation based on the GRADE approach. These recommendations were conditionally approved by the WHO Guidelines Review Committee in December 2011. According to these recommendations, a device with a mechanical source of negative pressure is recommended. In settings where these devices are not available, suction by a single-use or easy-to-clean bulb syringe is preferable to a mucous extractor with a trap. Further, if it is not possible to use a single-use bulb syringe or mucous extractor, then devices that can be easily and thoroughly cleaned should be used.	In June 2011, WHO led a technical consultation to update the evidence and recommendations on newborn resuscitation based on the GRADE approach. These recommendations were conditionally approved by the WHO Guidelines Review Committee in December 2011. According to these recommendations, a device with a mechanical source of negative pressure is recommended. In settings where these devices are not available, suction by a single-use or easy-to-clean bulb syringe is preferable to a mucous extractor with a trap. Further, if it is not possible to use a single-use bulb syringe or mucous extractor, then devices that can be easily and thoroughly cleaned should be used.
Donors/ stakeholders	None.	None.	None.
Pre- and post-sales support	Training is needed to ensure the correct use of the equipment. Maintenance and repair (in case of malfunctioning) are necessary.	Training is needed to ensure the correct use of the equipment. Maintenance and repair (in case of malfunctioning) are necessary.	Although the devices are intuitive to use, minimal training on the correct use of the device is necessary. Additional training may be required to reinforce the importance of cleaning and sterilization between uses since the devices may be reused in low-resource settings.
Need for demand creation	Need to engage governments to incorporate national resuscitation into national prenatal programs. Developing master training is also necessary to improve use of suction pumps.	Need to engage governments to incorporate national resuscitation into national prenatal programs. Developing master training is also necessary to improve use of suction pumps.	Need to engage governments to incorporate national resuscitation into national prenatal programs. Developing master training is also necessary to improve use of suction devices. May need to be bundled with resuscitation training mannequins, resuscitators, and warmers to provide quality services. Need to refer to guidance on selecting appropriate products.[9]

Supply Information	TECHNOLOGY/SOLUTION—TABLE 2		
	Penguin	**Uniflow™ Baby Aspirator (formally known as Mulford aspirator)**	**DeLee (mucus extractor)**
Description	Large one-piece suction device with top that opens.	Aspirator bulb device with one-way flow.	Devices connect a suction tube, mucus trap, and soft-tip catheter to the caregiver's mouth and the caregiver provides suction directly. 20 cc mucus trap.
Characteristics applicable for low-resource settings	Can be boiled or autoclaved for sterilization prior to reuse. No power requirement.	Reusable. Easy to use and creates good suction. No power requirement. The nozzle part comes off for cleaning. However, since the body of the device is not transparent, it is difficult to see whether it is cleared. For single patient use only.	Can be reused if sterilized. Note: Argyle™ De Lee Mucus Trap is marketed as single-use (disposable) device. No power requirement.
Developer and/or manufacturer	Laerdal Global Health/Laerdal Medical.	Developed by Thomas Mulford and manufactured by Albert International.	Multiple. Example: Argyle™ DeLee Mucus Traps (Covidien).
Status	Commercialized in 2010. 68 countries identified by the United Nations (UN) as focus countries relative to UN Millennium. It has been USFDA device listed and is developed to applicable standards and regulation required for CE marking. Self-declaration for CE marking is imminent within March 2011.	Commercialized.	Commercialized. The Argyle™ DeLee Mucus Trap is classified as Class I device and exempt from premarket approval by USFDA.

Supply Information	TECHNOLOGY/SOLUTION—TABLE 2		
	Penguin	**Uniflow™ Baby Aspirator (formally known as Mulford aspirator)**	**DeLee (mucus extractor)**
Efficacy/ effectiveness	Community-based neonatal resuscitation has been assessed in several countries (Argentina, DRC, India, Indonesia, Pakistan, and Zambia) where births are attended by SBAs, TBAs, and CHWs. They use a package of essential newborn care interventions—not resuscitation alone—although all had focus on resuscitation practice. Reduction in neonatal or perinatal mortality rates were in the range of 15 percent to 40 percent and reduction in intrapartum-related neonatal mortality rate ranged from 42 percent to 70 percent. First Breath, a multicenter study implemented by NICHD in rural communities in six countries (Argentina, DRC, Guatemala, India, Pakistan, and Zambia) also showed reduction in stillbirth and perinatal mortality in deliveries by birth attendants including TBAs.[8] Over 686,200 newborn lives could be saved by achieving full coverage of comprehensive EmOC and neonatal resuscitation for all births.[7]	Community-based neonatal resuscitation has been assessed in several countries (Argentina, DRC, India, Indonesia, Pakistan, and Zambia) where births are attended by SBAs, TBAs, and CHWs. They use a package of essential newborn care interventions—not resuscitation alone—although all had focus on resuscitation practice. Reduction in neonatal or perinatal mortality rates were in the range of 15 percent to 40 percent and reduction in intrapartum-related neonatal mortality rate ranged from 42 percent to 70 percent. First Breath, a multicenter study implemented by NICHD in rural communities in six countries (Argentina, DRC, Guatemala, India, Pakistan, and Zambia) also showed reduction in stillbirth and perinatal mortality in deliveries by birth attendants including TBAs.[8] Over 686,200 newborn lives could be saved by achieving full coverage of comprehensive EmOC and neonatal resuscitation for all births.[7]	Community-based neonatal resuscitation has been assessed in several countries (Argentina, DRC, India, Indonesia, Pakistan, and Zambia) where births are attended by SBAs, TBAs, and CHWs. They use a package of essential newborn care interventions—not resuscitation alone—although all had focus on resuscitation practice. Reduction in neonatal or perinatal mortality rates were in the range of 15 percent to 40 percent and reduction in intrapartum-related neonatal mortality rate ranged from 42 percent to 70 percent. First Breath, a multicenter study implemented by NICHD in rural communities in six countries (Argentina, DRC, Guatemala, India, Pakistan, and Zambia) also showed reduction in stillbirth and perinatal mortality in deliveries by birth attendants including TBAs.[8] Over 686,200 newborn lives could be saved by achieving full coverage of comprehensive EmOC and neonatal resuscitation for all births.[7]
Manufacturing quality and capacity	Manufactured by Laerdal Global Health, the nonprofit arm and sister company of Laerdal Medical.	Manufactured by Albert International, a company in the Albert Group. The company manufactures and sells rotational and injection-molded elastomer products for medical and technical usage as an original equipment manufacturer.	Argyle™ DeLee Mucus Trap is manufactured and marketed by Covidien (formally Tyco Healthcare), a large United States manufacturer. In addition to this device, several original equipment manufacturers are easily found especially in China (Alibaba.com).
Intellectual property (IP) ownership	Patent pending on the design of the device.	The design is protected by patent.	No IP.

Supply Information	TECHNOLOGY/SOLUTION—TABLE 2		
	Penguin	**Uniflow™ Baby Aspirator (formally known as Mulford aspirator)**	**DeLee (mucus extractor)**
Cost and cost drivers	US$3 (negotiated price for nonprofit purchasers). Other cost drivers include training and sterilization.	US$4 for the previous model. The price of the updated device is unknown. Other cost drivers include training and sterilization.	US$2. Mucus extractor is listed in the UNICEF Supply Catalogue at US$0.22 as an indicative price. Chinese manufacturers listed on Alibaba.com sell a mucus trap at less than US$0.2 per piece (freight on board) for a bulk purchase. Other cost drivers include training. If devices are reused cost of sterilization will be added.
Delivery/ procurement channels	The product has been available on a not-for-profit basis for newborn resuscitation projects in developing countries since April 2010. The device can be procured as an individual item. The device is also included in the NeoNatalie simulator complete kit.	The device can be procured by directly contacting the manufacturer. http://www.albertinternational.com/	DeLee mucus extractors can be purchased online or through local distributors. They are also available at drug or general stores.
Sustainable business models	Laerdal is partnering with Helping Babies Breathe (HBB) GDA and providing low-resource countries with this suction device as an individual item and in the NeoNatalie complete kit at a negotiated discount price. Creating partnership that includes multi-lateral agencies, industry partners, professional organizations, and program implementers could provide potential for a sustainable model.	Increasing sales volume will be a key to reduce production cost and compensate for a low profit margin that these suction bulbs are expected to generate. Suction bulbs could be included in midwifery or birth kits to increase the number of users. Also, these devices have demand in developed and emerging countries. However, the market in these countries appears to be saturated and product differentiation by design and/or quality will be necessary.	Increasing sales volume will be a key to reduce production cost and compensate for a low profit margin that these suction bulbs are expected to generate. Suction bulbs could be included in midwifery or birth kits to increase the number of users. Also, these devices have demand in developed and emerging countries. However, the market in these countries appears to be saturated and product differentiation by design and/or quality will be necessary.

Demand Information	TECHNOLOGY/SOLUTION—Table 2		
	NeoNatalie Penguin	**Uniflow™ Baby Aspirator (formally known as Mulford aspirator)**	**De Lee (Mucus Extractor)**
Existing demand	The device can be primarily used in clinics and communities. The primary users will be medical physicians, nurses, and SBAs. Users could include traditional birth attendants. The demand is driven by the number of clinics and birth attendants. For clinics, multiple devices might be necessary. Since this device is included in the NeoNatalie complete kit and can be used for training purposes, the demand could come from training programs.	The device can be primarily used in clinics and communities. The primary users will be medical physicians, nurses, and SBAs. Users could include traditional birth attendants. If devices cannot be sterilized, the demand will be driven by the number of babies born at clinics as well as the number of babies attended by birth attendants in communities. If devices can be sterilized and used for multiple babies, the demand is driven by the number of clinics and skilled nurse attendants. For clinics, multiple devices might be necessary.	The device can be primarily used in clinics and communities. The primary users will be medical physicians, nurses, and SBAs. Users could include TBAs. The demand is driven by the number of babies born at clinics as well as the number of babies attended by birth attendants in communities.
Attractiveness	The Penguin device is made in one piece of silicone, can be boiled or autoclaved, and withstands hundreds of uses. Shaped like a penguin, its beak is ideal for newborn oral and nasal suction. The head can opened for easy emptying and cleaning.	No data available on product acceptability although De Lee mucus extractors are widely sold in Asian countries.	No data available on product acceptability.
Price sensitivity	No data available.	No data available. However, price sensitivity for unbranded devices is likely to be high.	No data available.
Policy environment	In June 2011, WHO led a technical consultation to update the evidence and recommendations on newborn resuscitation based on the GRADE approach. These recommendations were conditionally approved by the WHO Guidelines Review Committee in December 2011. According to these recommendations, a device with a mechanical source of negative pressure is recommended. In settings where these devices are not available, suction by a single-use or easy-to-clean bulb syringe is preferable to a mucous extractor with a trap. Further, if it is not possible to use a single-use bulb syringe or mucous extractor, then devices that can be easily and thoroughly cleaned should be used.	In June 2011, WHO led a technical consultation to update the evidence and recommendations on newborn resuscitation based on the GRADE approach. These recommendations were conditionally approved by the WHO Guidelines Review Committee in December 2011. According to these recommendations, a device with a mechanical source of negative pressure is recommended. In settings where these devices are not available, suction by a single-use or easy-to-clean bulb syringe is preferable to a mucous extractor with a trap. Further, if it is not possible to use a single-use bulb syringe or mucous extractor, then devices that can be easily and thoroughly cleaned should be used.	In June 2011, WHO led a technical consultation to update the evidence and recommendations on newborn resuscitation based on the GRADE approach. These recommendations were conditionally approved by the WHO Guidelines Review Committee in December 2011. According to these recommendations, a device with a mechanical source of negative pressure is recommended. In settings where these devices are not available, suction by a single-use or easy-to-clean bulb syringe is preferable to a mucous extractor with a trap. Further, if it is not possible to use a single-use bulb syringe or mucous extractor, then devices that can be easily and thoroughly cleaned should be used.

Demand Information	TECHNOLOGY/SOLUTION—Table 2		
	NeoNatalie Penguin	**Uniflow™ Baby Aspirator (formally known as Mulford aspirator)**	**De Lee (Mucus Extractor)**
Donors/ stakeholders	American Academy of Pediatrics HBB implementers United Nations Population Fund (UNFPA) UNICEF The United States Agency for International Development (USAID) WHO The World Bank	None.	None.
Pre- and post-sales support	Training on the correct use of the device is necessary. Additional training may be required to reinforce the importance of cleaning and sterilization between uses.	Training on the correct use of the device is necessary. Additional training may be required to reinforce the importance of cleaning and sterilization between uses.	Training on the correct use of the device is necessary. Additional training may be required to reinforce the importance of cleaning and sterilization between uses.
Need for demand creation	Penguin devices have been used mostly for training through HBB implementers. Need to continue to engage governments to incorporate national resuscitation into national prenatal programs. Need to validate the performance of the device in field setting by collecting post-market data from countries currently implementing HBB with NeoNatalie equipment. Likely that the marketing strategy currently being employed to bundle the suite of NeoNatalie equipment (resuscitators, resuscitation training mannequins, and suction devices) will lead to increased demand.	Need to engage governments to incorporate national resuscitation into national prenatal programs. Developing master training is also necessary to improve use of suction devices. May need to be bundled with resuscitation training mannequins, resuscitators, and warmers to provide quality services. Need to refer to WHO policy guidance on selecting appropriate products; likely that this product will be overtaken by single-use or easy to use bulb syringe per WHO recommendation.	Need to engage governments to incorporate national resuscitation into national prenatal programs. Developing master training is also necessary to improve use of suction devices. May need to be bundled with resuscitation training mannequins, resuscitators, and warmers to provide quality services. Need to refer to guidance on selecting appropriate products.[9]

References

[1] World Health Organization. *Draft Guidelines on Basic Neonatal Resuscitation*. Provisionally approved December 2011; publication pending.

[2] The Partnership for Maternal, Newborn & Child Health. *A Global Review of the Key Interventions Related to Reproductive, Maternal, Newborn, and Child Health (RMNCH)*. Geneva;WHO:2011. Available at: http://www.scribd.com/doc/76572820/Essential-Interventions-MCH-2011. Accessed February 6, 2011.

[3] Maternal and Child Health Integrated Program, USAID. Assessing the quality of care for prevention, identification, and management of maternal and newborn complications at the time of birth: Results from 5 countries that conducted MCHIP Quality of Care survey. Available at: http://www.mchip.net/sites/default/files/MCHIPQoC.pdf. Accessed February 1, 2012.

[4] Multi-country rapid newborn resuscitation assessment for the UN commission on commodities for women's and children's health. January 2012 (unpublished).

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

[6] Lee AC, Cousens S, Wall SN, 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.* April 2011;11(3):S12.

[7] Wall SN, Lee AC, Carlo W, et al. Reducing intrapartum-related neonatal deaths in low- and middle-income countries—what works? *Seminars in Perinatology*. 2010;34:395–407.

[8] Carlo WA, Goudar SS, Jehan I et al. Newborn-care training and perinatal mortality in developing countries. *New England Journal of Medicine.* February 2010;362(7):614–623.

[9] PATH. Evaluation of manual neonatal bulb suction devices for use in low-resource settings. Seattle, WA: PATH; 2012.

[10] PATH. *Market Assessment of Neonatal Resuscitators, Training Mannequins, and Suction Devices in Countries within the Economic Community of West African States (ECOWAS)*. Unpublished report; 2009.

Neonatal Resuscitators

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

Current resuscitation technology is either a self-inflating bag-and-mask (B&M), or tube-and-mask (T&M)/mouth-to-mask (MTM) devices. International policy guidelines specify B&M devices as the first-line intervention, and the use of T&M/MTM devices is warranted only in environments where the self-inflating bags are not functional. B&M resuscitators are more familiar to providers, there is a wide variety on the market, and most models have a pressure-limiting valve that reduces risk of lung rupture. B&M resuscitators are usually more expensive and have more parts than T&M/MTM designs. T&M/MTM resuscitators may offer the user a feeling of greater control in delivering the pressure and monitoring the neonate's progress; however, they can be fatiguing to use, users may need additional training and practice to provide proper and consistent resuscitation, and the caregiver cannot give instructions or counseling during resuscitation as with the B&M design. It is also becoming increasingly difficult to find manufacturers of T&M/MTM designs. Important features for safe and correct use of resuscitators include the following:

- Properly sized bag. A bag specifically designed for providing appropriate tidal volumes for neonates can help reduce errors during use and simplify training. Volume sizes range from 240 ml to 750 ml, with 240-ml and 500-ml sizes being the most commonly used. Although data are not available, some practitioners assert that the 500-ml bag is preferable for use with neonates. The tidal volume required for ventilation of a term baby is only 4–8 ml/kg.[3] Hence, the 240-ml bag is adequate for ventilation. However, since mask leak is frequent, some prefer the 500-ml bag, as it can deliver more effective ventilation when there is mask leak. In addition, it is easier to give prolonged inspiratory time, which is very useful during the first few ventilations during resuscitation. When correctly used with minimal mask leak, there may be a risk of delivering excessive tidal volume, especially in low birth-weight (LBW) and preterm babies, which may be offset by squeezing the bag using one or two fingers against the thumb.

- Properly sized and form-fitting mask. Proper resuscitation depends on a good seal between the resuscitator and the neonate. Two sizes are available for use in the newborn period, mask size #1 for the term baby and for larger LBW and preterm babies, and mask size #0 for smaller LBW and preterm babies. While some companies supply both masks, many supply only size #1. In very low-resource settings with limited funds, initial priority can be given to the use of a size #1 mask, as it will cover a majority of the newborns. Masks may be round or anatomically shaped;[4] the most widely used mask is the Laerdal round mask.[5] One of the major challenges is to provide appropriate ventilation without excessive mask leak—which is very common and occurs across various levels of skilled health workers, including experienced neonatologists, resident doctors, neonatal nurses and midwives, and nurses attending deliveries. Mask leak can influence the volume of air that is actually delivered to the lungs; excess air can damage the lung, while inadequate volumes make resuscitation less effective. This highlights the need for good competency-based training and good supportive follow-up to maintain high-quality practices. In peripheral facilities, the limited number of deliveries presents challenges to maintaining skills.
- Pressure-limiting valve. Preventing lung damage is a paramount concern for anyone performing resuscitations. Conventionally, based on ISO standard requirements (ISO 10651-4; 2002), the B&M is fitted with a pressure-limiting valve that releases pressure within the range of 30–45 cm H_2O in order to avoid transmission of a high-peak inspiratory pressure that can damage the lung.[6] Equipment for measuring volumes of air provided is expensive and currently not feasible for low-resource centers. Hence, even with its limitations, the practical criteria when using the conventional self-inflating B&M with the pressure-limiting valve set for about 35 cm H_2O, with tolerance +/-5 cm H_2O based on ISO standards, is to ventilate the baby/manikin (simulator) in such a manner that there is appropriate chest expansion/rise and, where feasible to document, appropriate increase in the heart rate.
- Minimal dead airspace. Resuscitators that minimize dead airspace between the neonate's face and the non-rebreathing valve prevent the neonate from rebreathing expelled air with a higher concentration of CO_2.
- Assembly and disassembly. Ridged surfaces on parts that disassemble help identify these parts to the user as well as make the resuscitator easier to disassemble with wet hands. Color coding can help users distinguish different components. These and other thoughtful human-factors design features can augment the ease of assembly and disassembly.
- Standard mask connections. Standard-sized connections are important to ensure compatibility with replacement components and masks from other manufacturers. Standard connections for mask connectors are a 15-mm inner diameter and a 22-mm outer diameter. Similarly, mask stems should have a 15-mm outer diameter or 22-mm inner diameter.

For either B&M or T&M/MTM designs, correct usage and maintenance, including steps for prevention of infection, are critical. One of the main problems in usage includes possible frequent occurrence of mask leakage and delivery of tidal volumes that are too large or too small. Also, cleaning and disinfection/sterilization of ventilation bags with a large number of components that require reassembly is challenging.

In June 2011, the World Health Organization (WHO) led a technical consultation to update the evidence and recommendations on newborn resuscitation based on the Grades of Recommendation, Assessment, Development, and Evaluation (referred to as GRADE) approach. These recommendations were conditionally approved by the WHO Guidelines Review Committee in December 2011.[7] Relevant recommendations regarding resuscitators from these draft guidelines are as follows:

> "Self-inflating Bag and Mask: In newborns requiring positive pressure ventilation [resuscitation], ventilation should be provided using a self-inflating bag and mask. In an emergency situation where self-inflating bag is not functional, mouth-to-tube-and-mask or mouth-to-mask can be used for providing positive pressure ventilation."

The tables below describe several neonatal resuscitators, either currently on the market (Table 1) or under development (Table 2).

Supply Information	TECHNOLOGY/SOLUTION—TABLE 1				
	Self-inflating bag-and-mask (B&M) designs			Tube-and-mask (T&M)/mouth-to-mask (MTM) designs	
	Ambu® Oval Silicone	**Besmed BE-1303**	**Laerdal NeoNatalie™ Resuscitator**	**Zeal BlowSafe™ MTM1001**	**Laerdal Pediatric Pocket Mask**
Description	Multiuse, self-inflating 220-ml B&M device for neonates. Equipped with pressure-limiting valve. The textured surface of the silicone resuscitators combined with the unique support strap ensures that a comfortable and firm grip is guaranteed, allowing for effective ventilation over extended periods, without the problem of hand fatigue.	Multiuse 240-ml, self-inflating B&M device for low birth-weight (LBW) neonates. Equipped with round one-piece silicone mask and pressure-limiting valve.	Multiuse, self-inflating 240-ml B&M device for normal and LBW neonates. Equipped with round one-piece silicone mask and pressure-limiting valve.	Multiuse T&M device for normal birth-weight neonates. Equipped with round, one-piece silicone mask and pressure-limiting valve without position indication; cannot lock down pressure-limiting valve.	MTM device with round, one-piece silicone mask for infant. No pressure-limiting valve. Labeled for single use only.
Characteristics applicable for low-resource settings	Easy to hold, easy to use. Completely autoclavable for reuse.	Low cost; easy to use and to clean. Identified by PATH evaluation as one of several low-cost and high-quality resuscitators.[8]	Affordable, high-quality device with good brand recognition. Made of silicone and polysulphone and can be boiled or autoclaved.	Easy to clean; minimal parts. In the evaluation by PATH, the pressure-limiting valve could not be locked down.[8]	Easy to assemble; minimal number of parts. Product is labeled as single use.
Developer and/or manufacturer	Ambu A/S.	Besmed.	Laerdal Global Health/Laerdal Medical.	Zeal Medical Pvt. Ltd.	Laerdal Medical.
Status	Commercialized. Ambu Oval Silicone is marketed through their subsidiaries and distributors worldwide. It has 510(k) clearance as a Class II device and is CE marked.	Commercialized. No regulatory data available for this device. The United States Food and Drug Administration (USFDA) medical device database does not list this device.	Commercialized.	Commercialized. No regulatory data available for this device. The USFDA medical device database does not list this device.	Commercialized. Received 510(k) clearance.

Supply Information	TECHNOLOGY/SOLUTION—TABLE 1				
	Self-inflating bag-and-mask (B&M) designs			Tube-and-mask (T&M)/mouth-to-mask (MTM) designs	
	Ambu® Oval Silicone	Besmed BE-1303	Laerdal NeoNatalie™ Resuscitator	Zeal BlowSafe™ MTM1001	Laerdal Pediatric Pocket Mask
Efficacy/ effectiveness	For all three self-inflating B&M designs: Community-based neonatal resuscitation has been assessed in several countries (Argentina, Democratic Republic of Congo, India, Indonesia, Pakistan, and Zambia) where births are attended by skilled birth attendants, traditional birth attendants (TBAs), and community health workers who use a package of essential newborn care interventions, not resuscitation alone, although all had focus on resuscitation practice. Reduction in neonatal or perinatal mortality rates were in the range of 15%–40% and reduction in intrapartum-related neonatal mortality rate ranged from 42%–70%. First Breath, a multicenter study implemented by the National Institute of Child Health and Development in rural communities in six countries (Argentina, Democratic Republic of Congo, Guatemala, India, Pakistan, and Zambia), also showed reduction in stillbirth and perinatal mortality in deliveries by birth attendants, including TBAs.[2] 686,200 newborn lives saved by achieving full coverage of comprehensive emergency obstetric care and neonatal resuscitation for all births.[9]			No published data on use of the Zeal device. In study of four resuscitation devices among midwives in Indonesia[10] (Ambu neonate B&M, Topster B&M, Laerdal Pediatric Pocket Mask, and Tekno T&M) no significant difference in the ventilation volumes among the four devices or any difference in acceptability to midwives or infection prevention ability. Final selection was Tekno T&M device due to cost and cleaning considerations.	Mortality at day 28 after birth was 45% lower among live-born infants delivered by intervention birth attendants than control birth attendants (rate ratio 0.55, 95% confidence interval 0.33 to 0.90); greatest reductions in mortality were in the first 24 hours after birth: 7.8 deaths per 1,000 live births for infants delivered by intervention. Deaths due to birth asphyxia were reduced by 63% among infants delivered by intervention birth attendants (0.37, 0.17 to 0.81) and by 81% within the first two days after birth (0.19, 0.07 to 0.52). No effect on stillbirth.[11]
Manufacturing quality and capacity	Manufactured by Ambu, a large international company. Ambu has manufacturing sites in China and Malaysia.	Besmed is a large manufacturer/exporter in Taiwan specializing in respiratory, emergency, anesthesia, and other health care products. They are ISO9001 and ISO13485 certified, with Taiwan GMP quality standards. They have factories in Taiwan and China.	Manufactured by Laerdal Global Health, the nonprofit arm and sister company of Laerdal Medical.	Zeal is an Indian manufacturer of neonatal and pediatric equipment. Their primary target appears to be India. They claim that they are ISO9001:2000 compliant; however, it is unknown what manufacturing certificates they have.	Manufactured by Laerdal, an international company specializing in basic and advanced life support training products and emergency medical equipment. The company is ISO13485:2003 certified for manufacturing medical equipment.
Intellectual property ownership	No data available.	No data available.	Their core technologies are protected by patent.	No data available.	Their core technologies are protected by patent.

Supply Information	TECHNOLOGY/SOLUTION—TABLE 1				
	Self-inflating bag-and-mask (B&M) designs			Tube-and-mask (T&M)/mouth-to-mask (MTM) designs	
	Ambu® Oval Silicone	**Besmed BE-1303**	**Laerdal NeoNatalie™ Resuscitator**	**Zeal BlowSafe™ MTM1001**	**Laerdal Pediatric Pocket Mask**
Cost and cost drivers	US$213.66 (Medex Supply).[12] Distributor margin is generally large for high-end products.	~US$20 to US$30.	~US$15.	~US$15.	~US$13.
Delivery/ procurement channels	Can be procured through local distributors. Resuscitators are procured by national governments through tenders or by international agencies such as UNICEF in Southern African Development Community (SADC) countries.[13] The UNICEF Supply Catalogue lists two reusable B&M devices for purchase by the public sector: (1) 250-ml capacity for neonates <7 kg, and (2) 500-ml capacity for infants/children <30 kg.	Can be procured directly from the manufacturer. The manufacturer's international distribution network is unknown. Resuscitators are procured by national governments through tenders or by international agencies such as UNICEF in SADC countries.[13] The UNICEF catalogue lists two reusable B&M devices for purchase by the public sector: (1) 250-ml capacity for neonates <7 kg, and (2) 500-ml capacity for infants/children <30 kg.	The product has been available on a not-for-profit basis for newborn resuscitation projects in developing countries since April 2010. Laerdal is part of the Helping Babies Breathe (HBB) Global Development Alliance. They have committed to providing the NeoNatalie simulator and resuscitation tools to developing countries on a not-for-profit basis through 2015. The device is part of the "NeoNatalie Newborn Simulator complete model." The resuscitator can also be procured individually.	Can be procured directly from the manufacturer. The manufacturer's international distribution network is unknown. Resuscitators are procured by national governments through tenders or by international agencies in SADC countries.[13] The UNICEF catalogue lists two reusable B&M devices for purchase by the public sector: (1) 250-ml capacity for neonates <7 kg, and (2) 500-ml capacity for infants/ children <30 kg.	Can be procured directly from the manufacturer or through its local distributors. Resuscitators are procured by national governments through tenders or by international agencies such as UNICEF in SADC countries.[13] The UNICEF catalogue lists two reusable B&M devices for purchase by the public sector: (1) 250-ml capacity for neonates <7 kg, and (2) 500-ml capacity for infants/children <30 kg.
Sustainable business models	Distribution by private vendors is possible for high-end devices.	Although distribution by private vendors is possible for high-end devices, bulk purchase by public-sector purchasers will be more applicable for this low-cost device. Support is needed from governments or nongovernmental organizations (NGOs) to provide proper training on the device, since the manufacturer appears to have a limited network.	Laerdal is partnering with HBB to offer low-resource countries this resuscitator as an individual item and also as part of the NeoNatalie complete model, at a negotiated discount price. Alliances that include multilateral agencies, industry partners, professional organizations, and program implementers are promising as potentially sustainable models.	Although distribution by private vendors is possible for high-end devices, bulk purchase by public-sector purchasers will be more applicable for this low-cost device. Support is needed from NGOs or governments to provide proper training on this device, since the manufacturer appears to have a limited network.	This product was designed for professional rescuers and first responders, and the demand for the product in low-resource countries could be extremely limited. In addition, Laerdal is focusing on NeoNatalie for low-resource countries.

Demand Information	TECHNOLOGY/SOLUTION—TABLE 1				
	Self-inflating bag-and-mask (B&M) designs			Tube-and-mask (T&M)/mouth-to-mask (MTM) designs	
	Ambu® Oval Silicone	Besmed BE-1303	Laerdal NeoNatalie Resuscitator	Zeal BlowSafe™ MTM1001	Laerdal Pediatric Pocket Mask
Existing demand	Users for the Ambu high-end device limited to tertiary and secondary hospitals. The 2007 market demand was at least 72,000 neonatal resuscitation devices in SADC countries. Future market potential is estimated to be lower, at 38,000 devices.[13,14] The demand in other regions for resuscitators remains unknown. Market size is driven by number of users—facilities and/or skilled birth attendants that attend births. For facility-based birth, demand will depend on the number of locations within that facility that should have a resuscitator. For home-based births, demand will depend on the number of birth attendants who carry resuscitators with them. In all cases, the durability of the resuscitator is good and the product has extensive shelf life if stored properly.				
Attractiveness	High-end, high-quality resuscitator with a strong brand name.	Easy to use and clean; durable. A high-quality, low-cost device based on PATH's evaluation.[8]	An affordable product that incorporates high quality with strong brand name recognition.	Easy to clean since it is easy to assemble and reassemble. Durable.[8]	Although it is designed for single use, it is durable for multiple uses.[8] The mask is considered too large for neonates.[10]
Price sensitivity	Extremely price-sensitive product; known that high-priced product is purchased in some situations due to brand recognition; lack of product availability in low-resource settings partially due to lack of awareness about affordable options.				
Policy environment	Current World Health Organization (WHO) policy favors self-inflating B&M for positive pressure ventilation.				
Donors/ stakeholders	None.	None.	USAID, WHO, UNICEF, UNFPA, World Bank, American Academy of Pediatrics, and HBB partners and implementers.	None.	None.
Pre- and post-sales support	Requires training on correct usage, maintenance (e.g., checking whether there is any leakage), steps for preventing infection, and periodic refresher training.				
Need for demand creation	Need to engage governments to incorporate national resuscitation guidance into national prenatal programs. Developing master training is also necessary to improve use of B&M devices. May need to be bundled with resuscitation training manikins, suction devices, and warmers to provide high-quality services.	Need to engage governments to incorporate national resuscitation guidance into national prenatal programs. Developing master training is also necessary to improve use of B&M devices. May need to be bundled with resuscitation training manikins, suction devices, and warmers to provide high-quality services.	NeoNatalie resuscitators have been used mostly for training through HBB implementers. Further engagement with governments needed to increase demand. Likely that demand will increase for the NeoNatalie complete model, since it bundles resuscitators, training manikins, suction devices, and associated accessories.	As B&M is the current standard, further favorable evidence on use of T&M is necessary to generate demand. Unlikely that T&M products will remain viable in low-resource settings.	Clarification needed around positioning of this product within the product mix that Laerdal offers for low-resource settings before demand generation. Unlikely that T&M products will remain viable in low-resource settings.

Supply Information	TECHNOLOGY/SOLUTION—TABLE 2	
	Designs under development	
	Laerdal Simplified Silicone Resuscitator	Laerdal Upright Silicone Resuscitator
Description	Simplified, 240-ml, multiuse, self-inflating B&M resuscitator with fewer parts and changes in the mask.	Simplified, 300-ml, multiuse, self-inflating B&M resuscitator with fewer parts. Round silicone mask; 15-mm outer diameter connector with new snap-assembly function; built-in pressure-limiting valve in mask. Molded-in stiff ring to prevent unintended mask deformation by users.
Characteristics applicable for low-resource settings	Fewer parts—only eight parts, compared to ten parts in the standard design. Designed to address the need for a simplified device for use by peripheral health workers who are infrequent users of resuscitation equipment.	Fewer parts—only six parts; round silicon mask, one size. Bag is vertical/upright, in line with the mask stem. The bag can also stand upright, to reduce contamination before use/during storage. Designed to address mask leakage issues identified in other devices.[15,16]
Developer and/or manufacturer	Laerdal Global Health/Laerdal Medical.	Laerdal Global Health/Laerdal Medical.
Status	Under development.	Under development.
Efficacy/ effectiveness	No data available; will need to test new device designs with users in field settings for performance, acceptability, and impact.	No data available; will need to test new device designs with infrequent users in field settings for performance, acceptability, and impact.
Manufacturing quality and capacity	Laerdal Medical could manage manufacturing for this simplified device (as it does for NeoNatalie); and therefore, all Laerdal Medical's quality standards/certifications and capacity would apply.	Laerdal Medical could manage manufacturing for this simplified device (as it does for NeoNatalie); and therefore, all Laerdal Medical's quality standards/certifications and capacity would apply.
Intellectual property ownership	This is a simplified version of the NeoNatalie resuscitator. Core technologies are protected by patent.	This is a simplified and modified (vertical bag) version of the NeoNatalie resuscitator. Core technologies are protected by patent.
Cost and cost drivers	Not yet determined by developer.	Not yet determined by developer.
Delivery/ procurement channels	Currently under development; long-term commercialization and delivery pathways need to be identified. Helping Babies Breathe could be a potential channel for the short term.	Currently under development; long-term commercialization and delivery pathways needs to be identified. HBB could be a potential channel for the short term.
Sustainable business models	Not yet applicable; the product is still being developed. This product could benefit from demand created by HBB.	Not yet applicable; the product is still being developed. This product could benefit from demand created by HBB.

Demand Information	TECHNOLOGY/SOLUTION—TABLE 2	
	Designs under development	
	Laerdal Simplified Silicone Resuscitator	Laerdal Upright Silicone Resuscitator
Existing demand	Not applicable since the product is under development. Target users could be similar to those of the NeoNatalie resuscitator.	Not applicable since the product is under development. Target users could be similar to those of the NeoNatalie resuscitator.
Attractiveness	The product has fewer parts than the standard device, which is likely to enhance ease of use.	The product has fewer parts than the standard device, which is likely to enhance ease of use. Also, some users may prefer the ergonomics of an upright device.
Price sensitivity	Extremely price-sensitive product; it is known that high-priced products are purchased in some situations due to brand recognition. Lack of product availability in low-resource settings is partially due to lack of awareness about affordable options.	Extremely price-sensitive product; it is known that high-priced products are purchased in some situations due to brand recognition. Lack of product availability in low-resource settings is partially due to lack of awareness about affordable options.
Policy environments	Current WHO policy favors self-inflating B&M for positive pressure ventilation.	Current WHO policy favors self-inflating B&M for positive pressure ventilation.
Donors/ stakeholders	None.	None.
Pre- and post-sales support	The product is under development.	The product is under development.
Need for demand creation	Not applicable since the product is under development.	Not applicable since the product is under development.

References

[1] 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.

[2] Carlo WA, Goudar SS, Jehan I, et al. Newborn-care training and perinatal mortality in developing countries. *New England Journal of Medicine*. 2010;362(7):614–623.

[3] Schmolzer GM, Te Pas AB, Davis PG, Morley CJ. Reducing lung injury during neonatal resuscitation of preterm infants. *Journal of Pediatrics.* 2008;153(6):741–745.

[4] O'Donnell CP, Davies PG, Morley CJ. Positive pressure ventilation at neonatal resuscitation: review of equipment and international survey of practice. *Acta Pediatrica*. 2004;93(5):583–588.

[5] O'Donnell CP, Davis PG, Lau R, Dargaville P, Doyle L, Morley C. Neonatal resuscitation 2: an evaluation of manual ventilation devices and face masks. *Archives of Diseases in Childhood Fetal & Neonatal Edition.* 2005;90(5):F392–F396.

[6] ISO 10651-4:2002 page. International Organization for Standardization website. Available at: http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=30712. Accessed February 1, 2012.

[7] World Health Organization. *Draft Guidelines on Basic Neonatal Resuscitation*. Provisionally approved December 2011; publication pending.

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

[9] Wall S, Lee ACC, Niermeyer S, et al. Neonatal resuscitation in low-resource settings: what, who, and how to overcome challenges to scale up? *International Journal of Gynecology and Obstetrics*. 2009;107(1):S47–S64.

[10] Ariawan I, Agustini M, Seamans Y, Tsu V, Kosim MS. Choosing the appropriate neonatal resuscitation device for village midwives. *Journal of Perinatology.* 2011;31(10):664–670.

[11] Gill CJ, Phiri-Mazala G, Guerina NG, et al. Effect of training traditional birth attendants on neonatal mortality (Lufwanyama Neonatal Survival Project): randomised controlled study. *British Medical Journal*. 2011;342:d346.

[12] Ambu® device page. Medex Supply website. Available at: http://www.medexsupply.com/products/pid-45598/AmbuMarkIVReusableBabyResuscit.htm. Accessed January 28, 2012.

[13] PATH. *Summary of Results of Market Assessment of Neonatal Resuscitation Devices in Southern Africa Development Community Countries*. Seattle, WA: PATH; 2008.

[14] PATH. *Market Assessment of Neonatal Resuscitators, Training Mannequins, and Suction Devices in Countries within the Economic Community of West African States (ECOWAS)*. Unpublished report; 2009.

[15] Tracy MB, Klimek J, Coughtrey H, et al. Mask leak in one-person mask ventilation compared to two-person in newborn infant manikin study. *Archives of Diseases in Childhood Fetal & Neonatal Edition*. 2011;96(3):F195–F200.

[16] Wood FE, Morley CJ, Dawson JA, et al. Assessing the effectiveness of two round neonatal resuscitation masks: study 1. *Archives of Diseases in Childhood Fetal & Neonatal Edition*. 2008;93(3):F235–F237.

Resuscitation Training Manikins

A training manikin or simulator is a model of a baby that permits visualization of selected features of effective ventilation, such as chest rise. Although the simulator is not required for resuscitation of babies, it is a critical component for programs, as it is essential for *competency-based* training of health workers before practicing on babies. It is also useful for subsequent follow-up practice and during supervisory visits to improve quality of care, especially in centers with fewer births, where lack of exposure to adequate cases of needing resuscitation results in loss of skills. Various training materials are currently available that integrate use of this technology, including the World Health Organization Basic Newborn Resuscitation Guide, American Academy of Pediatrics resuscitation program, the UK Resuscitation Council on Newborn Life Support, and Helping Babies Breathe.[1] Recent data from 31 facilitators and 102 learners (pediatricians, obstetricians, medical officers, nurse midwives, nurses, and community health workers [CHWs]) in two sites in Kenya and Pakistan indicated that competency in the skill of newborn ventilation with bag and mask is complex and requires adequate time for instruction and possibly mentoring.[2] Because learning resuscitation skills is complex, providers can sometimes use resuscitation equipment inappropriately. This includes incompetent techniques such as poor or excessive ventilation with the resuscitator/bag and mask, and high negative-pressured suction being applied with some suction machines. Studies of the Helping Babies Breathe educational program conducted in Kenya and Pakistan showed that increased practice time, as well as regular retraining, is necessary to maintain effective bag/mask skills for neonatal resuscitation.

The use of high-fidelity simulation models was noted as a feature of a clinically effective training program in maternity care.[3] High-fidelity simulation provides the most realistic simulated experience with a manikin; it is computer based and driven by predefined software-derived scenarios or faculty-driven direct control (although this feature is often offset by higher cost). The ideal features of a suitable training manikin relate to appearance, airway patency, feedback during artificial ventilation, and chest compression. The manikin must display visual realism in terms of color, weight, size, material, and appropriate mouth size, and be appropriately floppy—not rigid. The manikin must enable jaw thrust, and the air entry must be limited if the neck is overflexed/overextended. Chest movement with bag/mask ventilation should be visible.

Currently available models of neonatal resuscitation manikins used in training are complex and expensive, ranging in price from around US$80 to US$21,000. Literature cites the US$450 Laerdal Resusci® Baby as the most commonly used manikin globally.[4] Very low-cost options for neonatal resuscitation training such as using a ball illustrated with eyes, nose, and mouth secured in a base are cited in literature.[5] However, the performance, suitability, and durability of these very low-cost options are questionable. In a review of community-based interventions for improving neonatal health outcomes in developing countries,[6] the authors asserted that “trained TBAs [traditional birth attendants] or CHWs

seem to be capable of learning resuscitation skills and saving newborn lives." They also said that all skilled attendants and possibly all TBAs and CHWs should be trained to provide proper newborn stimulation and ventilation. Expanding training in resuscitation skills to both skilled and unskilled providers requires a commitment to not only the initial training but periodic refresher training as well. The expansion of training programs and need for ongoing training, such as through the Global Development Alliance, will dramatically increase the demand for affordable resuscitation training equipment. The two tables below examine seven technologies/solutions for resuscitation training.

Supply Information	TECHNOLOGY/SOLUTION—TABLE 1			
	Resusci® Baby	NeoNatalie Newborn Simulator	Baby Buddy	CPR Prompt Training & Practice Infant Mannequin
Description	Features include: natural obstruction of the airway; head tilt/chin lift and jaw thrust; occluded airway with hyperextension; chest rise; realistic resistance for chest compression; anatomically correct landmarks and sternal notch; articulating arms, legs, and head, brachial pulse simulation; disposable non-rebreathing airways. Optional SkillGuide CPR performance indicator.	Features include: realistic size and appearance; and natural weight, feel, and touch when filled with lukewarm water. Uses squeeze bulbs to simulate birth cries, spontaneous breathing, and palpable umbilical pulse. Package comes with simulation squeeze bulbs with tubing and connectors, umbilical cord with connector and two ties, two sheets to simulate towels, head cap, and tube for topping body filling.	Features include: full body infant manikin with correct landmarks; sanitary, one-piece lung/mouth protection system; and visible chest rise when ventilated. Package comes with disposable lung/mouth bags and removable chest for easy lung/mouth bag installation.	Features include: head tilt/chin lift; visible chest rise; inner chest plate, giving students a bottoming out feel to ensure proper technique; and proper anatomical landmarks. The head is easy to clean, dishwasher safe, and can easily be sanitized. Removable chest plate for easy lung bag installation. Treated with Duracoat™, for realistic skin-like finish.
Characteristics applicable for low- resource settings	High-quality product made by a reputable company. The high price of the product is likely to be a factor that prevents achieving high penetration rates in low-resource countries.	High-quality product that is designed to provide highly realistic training simulation at a low cost. Easily cleaned.	Low cost, but requires disposable lung/mouth bags, which is an additional recurring cost.	Low cost. The head is easy to clean, dishwasher safe, and can easily be sanitized.
Developer and/or manufacturer	Laerdal Medical.	Laerdal Medical/Laerdal Global Health.	Adam, Rouilly.	Nasco.
Status	Commercialized. Training manikins are not regulated as medical devices.	Commercialized. Training manikins are not regulated as medical devices.	Commercialized. Training manikins are not regulated as medical devices.	Commercialized. Training manikins are not regulated as medical devices.
Efficacy/ effectiveness	No specific data on clinical effectiveness of this device. However, use of high-fidelity simulation models was noted as a feature of a clinically effective training program in maternity care.[3]	In Kenya and Pakistan, Helping Babies Breathe (HBB) training has demonstrated significant improvement in resuscitation knowledge and skills.[2] Preliminary analysis of 13,575 births in Tanzania revealed a significant decrease in early neonatal mortality, from 13.4 to 6.3 deaths per 1,000 live births after the implementation of training that used the NeoNatalie manikin.[7]	No specific data on clinical effectiveness of this device. However, use of high-fidelity simulation models was noted as a feature of a clinically effective training program in maternity care.[3]	No data available.

Supply Information	TECHNOLOGY/SOLUTION—TABLE 1			
	Resusci® Baby	**NeoNatalie Newborn Simulator**	**Baby Buddy**	**CPR Prompt Training & Practice Infant Mannequin**
Manufacturing quality and capacity	Manufactured by Laerdal, an international company specialized in basic and advanced life support training products and emergency medical equipment. The company has ISO 13485:2003 certification for manufacturing medical equipment.	Manufactured by Laerdal Global Health, the nonprofit arm and sister company of Laerdal Medical.	Manufactured by Adam, Rouilly. The company produces/supplies a wide range of medical training solutions, from venipuncture training tools and instruments to resuscitation simulators, and anatomical charts and models. No data is available about their manufacturing capacity and quality.	Manufactured by Nasco, which produces products for education, health care, agriculture, and industry. No data is available about their manufacturing capacity and quality.
Intellectual property ownership	Core technology is protected by a patent owned by Laerdal.	Core technology is protected by a patent owned by Laerdal.	No data available.	No data available.
Cost and cost drivers	Manikin only: US$460; with SkillGuide: US$805. Other cost drivers include disposable baby face, airways, and face shields, so trainees can share one manikin. Spare parts are also potential costs.	US$50. Laerdal is part of the Global Development Alliance (GDA). Laerdal has committed to offering NeoNatalie products on a not-for-profit basis for newborn resuscitation projects in developing countries through 2015	£88 (approx. US$140), including ten disposable lung/mouth bags.	US$57.95.
Delivery/ procurement channels	Procured through local distributors and the manufacturer's website. The United Nations Children's Fund (UNICEF) Supply Catalogue currently does not list any training manikins.	The product has been available on a not-for-profit basis for newborn resuscitation projects in developing countries since April 2010. The device can be procured with the NeoNatalie set or individually.	Procured through local distributors and the manufacturer's site. The UNICEF Supply Catalogue currently does not list any training manikins.	Procured through mail order catalogs. The UNICEF Supply Catalogue currently does not list any training manikins.
Sustainable business models	Distribution by private channels is possible for this high-end device.	Laerdal is partnering with the HBB GDA and providing low-resource countries with this training manikin as an individual item and in the complete kit at a negotiated discount price. Creating a partnership that includes multilateral agencies, industry partners, professional organizations, and program implementers provides a potentially sustainable model.	Distribution by private channels will be difficult for this low-cost product. Bulk purchase by public-sector purchasers (e.g., governments and nongovernmental organizations [NGOs]) will be necessary.	Distribution by private channels will be difficult for this low-cost product. Bulk purchase by public-sector purchasers (e.g., governments and NGOs) will be necessary.

Demand Information	TECHNOLOGY/SOLUTION—TABLE 1			
	Resusci® Baby	**NeoNatalie Newborn Simulator**	**Baby Buddy**	**CPR Prompt Training & Practice Infant Mannequin**
Existing demand	The demand is driven by the number of training programs and trainers.	The demand is driven by the number of training programs and trainers, with strong demand anticipated from HBB GDA implementing countries.	The demand is driven by the number of training programs and trainers.	The demand is driven by the number of training programs and trainers.
Attractiveness	High-quality product produced by a reputable company. Most commonly cited product in the literature.	High-quality, low-cost product endorsed by the HBB GDA. Water-filled manikin provides life-like sensation to user. Product allows assessment of key competencies, especially ability of trainee to ventilate adequately, position airway; durable, easy to take apart/reassemble/transport; easy to disinfect; culturally sensitive (e.g., dark- and light-skinned versions).[1]	Low cost, but requiring disposable lung/mouth bags might make this product less attractive.	Low cost. The head is easy to clean, dishwasher safe, and can easily be sanitized.
Price sensitivity	Lack of awareness about neonatal resuscitation and the importance of resuscitation training makes buyers/users extremely price sensitive to training manikins, except for a couple of products with strong brand equity.	Lack of awareness about neonatal resuscitation and the importance of resuscitation training makes buyers/users extremely price sensitive to training manikins, except for a couple of products with strong brand equity.	Lack of awareness about neonatal resuscitation and the importance of resuscitation training makes buyers/users extremely price sensitive to training manikins, except for a couple of products with strong brand equity.	Lack of awareness about neonatal resuscitation and the importance of resuscitation training makes buyers/users extremely price sensitive to training manikins, except for a couple of products with strong brand equity.
Policy environment	The HBB GDA is expanding training programs and need for ongoing training to the community level in low-resource countries.	The HBB GDA is expanding training programs and need for ongoing training to the community level in low-resource countries.	The HBB GDA is expanding training programs and need for ongoing training to the community level in low-resource countries.	The HBB GDA is expanding training programs and need for ongoing training to the community level in low-resource countries.
Donors/ stakeholders	None.	American Academy of Pediatrics, HBB implementers, United Nations Children's Fund, United Nations Population Fund, United States Agency for International Development, World Health Organization, World Bank.	None.	None.

Demand Information	TECHNOLOGY/SOLUTION—TABLE 1			
	Resusci® Baby	**NeoNatalie Newborn Simulator**	**Baby Buddy**	**CPR Prompt Training & Practice Infant Mannequin**
Pre- and post-sales support	The product comes with a skill guide. Maintenance and repair (in case of malfunctioning) are necessary.	Training on the correct use of the device is necessary.	Maintenance and repair (in case of malfunctioning) are necessary.	Maintenance and repair (in case of malfunctioning) are necessary.
Need for demand creation	Need to engage governments to incorporate national resuscitation into national prenatal programs. Developing master training is also necessary to improve use of suction pumps.	NeoNatalie has been used mostly for training through HBB implementing partners. Need to continue to engage governments to incorporate national resuscitation into national prenatal programs. Likely that demand will increase for the suite of NeoNatalie equipment that bundles resuscitation training manikins and suction devices.	Need favorable evidence on product performance.	Need favorable evidence on product performance.

Supply Information	TECHNOLOGY/SOLUTION—TABLE 2		
	Sani-Baby (Model 2121)	**Ambu® Baby Mannequin**	**S107 Multipurpose Patient Care &CPR Infant**
Description	Single-use airway/lung/face shield system; anatomical landmarks, including sternum and ribcage, plus substernal notch. No cleaning, no disinfecting, no disassembly required.	Corresponds to a baby up to one year old. The Ambu® patented hygienic system makes internal cleaning entirely unnecessary. Just as in real life, ventilation can be seen and natural exhalation through the nose and mouth can be felt and heard. Head can be both rotated and extended, but the airway opens only in the correct (sniff) position. Stomach ventilation can further be checked visually. The instructor can simulate obstruction of the airway by an on/off slider. The realistic brachial pulse provides correct training.	Bag/valve/mask and realistic chest rise, chest compression, and suctioning. Additional features such as external stoma sites. Oral, nasal, and digital intubation; nasal and oral gastric tubes placement; umbilical catheterization; and intravenous arm with variable, palpable pulses.
Characteristics applicable for low-resource settings	Might be affordable. Easy to use since the product does not require cleaning, disinfecting, or disassembly.	High-quality product made by a reputable company. The high price of the product is likely to be a factor that prevents achieving high penetration rates in low-resource countries.	No data available on the quality of the product. The high price of the product is likely to be a factor that prevents achieving high penetration rates in low-resource countries.
Developer and/or manufacturer	Simulaids Inc.	Ambu® A/S.	Gaumard Scientific.
Status	Commercialized. Training manikins are not regulated as medical devices.	Commercialized. Training manikins are not regulated as medical devices.	Commercialized. Training manikins are not regulated as medical devices.
Efficacy/ effectiveness	No specific data on clinical effectiveness of this device. However, use of high-fidelity simulation models was noted as a feature of a clinically effective training program in maternity care.[3]	No specific data on clinical effectiveness of this device. However, use of high-fidelity simulation models was noted as a feature of a clinically effective training program in maternity care.[3]	No specific data on clinical effectiveness of this device. However, use of high-fidelity simulation models was noted as a feature of a clinically effective training program in maternity care.[3]
Manufacturing quality and capacity	Manufactured by Simulaids Inc. The company produces a wide range of manikins and training manuals. No data available about their manufacturing capacity and quality.	Manufactured by Ambu®, a large international company. Ambu® has manufacturing sites in China and Malaysia.	Manufactured by Gaumard. The company develops and manufacturers teaching simulators for nursing and emergency care, and for obstetricians and gynecologists.
Intellectual property ownership	No data available.	Core technology is protected by a patent owned by Laerdal.	No data available.
Cost and cost drivers	US$109.	US$412 (five face pieces and 100 head bags, Amazon.com).	US$995.

Supply Information	TECHNOLOGY/SOLUTION—TABLE 2		
	Sani-Baby (Model 2121)	Ambu® Baby Mannequin	S107 Multipurpose Patient Care &CPR Infant
Delivery/ procurement channels	Procured online. Multiple online stores carry this product. The UNICEF Supply Catalogue currently does not list any training manikins.	Procured online. Multiple online stores carry this product. The UNICEF Supply Catalogue currently does not list any training manikins.	Procured through the manufacturer's sales force. Also can be purchased by ordering online or via telephone. The UNICEF Supply Catalogue currently does not list any training manikins.
Sustainable business models	Distribution by private channels will be difficult for this low-cost product. Bulk purchase by public-sector purchasers (e.g., governments and nongovernmental organizations) will be necessary.	Distribution by private channels is possible for this high-end device.	Creating a sustainable business model in low-resource countries is questionable. It will be difficult for public-sector purchasers to justify such a high price for the product with its low-brand equity.

Demand Information	TECHNOLOGY/SOLUTION—TABLE 2		
	Sani-Baby (Model 2121)	Ambu® Baby Mannequin	S107 Multipurpose Patient Care & CPR Infant
Existing demand	The demand is driven by the number of training programs and trainers.	The demand is driven by the number of training programs and trainers.	The demand is driven by the number of training programs and trainers.
Attractiveness	Could be affordable. Easy to use since the product does not require cleaning, disinfecting, or disassembly.	High-quality product produced by a reputable company.	Extremely high price with low brand recognition, which makes this product unattractive in low-resource settings.
Price sensitivity	Lack of awareness about neonatal resuscitation and the importance of resuscitation training makes buyers/users extremely price sensitive to training manikins, except for a couple of products with strong brand equity.	Lack of awareness about neonatal resuscitation and the importance of resuscitation training makes buyers/users extremely price sensitive to training manikins, except for a couple of products with strong brand equity.	Lack of awareness about neonatal resuscitation and the importance of resuscitation training makes buyers/users extremely price sensitive to training manikins, except for a couple of products with strong brand equity.
Policy environment	The Helping Babies Breathe Global Development Alliance (HBB GDA) is expanding training programs and need for ongoing training at the community level in low-resource countries.	The HBB GDA is expanding training programs and need for ongoing training at the community level in low-resource countries.	The HBB GDA is expanding training programs and need for ongoing training at the community level in low-resource countries.
Donors/ stakeholders	None.	None.	None.
Pre- and post-sales support	Maintenance and repair (in case of malfunction) are necessary.	Maintenance and repair (in case of malfunction) are necessary.	Maintenance and repair (in case of malfunction) are necessary.
Need for demand creation	Need favorable evidence on product performance.	Need to engage governments to incorporate national resuscitation into national prenatal programs. Developing master training is necessary to improve use of suction pumps.	Need favorable evidence on product performance to justify the high price.

References

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

[2] Singhal N, Lockyer J, Fidler H, et al. Helping Babies Breathe: global neonatal resuscitation program development and formative educational evaluation. *Resuscitation.* 2012;83(1):90–96.

[3] Crofts J, Winter C, Sowter M. Practical simulation training for maternity care—where we are and where next. *BJOG*. 2011;118(Suppl 3):11–16.

[4] O'Donnell C, Davis P, Lau R, et al. Neonatal resuscitation 2: an evaluation of manual ventilation devices and face masks. *Archives of Diseases in Childhood Fetal & Neonatal Edition*. 2005;90(5):F392–F396.

[5] Milner AD, Stokes GM, Tunell R, et al. Laboratory assessment of Laerdal mouth tube mask prototype resuscitation device. *Medical & Biological Engineering & Computing*. 1992;30(1):117–119.

[6] Bhutta ZA, Darmstadt GL, Hasan BS, et al. Community-based interventions for improving perinatal and neonatal health outcomes in developing countries: a review of the evidence. *Pediatrics*. 2005;115(2):519–617.

[7] Ersdal HL. Taking simulation beyond borders and frontiers. Presented at: The 17th Annual Meeting of the Society in Europe for Simulation Applied to Medicine, June 2–4, 2011; Granada.

Continuous Positive Airway Pressure (CPAP) Devices

Of the 4 million neonatal deaths worldwide every year,[1] approximately 1 million of those deaths are attributed to prematurity as the primary cause, with most dying from respiratory insufficiency.[2,3] Most of these deaths occur in low- and middle-income countries (LMIC) and other resource-limited settings. An estimated 21 percent of babies presenting with illness in the first six days of life have respiratory symptoms that may require respiratory support. This indicates a need for country-level programs to have ventilator support. Advances in mechanical ventilation in the neonatal intensive care unit (NICU) have greatly reduced mortality rates in prematurely born infants for whom these therapies are available, in higher resource settings.[4] However, a considerable body of evidence indicates that mechanical ventilation contributes significantly to chronic lung disease, or bronchopulmonary dysplasia (BPD), in premature infants thus treated.[5]

Continuous positive airway pressure (CPAP) technology is used for neonates with respiratory distress syndrome (RDS). The technology delivers a warmed and humidified blend of air and oxygen to the neonate through a mask or nasal prong interface. Blending of the oxygen with air necessitates a pressurized source of both oxygen and air, and can be accomplished using a dedicated blender, or by the use of two flowmeters. Adjustment of air and oxygen flows according to a look-up table achieves the required fraction of inspired oxygen (FiO_2) levels. Alternatively, entrainment (Venturi) devices are in development that suck room air into an oxygen flow to achieve the same effect. Existing devices are not capable of supporting pressures necessary for CPAP.

CPAP devices can be categorized into two types: (1) continuous or (2) variable flow. Variable flow devices exert a lower pressure during the expiratory cycle that further lowers the work of breathing. CPAP treatment avoids the risk factors arising from intubation and mechanical ventilation, allowing infants to develop respiratory structures and functions more normally.[6] A more recent modification of the standard CPAP circuit uses a column of water to create end-expiratory pressures that are accompanied by fluctuations arising from the bubbling of air exiting the underwater seal, thus producing bubbles and is known as a bubble CPAP (B-CPAP) device.[7] Evidence indicates that B-CPAP is more effective than CPAP generated by a mechanical ventilator, suggesting that the vibrations or noise in the pressure fluctuations resulting from the bubbling action contribute to gas exchange and/or lung recruitment.[8]

CPAP is generally used at the tertiary hospital level in developed countries with a recent trend towards use in non-tertiary hospitals as well.[9] CPAP can be expensive to purchase, operate, and maintain, and these devices require highly trained personnel to operate safely and effectively although in low-resource settings studies in Fiji and Malawi suggest that nurses can safely apply B-CPAP after appropriate training.[10, 11] Donation

of ventilation type equipment to resource-limited health care institutions can be problematic due to the requirement for maintenance, repair and resupply, as well as training for proper use of the devices.

B-CPAP devices that are commercially available in developed countries are often unaffordable or unavailable for purchase in resource-limited settings, and as a result many hospitals and clinics must rely on improvised B-CPAP devices—assembled at the point of care—to meet the clinical need for neonatal respiratory support. These improvised devices use components that are on hand or readily obtainable from local vendors and therefore employ a multitude of different approaches and technologies. The improvised systems, although crude, are capable of providing some level of respiratory support where no other option exists, but they are not without risk; oxygen blenders are not readily improvised, and consequently these devices will rely on a degree of leakage at the nares to entrain ambient air for delivery of less than 100 percent oxygen to the infant.

There are several ongoing efforts to improve the infant interface for CPAP devices. A project at Stanford University called AdaptAir aims to create an affordable, one-size-fits-all nasal interface. Western New England University—in collaboration with Engineering World Health—is developing a nasal mask designed to better conform to neonatal facial features. Finally, the Center for Innovation in Global Health Techologies at is developing a visual force indicator designed to fit with standard nasal prongs for the purpose of reducing the risk of septal erosion.

The ability to provide life-saving respiratory support to newborn infants in resource-limited communities throughout the world would have an enormous impact on health. Expanding the range of infants who can be managed successfully with less costly methods of ventilatory support thus would represent a major contribution to global public health. The two tables below provide information on a variety of CPAP and B-CPAP devices available and under development.

Supply Information	TECHNOLOGY/SOLUTION—TABLE 1		
	Commercially Available Technologies		
	Variable Flow	Continuous Flow	Bubble
	ARABELLA	CPAP 1002	Breath of Life
Description	A higher-end/more sophisticated technology, but available at reduced price compared to other mainstream, commercially-available variable-flow continuous positive airway pressure (CPAP) technologies. This particular device is variable flow (inspiratory vs. expiratory).[12]	Lower cost design (compared to variable flow); developed and manufactured in India.[13]	Low cost design and components, easy to manufacture and assemble. Blends using flowmeters.[14]
Characteristics applicable for low-resource settings	Requires a power supply.	Requires a power supply.	Requires a power supply.
Developer and/or manufacturer	Hamilton Medical, Switzerland.	Zeal Medical, India.	Medical Technology Transfer Service (MTTS), working with the East Meets West Foundation in Vietnam.
Status	Commercialized.	Commercialized.	Commercialized.
Efficacy/ effectiveness	Lower work of breathing than continuous flow devices.[2]	Standard CPAP technology effectiveness.[15,16,17]	Oscillations due to bubbling hypothesized to increase ventilation.[5]
Manufacturing quality and capacity	Swiss-based company with global-level manufacturing and distribution capability. Multinational corporation.	India-based manufacturer and supplier.	Vietnam-based manufacturing, efforts to establish International Standards Organization (ISO)-compliant manufacturing and distribution and use of the technology outside of Vietnam/Southeast Asia underway.
Intellectual property ownership	Proprietary.	Proprietary.	Proprietary.
Cost and cost drivers	US$4,000 to US$6,000.	US$1,700.	US$1,500.
Delivery/ procurement channels	Channels for hospital procurement.	Channels for hospital procurement.	Channels for hospital procurement. As of 2009, the East Meets West Foundation Breath of Life Program (BOL) has equipped over 95 percent of Vietnam's provinces with CPAP machines.[18]
Sustainable business models	Hamilton Medical bases its business model on initial sales of the device and routine service and maintenance.	Zeal Medical bases its business model on initial sales of the device and routine service and maintenance.	MTTS bases its business model on initial sales of the device through the BOL program and routine service and maintenance.

Demand Information	TECHNOLOGY/SOLUTION—TABLE 1		
	Commercially Available Technologies		
	Variable Flow	Continuous Flow	Bubble
	ARABELLA	CPAP 1002	Breath of Life
Existing demand	Market size is driven by the number of neonates with respiratory distress syndrome (RDS).	Market size is driven by the number of neonates with RDS.	Market size is driven by the number of neonates with RDS.
Attractiveness	High-end, sophisticated medical equipment—highly efficacious, requiring rigorous training and equipment maintenance. No data available on ease of use in low-resource settings.	Low-cost CPAP technology as compared to global-level manufacturing and distribution company products. No data available on ease of use in low-resource settings.	Low-cost CPAP technology as compared to global-level manufacturing and distribution company products. Locally manufactured by MTTS instructions, controls, and manuals in local language. Replacement parts easily obtained. Accessible technical support and maintenance in countries where BOL is operating. Durable and low maintenance. Tested in conditions of actual use and appropriately adapted. Not reliant on expensive consumables. Scalable for each country, hospital, and clinic conditions.
Price sensitivity	Extreme price sensitivity for low-resource usage for CPAP devices.	Extreme price sensitivity for low-resource usage for CPAP devices.	Extreme price sensitivity for low-resource usage for CPAP devices.
Policy environment	WHO lists standard CPAP and bubble CPAP devices as essential interventions for infants with RDS. 2010 European consensus guidelines provide recommendations for the use of CPAP devices for preterm infants with RDS.[19,20,21]	WHO lists standard CPAP and bubble CPAP devices as essential interventions for infants with RDS. 2010 European Consensus guidelines provide recommendations for the use of CPAP devices for preterm infants with RDS.[19,21,22]	WHO lists standard CPAP and bubble CPAP devices as essential interventions for infants with RDS. 2010 European Consensus guidelines provide recommendations for the use of CPAP devices for preterm infants with RDS.[19,21,22]
Donors/ stakeholders	None.	None.	Current and future East Meets West Foundation donors and supporters (e.g., the Lemelson Foundation, Save the Children, etc). Governments of Vietnam and other Southeast Asian countries.
Pre- and post-sales support	Requires training and field support.	Requires training and field support.	Requires training and field support.
Need for demand creation	Providers and other stakeholder will need awareness raising about benefits of CPAP devices over mechanical ventilation. Skills are required to use a CPAP device and this still poses a challenge to its widespread use.	Providers and other stakeholder will need awareness raising about benefits of CPAP devices over mechanical ventilation. Skills are required to use a CPAP device and this still poses a challenge to its widespread use.	Providers and other stakeholder will need awareness raising about benefits of CPAP devices over mechanical ventilation. Skills are required to use a CPAP device and this still poses a challenge to its widespread use.

Supply Information	TECHNOLOGY/SOLUTION—TABLE 2				
	Low-Cost Technologies in Development				
	Bubble				Indigenous Bubble
	DtM CPAP	**BabyBubbles**	**Low-Cost Breathing Assistant**	**HAB-CPAP**	**Locally assembled or improvised CPAP kits at hospital level**
Description	Advanced prototype that does not require a source of pressurized air. Includes an alarm and humidifier.[22]	Low-cost design and components, easy to manufacture and assemble.[23]	Design pressurizes ambient air, uses low-cost components. Easy to manufacture and assemble. Blends using flowmeters.[24]	Low-cost design and components, easy to manufacture and assemble. High amplitude bubble (HAB) CPAP, reduces the need for high-frequency ventilation, which can cause lung injury.[25]	CPAP kits are assembled with locally procured components, especially in low-resource environments. Several examples of this approach to technology access have occurred globally (India, etc.). Kit would be developed and tested in India with eventual global reach.
Characteristics applicable for low-resource settings	Battery operated.	Requires a power supply.	Requires a power supply.	Requires a power supply, may be battery powered.	No power required.
Developer and/or manufacturer	Design that Matters (DtM), Massachusetts Institute of Technology (MIT), and Rhode Island School of Design (RISD).	infantAIR.[23]	Stanford University and Inspire Medical (a nonprofit organization).	Seattle Children's Research Institute.	Local level neonatologists and clinicians, such as Dr. Ashish Jain, of Hindu Rau Hospital in Delhi, India.[26]
Status	In development.	In development.	In development.	In development.	Available within specific hospitals and regions.
Efficacy/ effectiveness	Oscillations due to bubbling hypothesized to increase ventilation.[5]	Oscillations due to bubbling hypothesized to increase ventilation.[5]	Oscillations due to bubbling hypothesized to increase ventilation.[5]	Higher amplitude oscillations may increase gas exchange.[27,28]	Currently limited to 100 percent oxygen. May be addressed with novel blender.
Manufacturing quality and capacity	No data available. DtM is a non-profit design organization.	No data available.	No data available.	Unknown, as the exact niche of this product is unclear.	Dependent on locally available materials and expertise. Procurement and assembly instructions may help.
Intellectual property (IP) ownership	Proprietary.	Data not available.	Proprietary.	Proprietary.	Generic, however local IP protection has been pursued by certain developers.
Cost and cost drivers	Target: US$268.	Target: US$160.	Target: US$200.	Target: US$100.	< US$5.
Delivery/ procurement channels	Hospital procurement channels.	Hospital and clinics. Aiming to implement the device in Rwandan hospitals first.[29]	Hospital procurement channels.	Hospital procurement channels.	Hospital procurement channels.
Sustainable business models	No data available.	No data available.	No data available.	No data available.	Created from existing onsite supplies. No business model required.

Demand Information	TECHNOLOGY/SOLUTION—TABLE 2				
	Low-Cost Technologies in Development				
	Bubble				Indigenous Bubble
	DtM CPAP	BabyBubbles	Low-Cost Breathing Assistant	HAB-CPAP	Locally assembled or improvised CPAP kits at hospital level
Existing demand	Market size is driven by the number of neonates with RDS.	Market size is driven by the number of neonates with RDS.	Market size is driven by the number of neonates with RDS.	Market size is driven by the number of neonates with RDS.	Market size is driven by the number of neonates with RDS.
Attractiveness	Low-cost approach to providing CPAP clinical benefit—this can mean improving neonates' survival if high cost CPAP devices are not accessible in the neonatal intensive care units (NICUs). No data available on ease of use in low-resource settings.	Low-cost approach to providing CPAP clinical benefit—this can mean improving neonates' survival if high cost CPAP devices are not accessible in the NICUs. No data available on ease of use in low-resource settings.	Low-cost approach to providing CPAP clinical benefit—this can mean improving neonates' survival if high cost CPAP devices are not accessible in the NICUs. No data available on ease of use in low-resource settings.	Low-cost approach to providing CPAP clinical benefit—this can mean improving neonates' survival if high cost CPAP devices are not accessible in the NICUs. No data available on ease of use in low-resource settings.	Kit can be assembled locally. Low-cost approach to providing CPAP clinical benefit—this can mean improving neonates' survival if high cost CPAP devices are not accessible in the NICUs.
Price sensitivity	Extreme price sensitivity for low-resource usage of CPAP devices.	Extreme price sensitivity for low- resource usage of CPAP devices.	Extreme price sensitivity for low-resource usage of CPAP devices.	Extreme price sensitivity for low-resource usage of CPAP devices.	Local approach to creating CPAP kits resulted from lack of access to more costly, sophisticated CPAP equipment.
Policy environment	WHO lists standard CPAP and bubble CPAP devices as essential interventions for infants with RDS. 2010 European Consensus guidelines provide recommendations for the use of CPAP devices for preterm infants with RDS.[19,21,22]	WHO lists standard CPAP and bubble CPAP devices as essential interventions for infants with RDS. 2010 European Consensus guidelines provide recommendations for the use of CPAP devices for preterm infants with RDS.[19,21,22]	WHO lists standard CPAP and bubble CPAP devices as essential interventions for infants with RDS. 2010 European Consensus guidelines provide recommendations for the use of CPAP devices for preterm infants with RDS.[19,21,22]	WHO lists standard CPAP and bubble CPAP devices as essential interventions for infants with RDS. 2010 European Consensus guidelines provide recommendations for the use of CPAP devices for preterm infants with RDS.[19,21,22]	WHO lists standard CPAP and bubble CPAP devices as essential interventions for infants with RDS. 2010 European Consensus guidelines provide recommendations for the use of CPAP devices for preterm infants with RDS.[19,21,22] There are practical barriers to consideration of risk versus benefit in using basic CPAP kit equipment.

Demand Information	TECHNOLOGY/SOLUTION—TABLE 2				
	Low-cost technologies in development				
	Bubble				Indigenous Bubble
	DtM CPAP	BabyBubbles	Low-Cost Breathing Assistant	HAB-CPAP	Locally assembled or improvised CPAP kits at hospital level
Donors/ stakeholders	Winner of the HSBC RISD International Award 2009. DtM funding: Otterloo Family Foundation; Lemelson Foundation; Lynch Family Foundation; Ashoka; Bridgeway Fund.[30]	National Collegiate Inventors and Innovators Alliance (NCIIA) grant for US$18,000. Award from Rice business plan competition of US$11,750. Winner in Saving Lives at Birth Initiative (SLAB) 2011 for testing efficacy of device in Malawi at rural district hospital in collaboration with 3rd Stone Design, Baylor School of Medicine and University of Malawi.	Partners with ICDDR,B, a leading research hospital in Dhaka, and LAMB, a rural hospital in Rajshahi, Bangladesh. Funded by individuals, family foundations, impact investors, federal grants, and Stanford University.[31]	PATH is a partner. Seattle Children's Research Institute receives finding from the Bill & Melinda Gates Foundation.	PATH winner of a SLAB award in 2011 to support further development and standardization of a CPAP kit originated at Hindu Rao Hospital.
Pre- and post-sales support	Will require training and field support.	Will require training and field support.	Will require training and field support.	Will require training and field support.	A guide to assembling the CPAP kit and component procurement/ identification might have benefit to hospital and regional neonatal care and support.
Need for demand creation	Providers and other stakeholders need to be made aware of the benefits of CPAP devices over mechanical ventilation. The skill required to operate a CPAP device still poses a challenge to its widespread use.	Providers and other stakeholders need to be made aware of the benefits of CPAP devices over mechanical ventilation. The skill required to operate a CPAP device still poses a challenge to its widespread use.	Evidence on product efficacy in low-resource settings will need to be generated to drive demand. Providers and other stakeholders need to be made aware of the benefits of CPAP devices over mechanical ventilation. The skill required to operate a CPAP device still poses a challenge to its widespread use.	Evidence on product efficacy in low-resource settings will need to be generated to drive demand. Providers and other stakeholders need to be made aware of the benefits of CPAP devices over mechanical ventilation. The skill required to operate a CPAP device still poses a challenge to its widespread use.	Evidence on product efficacy in low-resource settings will need to be generated to drive demand. Providers and other stakeholders need to be made aware of the benefits of CPAP devices over mechanical ventilation. A standardized approach to creating locally available CPAP kits might increase demand in other regions.

References

[1] Lawn JE, Cousens S, Zupan J, et al. 4 million neonatal deaths: When? Where? Why? *Lancet.* 2005;365:891–900.

[2] Singhal N, Bhutta ZA. Newborn resuscitation in resource-limited settings. *Seminars in Fetal and Neonatal Medicine.* 2008;13(6):432–439.

[3] Lemyre B, Davis PG, de Paoli AG. Nasal intermittent positive pressure ventilation (NIPPV) versus nasal continuous positive airway pressure (NCPAP) for apnea of prematurity. *Cochrane Database Systematic Review*. 2002:CD002272.

[4] Vidyasagar D, Singhal N. Neonatal Ventilator Care in Resource Limited Countries. In: Goldsmith JP, Karotkin EH, eds. *Assisted Ventilation of the Neonate.* Elsevier; 2011:Chapter 30.

[5] Pillow JJ, Travadi JN. Bubble CPAP: is the noise important? An in vitro study. *Pediatric Research.* 2005;57(6):826–830.

[6] Lee KS, Dunn MS, Fenwick M, et al. A comparison of underwater bubble continuous positive airway pressure with ventilator-derived continuous positive airway pressure in premature neonates ready for extubation. *Biology of the Neonate*. 1998;73(2):69–75.

[7] Ammari A, Suri M, Milisavljevic V, et al. Variables associated with the early failure of nasal CPAP in very low birth weight infants*. Journal of Pediatrics.* 2005;147(3):341–347.

[8] Richardson P, Jarriel S, Hansen TN. Mechanics of the respiratory system during passive exhalation in preterm lambs. *Pediatric Research.* 1989; 26(5):425–428.

[9] Roberts CL, Badgery-Parker T, Algert CS, et al. Trends in use of neonatal CPAP: a population-based study. *BioMed Central Pediatriacs.* 2011; 11:89.

[10] Koyamaibole L, Kado J, Qovu JD, et al. An evaluation of bubble-CPAP in a neonatal unit in a developing country: effective respiratory support that can be applied by nurses. *Journal of Tropical Pediatridrics*. 2006;52(4):249–253.

[11] van den Heuvel M, Blencowe H, Mittermayer K, et al. Introduction of bubble CPAP in a teaching hospital in Malawi. *Annals of Tropical Paediatrics.* 2011;319(1):59–65.

[12] Arabella web page. Hamiton Medical website. Available at: http://www.hamilton-medical.com/ARABELLA-infant-nasal-CPAP-sys.arabella.1.html. Accessed February 8, 2012.

[13] CPAP 1002 web page. Zeal Medical website. Avaialble at: http://www.zealmedical.com/cpap.htm. Accessed February 8, 2012.

[14] Breath of Life equipment web page. East Meets West Foundation website. Available at: http://www.eastmeetswest.org/Page.aspx?pid=378. Accessed February 8, 2012.

[15] Greenough A, Dimitriou G, Prendergast M, et al. Synchronized mechanical ventilation for respiratory support in newborn infants. *Cochrane Database of Systematic Reviews*. 2008;1CD000456.

[16] Ho JJ, Subramaniam P, Henderson-Smart DJ, et al. Continuous distending pressure for respiratory distress syndrome in preterm infants. *Cochrane Database of Systematic Reviews*. 2002;2:CD002271.

[17] Deorari A. Continuous distending pressure for respiratory distress in preterm infants: RHL commentary (last revised: 1 January 2010). *The WHO Reproductive Health Library*; Geneva: World Health Organization.

[18] Breath of Life web page. Medical Technology Transfer Services website. Available at: http://www.mtts-asia.com/en/network/breath-of-life. Accessed February 8, 2012.

[19] The Partnership for Maternal, Newborn & Child Health (PMNCH). *A Global Review of the Key Interventions Related to Reproductive, Maternal, Newborn and Child Health.* PMNCH: Geneva; 2011.

[20] Royal College of Paediatrics and Child Health (RCPCH). Management of Neonatal Respiratory Distress Syndrome. London RCPCH December 2000

[21] Sweet DG, Carnielli V, Greisen G, et al. European consensus guidelines on the management of neonatal respiratory distress syndrome in preterm infants—2010 update. *Neonatology*. June 2010;97(4):402–417.

[22] Design that Matters infant CPAP team presentation. Available at: http://www.designthatmatters.org/docs/dtm-blog/CPAP_final_presentation.pdf. Accessed February 8, 2012.

[23] infantAIR website. Available at: http://www.infant-air.com/main/index.html. Accessed February 8, 2012.

[24] Inspire Medical website. Available at: http://www.inspiremedical.org/Inspire/Welcome.html. Accessed February 8, 2012.

[25] Press release: Seattle Children's lands major funding with hopes of saving thousands of infant lives. August 16, 2011. Available at: http://www.eurekalert.org/pub_releases/2011-08/sc-scl081511.php. Accessed February 8, 2012.

[26] Low-Cost Bubble CPAP Kit and Oxygen Blender web page. Maternova website. Available at: http://maternova.net/health-innovations/low-cost-bubble-cpap-kit-and-oxygen-blender. Accessed February 8, 2012.

[27] Diblasi RM, Zignego JC, Smith CV, et al. Effective gas exchange in paralyzed juvenile rabbits using simple, inexpensive respiratory support devices. *Pediatric Research.* 2010;68(6):526–530.

[28] Diblasi RM, Zignego JC, Tang DM, et al. Noninvasive respiratory support of juvenile rabbits by high-amplitude bubble continuous positive airway pressure. *Pediatric Research.* 2010;67(6):624–629.

[29] infantAIR web page. National Collegiant Inventors and Innovators Alliance website. Available at: http://nciia.org/node/1264. Accessed February 8, 2012.

[30] Design that Matters CPAP web page. MANDATE website. Available at: http://mnhtech.org/technology/technologies-in-development/design-that-matters-dtm-cpap/. Accessed February 8, 2012.

[31] Bubble CPAP information page. Inspire Medical website. Available at: http://www.inspiremedical.org/Inspire/Welcome_files/Inspire%20One-Pager_201107.pdf. Accessed February 8, 2012.

Delivery of Oxygen

Oxygen is part of the recommended treatment for children and neonates that suffer hypoxemia. However, it remains inaccessible to a large proportion of severely ill patients admitted to hospitals in developing countries. This is particularly true for patients in small district hospitals where, even if some facility for delivering oxygen is available, supplies are often unreliable and the benefits of treatment may be diminished by poorly maintained and inappropriate equipment, poorly trained staff, or inadequate guidelines.[1]

Supplemental oxygen is not routinely recommended during resuscitation of newborns that have suffered from intrapartum anoxia and are not breathing properly at birth, especially for term infants. However, some infants who do not respond quickly and a significant number of preterm infants will require additional oxygen. Among newborns, in addition to pneumonia conditions such as respiratory distress syndrome, birth asphyxia, transient tachypnoea of the newborn, and sepsis may lead to hypoxemia.[2,3] Apnea and hypoventilation occur in otherwise healthy premature babies (usually <32weeks gestational age) due to immature respiratory drive and in babies of any gestational age with sepsis, asphyxia, seizures, or hypoglycemia. Judicious oxygen therapy is often necessary for these common conditions that are the cause of a large proportion of the neonatal deaths occurring globally each year.[4]

A key to reducing death due to hypoxemia is the sufficient supply of oxygen. The World Health Organization (WHO) recommends two delivery methods of oxygen, (1) an oxygen cylinder or (2) an oxygen concentrator. The process to refill and transport cylinders, however, has been described as expensive and challenging—especially in rural settings—which compound the oxygen supply problem at the patient level. On the other hand, oxygen concentrators are increasingly being used as an alternative source of medical oxygen in developing countries because they are capable of producing 90 percent oxygen from ambient air without the refill and transport stipulations. Different levels of personnel, resources, and infrastructure may entail different choices of systems and methods of administering oxygen. A comparison of oxygen cylinders and concentrators as a basis for oxygen systems is described in Figure 1 on the following page.[1]

Additionally, oxygen concentrators have been used successfully in hospitals in low-resource settings including Egypt,[5] Malawi,[6] Papua New Guinea,[7,8] The Gambia,[9] Nigeria,[10] and Nepal.[11] Duke, et al. have defined specifications for oxygen concentrators suited for use in a district hospital ward as shown in Figure 2 on the following page.[12]

Figure 1. Comparison of oxygen cylinders and concentrators as the basis for oxygen systems.[1]

Criteria	Oxygen cylinders	Oxygen concentrators
Power source required	No	Yes, continuously
Transport requirement	Regularly. By air only in chartered aircraft. Heavy and costly to transport	Only at time of installation
Exhaustible supply	Yes, standard cylinders last 2–3 days at most with continuous use	No, continuous supply as long as power remains uninterrupted
Establishment equipment costs	Oxygen flow meter (about US$400) and regulator (about US$200) per cylinder, costs moderate	Moderate up-front equipment cost (about US$1000), plus installation and commissioning, training
Ongoing costs	Cylinder refill costs moderate (US$30) but frequent, costs of transport from refilling station to hospital	Small: electricity, maintenance
Maintenance	Minimal	Moderate, both preventive maintenance and intermittent repairs; spare parts needed
Training	In-clinic use of oxygen and pulse oximetry, plus day-to-day trouble-shooting of cylinders and connectors	Additional recommended for preventive maintenance of concentrators, training for hospital engineers/technicians, clinical use of oxygen and pulse oximetry

Source: Table 12.3—Comparison of oxygen cylinders and concentrators as the basis for oxygen systems. From: World Health Organization. *The clinical use of oxygen in hospitals with limited resources: guidelines for health-care workers, hospital engineers, and managers*. Geneva: WHO; 2009. Page 98.

Figure 2. Key technical points and specifications for oxygen concentrators suited for use in a district hospital ward.[12]

- The concentrator should achieve >85% oxygen concentration at a flow rate of up to 10 L/min.
- The concentrator should operate at a voltage and frequency suitable for the local power supply; this differs between countries.
- For energy efficiency the power requirements should be close to 350 W for units providing 5 L/min, 410 W for 8-L/min units, and 600 W for 10-L/min units.
- The concentrator should have one or two outlets with individual flow controls and flow indicators.
- Outlet pressure should be no less than 55 kPa for units providing 5 L/min and 138 kPa for 8- and 10-L/min units.
- Weight should not exceed 25 kg.
- An hour meter should record total hours of unit operation.
- Maximum operating altitude should be not less than 2000 m, with not less than 85% oxygen concentration at maximum flow.
- Maximum operating temperature should be not less than 40°C.
- Maximum operating humidity should be not less than 95% relative humidity.
- A list of all spare or replacement parts and their costs for 40,000 hours of operation (e.g., compressor, sieve beds and valve spares kits) should be provided.
- The concentrator should comply with ISO 8359:1996 and IEC 60601-1 and carry a CE marking.
- The concentrator should be fitted with an oxygen monitor which gives an audible/visual alarm when the product gas is below 82% oxygen concentration
- A user manual intended for hospital use and a service manual with a troubleshooting guide should be provided.
- There should be a 60-month parts warranty at a defined cost.
- The unit should include either a 4-way flow splitter, together with all nozzles and blanking plugs, which can deliver flows of 0.5, 1.0 and 2.0 L/min, OR a flow meter stand. Each flow meter should be continuously adjustable with an accurate low flow scale acceptable for patient care, such as from 0.1 to 2 L/min (or higher flow as appropriate).

Source: Textbox 1—Key technical points and specifications for oxygen concentrators suited for use in a district hospital ward. From: Duke T, Peel D, Graham S, Howie S, Enarson Pm, Jacobson R. Oxygen concentrators: a practical guide for clinicians and technicians in developing countries. *Annals of Tropical Paediatrics*. 2010; 30:87–101.

In infants who have a persistent need for oxygen after resuscitation, oxygen should be warmed, humidified, and delivered using a system in which the concentration can be regulated. The inspired oxygen concentration should ideally be measured with an oxygen analyzer, continuously if possible or at a minimum of every hour. Delivery devices include a hood, face mask, nasal cannula, nasal continuous positive airway pressure or endotracheal tube if the infant requires assisted ventilation.[13]

Oxygen blenders mix medical grade compressed air and oxygen to provide a pressurized gas source ranging from low to 100 percent oxygen thereby allowing a controlled oxygen-air mix suitable for each individual patient. In developed countries, the device may be in metal and attached to the wall or a disposable device which is part of the mask over the patient's face. The hospital has separate pipelines for 100 percent oxygen and for air, no mixtures being allowed in the pipeline. In developing countries, very few places have an air oxygen mix. During use of an oxygen analyzer, some "mixing" has been anecdotally noticed when using oxygen hoods that have ports that can be opened as required.[14]

The following two tables illustrate options for oxygen sources (Table 1) and oxygen blending (Table 2).

Supply Information	TECHNOLOGY/SOLUTION—TABLE 1			
	Oxygen Sources			
	Compressed oxygen	**Liquid oxygen**	**Oxygen concentrator**	**Oxygen in a box**
Description	Compressed gas. Stored under pressure in a cylinder equipped with a flow meter and regulator to control the flow rate. Conventional means of supplying oxygen. Compressed oxygen must be kept upright and handled with care. Also, large cylinders are heavy and not made for mobility. Small cylinders can be filled from the larger tank for movement, but hospitals may require frequent refill if they serve a large number of patients who undergo oxygen therapy. Lack of availability at district hospital level.[15] Requires troubleshooting of cylinders and connectors.	Liquid oxygen. The liquid oxygen is stored in an insulated canister. Liquids are cheaper to ship and require less space than gas but require insulated containers to store. A single cylinder would last 860 times longer than the equivalent-sized container for a gas. A vaporizer is required to convert liquid oxygen to a gas. Lack of availability at district hospital level.[15]	Device that filters nitrogen from atmospheric air to produce 90% oxygen. Used as a safer and more convenient alternative to tanks of compressed oxygen. There is a built-in flow meter attached to the concentrator to allow the prescribed flow rate to be set.	Portable oxygen generation. Chemically produces pure, 100% humidified oxygen. Each Oxybox produces oxygen at different (controlled) flow rates for varying periods of time. Rebreathing capability and reduction of oxygen concentration from 100 percent to 50 percent allows extension of use to several hours.
Characteristics applicable for low-resource settings	Conventional means of supplying oxygen. Require routine maintenance and heavy to transport. Must use safe handling procedures.	The liquid oxygen system requires less space than compressed gas, but is more expensive to use. Liquids are cheaper to ship than gas but require insulated containers to store. A single cylinder would last 860 times longer than the equivalent-sized container for a gas. Require routine maintenance.	Does not require pressured oxygen or air. Concentrators have been estimated to be 25 percent to 50 percent more cost-effective than cylinders in resource-poor settings.[16] Require electricity and cost to maintenance and repair. Many concentrators may not be well suited to use in challenging tropical conditions; continuous power source necessary.[17]	Portable. Safe and easy to use. Requires no outside power source. More affordable compared to traditional portable oxygen sources like oxygen cylinders and concentrators. No regulatory or flow meter required. Disposable or recyclable. May not offer sufficient oxygen for neonates on longer-term therapy.
Developer and/or manufacturer	Multiple: for example, Praxair Inc., Airgas Inc.	Multiple: for example, Praxair.	Multiple: for example, VisionAire, NewLife seriese (AirSep), EverFlo, Millenium (Phillips).	Oxybox (General Electric).
Status	Commercialized.	Commercialized.	Commercialized.	Commercialized with 510(k) clearance and a CE mark.

Supply Information	TECHNOLOGY/SOLUTION—TABLE 1			
	Oxygen Sources			
	Compressed oxygen	**Liquid oxygen**	**Oxygen concentrator**	**Oxygen in a box**
Efficacy/ effectiveness	Data on effectiveness of oxygen systems in low-resources settings relate to childhood pneumonia only. One study in five hospitals in Papua New Guinea demonstrated that after the improved system including pulse oximetry and oxygen concentrators was introduced, the risk of death for a child with pneumonia was 35 percent lower than was that before the project began (risk ratio 0.65 [0.52-0.78], p<0.0001). In the same study, the estimated costs of this system were US$51 per patient treated, US$1,673 per life saved, and US$50 per disability-adjusted life-year averted.[7]	Data on effectiveness of oxygen systems in low-resources settings relate to childhood pneumonia only. One study in five hospitals in Papua New Guinea demonstrated that after the improved system including pulse oximetry and oxygen concentrators was introduced, the risk of death for a child with pneumonia was 35 percent lower than was that before the project began (risk ratio 0.65 [0.52-0.78], p<0.0001). In the same study, the estimated costs of this system were US$51 per patient treated, US$1,673 per life saved, and US$50 per disability-adjusted life-year averted.[7]	Data on effectiveness of oxygen systems in low-resources settings relate to childhood pneumonia only. One study in five hospitals in Papua New Guinea demonstrated that after the improved system including pulse oximetry and oxygen concentrators was introduced, the risk of death for a child with pneumonia was 35 percent lower than was that before the project began (risk ratio 0.65 [0.52-0.78], p<0.0001). In the same study, the estimated costs of this system were US$51 per patient treated, US$1,673 per life saved, and US$50 per disability-adjusted life-year averted.[7]	Data on effectiveness of oxygen systems in low-resources settings relate to childhood pneumonia only. One study in five hospitals in Papua New Guinea demonstrated that after the improved system including pulse oximetry and oxygen concentrators was introduced, the risk of death for a child with pneumonia was 35 percent lower than was that before the project began (risk ratio 0.65 [0.52-0.78], p<0.0001). In the same study, the estimated costs of this system were US$51 per patient treated, US$1,673 per life saved, and US$50 per disability-adjusted life-year averted.[7]
Manufacturing quality and capacity	Multiple: Airgas and Praxair are two of the largest companies in North America. Praxair is certified with ISO 9002 certification.	Multiple: Airgas and Praxair are two of the largest companies in North America.	Multiple: Manufactured by companies with global-level capacity/capability.	Manufactured by GE with global-level manufacturing capacity/capability.
Intellectual property ownership	No data available.	No data available	No data available.	Core technology protected by intellectual property and licensed to GE.
Cost and cost drivers	No data available on pricing of oxygen with a cylinder. Cylinders can be reused for refilling.	No data available. Cylinders can be reused for refilling.	Unit cost ranges fromUS$525 toUS$2,950.[17] US$853.18 (UNICEF supply catalog). Other costs include training, maintenance, and repair. Cost of equipment (26 units) and program was US$104,077.[6]	No data available. In addition to the cost of the device, training will be necessary.

Supply Information	TECHNOLOGY/SOLUTION—TABLE 1			
	Oxygen Sources			
	Compressed oxygen	Liquid oxygen	Oxygen concentrator	Oxygen in a box
Delivery/ procurement channels	Distribution though private-sector channels.	Distribution though private-sector channels.	Distribution though private-sector channels.	Although distribution through private-sector channels is possible, bulk procurement by government and nongovernmental organizations (NGOs) will be desired for this low-cost, low-margin device.
Sustainable business models	Distribution through manufacturers' local distributors.	Distribution through manufacturers' local distributors.	Distribution through manufacturer's local distributors. Need to develop non-electric-powered, low-cost device for low-resource countries. Need to develop programs for maintenance/repair to ensure sustainable use.	Low-resource countries through global health initiatives. A sustainable business model can be achieved through public-private partnerships.

Demand Information	TECHNOLOGY/SOLUTION—TABLE 1			
	Oxygen Sources			
	Compressed Oxygen	Liquid oxygen	Oxygen concentrator	Oxygen in a box
Existing demand	The market size will be driven by the number of patients that require oxygen therapy primarily in referral hospitals. The use of oxygen will not be limited to mothers and newborns. The market could be expanded to secondary health care facilities if the distribution network is strengthened.	The market size will be driven by the number of patients that require oxygen therapy primarily in referral hospitals. The use of oxygen will not be limited to mothers and newborns. The market could be expanded to secondary health care facilities if the distribution network is strengthened.	The market size will be driven by the number of referral and secondary hospitals that require oxygen therapy. The use of the oxygen concentrator is not limited to mothers and newborns.	The market size will be driven by the number of referral and secondary hospitals. If policy favors use of oxygen therapy at lower-level facilities and if skilled personnel are available, the market could be extended to lower-level health care facilities.
Attractiveness	Cylinder can reused and refilled for cost saving.	Cylinder can reused and refilled for cost saving. Requires less space than compressed gas. Liquids are cheaper to ship although they require insulated containers to store. A single tank would last 860 times longer than the equivalent sized container for a gas.	More cost-effective than cylinders. Does not require pressurized oxygen or air.	Portable and easy to use. Do not require electricity or flow meter.
Price sensitivity	Not applicable.	Not applicable.	No data available.	Not applicable.
Policy environment	Oxygen is a part of the recommended treatment for children and neonates that suffer hypoxemia. WHO recommends two methods of providing oxygen, (1) an oxygen cinder or (2) oxygen concentrator.[1]			
Donors/ stakeholders	WHO, UNICEF, International Union against Tuberculosis and Lung Disease.			
Pre- and post-sales support	Require troubleshooting of cylinders and connectors.	Require troubleshooting of cylinders and connectors.	Require training, maintenance, and repair.	Some training is necessary.
Need for demand creation	Need to engage governments to incorporate resuscitation into national prenatal programs. A recent call to action can be a useful advocacy tool.[18]	Need to engage governments to incorporate resuscitation into national prenatal programs. A recent call to action can be a useful advocacy tool.[18]	Need to engage governments to incorporate resuscitation into national prenatal programs. The demand for these devices might be limited in low-resource settings since they require training, maintenance, and electricity to run the devices. A recent call to action can be a useful advocacy tool.[18]	Need to engage governments to incorporate resuscitation into national prenatal programs. Generate favorable evidence on product performance and create use-case scenario to expand the market to lower-level health care facilities. A recent call to action can be a useful advocacy tool.[18]

Supply Information	TECHNOLOGY/SOLUTION—TABLE 2	
	Oxygen Blending	
	Hospital blenders	Entrainment (Venturi) device
Description	Blends compressed air and oxygen, delivering pressurized gas at precise concentrations. Require both pressurized oxygen and air as sources.	A low-cost device that blends compressed oxygen and ambient air, typically incorporating a mask and large-bore, collapsible tubing.
Characteristics applicable for low-resource settings	Require both pressurized oxygen and air. Expensive. Not appropriate for low-resource setting.	Low cost. Works with ambient air and does not required pressured air. Still requires pressurized oxygen.
Developer and/or manufacturer	Multiple: for example, Bird® Blenders (Care Fusion), Blender Buddy (Maxtec Inc.).	Multiple: for example, Fisher & Paykel.
Status	Commercialized.	Commercialized.
Efficacy/ effectiveness	No data available.	No data available.
Manufacturing quality and capacity	Multiple: Some companies with global-level manufacturing capacity and standard.	Manufactured by multiple companies with global-level manufacturing capacity and standard.
Intellectual property ownership	No data available.	No data available.
Cost and cost drivers	Unit cost ranges from US$750 to US$1,000.[19]	No data available. Pediatric Venturi mask costs US$3.90 (+US$8.35 shipping and handling at Amazon.com).
Delivery/ procurement channels	Distribution though private-sector channels.	Distribution though private-sector channels.
Sustainable business models	Distribution through manufacturer's local distributors. Need to develop a non-electric-powered, low-cost device for low-resource countries. Need to develop programs for maintenance/repair to ensure sustainable use.	Bulk procurement is necessary by governments and NGOs to compensate for low profit margin.

Demand Information	TECHNOLOGY/SOLUTION—TABLE 2	
	Oxygen blending	
	Hospital blenders	Entrainment (Venturi) device
Existing demand	Market size is driven by the number of patients that require oxygen therapy primarily in referral hospitals. The use is not limited to mothers and newborns.	Market size is driven by the number of patients that require oxygen therapy primarily in referral hospitals. The use is not limited to mothers and newborns.
Attractiveness	Can deliver oxygen at precise concentration.	Low cost.
Price sensitivity	No data available.	No data available.
Policy environment	Oxygen is a part of the recommended treatment for children and neonates that suffer hypoxemia. WHO recommends two methods of delivering oxygen, (1) an oxygen cinder or (2) oxygen concentrator.[1]	Oxygen is a part of the recommended treatment for children and neonates that suffer hypoxemia. WHO recommends two methods of delivering oxygen, (1) an oxygen cinder or (2) oxygen concentrator.[1]
Donors/ stakeholders	WHO, UNICEF, International Union against Tuberculosis and Lung Disease.	WHO, UNICEF, International Union against Tuberculosis and Lung Disease.
Pre- and post-sales support	Require training, maintenance, and repair.	Require instructions to use, but no training is necessary.
Need for demand creation	Need to engage governments to incorporate resuscitation into national prenatal programs. The demand for these devices might be limited in low-resource settings since they require training, maintenance, and electricity to run the devices. A recent call to action can be a useful advocacy tool.[18]	Need to engage governments to incorporate resuscitation into national prenatal programs. The demand for these devices might be limited in low-resource settings since they require training, maintenance, and electricity to run the devices. A recent call to action can be a useful advocacy tool.[18]

References

[1] World Health Organization. *The Clinical Use of Oxygen in Hospitals With Limited Resources: Guidelines for Health-Care Workers, Hospital Engineers, and Managers*. Geneva: WHO; 2009.

[2] Duke T, Blaschke AJ, Sialis S, et al. Hypoxaemia in acute respiratory and non-respiratory illness in neonates and children in a developing country. *Archives of Disease in Childhood.* 2002;86:108–112.

[3] Duke T. Neonatal pneumonia in developing countries. *Archives of Disease in Childhood Fetal Neonatal Edition.* 2005;90:211–219.

[4] Lawn JE, Cousens S, Zupan J, Lancet Neonatal Survival Steering Team. 4 million neonatal deaths: When? Where? Why? *Lancet.* 2005;365:891–900.

[5] Dobson M, Peel D, Khallaf N. Field trial of oxygen concentrators in upper Egypt. *Lancet*. 1996;347:1597–1599.

[6] Enarson P, La Vincente S, Gie R, et al. Implementation of an oxygen concentrator system in district hospital paediatric wards throughout Malawi. *Bulletin of the World Health Organization.* 2008;86:344–348.

[7] Duke T, Wandi F, Jonathan M, et al. Improved oxygen systems for childhood pneumonia: a multihospital effectiveness study in Papua New Guinea. *Lancet*. 2008;372:1328–1333.

[8] Matai S, Peel D, Jonathan M, Wandi F, Subhi R, Duke T. Implementing an oxygen programme in hospitals in Papua New Guinea. *Annals of Tropical Paediatrics.* 2008;28:71–78.

[9] Howie SRC, Hill S, Ebonyi A, et al. Meeting oxygen needs in Africa: an options analysis from the Gambia. *Bulletin of the World Health Organization.* 2009;87:763–771.

[10] Mokuola OA, Ajayi OA. Use of an oxygen concentrator in a Nigerian neonatal unit: economic implications and reliability. *Annals of Tropical Paediatrics.* 2002;22:209–212.

[11] Litch JA, Bishop RA. Oxygen concentrators for the delivery of supplemental oxygen in remote high-altitude areas. *Wilderness and Environmental Medicine.*2000;11(3):189–191.

[12] Duke T, Peel D, Graham S, Howie S, Enarson PM, Jacobson R. Oxygen concentrators: a practical guide for clinicians and technicians in developing countries. *Annals of Tropical Paediatrics*. 2010;30:87–101.

[13] Adams JM, LE Weisman, Kim MS. *Oxygen therapy and monitoring in the newborn*. Waltham, MA: UpToDate; 2008.

[14] Personal communication with Dr. Indira Narayanan. February 6, 2012.

[15] World Health Organization. Informal Consultation on Clinical Use of Oxygen. Meeting Report. October 2–3, 2003.

[16] Dobson MB. Oxygen concentrators offer cost savings for developing countries: a study based in Papua New Guinea. *Anesthesia*. 2007;46(3):217–219.

[17] David P, Howie S. Oxygen concentrators for use in tropical countries: a survey. *Journal of Clinical Engineering*. 2009;34(4):205–209.

[18] Duke T, Graham SM, Cherian MN, et al. Oxygen is an essential medicine: a call for international action. *International Journal of Tuberculosis and Lung Disease.* 2010;14(11):1362–1368.

[19] WT Farley, Inc. website. Available at: http://www.wtfarley.com/Oxygen-Air-Blenders_c_165.html. Accessed February 8, 2012.

Pulse Oximeter

Supplemental oxygen is not routinely recommended during resuscitation of newborns who have suffered from intrapartum anoxia and are not breathing properly at birth, especially for term infants. However, some infants who do not respond quickly as well as a significant number of preterm infants will require additional oxygen. Normal oxygen saturation as measured by pulse oximetry (SpO2) levels are between 94% and 99%. Babies at birth may have SpO2 levels near 90% that subsequently rise quickly. In general, oxygen is usually recommended when the SpO2 falls below 90%. One of the challenges with oxygen is that both hypoxia and hyperoxia carry risks, such as potential damage to the brain. In preterm infants excessive oxygen can result in retrolental fibroplasia leading to visual disability and even complete blindness. Thus, it is essential to monitor oxygen levels.

Ideally, oxygen concentration administered (FiO2) should be noted with an oxygen analyzer. In low-resource settings, the priority is to note oxygen levels in babies. The gold standard is to monitor oxygen levels by estimating blood gases. This employs invasive methods such as blood sampling or uses arterial catheters requiring staff competence, costly equipment, and reagents that can present challenges in low-resource centers. Invasive methods also carry increased risk of infection. Noninvasive methods include use of a transcutaneous oxygen monitor and the pulse oximeter. The former is more costly, requires reagents, and the sensor site has to be changed periodically as it can heat up and injure the skin, especially in preterm babies. The pulse oximeter is currently the device that has found widespread application, including in developing-countries where the priority locations are in hospitals up to district levels. It can not only help in detecting the need for oxygen, but also avoid unnecessary administration that besides helping the baby can save costs.

Pulse oximetry is a simple noninvasive method of monitoring the percentage of hemoglobin (Hb) that is saturated with oxygen. The pulse oximeter consists of a probe attached to the patient's finger, toe, forehead, or ear lobe that is linked to a computerized unit. The unit displays the percentage of Hb saturated with oxygen together with an audible signal for each pulse beat, a calculated heart rate, and in some models a graphical display of the blood flow past the probe. Audible alarms which can be programmed by the user are provided.[1] A source of light originates from the probe at two wavelengths (650 nm and 805 nm). The light is partly absorbed by Hb by amounts which differ depending on whether it is saturated or desaturated with oxygen. By calculating the absorption or reflectance at the two wavelengths the processor can compute the proportion of Hb which is oxygenated.[1] It is important to note that the way the device functions may be influenced by a number of factors and at times false or unreliable readings could result, for example, poor perfusion of the skin in contact with the sensor as can happen with temperature imbalance, low blood pressure, or shock.

Availability of pulse oximetry is poor in resource-limited settings. Non-cost barriers to availability of oximetry include distribution, policy, education, and guidelines. Service and access to parts are frequently cited barriers to the availability of functional oximetry. The current price of pulse oximeters used in developed-country facilities is roughly US$2,000 for the oximeter and US$80 for the probe. There are also several portable oximeters made by General Electric and Masimo in the US$500 to US$600 range. A simple web search also reveals dozens of cheap oximeters of unknown reliability and conformance to standards in the US$50 to US$150 range. A World Health Organization (WHO) report on pulse oximeters in 2004 identified six models costing less than US$1,500 that had acceptable specifications. Probes and the connecting cables are delicate and are easily damaged during normal use. Often, pulse oximeters have been found unusable due to failed probes[2] and have been consigned to the cupboard because providers had no mechanism for ordering a replacement due to lack of knowledge, protocol, a local distribution agency, or funding.[3]

Sensor probes also vary and can be fixed on the finger, skin, palms, or soles. The latter two sites are commonly used in the newborn period. Replacement pulse oximeter probes are available. Some are intended to be disposable but are frequently reused on several patients over a week or more until the light emitting diode (LED) signal fades. These are often difficult to clean, and the adhesive wears off after a few uses.[4] There are also several types of longer-life digital probes that are more expensive. Several third-party sources have begun to supply reusable sensors with a claimed lifetime in the range of 9 months to 15 months. Manufacturers of such sensors typically are not the manufacturers of pulse oximeters but claim to supply sensors that work with nearly all currently available pulse oximeters. A landscape assessing the performance and durability of these aftermarket sensors has not been conducted.[4]

The following table describes three pulse oximeters.

Supply Information	TECHNOLOGY/SOLUTION		
	TuffSat®	**Freeplay/PET**	**Lifebox**

Description	Specifically developed to perform in any clinical environment, the TuffSat® oximeter can be used for home, transport, emergency medical services (EMS), home care and hospital use. Other product features include:
	• Lightweight, ergonomic design.
	• Water-resistant.
	• One-hand operation.
	• Carrying case with belt clip.
	• Large backlit LCD display.
	• 3-year warranty.
		The Freeplay/PET design has a flexible power design allowing off-grid operation with a built-in hand-crank generator. If wind-up power is used, 30 seconds of winding results in an average of 2 minutes 55 seconds of continuous use.
		This device measures the percentage of oxygen present in the blood using a well-established noninvasive method of shining light of different wavelengths through the skin. Advanced arrangements have been made for EMCO (an Indian medical technology company) to manufacture an innovative pulse oximeter that uses a sophisticated digital original equipment manufacturer (OEM) module manufactured by Nonin.
			Lifebox is the lowest-cost detection device of oxygen (O2) saturation.
			Designed to the following World Health Organization (WHO) specifications:
			• Robust and durable design.
			• Accurate oxygen saturation measurement (+/-2%).
			• Audible and visual alarms.
			  ▪ Fixed 90% oxygen saturation alarm.
			  ▪ Heart rate alarm (high 120/low 60).
			  ▪ High and low alarm priorities.
			  ▪ Low-battery alarm.
			• Pulse waveform display.
			• Variable pulse tone (lower saturation, deeper tone).
			• Numeric displays for oxygen saturation and pulse rate.
			• Ergonomic display.
			Mains electrical supply with a rechargeable battery.

Characteristics applicable for low-resource settings	Fewer false alarms. Exceeds international durability standards. Uses AA-sized rechargeable batteries.	Allows for off-grid operation with a built-in hand-crank generator.	Designed specifically to WHO specifications for use in low-resource settings. Uses AA-sized rechargeable batteries
Developer and/or manufacturer	General Electric (GE).	Freeplay Energy, acquired in 2010 by Euro Suisse.[5] Uses components from Ultrasound Technologies Ltd, Wales UK.	Acare Technology Co., Ltd. (Taiwan).
Status	Commercialized. United States Food and Drug Administration approved.	Arrangements have been made for EMCO to manufacture an innovative pulse oximeter that uses a sophisticated digital OEM module manufactured by Nonin.[6]	Commercialized and distributed through Lifebox Global Not-For-Profit.

Supply Information	TECHNOLOGY/SOLUTION		
	TuffSat®	Freeplay/PET	Lifebox
Efficacy/ effectiveness	Data not available.	Five prototypes were tested in field trials in South Africa to ascertain accuracy and usability. The results indicate that the prototype gives accurate saturation readings when compared to a standard oximeter model with no significant differences when the readings are compared (n= 60). The prototype readings remain accurate as the power runs low and the device switches off (n=20).[7] Health workers found the prototype user-friendly, helpful, and appropriate for low-resource settings. Further studies are needed to assess the clinical impact of this device on clinical outcome in different settings.[8]	Oxygen saturation as measured by pulse oximetry (SpO2) has successfully predicted adverse maternal outcomes. The area under the receiver-operator characteristic curve (AUC ROC) was 0.71 (95% confidence interval [CI] 0.65 to 0.77). Combining the symptoms of chest pain and/or dyspnea with pulse oximetry improved this predictive ability (AUC ROC 0.73; 95% CI 0.67 to 0.78). When SpO2 was stratified into risk groups using inflection points on the ROC curve, the highest-risk group (SpO2 90% to 93%) had an odds ratio of 18.1 (95% CI 8.2 to 40.2) for all outcomes within 48 hours when compared with the baseline group (SpO2 98% to 100%).[9]
Manufacturing quality and capacity	Manufactured by GE Healthcare (formerly Datex-Ohmeda).	Freeplay has arranged for EMCO to manufacture the technology, but a lack of funding has hindered the establishment of a manufacturing and distribution network.	This WHO-audited manufacturer meets all requirements and is capable of scaling to meet the need.
Intellectual property (IP) ownership	Patented TruTrak™ data sampling provides consistent accurate SpO2 readings, even during patient motion and low perfusion.	Freeplay has IP on technology that converts human, solar, and rechargeable energy into electricity. The design licenses Nonin technology, and US$200 of the US$600 unit price repays Nonin royalties.	None.
Cost and cost drivers	US$450 to US$600.	Current price US$600. Target price is US$150 to US$200.	US$250 with replacement probes of US$25 each.[10]
Delivery/ procurement channels	GE does not have current distribution channels to low-resource settings but is building capacity to reach low-resource settings through their Healthymagination initiative.	Freeplay partners with Powerfree Education and Technology (PET), a nonprofit based in South Africa.	LIfebox is developing potential delivery and procurement channels.
Sustainable business models	Multinational corporation with multiple product lines. The challenge is to create a sustainable business model while serving lower-resource settings.	Small company with a variety of technologies. Most widely known for its Freeplay radios that are procured by the United Nations Children's Fund.	Lifebox Global Not-For-Profit is funded in part by Smile Train. Smile Train also influences the organization through strategic executive involvement. Acare Technology Co. is assumed to make a very small profit on each sale.

Demand Information	TECHNOLOGY/SOLUTION		
	TuffSat®	**Freeplay/PET**	**Lifebox**
Existing demand	Market size is driven by the number of health facilities (at all levels). Current estimates indicate that on average 50 percent to 90 percent of operating rooms in developing countries are not equipped with functional pulse oximeters.[11] Market sustainability will likely initially come from the anesthesia applications of pulse oximetry. There are an estimated 208,200 operating rooms in low- and middle-income countries. Conservative estimates suggest that at least 100,000 pulse oximeters will be needed to fill the current need. The global pulse oximetry market is substantially larger—estimated toward US$1 million unit market.	Market size is driven by the number of health facilities where mains power is not reliable. Current estimates indicate that on average 50 percent to 90 percent of operating rooms in developing countries are not equipped with functional pulse oximeters[11]; this device may fit this market opportunity in the future. Market sustainability will likely initially come from the anesthesia applications of pulse oximetry. There are an estimated 208,200 operating rooms in low- and middle-income countries. Conservative estimates suggest that at least 100,000 pulse oximeters will be needed to fill the current need. The global pulse oximetry market is substantially larger—estimated toward US$1 million unit market.	Market size is driven by the number of health clinics that meet specific criteria listed on www.lifebox.org. Current estimates indicate that on average 50 percent to 90 percent of operating rooms in developing countries are not equipped with functional pulse oximeters[11]; this device may fit this market opportunity in the future. Market sustainability will likely initially come from the anesthesia applications of pulse oximetry. There are an estimated 208,200 operating rooms in low- and middle-income countries. Conservative estimates suggest that at least 100,000 pulse oximeters will be needed to fill the current need. The global pulse oximetry market is substantially larger—estimated toward US$1 million unit market.
Attractiveness	Cost is high.	No reliance on external sources of power. Cost is high.	Cost of unit and replacement probes sets a new low-cost standard for pulse oximetry, while product quality and appropriateness for low-resource settings is high.
Price sensitivity	No data available.	No data available.	No data available.
Policy environment	Policy is improving dramatically due to recent WHO and affiliated activities such as Safe Surgery Saves Lives, the Global Oximetry project, as well as the recent publication of the WHO 2009 publication *Guidelines for Appropriate Oxygen Technology in Hospitals with Limited Resources*.	Policy is improving dramatically due to recent WHO and affiliated activities such as Safe Surgery Saves Lives, the Global Oximetry project, as well as the recent publication of the WHO 2009 publication *Guidelines for Appropriate Oxygen Technology in Hospitals with Limited Resources*.	Policy is improving dramatically due to recent WHO and affiliated activities such as Safe Surgery Saves Lives, the Global Oximetry project, as well as the recent publication of the WHO 2009 publication *Guidelines for Appropriate Oxygen Technology in Hospitals with Limited Resources*.
Donors/ stakeholders	None.	Freeplay partners with PET and receives funding from the Sir Halley Stewart Trust in the United Kingdom.[12] Awarded a Bill & Melinda Gates Foundation US$100,000 Phase I Grand Challenge grant to develop low-cost pulse oximetry probes for low-resource settings to complement the PET pulse oximeter.	Global Pulse Oximetry Project. Lifebox. Preeclampsia Integrated Estimate of Risk (PIERS). Smile Train. WHO.

Demand Information	TECHNOLOGY/SOLUTION		
	TuffSat®	Freeplay/PET	Lifebox
Pre- and post-sales support	Some training is required. Providers need to know how to operate the oximeter, its alarms and menus, and how to attach it to the patient. This includes the ability to distinguish artifactual readings. Providers must know how to maintain and clean the apparatus between patients and must understand how to maintain the charge in a rechargeable battery. The local arrangements for servicing or replacing a device and its probes are also critical for sustained oximetry use.	Some training is required. Providers need to know how to operate the oximeter, its alarms and menus, and how to attach it to the patient. This includes the ability to distinguish artifactual readings. Providers must know how to maintain and clean the apparatus between patients and must understand how to maintain the charge in a rechargeable battery. The local arrangements for servicing or replacing a device and its probes are also critical for sustained oximetry use.	Some training is required. Providers need to know how to operate the oximeter, its alarms and menus, and how to attach it to the patient. This includes the ability to distinguish artifactual readings. Providers must know how to maintain and clean the apparatus between patients and must understand how to maintain the charge in a rechargeable battery. The local arrangements for servicing or replacing a device and its probes are also critical for sustained oximetry use.
Need for demand creation	The East Meets West Foundation and The Global Pulse Oximetry Project's advocacy has increased demand, though further advocacy is warranted.	The East Meets West Foundation and The Global Pulse Oximetry Project's advocacy has increased demand, though further advocacy is warranted.	The East Meets West Foundation and The Global Pulse Oximetry Project's advocacy has increased demand, though further advocacy is warranted.

References

[1] Fearnley SJ. Pulse Oximetry *Update in Anesthesia*. 1995; 5:Article 2. Available at: http://www.nda.ox.ac.uk/wfsa/html/u05/u05_003.htm. Accessed February 1, 2012.

[2] Matai S, Peel D, Wandi F, et al. Implementing an oxygen programme in hospitals in Papua New Guinea. *Annals of Tropical Paediatrics*.2008;28: 71–78.

[3] Global Pulse Oximetry Project. *First International Consultation Meeting, WHO Headquarters, Geneva, Switzerland, 29th and 30th October 2008, Background Document*. Available at: http://www.who.int/patientsafety/events/08/1st_pulse_oximetry_meeting_background_doc.pdf. Accessed February 1, 2012.

[4] World Health Organization (WHO).The Clinical Use of Oxygen: Guidelines for Appropriate Oxygen Technology in Hospitals with Limited Resources. Geneva: WHO; 2009.

[5] Freeplay website. Available at: http://www.freeplayenergy.com/page-view.php?pagename=Home&language=. Accessed February 1, 2012.

[6] Pulse oximeter web page. Powerfree Education Technology website. Available at: http://pet.org.za/products.php?view=2. Accessed February 1, 2012.

[7] Human-powered health care. *The Economist.* December 2, 2004. Available at: http://www.economist.com/node/3422999. Accessed February 8, 2012.

[8] Bezuidenhout H, Woods D, Wyatt J, et al. Are you blue yet? Developing low cost, alternative powered pulse oximetry for ill babies and children. *Institution of Engineering and Technology Digest*. 2006;11370:83–87.

[9] Millman AL, Payne B, Qu Z, et al. Oxygen saturation as a predictor of adverse maternal outcomes in women with preeclampsia. *Journal of Obstetrics and Gynaecology Canada*. 2011;33(7):705–714 . Available at: http://www.jogc.com/abstracts/full/201107_Obstetrics_2.pdf. Accessed February 1, 2012.

[10] Haughton D, Sun A, Wong A. *Final Report: Pulse Oximeter Probe Adapter*. Duke University. December 22, 2011. [unpublished]

[11] World Health Organization. *Expression of Interest: Global Pulse Oximetry*. Geneva: WHO; 2008.

[12] About Us page. Power Free Education Technology website. Available at: http://www.pet.org.za/about.php?view=1. Accessed February 1, 2012.

Thermoregulation

Normal body temperature range is between 37.5°C and 36.5°C (skin/axillary). According to World Health Organization (WHO) guidelines, neonatal hypothermia occurs when a newborn's body temperature drops below 36.5°C. This is usually caused by having the baby in a cold, drafty environment, especially with inadequate covering. It also occurs at birth even in warm climates if the baby is not immediately dried and wrapped (including the head that presents a large surface area). Loss of body heat occurs due to convection, conduction, and evaporation. Preterm and low-birth-weight babies have a relatively larger surface area for the weight and smaller amounts of fat including brown fat that helps to generate heat and hence have greater risks of hypothermia.

Mild hypothermia is also called cold stress and occurs when the infant's body temperature is between 36.5°C and 36°C. If body temperature starts dropping, steps must be taken to rewarm the infant. Moderate hypothermia occurs between 35.9°C and 32°C and can lead rapidly to severe hypothermia if the infant is not warmed immediately. A body temperature of less than 32°C is severe hypothermia; at this temperature the infant is in danger and skilled care must be provided.[1]

High-risk practices that sometimes occur in health facilities include inadequate warmth in delivery rooms, improper or delayed drying and wrapping of the newborn, bathing immediately after birth, reduced and delayed contact with the mother, and delayed initiation of breastfeeding.[2] Routine practices and care of the newborn should include providing a warm delivery room, drying the infant immediately after birth and wrapping the newborn in a warm soft blanket, covering the head with a knit hat, and making sure that the surfaces with which the infant will be in contact are warm and away from drafts. Keeping the baby in skin-to-skin contact on the mother's chest and covering the body and head with a suitable cloth/blanket is a very effective way to keep the baby warm soon after birth and during transport for referral. It is also useful for rewarming a baby who has become hypothermic. Skin-to-skin contact for warming and promotion of breastfeeding is one of the important components of essential newborn care.[3]

Wraps of various kinds and heated mattresses/pads are also used as barriers to heat loss. Evidence suggests that these barriers and wraps are effective in infants born at 28 weeks or less but showed no effect on infants from 28 to 31 weeks gestation.[4] In 2006, the International Liaison Committee on Resuscitation revised its recommendations on care of the newborn to include "proven value of occlusive wrapping of very-low–birth-weight infants <28 weeks gestation to reduce heat loss."[5] One recent study, however, pointed out that a problem can occur with

temperature maintenance in wrapped infants if the newborn urinates into a plastic wrap.[6] Overall, however, the level of evidence to support the use of skin-to-skin contact and plastic wraps to improve survival of preterm newborns is strong.[7]

The first-line intervention for thermoregulation of neonates is skin-to-skin care; in cases where skin-to-skin care is not available or the baby is extremely sick or undergoing specific procedures, thermoregulation devices play a role by complementing the use of skin-to-skin care. If the newborn's temperature falls to less than 36°C, or if the newborn is sick or low birth weight, warming and rewarming the baby is especially important. Devices commonly used to provide warmth include commercially available radiant overhead heaters, incubators, and heated mattresses/beds. Radiant heaters allow easier access to the babies for providing care. In some centers, low-cost warming tables that use bulbs to provide light and warmth have been locally manufactured for use in delivery rooms. They are particularly useful for providing care such as resuscitation of babies who are not breathing properly at birth. The use of infant warmers and incubators are meant to prevent excessive heat loss in at-risk newborns or to rewarm and stabilize the temperature in a newborn that has experienced rapid heat loss. A recent Cochrane review compared the use of infant warmers to incubators and found that radiant warmers increase water loss in low-birth-weight babies in the newborn period. This water loss needs to be taken into account when daily fluid requirements are calculated; however, there was not enough information available to assess other important effects of radiant warmers[8] or to guide clinical practice.

If well maintained, functioning, and used properly, incubators can help stabilize and warm newborn infants, particularly low-birth-weight infants and at-risk newborns. Most country programs cannot afford incubators and find them difficult to maintain. Incubators cost thousands of dollars and are available primarily in urban hospitals. Often when incubators are available, they are in disrepair. There is also an increased risk of infection if cleaning/disinfection is not carried out appropriately and regularly. A recent report on a novel recycled incubator technique suggests that appropriately recycled incubators are good substitutes to the less affordable modern incubators in Nigeria.[9]

All babies being provided additional warmth by the above-mentioned devices need to be carefully monitored to ensure that the temperature maintenance is appropriate and that the baby does not become overheated. Both radiant heaters and incubators can have an additional servo-control option; a probe with a sensor is attached to the skin of the baby allowing continuous monitoring of the skin temperature that feeds into the system to regulate the heat supply. However, care has to be taken to ensure that the sensor is properly fixed on the baby's skin since partially detached probes can result in the overheating of the baby.

This document and the following two tables focus primarily on infant warmers for use at the facility level as options that complement skin-to-skin care. Thermal management of sick newborns suffering from neonatal encephalopathy following hypoxia, and devices with the potential to provide therapeutic hypothermia are not included.

Supply Information	TECHNOLOGY/SOLUTION—TABLE 1		
	Facility Use		
	Lullaby™ Baby Warmer	**Babytherm®**	**Indian-made radiant infant warmers**
Description	The Lullaby™ Baby Warmer is an open-care infant warming system that has the following features: • The micro-processor creates a consistently warm bed for baby with built-in monitors and alarms that notify caregivers of critical temperature events. • Automatic and manual control modes. • Skin-temperature probe. • Large light-emitting diode (LED) screen. • Visually coded control panel and color-coded safety alarms are simple to understand, no matter what the user's language. • Extra procedure light. • Bed-tilt mechanism. • X-ray tray below the mattress allows for imaging without moving infant.[10]	The Babytherm® is an open-care infant warming system that has the following features: • ThermoMonitoring™ central and peripheral temperature monitoring. • Automatic and manual control modes. • Skin-temperature probe. • Display has button descriptions and text in 11 languages. • Extra procedure light. • Bed-tilt mechanism.[11] It comes in three models—an infant warming system providing radiant heat (BabyTherm® 8004), an infant warming system providing radiant and conductive heat (BabyTherm® 8010), and a warming bed providing conductive heat (BabyTherm® 8000).	Radiant warmers are open-care infant warming systems. There are numerous higher-quality, relatively low-cost models made in India. Several designs range from a basic model to designs with several features such as: • LED screen. • Bed-tilt mechanism. • Skin-temperature probe. • Extra procedure light. • Automatic and manual control modes. • Alarms.[12]
Characteristics applicable for low- resource settings	Requires a power supply. Intended for urban and semi-urban settings in developing countries for.	Requires a power supply Not focused on developing countries.	Requires a power supply. Made in India.
Developer and/or manufacturer	General Electric (GE). Part of the East Meets West Foundation's Breath of Life (BOL) Program.[13]	Dräger (also spelled Draeger).	Multiple; examples include: Shreeyash Electro Medical (Pune); Zeal Medical (Mumbai); Meditrin (Mumbai); Phoenix (Chennai); Bird Meditech (Mumbai); Medicaid (Delhi); Mediserve (Delhi); Mech Tech Lab (Pune); and Lectromedik Pvt. Ltd. (Bangalore).
Status	Commercialized. Initial market is India. Will meet the applicable international quality standards of the International Electro-technical Commission.[14] This device will not be for sale in the United States. Not seeking United States Food and Drug Administration approval.	Commercialized. The Babytherm® 8000 is not available in the United States, while the other two (8004 and 8010) are available in the United States.	Commercialized.

Supply Information	TECHNOLOGY/SOLUTION—TABLE 1		
	Facility Use		
	Lullaby™ Baby Warmer	Babytherm®	Indian-made radiant infant warmers
Efficacy/ effectiveness	Meets industry standard including IEC 60601 (a series of technical standards for the safety and effectiveness of medical electrical equipment, published by the International Electrotechnical Commission. In a study of three radiant infant warmers (Dräger Babytherm® 8010, GE Healthcare Panda® iRes; Fisher&Paykel IW930) using preselected power outputs, exposure temperature varied significantly among devices at 0, 10, and 20 minutes. Room temperature did not significantly influence temperature under infant warmer.[15]	Meets industry standard including IEC 60601 (a series of technical standards for the safety and effectiveness of medical electrical equipment, published by the International Electrotechnical Commission). In a study of three radiant infant warmers (Dräger Babytherm® 8010, GE Healthcare Panda® iRes, Fisher&Paykel IW930) using preselected power outputs, exposure temperature varied significantly among devices at 0, 10, and 20 minutes. Room temperature did not significantly influence temperature under infant warmer.[15]	Meets industry standard including IEC 60601 (a series of technical standards for the safety and effectiveness of medical electrical equipment, published by the International Electrotechnical Commission).
Manufacturing quality and capacity	Designed and manufactured in Bangalore.[16]	Manufactured in Telford, PA.	Manufactured in India.
Intellectual property (IP) ownership	Proprietary.	Patented smartSWIVEL® mechanism that automatically focuses radiant warmth on the baby, even if the radiant heater is moved to one side.	Likely no patents as there are many similar designs on the market.
Cost and cost drivers	US$2,700. Claims to be priced 70 percent lower than imported baby warmers of the same class.	Information is not available; likely between US$10,000 to US$20,000.	US$300 to US$1,400.
Delivery/ procurement channels	Target markets would be public and private hospitals with insufficient thermal care options. Likely purchasers are ministries of health (MOH) or donors, not end-users (mother/child) or frontline health care workers. The East Meets West Foundation will distribute GE's Lullaby™ warmers in India, the Philippines, and Indonesia through the BOL program.[17]	Target markets would be public and private hospitals with insufficient thermal care options. Likely purchasers are MOH or donors, not end-users (mother/child) or frontline health care workers.	Target markets would be public and private hospitals with insufficient thermal care options. Likely purchasers are MOH or donors, not end-users (mother/child) or frontline health care workers.
Sustainable business models	Multinational corporation with multiple product lines. The challenge is to create a sustainable business model while serving low-resource settings.	Multinational corporation with multiple product lines. The challenge is to create a sustainable business model while serving low-resource settings.	Multiple manufactures in the Indian market makes competition high.

Demand Information	TECHNOLOGY/SOLUTION—TABLE 1		
	Facility Use		
	Lullaby™ Baby Warmer	Babytherm	Indian-made radiant infant warmers
Existing demand	Rough estimates of the market size for the facility market in low-resource settings (specifically Africa), with an estimated three nurses/midwives per device, equals 70,000 devices.	Rough estimates of the market size for the facility market in low-resource settings (specifically Africa), with an estimated three nurses/midwives per device equals, 70,000 devices.	Rough estimates of the market size for the facility market in low-resource settings (specifically Africa), with an estimated three nurses/midwives per device, equals 70,000 devices.
Attractiveness	Expensive. Probe on baby helps prevent overheating.	Expensive. Not designed keeping low-resource settings in mind.	Indian products are less expensive than imported models and still good quality, but temperature control may not be as accurate.
Price sensitivity	The value proposition for purchasing decision-making needs to be developed as it would require a quantitative understanding of the total health system costs and benefits.	The value proposition for purchasing decision-making needs to be developed as it would require a quantitative understanding of the total health system costs and benefits.	The value proposition for purchasing decision-making needs to be developed as it would require a quantitative understanding of the total health system costs and benefits.
Policy environment	First-line intervention is skin-to-skin care.[18,19] Infant warmers are used to complement skin-to-skin care.	First-line intervention is skin-to-skin care.[18,19] Infant warmers are used to complement skin-to-skin care.	First-line intervention is skin-to-skin care.[18,19] Infant warmers are used to complement skin-to-skin care.
Donors/ stakeholders	East Meets West Foundation.	None.	None.
Pre- and post-sales support	Maintenance and repairs and availability of spare parts are important considerations. Possible insensible water loss may occur and should be monitored.	Maintenance and repairs and availability of spare parts are important considerations. Possible insensible water loss may occur and should be monitored.	Maintenance and repairs and availability of spare parts are important considerations. Possible insensible water loss may occur and should be monitored.
Need for demand creation	Need to clarify guidelines for complementary use of infant warmer with skin-to-skin care; need to raise awareness about various products and relative quality and performance with purchasing agents at the national level.	Need to clarify guidelines for complementary use of infant warmer with skin-to-skin care; need to raise awareness about various products and relative quality and performance with purchasing agents at the national level.	Wide availability in the Indian market. Price still not affordable for lower-level and remote facilities. Need to clarify guidelines for complementary use of infant warmer with skin-to-skin care; need to raise awareness about various products and relative quality and performance with purchasing agents at national level.

Supply Information	TECHNOLOGY/SOLUTION—TABLE 2		
	Facility Use		Transport Use
	KSE Infant Warmer	Extremely affordable solar infant warmer	Embrace Infant Warmer
Description	The KSE Infant Warmer is an open-care infant warming system that has the following features: automatic and manual control modes, adjustable height and adjustable manual power warmer, extra procedure light, and remote thermo-resistive temperature sensor for monitoring of patient body temperature.	The solar infant warmer harnesses solar power using rugged, light-weight, high-efficiency solar modules and an inexpensive, nontoxic phase-change material to store and maintain heat as well as low-cost temperature-monitoring technology. The design uses a photovoltaic module to generate electricity that melts thin panels of the phase-change material in a custom electric heating chamber.	Embrace is a transport warmer with phase-change material that heats up to 37°C within 10 to 15 minutes to maintain warmth for up to 4 hours without the need to reheat the pouch. A bag opens to allow for feeding, and can fully open to double as a hot bed. It has three components: a sleeping bag, a sealed pouch of wax, and a heater. The warmer swaddles the baby, and a heated pouch of wax is placed in an adjacent compartment in the sleeping bag. The pouch can be heated via an electrical heater or with hot water. It is waterproof, reusable, and washable; it can be boiled.[20]
Characteristics applicable for low- resource settings	Requires a power supply. Made in Vietnam.	No power supply needed. Designed to keep low-resource settings in mind.	No power supply needed. The heating bag can be warmed with hot water.
Developer and/or manufacturer	KSE Medical is the manufacturer. Also called MMTS (Medical Techology Transfer Service) Warmer.[21] Part of the East Meets West's BOL program.	High Flex Solar, Inc. Partnering with PATH.	Embrace Innovations (a C Corporation/social enterprise), is responsible for manufacturing, distribution, and sales. Embrace Innovations will also conduct research and development to create new low-cost maternal and child health innovations for the developing world. The Embrace 501(c)(3) will focus on product dissemination, education, and advocacy.[22]
Status	Commercialized.	In concept phase. Plan to develop and test a prototype with user groups based in department of health facilities such as the Ethekwini District Hospital in KwaZulu Natal Province in South Africa.	In development. Initial market is India.

Supply Information	TECHNOLOGY/SOLUTION—TABLE 2		
	Facility Use		Transport Use
	KSE Infant Warmer	Extremely affordable solar infant warmer	Embrace Infant Warmer
Efficacy/ effectiveness	No data available.	Product concept; no data available.	A thermal-coupled mannequin simulating a low birth-weight infant was used to model the thermal regulation of the Embrace Infant Warmer. At Lund University in Sweden, results were compared to the performance of a WHO-recommended heated water mattress (~US$6,000). Data show that the Embrace Infant Warmer reduces heat loss as well as a heated water mattress does. Animal testing on the Embrace Infant Warmer was conducted at the University of Utah. Results showed that warmer was able to maintain temperature effectively in preterm lamb. A pilot study on 20 low-birth-weight neonates was conducted to test efficacy of the Embrace Infant Warmer as a complement to skin-to-skin care in providing external thermal support to low-birth-weight neonates at risk of environmental hypothermia. The study was conducted by Dr. R. Kishore Kumar and the team at Cradle Hospital, Bangalore. This pilot study has suggested the following: • No incidence of an adverse event or a serious adverse event has been reported in any of the participants. • Positive warming was witnessed in the Embrace while the standard of care exhibited negative warming. A follow-up multicenter study has been started across four major hospitals in Bangalore with a larger sample size and stratified randomization across weight ranges to obtain statistically significant results and to minimize the effect of site-specific biases. Embrace also planned to conduct a study at Stanford University in early 2011; results unknown.
Manufacturing quality and capacity	Developed and tested at the National Hospital of Pediatrics in Hanoi, Vietnam.	HighFlex Solar, Inc., of San Jose is the provider of the photovoltaic modules and power controllers that optimize the power generated from the solar panel.	Embrace Innovations (a C Corporation/social enterprise), is responsible for manufacturing, distribution, and sales. Manufactured in China and India; no information available on manufacturing quality certifications or capacity.
Intellectual property (IP) ownership	Information not available.	Under negotiation; Highflex Solar could retain some IP ownership.	The Embrace 501(c)(3) has the full patent on this product in the United States, India, and 20 other countries. The US patent has been issued with most claims approved.
Cost and cost drivers	US$1,630.	Target price is about US$200 at a production volume of 10,000 units.	US$200.

Supply Information	TECHNOLOGY/SOLUTION—TABLE 2		
	Facility Use		Transport Use
	KSE Infant Warmer	Extremely affordable solar infant warmer	Embrace Infant Warmer
Delivery/ procurement channels	Target markets would be public and private hospitals with insufficient thermal care options. Likely purchasers are MOH or donors, not end-users (mother/child) or frontline health care workers. Partnership with East Meets West BOL program.	Target markets would be public and private hospitals with insufficient thermal care options. Likely purchasers are MOH or donors, not end-users (mother/child) or frontline health care workers.	The primary market segment is private institutions: small institutions in rural and semi-urban areas where babies are born, but no equipment is available to care for them. Clinics can use the device both for transportation (particularly in cases where referral hospitals are far away) and for continuous usage within the clinic. The target market will also include private clinics that are over capacity; often times low-birth-weight babies are discharged early (before they reach 2.5 kg) because of overcrowded facilities. Likely purchasers are MOH or donors, not end-users (mother/child) or frontline health care workers. Linked with the GE Healthcare commitment of at least 10,000 units in the first year. They will be global nonexclusive distributors of the product including partnering with the rural arm of Novartis, Novartis Arogya Parivar, which reaches the target segment of clinicians and a third-party pharmaceutical distributor called Pharmexx (India) to distribute product on a trial basis.[23]
Sustainable business models	Small organization based in Vietnam.	HighFlex Solar, Inc., of San Jose, California is a small technology company. Another manufacturer would need to be identified to create the entire device (with HighFlex as a provider of the solar component), so sustainability would need to be built over time.	Embrace is a 501(c)(3) nonprofit entity for product dissemination, education, and advocacy. Embrace Innovations is a for-profit social enterprise corporation for manufacturing, distribution, and sales. Embrace needs to raise US$1.5 million over the next four years to take the product worldwide.

Demand Information	TECHNOLOGY/SOLUTION—TABLE 2		
	Facility Use		Transport Use
	KSE Infant Warmer	Extremely affordable solar infant warmer	Embrace Infant Warmer
Existing demand	Rough estimates of the market size for the facility market in low-resource settings (specifically Africa) with an estimated three nurses/midwives per device equals 70,000 devices.	Rough estimates of the market size for the facility market in low-resource settings (specifically Africa) with an estimated three nurses/midwives per device equals 70,000 devices.	Rough estimates of the market size for transport-related devices in low-resource settings (specifically Africa) with one device per rural nurse/midwife puts the number of necessary devices at approximately a half million. Embrace is focusing on meeting demand in India only at this time.
Attractiveness	Relatively expensive. Locally manufactured by MTTS; instructions, controls, and manuals in local language. Replacement parts easily obtained; durable and low maintenance; accessible technical support and maintenance; not reliant on expensive consumables. Tested in conditions of actual use and appropriately adapted. Scalable for each country, hospital, and clinic conditions.	Potential to be low cost. No need for power.	US$200 price is likely too high, especially if it is meant only for transport. No need for power; portable. Safe and intuitive to use; easy to clean. Allows close mother/caregiver-to-child interaction.
Price sensitivity	The value proposition for purchasing decision-making needs to be developed as it would require a quantitative understanding of the total health system costs and benefits.	The value proposition for purchasing decision-making needs to be developed as it would require a quantitative understanding of the total health system costs and benefits.	The value proposition must be articulated as compared to kangaroo mother care (KMC), a free method, which is found to be an effective mode of transport.[18,24] However, the opportunity for the Embrace Infant Warmer may be where KMC is less appropriate/feasible, such as when very sick infants are in need of critical care during transport.
Policy environment	First-line intervention is skin-to-skin care.[18,19] Infant warmers are used to complement skin-to-skin care.	First-line intervention is skin-to-skin care.[18,19] Infant warmers are used to complement skin-to-skin care.	First-line intervention is skin-to-skin care.[18,19] Infant warmers are used to complement skin-to-skin care.
Donors/ stakeholders	East Meets West Foundation.	PATH. Finalist in the Saving Lives at Birth Challenge, 2011.[25]	Partner with GE Healthymagination. Winner of many awards such as the 2011 INDEX Award.
Pre- and post-sales support	Maintenance and repairs and availability of spare parts are important considerations. Possible insensible water loss may occur and should be monitored.	Maintenance and repairs and availability of spare parts are important considerations. Possible insensible water loss may occur and should be monitored.	Cleaning the device between uses is an important consideration. If used for transport, it is unclear how the Embrace warmers are collected by the provider to return to the health facility after being used to transport the baby.

Demand Information	TECHNOLOGY/SOLUTION—TABLE 2		
	Facility Use		Transport Use
	KSE Infant Warmer	Extremely affordable solar infant warmer	Embrace Infant Warmer
Need for demand creation	Guidelines for complementary use of infant warmer with skin-to-skin care need to be clarified. There is a need to raise awareness about various products and relative quality and performance with purchasing agents at the national level.	Guidelines for complementary use of infant warmer with skin-to-skin care need to be clarified. There is a need to raise awareness about various products and relative quality and performance with purchasing agents at the national level. Also, there is a need to generate evidence of product effectiveness in low-resource settings.	Guidelines for complementary use of infant warmer with skin-to-skin care need to be clarified. There is a need to raise awareness about various products and relative quality and performance with purchasing agents at the national level.

References

[1] World Health Organization. *Thermal Protection of the Newborn: A Practical Guide*. Geneva: WHO; 1997. Available at: http://www.who.int/maternal_child_adolescent/documents/ws42097th/en/.

[2] Kumar V, Shearer JC, Kumar A, Darmstadt GL. Neonatal hypothermia in low resource settings: a review. *Journal of Perinatology*. 2009;29(6):401–412.

[3] Saving Newborn Lives. *Care of the Newborn Training Guide*. Washington, DC: Save the Children; 2004. Available at: http://resourcecentre.savethechildren.se/node/1946.

[4] McCall EM, Alderdice F, Halliday HL, Jenkins JG, Vohra S. Interventions to prevent hypothermia at birth in preterm and/or low birthweight infants. *Cochrane Database System Review*. 2008;(1):CD004210.

[5] The International Liaison Committee on Resuscitation. The International Liaison Committee on Resuscitation (ILCOR) consensus on science with treatment recommendations for pediatric and neonatal patients: pediatric basic and advanced life support. *Pediatrics*. 2006;117:e955–e977. Available at: http://pediatrics.aappublications.org/cgi/content/full/117/5/e955.

[6] Lee Hc, Ho QT, Rhine WD. A quality improvement project to improve admission temperatures in very low birth weight infants. *Journal of Perinatology*. 2008;28(11):754–758.

[7] Barros FC, Bhutta ZA, Batra M, et al. Global report on preterm birth and stillbirth (3 of 7): evidence for effectiveness of interventions. *BioMed Central Pregnancy and Childbirth.* 2010;10(S1):S3.

[8] Flenady V, Woodgate PG. Radiant warmers versus incubators for regulating body temperature in newborn infants. *Cochrane Database of Systematic Reviews.* 2003;4:CD000435.

[9] Amadi HO, Azubuike JC, Etawo US. The impact of recycled neonatal incubators in Nigeria: a 6-year follow-up study. *International Journal of Pediatrics*. 2010;2010:269293.

[10] Lullaby Warmer brochure. GE Healthcare website. Available at: http://www.gehealthcare.com/euen/maternal-infant-care/docs/Lullaby_Warmer_bro_e.pdf. Accessed February 2, 2012.

[11] Babytherm 8004/8010 page. Dräger Medical website. Available at: http://www.draeger.us/Pages/Hospital/Babytherm-8004-8010.aspx. Accessed February 2, 2012.

[12] Radiant warmers page. Website of the WHO Collaborating Centre for Training and Research in Newborn Care at the All India Institute of Medical Sciences. Available at: http://www.newbornwhocc.org/pdf/radi.pdf. Accessed February 2, 2012.

[13] Breath of Life page. East Meets West website. Available at: http://www.eastmeetswest.org/page.aspx?pid=344. Accessed February 2, 2012.

[14] Lullaby Warmer factsheet. GE corporate website. Available at: http://files.gecompany.com/healthymagination/products/lullaby_warmer_factsheet.pdf. Accessed February 2, 2012.

[15] Trevisanuto D, Coretti I, Doglioni N, Udilano A, Cavallin F, Zanardo V. Effective temperature under radiant infant warmer: does the device make a difference? *Resuscitation.* 2011;82(6):720–723.

[16] GE sings a new Lullaby for every newborn [press release]. Chennai, India: GE Healthcare; May 29, 2009. Available at: http://www.genewscenter.com/content/detailEmail.aspx?ReleaseID=7497&NewsAreaID=2&changeCurrentLocale=5. Accessed February 2, 2012.

[17] General Electric Company news page. 4-Traders website. Available at: http://www.4-traders.com/GENERAL-ELECTRIC-COMPANY-4823/news/GENERAL-ELECTRIC-COMPANY-GE-Healthcare-Partners-with-East-Meets-West-Foundation-To-Deliver-Neonatal--13896690/. Accessed February 2, 2012.

[18] World Health Organization. *Kangaroo Mother Care: A Practical Guide*. Geneva: WHO; 2003. Available at: www.who.int/making_pregnancy_safer/documents/9241590351/en/.

[19] World Health Organization. *Essential Newborn Care Course*. Geneva: WHO; 2010. Available at: www.who.int/making_pregnancy_safer/documents/newborncare_course/en/.

[20] Embrace product pages. Embrace website. Available at http://embraceglobal.org/main/product?section=howitworks. Accessed February 2, 2012.

[21] KSE infant warmer page. KSE Medical website. Available at: http://www.ksemedical.com/products.php?view=detail&cid=3&id=2. Accessed February 2, 2012.

[22] Introducing Embrace's New Organizational Structure [press release/newsletter]. San Francisco, CA: Embrace; January 2012. Available at: http://embraceglobal.org/main/about?section=newsletter. Accessed February 6, 2012.

[23] GE Healthcare and Embrace-team up to help address infant mortality [press release]. GE Healthcare website. Available at: http://newsroom.gehealthcare.com/articles/ge-healthcare-and-embrace-team-up-to-help-address-infant-mortality/. Accessed February 2, 2012.

[24] Sontheimer D, Fischer CB, Buch K. Kangaroo transport instead of incubator transport. *Pediatrics.* 2004;113;920–923.

[25] Extremely affordable solar-powered infant warmer to complement skin-to-skin care. Finalist at the Saving Lives at Birth Grand Challenge 2011. Available at: http://www.savinglivesatbirth.net/summaries/72. Accessed February 1, 2012.

Mechanical Ventilation

More than a million deaths of newborn infants are attributed to prematurity as the primary cause, with most dying from respiratory insufficiency.[1,2] Most of these deaths occur in low- and middle-income countries and other resource-limited settings. An estimated 21% of babies presenting with illness in the first 6 days have respiratory symptoms that may require respiratory support. This indicates a need for country-level programs to support increased use of ventilators. Advances in mechanical ventilation in the neonatal intensive care unit in higher-resource settings have greatly reduced mortality rates in prematurely born infants for whom these therapies are available.[3]

A mechanical ventilator is an automatic machine designed to assist the body in breathing, allowing gas exchange to occur within the lungs. Mechanical ventilators can be categorized into conventional (pressure and volume) and high-frequency ventilators.[4] Pressure ventilators can be set to a specific peak inspiration pressure, whereas volume ventilators are set to a tidal volume. High-frequency ventilation involves small tidal volume at a high number of inspirations or breaths per minute.

Mechanical ventilator equipment can be expensive to purchase, operate, and maintain, and these devices require highly trained personnel to operate safely and effectively. Donation of ventilation-type equipment to resource-limited health care institutions can be problematic due to the requirement for maintenance, repair, and resupply, as well as training for proper use of the devices.

The ability to provide life-saving respiratory support to newborn infants in resource-limited communities throughout the world would have an enormous impact on health. In addition, expanding the range of infants who can be managed successfully with less-costly methods of ventilatory support would represent a major contribution to health care in the United States and other developed countries.

The tables below include several commercially available ventilators (Table 1) as well as three ventilators in development (Table 2).

Supply Information	TECHNOLOGY/INTERVENTION—TABLE 1			
	Commercially Available			
	Pedivent E20	Babylog® VN500	Newport E100M	AVEA® Ventilator System
Description	Designed to accommodate a range of patients from small low-birth-weight (LBW) neonates to 15 kg pediatric patients. Three modes of operation including continuous positive airway pressure (CPAP), continuous mandatory ventilation (CMV), and synchronized intermittent mandatory ventilation (SIMV) help to resuscitate, ventilate, and ease weaning the baby with simplified operation maintaining a high standard of accuracy.	The VN500 is the most advanced version of neonatal ventilator that Dräger (also spelled Draeger) has developed. It is specifically designed for infants up to 10 kg. It is capable of pressure, volume, and (outside the United States), high-frequency ventilation, and has several triggering algorithms. Its user interface visualizes pulmonary function for ease of understanding. It includes an internal battery for portability.	The Newport E100M is designed to deliver reliability and versatility. It is ideal for most patient applications, eliminating the need for and expense of age-specific or application-limited equipment. The preventative maintenance program results in a lower cost of ownership over the life of the product.	A versatile critical-care ventilator for neonatal, pediatric, and adult patients featuring both invasive and noninvasive applications, including infant nasal SIMV. Integrated BiCore™ advanced pulmonary monitoring, heliox administration, and volumetric capnography give the user tools to improve patients' clinical outcomes. Contains a lightweight, internal, battery-powered compressor for portability.
Characteristics applicable for low-resource settings	Designed for LBW neonates. Requires rigorous training and maintenance which might make this product unattractive for low-resource settings.	High-end, high-quality product. Can be operated with battery power. Requires rigorous training and maintenance which might make this product unattractive for low-resource settings.	Can be operated with battery power. Requires rigorous training and maintenance which might make this product unattractive for low-resource settings.	High-end, high-quality product. Can be operated with battery power. Requires rigorous training and maintenance which might make this product unattractive for low-resource settings.
Developer and/or manufacturer	Breathline Equipment.	Dräger Medical.	Newport Medical Instruments.	CareFusion Corporation.
Status	Commercialized. Regulatory status is unknown.	Commercialized. Dräger released this VN500 model in Canada in October 2010. The US Food and Drug Administration medical device database does not list this model, indicating that the product has not yet obtained 510(k) clearance. The previous models—the Babylog® 8000 and 8000 plus—obtained 510(k) clearances as Class II devices.	Commercialized, with 510(k) clearance.	Commercialized, with 510(k) clearance.

Supply Information	TECHNOLOGY/INTERVENTION—TABLE 1			
	Commercially Available			
	Pedivent E20	**Babylog® VN500**	**Newport E100M**	**AVEA® Ventilator System**
Efficacy/ effectiveness	Data on the efficacy/effectiveness of specific ventilators are not available. In five trials on infants with respiratory distress (n= 359), one study showed higher neonatal mortality in the mechanical ventilation (MV) group [7/10 vs 1/10; RR 7.00 (1.04, 46.95)]. Overall the risk of any reported mortality was less frequent in the MV group with the upper 95% confidence limit on 1.00 [summary RR 0.86 (0.74, 1.00), RD -0.10 (-0.20, -0.01), NNT 10 (5, 100)]. In infants with a birth weight of 1 kg–2 kg, no significant difference in mortality was found [summary RR for two trials 0.86 (0.70, 1.07)]. In infants with a birth weight of more than 2 kg, one study reported a significant reduction in mortality in the MV group compared with the control [RR 0.67 (0.51, 0.86)]; overall for this birth weight group, there was a significant reduction in mortality with MV in the two trials [summary RR 0.67 (0.52, 0.87), RD -0.27 (-0.45, -0.10), NNT 4 (2, 10)].[5]			
Manufacturing quality and capacity	India-based company with ISO 9001 certification.	Manufactured by Dräger. Germany-based large company with international manufacturing.	Manufactured by Newport. Certified with ISO 13485.	Manufactured by CareFusion with global-level manufacturing.
Intellectual property ownership	Data not available.	Data not available.	Data not available.	Data not available.
Cost and cost drivers	Data not available. Neonatal mechanical ventilators typically cost between US$3,000 and US$10,000. Other costs include training, maintenance, repair, and disposables such as tubes.	$10,000. Other costs include training, maintenance, repair, and disposables such as tubes.	Data not available. Neonatal mechanical ventilators typically cost between US$3,000 and US$10,000. Other costs include training, maintenance, repair, and disposables such as tubes.	Data not available. Neonatal mechanical ventilators typically cost between US$3,000 and US$10,000. Other costs include training, maintenance, repair, and disposables such as tubes.
Delivery/ procurement channels	Can be procured through distributors. The manufacturer does not appear to have a distribution network outside India.	Can be procured through the manufacturer's sales force and local distributors. The manufacturer has a wide international distribution network.	Can be procured through the manufacturer's sales force and local distributors. The company has a decent international distribution network.	Can be procured through the manufacturer's sales force and local distributors. The manufacturer has a wide international distribution network.
Sustainable business models	Distribution by private vendors is possible.	Distribution by private vendors is possible.	Distribution by private vendors is possible.	Distribution by private vendors is possible.

Demand Information	TECHNOLOGY/INTERVENTION—TABLE 1			
	Commercially Available			
	Pedivent E20	Babylog® VN500	Newport E100M	AVEA® Ventilator System
Existing demand	The primary users will be tertiary hospitals. The market size will be driven by the number of tertiary hospitals.	The primary users will be tertiary hospitals. The market size will be driven by the number of tertiary hospitals. The size of the market for this device is likely to be limited in the public sector in developing countries due to its high price.	The primary users will be tertiary hospitals. The market size will be driven by the number of tertiary hospitals.	The primary users will be tertiary hospitals. The market size will be driven by the number of tertiary hospitals.
Attractiveness	Relatively simple to use. Designed for LBW babies.	High-end, high-quality ventilator. Dräger has extremely strong brand equity.	High-end, high-quality ventilator.	High-end, high-quality ventilator.
Price sensitivity	Users in low-resource setting are generally very price sensitive. However, users might be less price sensitive to high-end products especially since mechanical ventilators are generally used in tertiary hospitals.			
Policy environment	The World Health Organization (WHO) recommends that advanced resuscitation procedures for newborns who fail to respond to bag-and-mask resuscitation can be introduced in a health care institution if the following criteria are met: (a) trained staff with the necessary equipment and supplies are available, (b) at least two skilled persons are available to carry out the resuscitation, (c) there are sufficient deliveries for the skill to be maintained, and (d) the institution has the capacity to care for or to transfer newborns who suffer severe birth asphyxia since they are expected to have problems after being resuscitated.[6]			
Donors/ stakeholders	WHO.	WHO.	WHO.	WHO.
Pre- and post-sales support	Requires training and field support and ongoing maintenance.	Requires training and field support ongoing maintenance.	Requires training and field support ongoing maintenance.	Requires training and field support ongoing maintenance.
Need for demand creation	Need to engage governments to incorporate resuscitation into national prenatal programs. Need to create programs to offer maintenance and repair at low cost.	Need to engage governments to incorporate resuscitation into national prenatal programs. For this high-end device, demand in low-resource settings will be limited.	Need to engage governments to incorporate resuscitation into national prenatal programs. Need to create programs to offer maintenance and repair at low cost.	Need to engage governments to incorporate resuscitation into national prenatal programs. For this high-end device, demand in low-resource settings will be limited.

Supply Information	TECHNOLOGY/INTERVENTION—TABLE 2		
	Under Development		
	OneBreath	Portable, Low-Cost Ventilator[7]	Hansen Vent
Description	Includes fewer parts for cost reduction; airflow is measured and controlled with propriety software rather than hardware. Focus on emergency readiness and general use in developing countries. To ensure operability and portability during earthquakes, floods, tsunamis, and other disasters, the compact plastic housing is rugged, grime-resistant, stackable, and easy to carry. To cope with power outages, units come with a seven-hour rechargeable battery. Because expert technicians are few and far between during disasters, the units are simple enough for novices to operate and repair, and the cost of replacing a breathing tube is US$0.50, rather than the US$180 required with high-end ventilators.	Aims for simplicity, low cost, and ease of maintenance. Consisting of a case that encloses a manual pump, it has only three control knobs—one each to adjust volume, speed, and number of breaths. A battery powers the ventilator, which would be extremely useful in disaster situations. Can detect and prevent over-pressurizing of the lungs, a life-threatening complication that often occurs with manual ventilation.	Designed to transmit higher pressure and lower frequency vibrations than the conventional systems with the aim to ensure sufficient pressure in the lungs to avoid collapse. To prevent the pressure from going to zero, the exhalation tube is adjusted to different depths in the water and a variety of different angles through which the bubbles are blown out.
Characteristics applicable for low-resource settings	Lower cost. Simple to operate and repair. Compact housing for durability. Can be operated with battery power.	Low cost. Easy to use, maintain, and repair. Can be operated with battery power.	Higher pressure and lower frequency vibrations than the conventional systems, at low cost.
Developer and/or manufacturer	Stanford University/OneBreath (Matthew Callaghan).	Massachusetts Institute of Technology/ Boston University (Jussi Saukkonen).	Seattle Children's Research Institute.
Status	Under development.	Under development.	Under development.
Efficacy/ effectiveness	Data on the efficacy/effectiveness of specific ventilators, or these ventilators in development, are not available. In five trials on infants with respiratory distress (n= 359), one study showed higher neonatal mortality in the MV group [7/10 vs 1/10; RR 7.00 (1.04, 46.95)]. Overall the risk of any reported mortality was less frequent in the MV group with the upper 95% confidence limit on 1.00 [summary RR 0.86 (0.74, 1.00), RD -0.10 (-0.20, -0.01), NNT 10 (5, 100)]. In infants with a birth weight of 1 kg–2 kg, no significant difference in mortality was found [summary RR for two trials 0.86 (0.70, 1.07)]. In infants with a birth weight of more than 2 kg, one study reported a significant reduction in mortality in the MV group compared with the control [RR 0.67 (0.51, 0.86)]; overall for this birth weight group, there was a significant reduction in mortality with MV in the two trials [summary RR 0.67 (0.52, 0.87), RD -0.27 (-0.45, -0.10), NNT 4 (2, 10)].[5]		
Manufacturing quality and capacity	Not applicable since the product is still under development.	Not applicable since the product is still under development.	Not applicable since the product is still under development.
Intellectual property ownership	Data not available.	Data not available.	Data not available.

Supply Information	TECHNOLOGY/INTERVENTION—TABLE 2		
	Under Development		
	OneBreath	Portable, Low-Cost Ventilator[7]	Hansen Vent
Cost and cost drivers	Target price of US$800. Other costs include training, maintenance, repair, and disposables such as tubes. The equipment is designed to achieve ease of maintenance and repair.	Target price of US$100. Other costs include training, maintenance, repair, and disposables such as tubes. The equipment is designed to achieve ease of maintenance and repair.	Target price of US$100. Other costs include training, maintenance, repair, and disposables such as tubes.
Delivery/ procurement channels	Not applicable. The product is under development.	Not applicable. The product is under development.	Not applicable. The product is under development.
Sustainable business models	Require high sales volume to compensate for a potentially low profit margin. Bulk procurement by governments, international agencies, or nongovernmental organizations (NGOs) will be necessary initially. Might need to engage local partners to provide training and repair at low cost.	Require high sales volume to compensate for a potentially low profit margin. Bulk procurement by governments, international agencies, or NGOs will be necessary initially. Might need to engage local partners to provide training and repair at low cost.	Require high sales volume to compensate for a potentially low profit margin. Bulk procurement by governments, international agencies, or NGOs will be necessary initially. Might need to engage local partners to provide training and repair at low cost.

Demand Information	TECHNOLOGY/INTERVENTION—TABLE 2		
	Under Development		
	OneBreath	Portable, Low Cost Ventilator	Hansen Vent
Existing demand	The primary users will be tertiary hospitals.[8] The market size will be driven by the number of tertiary hospitals. Demand could be found in the ambulatory/emergency care market because of the size of the device.	The primary users will be tertiary hospitals.[8] The market size will be driven by the number of tertiary hospitals. Demand could be found in ambulatory/emergency care market because of the size of the device.	The primary users will be tertiary hospitals.[8] The market size will be driven by the number of tertiary hospitals. Demand could be found in ambulatory/emergency care market because of the size of the device.
Attractiveness	Lower target cost, easy to maintain and repair. Durable. Battery lasts seven hours.	Low target cost, easy to maintain and repair due to the device having fewer parts.	Low target cost. Higher pressure and lower frequency vibrations than the conventional systems.
Price sensitivity	Users in low-resource setting are generally very price sensitive. However, users might be less price sensitive to high-end products, especially since mechanical ventilators are generally used in tertiary hospitals.[8]		
Policy environment	WHO recommends that advanced resuscitation procedures for newborns who fail to respond to bag-and-mask resuscitation can be introduced in a health care institution if the following criteria are met: (a) trained staff with the necessary equipment and supplies are available, (b) at least two skilled persons are available to carry out the resuscitation, (c) there are sufficient deliveries for the skill to be maintained, and (d) the institution has the capacity to care for or to transfer newborns who suffer severe birth asphyxia since they are expected to have problems after being resuscitated.[6]		
Donors/ stakeholders	WHO.	WHO.	WHO.
Pre- and post-sales support	Requires training and field support and ongoing maintenance.	Requires training and field support and ongoing maintenance.	Requires training and field support and ongoing maintenance.
Need for demand creation	Need favorable data on product performance and effectiveness to generate demand.	Need favorable data on product performance and effectiveness to generate demand.	Need favorable data on product performance and effectiveness to generate demand.

References

[1] Singhal N, Bhutta ZA. Newborn resuscitation in resource-limited settings. *Seminars in Fetal and Neonatal Medicine.* 2008;13(6):432–439.

[2] Lemyre B, Davis PG, de Paoli AG. Nasal intermittent positive pressure ventilation (NIPPV) versus nasal continuous positive airway pressure (NCPAP) for apnea of prematurity. *Cochrane Database of Systematic Review.* 2002(1):CD002272.

[3] Vidyasagar D, Singhal N. Neonatal ventilator care in resource-limited countries. In: Goldsmith JP, Karotkin EH, eds. *Assisted Ventilation of the Neonate.* 5th edition. St. Louis, MO, USA: Saunders/Elsevier; 2011.

[4] Chatburn R. *Fundamentals of Mechanical Ventilation*. Cleveland Heights: Mandu Press; 2003.

[5] Henderson-Smart DJ, Wilkinson AR, Raynes-Greenow CH. Mechanical ventilation for newborn infants with respiratory failure due to pulmonary disease. *Cochrane Database of Systematic Reviews*. 2002;4:CD002770.

[6] World Health Organization. *Basic Newborn Resuscitation: A Practical Guide.* WHO; Geneva; 1998. Available at: http://whqlibdoc.who.int/hq/1998/WHO_RHT_MSM_98.1.pdf. Accessed February 1, 2012.

[7] Low-cost maternal and infant mechanical ventilators for developing countries. Jussi Saukkonen, Boston University School of Medicine, Primary Investigator. Phase 1 grantee in Grand Challenges Exploration Round 5, November 2010, on the topic "Create new technologies to improve the health of mothers and newborns." Available at the Bill & Melinda Gates Foundation Grand Challenges website: http://www.grandchallenges.org/explorations/Pages/grantsawarded.aspx?Round=all&Phase=all&ProjectID=503. Accessed February 1, 2012.

[8] NOTE: Preference for higher-end devices and bias against "lower-cost" devices sometimes surfaces at higher levels of care, even when there is data supporting the quality, efficacy, cost effectiveness, etc., of a lower-cost device. This can be a barrier for developers/manufacturers of lower-cost devices.