volume 18 no 1 pp 117–128 january 2013

Systematic Review

Innovative newborn health technology for resource-limited environments

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Abstract

objectives To review medical devices addressing newborn health in resource-poor settings, and to identify existing and potential barriers to their actual and efficient use in these settings.
methods We searched Pubmed as our principal electronic reference library and dedicated databases such as Maternova and the Maternal and Neonatal Directed Assessment of Technology. We also researched standard public search engines. Studies and grey literature reports describing devices for use in a low- or middle-income country context were eligible for inclusion.
results Few devices are currently described in the peer-reviewed medical or public health literature. The majority of newborn-specific devices were found in the grey literature. Most sources described infant warmers, neonatal resuscitators, and phototherapy devices. Other devices address the diagnosis of infectious diseases, monitoring of oxygen saturation, assisted ventilation, prevention of mother-to-child transmission of HIV, assisted childbirth, weight or temperature assessment, and others.
conclusion Many medical devices designed for newborns in the developing world are under development or in the early stages of production, but the vast majority of them are not available when and where they are needed. Making them available to mothers, newborns, and birth attendants in resource-limited countries at the time and place of birth will require innovative and creative production, distribution, and implementation approaches.

keywords newborn, technology, device, innovation, low- or middle income country, resource-limited

Introduction

The World Health Organization (WHO) summarizes medical devices as 'health technologies that are not medicines, vaccines, or clinical procedures but are used in diagnosis, prevention, or treatment' and estimates that there are over 1.5 million device types used in health care, mostly in the developed world. Over the past few decades, technological leaps in the development of medical devices have occurred, but these innovations have generally been limited to the industrialized world (WHO 2011). With the growing interest in global health, health technologies appropriate for resource-poor environments have received increasing attention. Appropriate technologies are defined succinctly by WHO as 'scientifically valid, adapted to local needs, acceptable to both patient and healthcare personnel, and that can be utilized and maintained with resources the community or country can afford.' (WHO 2010). Yet, due to lack of capacity and pertinent needs assessments, most appropriate technologies remain out of reach for the majority of people who need them (Sinha & Barry 2011). Many of the available technologies are not commercialized, and stakeholders are often unaware of these innovations (Piot 2012).

Newborns and their mothers are particularly vulnerable populations in developing countries. Globally, more than half of all deliveries take place at home, in an environment that most often lacks basic hygiene requirements (Zupan 2005). Health systems are often either absent or incapable of addressing essential maternal and neonatal requirements for survival. As a result, 99% of all newborn and maternal deaths globally occur in the developing world (Lawn *et al.* 2005). Worldwide, far more than 3 million newborns die each year (Black *et al.* 2010). Overall, neonatal mortality (newborn deaths among live births within the first 28 days of life) accounts for an estimated 41% of mortality in children under 5 years of age (Oestergaard *et al.* 2011). This percentage has been increasing over the past decade, indicating less progress in improving the health and survival of newborns than for children under 5 years of age. Achieving the fourth Millennium Development Goal (MDG) of reducing deaths in children under 5 years of age by two-thirds between 1990 and 2015 (United Nations 2012) will require a significant reduction of neonatal mortality. Innovation, defined as 'the process of putting an idea into practice among groups for whom this idea is new', (Bradley 2012) is part of what will drive the development of appropriate technologies towards the fourth MDG.

The global gap in newborn mortality might be in part attributable to the lack of access to innovative medical technology in most of the developing world. In contrast, an established high-tech medical device industry in industrialized countries uses effective marketing strategies to make medical technology available to the vast majority of newborns, albeit at immense financial cost.

It is frequently argued that technologies, or devices with a direct impact on newborn health outcomes, are often not needed or not enough to improve the health outcome of most newborns (Howitt *et al.* 2012; Lunze & Hamer 2012). However, while there is a focus of newborn health efforts on seemingly cheaper and easier approaches, such as behavior change for health promotion and disease prevention (e.g. hand washing of mother and birth attendant in cases where there is one, skin-to-skin care to promote breastfeeding and keep newborns warm), these are not implemented or practiced universally (Bhutta *et al.* 2005).

Substantial neonatal mortality might be addressed by the use of appropriate health technology for sick and at-risk babies. The most common causes of newborn deaths globally are complications related to prematurity (29%), birth asphyxia (23%), and severe infections (30%) (Lawn *et al.* 2005), challenges that in industrialized countries are routinely addressed with the intensive use of dedicated health technology. Even in resource-limited countries, the majority of these conditions could potentially be impacted by appropriate health technology, with low-cost and effectively disseminated neonatal resuscitation devices such as suction, bag and mask systems, as well as infant warmers, phototherapy systems, and mechanical ventilation assist systems. Other devices can be used to address severe infections.

Out of a growing recognition that the majority of newborns die from preventable causes and that an equitable approach demands a chance of survival for all newborns, devices appropriate for resource-limited environments have received increasing attention. To combat neonatal mortality, new investments in research and development have given rise to a robust pipeline of new technologies in this arena. However, the ratio of this promising pipeline to devices actually marketed and widely distributed is woefully small (Howitt *et al.* 2012).

It is possible that many program planners and decision makers are not aware of existing solutions for resource-poor environments. The aim of our study was to provide a compilation of existing, publicly described medical devices to diagnose, treat and prevent medical problems in newborns for potential use in resource-limited settings. The goal of the resultant compilation is to inform practitioners of various potential solutions which are in different stages of development. Using selected cases, we also aimed to identify relevant barriers to their actual and efficient use in the developing world.

Methods

To identify appropriate newborn technology to be included in our compilation, we conducted a Pubmed search, starting in January 2011, with a final revision in September 2012, using the following key words: 'neonatal medical devices in resource-poor environments', 'neonatal medical devices in resource poor settings' and 'medical devices in resource poor settings and newborn care', subsequently replacing the term 'resource-poor environments' with the following equivalents: Low income countries, poor countries, third world, third world countries, developing countries. We also used the following search term combinations: medical devices AND low income, medical devices AND third world countries, medical devices AND poor countries, neonatal devices AND poor countries, neonatal devices AND third world countries, neonatal devices AND developing countries, medical devices AND economics, medical devices AND low-income countries, medical devices AND 'underserved communities'. We verified the sensitivity of our search strategy with a variety of searches in Pubmed (for example, we used the 3 limits available for infants: All infants = birth-23 months; Newborns = birth-1 month; infant = 1–23 months) to ensure that search results did not differ when using related terms.

We complemented this by a search using Google and Google Scholar with the following key words: 'neonatal medical devices in resource-poor environments', 'neonatal medical devices in resource poor settings' & 'medical devices in resource poor settings and newborn care'.
To identify additional devices, we also searched databases such as the Maternova.net (Maternova 2012a,b) and the Maternal and Neonatal Directed Assessment of Technology database (Research Triangle Institute 2010), Appropedia (Appropedia 2012), Design for the Other 90% (Cooper-Hewitt 2011), Engineering for Change

(Engineering for Change 2012), and Health Unbound (Health Unbound 2012).

We limited results to findings applicable to low-income countries. Cookies were enabled during the search. We did not assess study or reference quality. Eligible for inclusion in the compilation were all devices that were explicitly developed for resource-limited settings and described as being in development, piloted, in clinical trials or those that have been marketed. We excluded devices which were not specifically designed for use in resource-limited settings.

Results

We identified a range of medical devices described in the public domain (Table 1). We found only eight medical devices described in the peer-reviewed medical or public health literature, and the majority of the about 40 newborn-specific devices were described only in the grey literature or in a new set of online databases.

The majority of newborn-specific devices we found were infant warmers, neonatal resuscitators, and devices to diagnose and treat hyperbilirubinemia. Other devices found were designed to diagnose or treat infectious diseases (including the prevention of mother-to-child transmission of HIV), pulse oximeters to monitor oxygen saturation, as well as devices to assist ventilation (including Continuous Positive Airway Pressure [CPAP] devices), assist childbirth, measure newborn weight or temperature, and other devices.

Overall, the majority of the devices were developed in the United States and in Europe. Only a small minority were developed in Asia, and only two were developed in Sub-Saharan Africa.

Discussion

In low-resource settings, medical devices are generally unavailable, underutilized or misused (WHO 2011). In order to provide a compilation of innovative newborn health technologies that are publicly accessible, we conducted a systematic search to identify appropriate devices. Few devices were described in peer-reviewed journal articles, which would make them easily available on academic standard resources such as PubMed. Databases and existing platforms (Maternova 2012a,b) provide useful information about current progress to improve maternal and child health in the developing world, although at this point in time they lack peer review and scrutiny from practitioners. While we aimed to be inclusive in our review, given the lack of evidence-based criteria for appropriateness of technologies, it is often unclear which device has a realistic potential to find its application in resource-poor environments. Of the various devices we identified, the vast majority are still in development.

There are some notable exceptions. The *East meets West Foundation's Breath of Life* program (BOL) has developed a successful model to produce, market and integrate newborn medical devices into health care systems in Asia. BOL collaborates with Medical Technology Transfer and Services (MTTS), a private company that produces and distributes technologies to hospitals in Vietnam, Laos, Cambodia, East Timor, Philippines, Myanmar, India, Bangladesh and Thailand (East Meets West Foundation 2012). The company adapts technologies from developed countries to suit the needs of resource-limited nations. In each of these countries, MTTS collaborates with local health authorities and involves them in integrating health innovations into their health care systems. Such integration might include training health care professionals on how to use and maintain technologies. For example, after introducing the BOL CPAP in the National Hospital of Pediatrics in Vietnam in 2003, MTTS showed a 20% decrease in newborn mortality within the first 24 h (East Meets West Foundation 2012). Currently, 95% of hospitals in Vietnam are equipped with CPAP devices distributed by the BOL program.

In current practice, most health technologies in the developing world are still donated, often ignoring local needs and rarely being used beyond the initial year (Sinha & Barry 2011). Medical devices appropriate for low and middle income countries need to be adapted to local needs (WHO 2010). Developing countries rarely have the capacity for servicing, procuring spare parts low cost, yet devices need to be sophisticated enough to effectively, efficiently, safely, and reliably fulfill their purposes. Since medical care is often provided in harsh, rugged terrain in low income settings, devices need to be robust enough, function where electricity, water and other basic conditions are not (constantly) met, be affordable and easily accessible without depending on sophisticated expertise to operate, maintain, and service, or on replacement parts which are logistically difficult to obtain. Partly as a result of these challenges, appropriate technologies remain out of reach for the majority of people who need them.

While many devices have been created by innovators in the private sector and in academia, the vast majority of these technologies never leave the stages of development or prototype production. Many academic initiatives lack sustainability, as many projects developed by students are not followed through when the students graduate. Smaller startup companies and ventures from universities

Table 1 Medical devices for newborns in the developing world

Name of device/ company	Brief description as provided by manufacturer	Developmental stage	Projected retail price	References
Temperature measurement devices				
ThermoSpot	Liquid crystal adhesive thermoindicator which Indicates temperature using colorimetric changes to alert non-literate caregivers to onset of hypothermia	Marketed in the United Kingdom by Teaching AIDS At Low Cost (TALC) and in the United States by Maternova	25 disks for $10 USD	Kambarami *et al.* (2002)
Infant warmers				
Embrace infant warmer	Designed like a sleeping bag, with a heat source (phase change material) that maintains the device at a constant temperature of 37°C for 4–6 h, reheated either electrically (marketed) or in hot water (in development)	Marketed in India to health facilities	$25-$200 USD	Sinha and Barry (2011), Embrace (2012)
Blantyre hot cot	Crib uses four light bulbs to warm the air around the infant. Electricity dependent. An automatic thermostat is designed to switch off the bulbs in the crib when ambient air reaches a pre-defined temperature threshold	Available in Malawi; handbuilt	$50	Connexions and Lipper (2009)
Breath of Life (BOL) infant warmer and resuscitator	Infant warmer that maintains the infant at a standard temperature of 37°C, also functions as an infant resuscitator. Part of a suite of devices	Marketed in Vietnam by East meets West Foundation and Medical Technology Transfer Services (MTTS)	Not available	Maternova; East Meets West Foundation (2012)
Liferaft Infant Incubator	Designed for developing countries, to withstand harsh conditions for long periods of time. It is power-dependent and includes a heater, is self sterilizing and fitted with a LED phototherapy system	Commercial production to commence following successful validation of lifecycle testing	Not available	Seattle Children's Hospital's (2010)
Neonurture	Neonatal incubator using easily replaceable car parts, providing a clean, thermoregulated environment. It is easily transportable and it is battery operated, allowing it to function when there is no power	In development, pretested in the United States and South Asia by CIMIT and Medicine Mondiale	Not available	Design that Matters (2011)
Hansen incubator	Not been fully developed, tested in rabbits and shown to provide sufficient respiratory support	In development. Collaboration between PATH and the Seattle Children's Hospital	Not available	Seattle Children's Hospital's (2010)
Styropor box	Styrofoam box used as a transport incubator, where the baby can receive warmth, nutrition, oxygen and circulatory support during transportation. Evaluated in India for infant care and transport	Tested in the Rural Neonatal Care Project, Dahanu, Pune, India	Minimal costs	Gosavi *et al.* (1998), Shende *et al.* (1998), Daga *et al.* (2000)
Warmilu's IncuBlanket	A wrapping warmer with aluminized polyester for insulation	Undergoing clinical testing in Bangalore, India	$60	WarmiLu (2012)
Mkat	Table-mounted, tent-like; the top part easily and quickly detaches for full access, and traditional arm holes allow for routine access. Ships flat	Prototyped, not commercialized	$200	Design that Matters (2011)
IncuVive	Uses recycled water from a reservoir under the baby-water is heated and sent through plastic tubes, keeping the infant at 37 degrees Celsius	Prototyped	$50	IncuVive (2012)

Table 1 (*continued*)

Name of device/ company	Brief description as provided by manufacturer	Developmental stage	Projected retail price	References
Pulse oximeters				
Lifebox GPOP pulse oximeter	The Lifebox pulse oximeter marketed primarily for intraoperative monitoring to make surgery safer in low income countries. Has a handheld design with light and sound alerts, can be fitted with neonatal probes	Marketed: manufactured by Acare Technology in Taiwan	$250	Lifebox (2012)
Powerfree Education & Technology Pulse Oximeter	Pulse oximeter developed by a non-profit organization in South Africa, will be manufactured by EMCO, a medical technology company in India	In development by Powerfree Education Technology,	Not available	Powerfree Education Technology (2012)
ChoiceMed Desktop Pulse Oximeter MD2000A	Light-weight device, battery operated with a battery time of up to 24 h. It can store information on up to 100 patients. It has audio and visual alarms. It can be used in adult, child and newborn patients. Data can be uploaded using a USB key	Originally developed by MTTS together with the East meets West BOL initiative and CHOICEMED	Not available	MTTS (2012)
Neonatal portable pulse oximeter	Portable neonatal pulse oximeter to fit a newborn's palm or foot	In development by Rice University. Piloted at Queen Elizabeth Hospital in Malawi and in Niger	Not available	Maternova; Lin *et al.* (2009)
Continuous Positive Airway Pressure (CPAP) systems or alternatives				
Infant AIR, Baby Bubble	Driven by two aquarium pumps; pressure regulator is a standard plastic water bottle with a plastic straw (amount of pressure is determined by water level in the bottle)	In development	Not available, projected to be under $150	Rice 360 Institute for Global Health (2012)
High-Amplitude Bubble CPAP	High-Amplitude Bubble Continuous Positive Airway Pressure device, to be used alone or together with ventilator	In development by the Seattle Children's Hospital, piloted in adolescent rabbits	Projected at less than 10% of conventional CPAP systems	Diblasi *et al.* (2010)
BOL CPAP by MTTS, the East Meets West Foundation	Mobile system with portable mini compressor. Its temperature can be controlled both automatically using a sensor or manually	Marketed	Not available	MTTS (2012)
Indigenous CPAP device	Indigenously prepared nasal bubble CPAP with set end expiratory pressure	Assembled at Sassoon General Hospital, Pune, India	$ 4.50	Kinikar *et al.* (2011)
Newborn resuscitation and suction device				
Neonatalie resuscitator by Laerdal	A low-cost bag-valve-mask unit made of silicone and polysulphonate, can be boiled or autoclaved, durable. Delivered with two mask sizes	Marketed	$15	Laerdal (2012)
Inspire Low-Cost Breathing Assistant	The device draws in ambient air and filters, humidifies, and compresses it for delivery to the patient at an adjustable flow rate	In development by Stanford University	Approximately $200	Maternova (2012a,b)

Table 1 (*continued*)

Name of device/ company	Brief description as provided by manufacturer	Developmental stage	Projected retail price	References
Bulb suction device device by Laerdal and others	Many types of bulb syringes are available. Laerdal makes a version that is transparent, penguin-shaped oral or nasal suction device, can be easily cleaned and reused, is durable and storable	Marketed	$3 USD	Laerdal (2012)
Weighing device				
BIRTHweigh III scale and others	Scale using color coded and tactile indicators to detect underweight infants and to distinguish between different weight ranges – many other devices exist, including sling and suspension scales	In development by PATH, pretested in Indonesia, Nepal and in India	Not available	PATH (2012a,b)
Mechanical ventilation devices				
Hansen ventilator	Has fewer parts compared to most ventilators, battery operated. Was tested in paralyzed young rabbits and shown to provide sufficient respiratory support	In development by the Seattle Children's Hospital in partnership with PATH	Not available	Diblasi *et al.* (2010); Seattle Children's Hospital's 2010
NeoPuff Infant T-piece resuscitator	A manually operated, gas-powered resuscitator designed to provide breaths at a set flow with consistent Peak Inspiratory Pressure (PIP) and Positive End Expiratory Pressure (PEEP) to infants	Marketed by Fisher & Paykel Healthcare, New Zealand	Not available	Maternova (2012a,b)
Hyperbilirubinemia detection and phototherapy devices				
Super Light Emitting Diodes	'Super Light Emitting Diodes (LEDs)' assembled together in a capsule using nanotechnology. A phototherapy unit comprised of five super LED capsules was tested in a study in Brazil to treat neonatal bilirubinemia	In development	Not available	Martins *et al.* (2007)
Long Lasting LEDs	Eight rows of ten long lasting LEDs mounted on breadboards, easily replaceable bulbs. Submitted for CE certification	In development, piloted in Swaziland, Malawi and Nicaragua by Johns Hopkins School of Public Health	Less than $30USD	Connexions and Lipper (2009)
Project Firefly	Phototherapy device with top and bottom lights, robust enclosed housings, table-top size, removable and cleanable single-infant bassinet for remote settings, to be piloted in Vietnam and Southeast Asia	In development by Design that Matters, the East Meets West Foundation and Vietnamese manufacturer MTTS	Not available	Design that Matters (2011)
BOL Phototherapy	This is part of a suite of neonatal technologies meant for referral hospitals. Mobile and height adjustable system, with three LED panels, each of which includes 336 LEDs.	Marketed Developed by East Meets West and MTTS	Not available	MTTS (2012)

Table 1 (*continued*)

Name of device/ company	Brief description as provided by manufacturer	Developmental stage	Projected retail price	References
Brilliance	Light Emitting Diode device designed by Design Revolution, a company in the U.S. that produces low cost technology for the developing world. The company contracted with Phoenix Medical Systems in Chennai, India, to market and distribute the device	Marketed	Not available	Maternova (2012a,b)
Bililight	Phototherapy unit developed by students from North Carolina State University. The designers plan to pretest the device in Africa and in Central America	In development	Not available	Engineering World Health (2009)
Home phototherapy system	Designed in Iran to provide home treatment, small, can be placed next to the mother's bed, foldable. Produced by TosanCo	Marketed	Not available	Design to Improve Life (2012)
BluLine PhotoTherapy	Academic classroom project developing a phototherapy device based on LEDs as light source, can be powered by a car or motorcycle battery; pretested in Tanzania, Nicaragua, and Honduras	In development by Duke University	Not available	Malkin and Anand (2010)
Devices aiming to prevent Mother-To-Child Transmission of HIV				
JustMilk HIV breastshield	Disposable breast shield that could be covered with sodium dodecyl sulfate (SDS), thus inactivating HIV in breastmilk. Developed by Duke University in collaboration with MIT	In development; device acceptability was tested in Kenya by PATH in 2009	Not available	Just Milk (2012)
Infant HIV test	Rapid PCR-based test that does not require pipetting or refrigeration. The analyzer can be recharged using a car battery	In development by Northwestern University's CIGHT program	Not available	Maternova (2012a,b)
Nevirapine	Small foil bag with instructions on Nevirapine use for Prevention of Mother-To-Child Transmission of HIV (PMTCT) and safe storage of the medication for up to 2 months	Marketed by PATH, collaboration with USAID and Boehringer Ingelheim	Donated by Boehringer Ingelheim since 2007	PATH (2011)
Delivery kits				
Enhanced Newborn Care Kit by PATH	The kit contains a sheet for delivery, soap for the birth assistant to wash hands, cord ties and a blade for cutting the umbilical cord, a hat to keep the newborn's head warm and pictures to provide messages about newborn care for mothers and birth assistants	Marketed; previous version rolled out in Bangladesh, Egypt and Nepal in collaboration with John's Hopkins University and Save the Children	Not available	PATH (2008)

Table 1 (*continued*)

Name of device/company	Brief description as provided by manufacturer	Developmental stage	Projected retail price	References
Other birth kits	Birth kits developed by various organizations around the world that have been in use for a number of years	Various	Usually around $1–5USD	
Other devices				
NeoSyp, Rice University	Mechanical intravenous drug pump with reduced error rate	In development by Rice University	about $150	Rice 360 Institute for Global Health (2012)
SafeSnip for umbilical cord	Umbilical plastic clamp for the developing world that cuts, seals, and disinfects an umbilical cord in a single step	In development	Not available	Appropedia (2012)
Uniject by PATH	Disposable syringe prefilled with nevirapine. Health workers can correctly use the device with less than 2 h of training. Clinical trials are underway	Marketed	Not available	PATH (2012a,b)
Philips Breath Counter, Philanthropy by Design Initiative	Breath Counter to detect pneumonia, used by pressing a button to registers each breath taken for one minute. Solar -powered	Developed but not marketed	Not available	Chantaroj and Techasatid (2012), Philips (2012)
Beeping timer to assess breathing rate	Battery-operated device to assist with assessing an accurate breathing rate to detect cases of pneumonia	Used by trained health workers for specific study	Not available	Pandey *et al.* (1991)
Acute Respiratory Infection Counting Beads	These counting beads are based on the Acute Respiratory Infections Timer developed by UNICEF and WHO in the 1990s. The beads are color coded and age-specific, and improve accuracy of breath counts, which aids in the diagnosis of pneumonia	In development	N/A	Maternova (2012a,b)

face enormous challenges in developing distribution strategies for their products. Most corporations, if at all interested in markets outside of the developed world, have distributor networks limited to major urban centers without reliable reach to rural areas where the needs are greatest.

Recent waves of competitions and calls for proposals have acted as a 'pull mechanism' drawing in innovative ideas for life-saving devices to improve maternal and newborn. These include the WHO call for innovative technologies launched in 2008; the First Global Forum on Medical Devices held in September 2010 in Bangkok, Thailand; the new Grand Challenges competition entitled 'Saving Lives at Birth' initiated in 2011 by the Bill and Melinda Gates Foundation, in collaboration with USAID, the Norwegian Government, Grand Challenges Canada, and the World Bank; and the BIO Ventures for Global Health Quotient Prize.

Our results suggest that most medical devices used for newborns in resource poor settings have been developed in wealthier nations and exported to the developing world. They hence remain relatively expensive and are often unaffordable for the poor even in simpler, less expensive iterations. In addition, these medical devices often cannot withstand the harsh conditions in the developing world, such as frequent power cuts. They typically also require considerable technical expertise to operate and to maintain; when they break down, service from the manufacturer is often lacking and even simple spare parts needed to repair devices are often inaccessible. Increasingly, medical devices are being developed specifically with low-resource settings in mind, to better address local needs and requirements.

While competitions and funding calls might incentivize the development of further products, it is mostly unclear how resulting devices will subsequently be supported to enter the processes of mass marketing, production, and distribution. While the Gates Foundation has funded high-risk projects, these are at risk of adding to what some call 'the valley of death' of innovation, or hopeful ideas with no mechanism for marketing or scale up. Many promising solutions have never been distributed and implemented for lack of funding, lack of a viable manufacturer, lack of business acumen on the part of the team, and inability to initiate manufacturing at viable product quantities, or other reasons.

We found relatively little information on user acceptability, pricing and distribution strategies for most of the life-saving technologies described publicly. Harnessing business methods to effectively distribute health technologies to the poor, analogous to soda makers and cell phone providers, has raised much hope in global health. Yet, most of the industry still has to assess the potential of adapting business to the bottom of the pyramid markets, or the poorest but largest socio-economic group of the global economy. This marketing strategy bases profits on low profit margins and high sales volumes rather than on the mostly prevalent model of high profit margins and low volume markets. While there is a vivid demand for beverages and cell phone refills even in the most remote areas of the globe, a universal commercial demand for saving newborn lives has yet to be created. Targeted marketing of high-quality, appropriate newborn devices to the bottom of the pyramid market might facilitate the creation of such demand.

The results of this study suggest that infant warmers and incubators to prevent and treat hypothermia have received significant attention from innovators and provide some case examples for a successful marketing of technology. Hypothermia puts the newborn's chance of survival at risk, particularly at the beginning of life (Lunze & Hamer 2012). Newborns, especially premature ones and those with low birthweight (<2.5 kg), are at particularly high risk of hypothermia, even in tropical climates (Lunze *et al.* forthcoming). Thermal protection of the newborn includes warming the birth place, keeping newborns dry and warm immediately after delivery before the cord is cut, and skin-to-skin care (SSC) with the mother or another caretaker (WHO 1996). Although thermoprotection and the prevention of hypothermia are relatively uncomplicated interventions, they are often not implemented, illustrating how seemingly simple interventions are not being scaled-up in most settings. For example, SSC with the mother or other caretaker is considered the primary, preferable method to keep newborns warm independent of any technology. Keeping the mother and the baby together further promotes bonding and early initiation of breastfeeding. Breastfeeding should start within 2 h of delivery to provide the infant with carbohydrates to produce body heat and prevent hypoglycemia and hypothermia. However, since in reality SSC is often not practiced and sometimes not feasible, appropriate devices could carry a message, a reminder to practice thermal protection, thus complementing or facilitating SSC rather than replacing it.

Left untreated, pathologic hyperbilirubinemia can progress and lead to severe problems (kernikterus) and disability in newborns (Slusher *et al.* 2011). Worldwide, studies on the proportion of newborn mortality attributable to severe newborn hyperbilirubinemia are lacking. The need for newborn technologies to diagnose and treat hyperbilirubinemia in the developing world has recently been emphasized (Slusher *et al.* 2011). The results of our study indicate an increasing interest in the matter and an opportunity to combine efforts to address this specific burden globally. One prerequisite is an effective distribution strategy once devices are designed and engineered appropriately.

Digital rectal, axillary, or tympanic thermometers are used for temperature measurements in newborns but are not available in most resource-poor settings. While human touch might be a proxy method for body temperature, it lacks the sensitivity and specificity of thermometers. An example of a device evaluated and marketed to prevent hypothermia is the Thermospot^{TM}, which indicates whether the newborn has hypothermia (Kambarami *et al.* 2002).

The Embrace infant warmer (Sinha & Barry 2011) started as a student project. Unlike most academic projects which often lack follow up after students graduate, the makers of the Embrace devices may have made their endeavor more likely to succeed by founding a company and moving forward all aspects of device implementation, from engineering and design improvements to partnering with major companies to facilitate distribution in India, where the device is currently being marketed (Embrace 2012).

Although birth asphyxia accounts for almost a quarter (23%) of all newborn deaths, newborn resuscitation is often not performed in resource-limited settings due to insufficient provider skills and lack of equipment (Coffey *et al.* 2012). The Laerdal Foundation has developed and is marketing low cost bulb and mask resuscitators, as well as suction devices, and an adapted simulation training model (Laerdal 2012). With personal support from the company's founder and CEO, and partnered with major relevant organizations, this equipment is now widely used by the Helping Babies Breathe (HBB) initiative, an evidence-based educational program to teach neonatal resuscitation techniques in resource-limited areas by the American Academy of Pediatrics (AAP) in collaboration with the WHO, US Agency for International Development (USAID), Saving Newborn Lives, the National Institute of Child Health and Development, and a number of other global health organizations (Helping Babies Breathe 2012).

Developing countries often lack regulatory approval mechanisms such as FDA approval in the US or the CE mark in Europe to ensure quality and safety. A prerequisite for widespread success might be the establishment of quality standards for appropriate technology, ideally spearheaded by an international organization. For example, the WHO developed guidelines for regulating medical devices (WHO 2003). Stringent quality standards will also facilitate reverse innovations and might help protect the intellectual properties of certified devices. In contrast to innovations developed in the western world and adapted for export to the developing world, it is conceivable that some of the devices developed for the purposes of resource limited settings may be useful in the developed world and may be 'reverse innovations'. The term 'reverse innovation' refers to the adaptation of devices from the developing world to wealthier nations. An example of a 'reverse innovation' is the MAC 800 General Electric, an easily transportable electrocardiogram that was destined for use in China and was later found to be useful by physicians in the United States (Lim & Piaw 2011).

While our compilation of medical devices described in this paper might not be an exhaustive list of all devices in development, we did not aim to provide a comprehensive catalogue of all existing solutions. Rather, we tried to compile and analyze solutions that have entered and are described in the public domain. Many more innovations that we might not be aware of or that are kept confidential might be in the pipeline. Although some innovators present full information about a product's engineering and design processes and provide valuable insight for others working on similar challenges in similar settings (Malkin & Anand 2010), others are hesitant to make their product specifics public out of intellectual property concerns. This illustrates the value of a forum for newborn health technology such as Maternova, where practitioners working in the field, as well as innovators from academia, NGOS, and industry, find a platform for exchange and coordination of efforts of those interested in collaborations.
A crowdsourced platform to generate user reviews on the products already in use could facilitate this process, an initiative that these authors and Maternova are pursuing.

Conclusion

We identified a variety of medical devices that have the potential to improve newborn health in resource limited settings. There is substantial skepticism as to whether health technology is needed at all in the context of competing agendas and the proven effectiveness of behavior changes in community-based health care. However, even seemingly simple interventions such as keeping the newborn warm are currently not widespread, let alone universal practices. When newborn health devices are distributed and utilized appropriately during childbirth, they can potentially improve neonatal health outcomes and survival. In addition, bundled together with other maternal and child health interventions, they have the potential to serve as a visual reminder for infant care and to carry educational messages around maternal health and essential newborn care. More robust and rapid commercialization strategies must be developed to ensure that newborn health devices leave the research and development pipeline and be made available in resource-limited settings where most newborns die.

Newborn mortality remains a significant global health disparity. Meeting the fourth Millennium Development Goal of reducing deaths in children under 5 years will require making significant investments in reducing neonatal mortality over the next few years. Faster development, commercialization and distribution of newborn health technology might be part of the solution.

Acknowledgements

We thank the reviewers for their very constructive input, and Emily Fallon, Shipra Srihari, Rachel Thakore, and Elizabeth Adler from Maternova for their contribution to data research. At Touro University, we thank Sarah New, Scott Drew, and Felicia Dunlap for their assistance with preparing the bibliography, Dr. Alessandra Bazzano and Sarah Sullivan for helpful feedback, and Tamara Trujillo for her assistance with the search strategy.

References

Appropedia (2012) Appropedia. Available at: http://www.appropedia.org/Welcome_to_Appropedia (accessed 3 October 2012).

Bhutta ZA, Darmstadt GL, Hasan BS & Haws RA (2005) Community-based interventions for improving perinatal and neonatal health outcomes in developing countries: a review of the evidence. *Pediatrics* **115**(Suppl. 2), 519–617.

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

Bradley HE (2012) Dissemination, Diffusion, and Scale Up of Family Health Innovations. Available at: http://www.gatesfoundation.org/global-health/Documents/yale-global-health-report.PDF (accessed 3 October 2012).

Chantaroj S & Techasatid W (2012) Effect of polyethylene bag to prevent heat loss in preterm infants at birth: a randomized controlled trial. *Journal of the Medical Association of Thailand* **94**(Suppl. 7), S32–S37.

Coffey P, Kak L, Narayanan I *et al.* (2012) Newborn Resuscitation Devices. Available at: http://www.everywomaneverychild.org/images/UN_Comission_Report_Resuscitation_Devices_COMPLETE_reduced.pdf (accessed 3 October 2012).

Connexions and Lipper A (2009) Neonatal Incubator and Bilirubin Phototherapy Device. Available at: http://cnx.org/content/m19530/latest/ (accessed 3 October 2012).

Cooper-Hewitt (2011) Design for the other 90%. Available at: http://other90.cooperhewitt.org/ (accessed 3 October 2012).

Daga SR, Verma B, Ahuja VK & Anaokar A (2000) Oxygen administration to a baby in styropor box. *Indian Pediatrics* **37**, 911–912.

Design that Matters (2011) Portfolio, Projects: Design that matters. Available at: http://designthatmatters.org/portfolio/projects/ (accessed 3 October 2012).

Design to Improve Life (2012) Home Phototherapy. Available at: http://www.designtoimprovelife.dk/index.php?option=com_content_custom&view=article&id=181:home-phototherapy&catid=10:finalists-2009&Itemid=293&Itemid=229 (accessed 3 October 2012).

Diblasi RM, Zignego JC, Smith CV, Hansen TN & Richardson CP (2010) Effective gas exchange in paralyzed juvenile rabbits using simple, inexpensive respiratory support devices. *Pediatric Research* **68**, 526–530.

East Meets West Foundation (2012) East Meets West Foundation. Available at: http://www.eastmeetswest.org/Page.aspx?pid=344 (accessed 3 October 2012).

Embrace (2012) The Embrace Infant Warmer Is A Product With A Mission. Available at: http://embraceglobal.org/main/product (accessed 3 October 2012).

Engineering for Change (2012) Health. Available at: https://www.engineeringforchange.org/topic/view/health;jsessionid=CE355D98ADDF7A76ED3906C1EE781C4F.asmeworker1 (accessed 3 October 2012).

Engineering World Health (2009) NC State chapter of EWH works to improve treatment of hyperbilirubinemia in infants. Available at: http://ewh.org/index.php/daladala/ncsu/ (accessed 3 October 2012).

Gosavi DV, Swaminathan M & Daga SR (1998) Appropriate technology in transportation of sick newborns in developing countries. *Tropical Doctor* **28**, 101–102.

Health Unbound (2012) Health Unbound. Available at: http://www.healthunbound.org/ (accessed 3 October 2012).

Helping Babies Breathe (2012) The Golden Minute – Helping Babies Breathe. Available at: http://www.helpingbabiesbreathe.org/.

Howitt P, Darzi A, Yang G *et al.* (2012) Technologies for global health. *Lancet* **380**, 507–535.

IncuVive (2012) Products. Available at: http://incuvive.weebly.com/products.html (accessed 3 October 2012).

Just Milk (2012) Just Milk. justmilk.org.

Kambarami R, Chidede O & Pereira N (2002) ThermoSpot in the detection of neonatal hypothermia. *Annals of Tropical Paediatrics* **3**, 219–223.

Kinikar A, Kulkarni R, Valvi C & Gupte N (2011) Use of indigenous bubble CPAP during swine flu pandemic in Pune, India. *Indian Journal of Pediatrics* **78**, 1216–1220.

Laerdal (2012) Laerdal Global Health.

Lawn JE, Cousens S & Zupan J (2005) 4 million neonatal deaths: When? Where? Why? *Lancet* **365**, 891–900.

Lifebox (2012) Lifebox. Available at: http://www.lifebox.org/.

Lim J & Piaw TC (2011) Where Innovation's A Matter of Life and Death. Available at: http://bschool.nus.edu/Staff/bizteocp/2011_TODAY.pdf (accessed 3 October 2012).

Lin J, Ma J & Cahill D (2009) Neonatal Pulse Oximeter. Available at: http://cohesion.rice.edu/collaborations/btb/emplibrary/ACF4E57.pdf (accessed 3 October 2012).

Lunze K, Bloom D, Jamison D & Hamer D (forthcoming) Neonatal Hypothermia – a Global Challenge for Newborn Survival. BMC Medicine.

Lunze K & Hamer DH (2012) Thermal protection of the newborn in resource-limited environments. *Journal of Perinatology* **32**: 317–324.

Malkin R & Anand V (2010) A novel phototherapy device: the design community approach for the developing world. *IEEE Engineering in Medicine and Biology Magazine* **29**, 37–43.

Martins BM, de Carvalho M, Moreira ME & Lopes JM (2007) Efficacy of new micro processed phototherapy system with five high intensity light emitting diodes (Super LEDs). *Journal of Pediatrics* **83**, 253–258.

Maternova (2012a) Innovative Redesign of the Acute Respiratory Infection Timer. Available at: http://maternova.net/health-innovations/innovative-redesign-acute-respiratory-infection-timer (accessed 3 October 2012).

Maternova (2012b) Maternova. Available at: http://maternova.net/ (accessed 3 October 2012).

MTTS (2012) Medical Technology Transfer and Services. Available at: http://www.mtts-asia.com/en/products.

Oestergaard MZ, Inoue M, Sachiyo Yoshida S *et al.* (2011) Neonatal mortality levels for 193 countries in 2009 with trends since 1990: a systematic analysis of progress, projections, and priorities. *PLoS Medicine* **8**, e1001080.

Pandey MR, Daulaire NM, Starbuck ES, Houston RM & McPherson K (1991) Reduction in total under-five mortality in western Nepal through community-based antimicrobial treatment of pneumonia. *Lancet* **338**, 993–997.

PATH (2008) PATH and partners launch enhanced newborn care kit project at Clinton Global Initiative.

PATH (2011) Packaging HIV protection for infants: A foil pouch helps give HIV-positive mothers a way to protect their children. Available at: http://www.path.org/projects/nevirapine_pouch.php (accessed 3 October 2012).

PATH (2012a) The radically simple Uniject injection system. Available at: http://www.path.org/our-work/uniject.php.

PATH (2012b) Technology Solutions for Global Health: Birthweigh III. Available at: http://www.path.org/publications/files/TS_update_bw3.pdf (accessed 3 October 2012).

Philips (2012) Fighting Pneumonia: Philanthropy by Design. Available at: http://www.design.philips.com/shared/assets/design_assets/downloads/portfolio/FightingPneumonia.pdf (accessed 3 October 2012).

Piot P (2012) Innovation and technology for global public health. *Global Public Health* **7**(Suppl. 1), S46–S53.

Powerfree Education Technology (2012) Pulse Oximeter. Available at: http://pet.org.za/products.php?view=2 (accessed 3 October 2012).

Research Triangle Institute (2010) Maternal and Neonatal Directed Assessment of Technology database. Available at: http://mnhtech.org/technology/technology-briefs/ (accessed 3 October 2012).

Rice 360 Institute for Global Health (2012) Nursery of the Future. Available at: http://www.rice360.rice.edu/tech(accessed 3 October 2012).

Seattle Children's Hospital (2010) 2010 Academic Annual Report: Best of 2010, Seattle Children's Hospital, Research and Foundation. Available at: http://www.seattlechildrens.org/healthcare-professionals/aar/2010/highlights/ (accessed 3 October 2012).

Shende SR, Daga SR & Kinikar NA (1998) Use of a styropor box for thermal control of low birth-weight babies after discharge from hospital. *Journal of Tropical Pediatrics* **44**, 183–184.

Sinha SR & Barry M (2011) Health technologies and innovation in the global health arena. *New England Journal of Medicine* **365**, 779–782.

Slusher TM, Zipursky A & Bhutani VK. (2011) A global need for affordable neonatal jaundice technologies. *Seminars in Perinatology* **35**: 185–191.

United Nations (2012) Millenium Development Goals. Available at: http://www.un.org/millenniumgoals/ (accessed 1 Ocotber 2012) (accessed 3 October 2012).

WarmiLu (2012) The IncuBlanket. Available at: http://www.warmilu.org/ (accessed 3 October 2012).

WHO (1996) Essential newborn careAvailable at http://helid.digicollection.org/en/d/Js2892e/ (accessed 3 October 2012).

WHO (2003) Medical Device Regulations: Global Overview and Guiding Principles. Available at: http://www.who.int/medical_devices/publications/en/MD_Regulations.pdf (accessed 3 October 2012).

WHO (2010) Medical Devices: Managin the Mismatch – An outcome of the Priority Medical Devices project. Available at: http://whqlibdoc.who.int/publications/2010/9789241564045_eng.pdf (accessed 3 October 2012).

WHO (2011) First WHO Global Forum on Medical Devices: Context, Outcomes, and Future Actions. Available at: http://www.who.int/medical_devices/gfmd_report_final.pdf (accessed 3 September 2012).

Zupan J (2005) Perinatal mortality in developing countries. *New England Journal of Medicine* **352**, 2047–2048.

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